The Development of a Policy Analysis Logic Model to Support Public Medicine Availability Initiatives in the Context of VAN

by

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Declaration

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Abstract

The *Visibility and Analytics Network (VAN)* aims to improve public sector medicine availability from a supply chain perspective. The Bill and Melinda Gates Foundation (with inputs from multiple global health organisations and funders) developed a VAN Blueprint, using proven private sector operating models that aim to guide sub-Saharan African (SSA) countries to subsequently customise a VAN Operating Model specific to their context and country's needs. People, processes, technology and policy must be organised and aligned from a national level to the facilities level in order to achieve the VAN defined goals and objectives. However, at an aggregated level, there is a lack of understanding of the enabling and limiting effect of country-specific policies on such an initiative; including how policy decisions and strategies can be better aligned to accommodate the VAN.

This research study develops a policy analysis logic model (named PoliVAN) that aims to assist actors (i.e. government authorities, policymakers and VAN role players) with making insightful policy and legislation decisions to enable the implementation and operationalisation of their country's VAN Operating Model. The proposed PoliVAN logic model underwent a complete evaluation strategy (verification and validation) with subject matter experts, over four progressive stages: (i) theoretical verification of the inherent theory; (ii) validation of the relevance and contextual appropriateness of the PoliVAN logic model through subject matter expert engagement; (iii) application of the PoliVAN logic model to two South African case studies; and (iv) a transferability validation, through engagement with SSA country VAN representatives.

The application of the PoliVAN logic model—demonstrated through the outcomes of the case studies—yielded information, insights and decision support that contribute towards making informed policy reform decisions and strategies to successfully support the implementation and operationalisation of a VAN Operating Model. This study then further investigates the transferability of the PoliVAN logic model and the possibility for it to be utilised in an SSA country context. An amalgamation of the context-specific changes required to apply the PoliVAN logic model, gained through the application of the South African case studies, were

discussed with SSA country VAN representatives. Through this engagement, insights were gained on the PoliVAN transferability and the context-specific notions. Furthermore, this study concluded with the necessary prerequisites to implement a PoliVAN logic model.

In light of the aforementioned discussion, the PoliVAN has significantly contributed towards the gap highlighted in the VAN Blueprint regarding policy insights to assist countries with the implementation and operationalisation of their VAN Operating Model. The PoliVAN encompasses the necessary best-practices tools and guides the relevant actors on how to make informed policy decisions that consequently contribute towards the successful implementation and operationalisation of a country's VAN Operating Model. The success of a VAN hinges on the enabling environment of policies and legislation and this study provides the necessary guidance, in the form of the PoliVAN logic model, on how to identify, analyse and develop policy-specific strategies that supports a country's VAN, and subsequently support the medicine availability initiative for SSA countries in need of this approach.

Opsomming

Die Sigbaarheid Analitiese Netwerk (Eng. VAN) beoog om die beskikbaarheid van medisyne in die openbare gesondheidsorgsektor vanuit 'n voorsieningskettingperspektief te verbeter. Die Bill en Melinda Gates-stigting (met insette van verskeie wêreldwye gesondheidsorganisasies en befondsers) het die VAN-raamwerk ontwikkel deur gebruik te maak van bewese privaat gesondheidssektorbedryfsmodelle. Hierdie modelle is daarop gemik om ontwikkelende lande (in Afrika, suid van die Sahara (SSA)) te lei om die VAN, spesifiek aan hulle konteks en land se behoeftes, te ontwikkel. Mense, prosesse, tegnologie en beleide moet van nasionaletot die fasiliteitsvlak georganiseer en in lyn gebring word om die doelwitte van die VAN te bereik. Daar is egter onduidelikheid oor tot watter mate die beleid van 'n spesifieke land die uitvoerbaarheid van die VAN inisiatief ondersteun of stuit; insluitend hoe beleidsbesluite en strategieë beter beplan kan word om die VAN te ondersteun.

Hierdie navorsingstudie ontwikkel 'n beleidsanalise logikamodel (Eng. PoliVAN) wat daarop gemik is om belanghebbendes (soos regeringsowerhede, beleidmakers en VAN rolspelers) te help met insiggewende beleids- en wetgewingsbesluite om die implementering van hul land se VAN te bewerkstellig. Die voorgestelde PoliVANlogikamodel het 'n volledige evalueringsproses met kundiges in die vakgebied ondergaan, oor vier opeenvolgende fases: (i) bevestiging van die inherente teorie; (ii) bevestiging van die relevansie en kontekstuele toepaslikheid van die PoliVANlogikamodel tydens 'n betrokkenheidswerkswinkel met kundiges in die vakgebied; (iii) toepassing van die PoliVAN-logikamodel in twee gevallestudies wat handel oor Suid-Afrika se VAN; en (iv) 'n ondersoek met VAN verteenwoordigers van SSAlande om die vermoë van die oordraagbaarheid van die PoliVAN-logikamodel na verskillende landskontekste te bepaal.

Die toepaslikheid van die PoliVAN-logikamodel word gedemonstreer deur die uitkomste van die gevallestudies, wat inligting, insigte en besluitnemingssteun verskaf wat gebruik kan word om ingeligte beleidsvormingsbesluitneming te ondersteun en daarna beleidsstrategieë te ontwikkel om sodoende die VAN suksesvol te implementeer. Hierdie studie ondersoek dan verder ook die oordraagbaarheid van die

PoliVAN-logikamodel en die moontlikheid vir ander SSA-lande om hierdie beleids-toepassing te benut. Samevatting van die konteks-spesifieke veranderinge wat nodig is om die PoliVAN-logikamodel toe te pas, wat tydens die Suid-Afrikaanse gevallestudies uitgelig is, is met VAN-verteenwoordigers van die SSA-lande be-spreek. Die besprekings met SSA VAN verteenwoordigers het insigte verskaf oor die oordraagbaarheid van die PoliVAN-logikamodel en die konteks-spesifieke fak-tore wat in ag geneem moet word. Hierdie studie word afgesluit met 'n bespreking van die nodige voorvereistes om 'n PoliVAN-logikamodel te implementeer.

Die PoliVAN-logikamodel het, gegewe die bogenoemde bespreking, 'n beduidende bydrae gelewer tot die onduidelikheid wat in die VAN-raamwerk uitgelig is ra-kende beleidsinsigte om lande te help met die implementering en bedryfsaamhede van hul VAN-bedryfsmodel. Die PoliVAN-logikamodel omvat die nodige, beste praktyk, analise-instrumente en help die betrokke belanghebbendes oor hoe om ingeligte beleidsbesluite te neem wat gevolglik bydra tot die suksesvolle imple-mentering van 'n land se VAN-bedryfsmodel. Die sukses van die VAN is afhanklik van die bemagtigende omgewing van beleid en wetgewing, en hierdie studie bied die nodige leiding in die vorm van die PoliVAN-logikamodel oor hoe om beleidspe-sifieke strategieë wat 'n land se VAN ondersteun, te identifiseer, te ontleed en te ontwikkel. Gevolglik ondersteun hierdie studie die inisiatief vir beskikbaarheid van medisyne vir SSA-lande wat hierdie benadering benodig.

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"Ambition is the path to success. Persistence is the vehicle you arrive in."

—Bill Bradley

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Acronyms and Abbreviations

Acronyms

3PL	Third-Party Logistics
AMD	Affordable Medicines Directorate
ARC	African Resource Centre
BPRM	Blueprint Reference Model
CFO	Chief Financial Officer
EDP	Essential Drug Programme
EML	Essential Medicines List
FEFO	First Expiry First Out
FIFO	First In First Out
HOPS	Head of Pharmaceutical Services
HRM	Human Resource Management
HTA	Health Technology Assessment
IT	Information Technology
KPI	Key Performance Indicators
MCA	Multi-Criteria Analysis
MPC	Master Procurement Catalogue
NDoH	National Department of Health
NEMLC	National Essential Medicines List Committee

NGO	Non-Government Organisation
NHI	National Health Insurance
Pi	Participant number i, $i=1,...,n$.
PHC	Primary Healthcare
PLF	Pharmaceutical Logistics Framework
PMPU	Provincial Medicine Procurement Unit
PoliVAN	Policy analysis method for the VAN
PPTC	Provincial Pharmaceutical Therapeutic Committee
PTC	Pharmaceutical Therapeutic Committee
RO	Research Objective
SDG	Sustainable Development Goal
SHA	Stakeholder Analysis
SIMA	Strategic framework to Improve Medicine Availability
SKU	Stock Keeping Unit
SME	Subject-Matter Expert
SOP	Standard Operating Procedure
SSA	Sub-Saharan Africa
STG	Standard Treatment Guideline
SVS	Stock Visibility Solution
UNICEF	United Nations International Childrens Emergency Fund
USAID	United States Agency for International Development
VAN	Visibility and Analytics Network
WHO	World Health Organisation

Chapter 1

Introduction

This chapter presents an overview of the current challenges faced by sub-Saharan African (SSA) countries' healthcare delivery systems, and provides an overview of how the challenges that have led to the development of a national initiative for medicine availability. A brief description of this initiative follows, aiming to provide insight into the current opportunities for improvements, which is then substantiated by the relevant research disciplines (or the lack thereof). The research problem of this project is defined along with the research aim and objectives, and how they will be achieved.

A structured evaluation strategy is provided that clearly identifies the different methods of verification and validation approaches considered for this study. This is followed by a schematic and description of the layout and structure of this study.

1.1 Background

The World Health Organisation defines health as, a "state of complete physical, mental and social well-being" (World Health Organization, 1998). However, providing access to good quality, and equitable medicines is still a shortfall for many health systems across the globe (Bigdeli *et al.*, 2013). In order to improve population health, and thus also access to good-quality and equitable medicines (which is in line with the 2030 Sustainable Development Goals (SDG)[1]), the interest in utilising primary healthcare (PHC)[2] in low- and middle-income countries to facilitate the attainment of such goals has increased (Van Lerberghe, 2008).

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[1]SDG 3: Ensure healthy lives and promote well-being for all at all ages. More specifically, SDG 3.8: "Achieve...access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all" (World Health Organization, 2016).

[2] The primary healthcare (PHC) concept was initiated by the World Health Organisation (WHO) at the International Conference for Primary Healthcare in the 1978 Alma Alta Deceleration. This declaration defined PHC as "...the first level of contact of individuals, the family and community with the national health system bringing healthcare as close as possible to where people live and work, and constitutes the first element of a continuing healthcare process" (World Health Organization & UNICEF, 1978).

The availability of essential medicines is a critical aspect to ensuring population health (World Health Organization & UNICEF, 1978). For the majority of SSA countries, stock-outs, or the non-availability of essential medicines at PHC level (as well as other public health establishments[1]), have increased over the past decades (Hedman, 2016). This current hardship is the result of insufficient supply chain management capabilities in the system to deliver the supply chain processes effectively. The challenges regarding supply chain capabilities in public healthcare systems are further discussed in Subsection 1.1.1. A medicine availability initiative, derived from these supply chain-related challenges, is introduced in Subsection 1.1.2. Policy-related problems are highlighted from the medicine availability initiatives and are discussed in Subsections 1.1.3 and 1.1.4, which introduce the research problem further discussed in Section 1.2.

1.1.1 Supply chain-related challenges in healthcare

Research has shown that there are multiple factors that contribute towards the shortages of essential medicines at healthcare establishments (Hedman, 2016). Such factors range across the operational, strategic, and tactical levels of the health system, i.e. delays in national tender awards; suppliers being out of stock; insufficient funds; erratic orders from PHC clinics and hospitals; poor communication and flow of information between various stakeholders; limited use of technology solutions; and insufficient staff. However, there are a number of challenges, like poor stock management; lack of high-quality data; and a lack of adequately skilled professionals that are present in a significant number of healthcare supply chains (Berger *et al.*, 2010).

The aforementioned are key contributors to medicine shortages and are in line with the components of a healthcare procurement system, which is vital for the access to healthcare (World Health Organization, 2007). A procurement system is based on obtaining the right commodities, in the right amounts, at the right place, and at the right time (Usaid Deliver Project, 2011). Therefore, the key contributors toward essential medicine stock-outs at facilities relies heavily on the system's procurement capabilities (Hedman, 2016).

Public drug supply chains differ from commercial supply chains due to the extended global pipelines, the uncertainty and fluctuation in demand, and the high product level requirements (Raja & Mohammad, 2004). The procurement of medicines is not possible without effective and efficient supply chain coordination (Kruger, 2016). Despite the availability of supply chain tools for the procurement of medicines, none of the tools are valuable without adequate resources using and managing them (Kleynhans *et al.*, 2017; Raja & Mohammad, 2004). Although great strides have been made to improve medicine availability, issues with in-country

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[1]Health establishments include, e.g. hospitals at secondary and tertiary level.

supply chains are still resulting in high stock-outs and wastages at facilities (Dza *et al.*, 2013). This in turn negatively affects the availability of medicines at the point and time of need (Goel & Llewellyn, 2015; Llewellyn, 2016). Pharmaceutical supply in many parts of SSA is overwhelmed (Quick *et al.*, 2005), and it is argued that policymakers, healthcare managers and regulatory authorities must fundamentally change and adapt their way of thinking, as the real challenge is to identify, design, select, and implement the best solutions for each country's specific context (Quick *et al.*, 2005).

1.1.2 The medicine availability initiative: Visibility and Analytics Network

To address these supply chain-related issues, the Bill and Melinda Gates Foundation (along with inputs from multiple global health organisations and funders, namely: USAID; Global Fund; UNICEF; and multiple African governments) conceptualised the idea of a Visibility and Analytics Network (VAN) as an area of focus when resolving issues of medicine availability from a supply chain perspective (Goel & Llewellyn, 2015). The VAN initiative is a blueprint (documented in a Blueprint Reference Model (BPRM)) that aims to adapt private sector operating model approaches, in the interest of improving public sector medicine availability. The design goal is to ensure the availability of the right commodities at the right time and place and in the right quantities (Llewellyn, 2016)—the blueprint describes the design of public pharmaceutical supply chains at a level of detail that enables countries to design and implement a VAN Operating Model[1] specifically for their needs.

The VAN is a combination of different elements, namely: people, processes, technology and policies. These elements must be organised and aligned from a national level to the facilities level in order to achieve the stated goals and objectives (Llewellyn, 2016). The BPRM provides design approaches for the people that are involved, the processes for the implementation and operations of a VAN, and the integrated information technology system that would be incorporated; however, the BPRM lacks the understanding of how countries' existing policy and legal framework will enable or limit the operationalisation and implementation of a VAN in a country. And subsequently, how to develop policy-specific decisions and strategies for the VAN (policy element). The next section discusses the role of policy analysis to inform policy decisions and strategies.

1.1.3 Policy analysis as a decision-making tool

Dunn (1981) states that policy analysis is a generic name for a range of problem-solving techniques and tools to study the characteristics of established policies, how policies are formulated,

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[1]In this study, the term 'VAN' is used when referring to the initiative. The term 'VAN Operating Model' is used when referring to a country-specific operating model design from the BPRM.

and what their consequences are towards the given context. The role of policy analysis in the development of policy decisions and strategies has been an evolving topic since the 1950s (Peters & Pierre, 2006). Policy analysis has proven its ability to support decision-making strategies through the following measures (to name a few) (Dunn, 1981): analysing public policies retrospectively or prospectively; assessing future implications of current (or new) policies on a new (or current) system; and determining if already existing policies need to be modified, or terminated. Based on the above-mentioned opportunities that the role of policy analysis has on decision-making strategies—the choice to incorporate policy analysis into decision-making strategies for public systems does not raise any issues; and it is merely the selection of the policy analysis model or approach (given the context) that needs to be considered.

1.1.4   Policy analysis for public healthcare delivery systems

The role of policy analysis is a well-established discipline, but some argue that it has been overlooked when it comes to the healthcare sector in developing countries (Walt & Gilson, 1994). According to a detailed literature review study[1] done by Franco & Alfonso-Lizarazo (2017), "pharmaceutical supply chain is a significant topic with important real-world applications; however, despite some recent developments, there remain few works on this subject." This statement refers to the role of policy analysis on pharmaceutical supply chains. Although the study identifies some policy analysis approaches in the pharmaceutical sector, a considerable number (if not all) of the approaches are developed for the private sector—focusing on the optimisation of product development, inventory optimisation, distribution networks, and minimising total cost.

Other types of challenges in the healthcare sector, for which policy analysis approaches have been developed, are: (i) issues relating to population health, such as disease epidemiology; diabetes and substance abuse (Homer & Hirsch, 2006); (ii) the flow of patients in hospitals and clinics (Clissold *et al.*, 2015); (iii) forecasts with regards to healthcare facilities and health workforce requirements for the public sector (Avoka Asamani *et al.*, 2018); (iv) the use of a multi-criteria decision analysis tool to inform the value assessment of new medical technologies (Kanavos & Angelis, 2015); and (v) pricing policing, i.e. ensuring efficient expenditure (Docteur & Paris, 2009). These examples provide a wide range of the possible policy analysis models. However, there are no comprehensive policy analysis methods that exist for the restructuring of a pharmaceutical supply chain, and how existing country policies could potentially affect the operationalisation of such change.

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[1]A structured review that considers policy analysis models developed for pharmaceutical supply chains (Franco & Alfonso-Lizarazo, 2017).

1.2   Problem statement

As mentioned, the BPRM for the development of a VAN Operating Model lacks sufficient insight about the enabling and limiting effect that existing country-specific policies might have on the implementation and operationalisation of a VAN Operating Model. Furthermore, most policy analysis approaches that are developed for a pharmaceutical system either focus on opti- mising individual functions of a supply chain, or analyse the impact of the different operational functions on one another within the supply chain network. Based on the preliminary investiga- tion of policy analysis methods done in Subsection 1.1.3, there is currently no comprehensive approach available that analyses the effect of a country's existing policy and legal framework on the change in the design of its public pharmaceutical supply chain. Thus, in the context of VAN, a need exists to identify the relevant policies affecting a VAN Operating Model and subsequently to determine the effect of these policies and legislations on the implementation of the VAN initiative for SSA countries.

1.3   Aim and objectives

The aim of this study is to investigate to what extent a country's existing policy and legal framework affect change in the design of its pharmaceutical supply chain (specifically through the implementation of the VAN initiative), and to develop a proposition or method that as- sists government authorities, policymakers and VAN personnel on how to identify, analyse and develop policy-specific decisions and strategies to support the implementation of a VAN Op- erating Model in a specific country. Additionally, the aim is to support the policy element of the BPRM by developing a proposition or method in such a manner that any country planning to implement a VAN Operating Model can have useful insight from a policy perspective when designing their VAN Operating Model. The research objectives (RO) that will support the attainment of the aforementioned aim are divided into four key objectives, each in turn with a number of sub-objectives. The objectives are:

Research objective 1: To provide context to this study by understanding the elements, com- ponents, and operations of a VAN Operating Model.

RO 1.1: Investigate the BPRM to understand the different design elements;

RO 1.2: Understand the contextualisation and outcome from developing a country-specific VAN from the BPRM: South African VAN Operating Model; and

RO 1.3: Understand the enablers that are required to successfully implement a VAN Oper- ating Model.

Research objective 2: To identify the link between (and indirectly the effect of) pharmaceutical supply chain policies and a VAN Operating Model.

RO 2.1 Investigate the key operations and functions of a pharmaceutical supply chain to grasp the complexity of the problem;

RO 2.2 Identify the link between policies and the operations of a pharmaceutical supply chain; and

RO 2.3 Identify and synthesise the similarities between the operations of a pharmaceutical supply chain and the VAN Operating Model.

Research objective 3: : To explore policy analysis approaches that enable decision-making strategies regarding the effect of policies on an operating model such as VAN.

RO 3.1 Identify policy analysis methods that enable decision-making; and

RO 3.2 Identify methods to analyse the effect of policies on a system.

Research objective 4: : To propose a policy analysis approach that enables insight on how to identify, analyse and develop policy-specific decisions and strategies to support the BPRM with the design and implementation of a VAN Operating Model from a policy perspective.

RO 4.1 Incorporate relevant and context-appropriate methods that identify relevant VAN-specific policies and analyse the effect these policies have on a VAN Operating model with decision-making analysis approaches and strategies;

RO 4.2 Verify the literature used and assumptions made to develop a policy analysis method; and

RO 4.3 Perform validation processes to gain insight, make recommended changes, test the applicability and develop context-specific prerequisites for future implementation.

1.4 Research approach, methodology overview and evaluation

The research design adopted in this study consists of an amalgamation of exploratory theory development, policy analysis logic model[1] building and evaluation. The research approach, research methodology and evaluation strategy are presented in the following subsections.

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[1]In this study, the developed policy analysis method for a VAN is referred to as the PoliVAN logic model. Details regarding the origin of the name and the reason for it being a logic model are discussed in Chapter 5.

1.4.1 Research approach

Mouton (2001) provides a research design typology to assist with the planning of a research study (see Figure 1.1). This study takes a non-empirical research approach. Primarily, this study is non-empirical in nature because it seeks to explore, observe and review existing literature in different areas of research fields (Mouton, 2001). This study then synthesises the literature review to systematically develop the PoliVAN logic model. Following this, an empirical research approach is conducted to gain knowledge and insight into the application of policy analysis on a public pharmaceutical supply chain. The outcomes presented by the PoliVAN logic model are subsequently used to present research findings on how policy analysis can be utilised as a decision-making model for an initiative such as VAN.
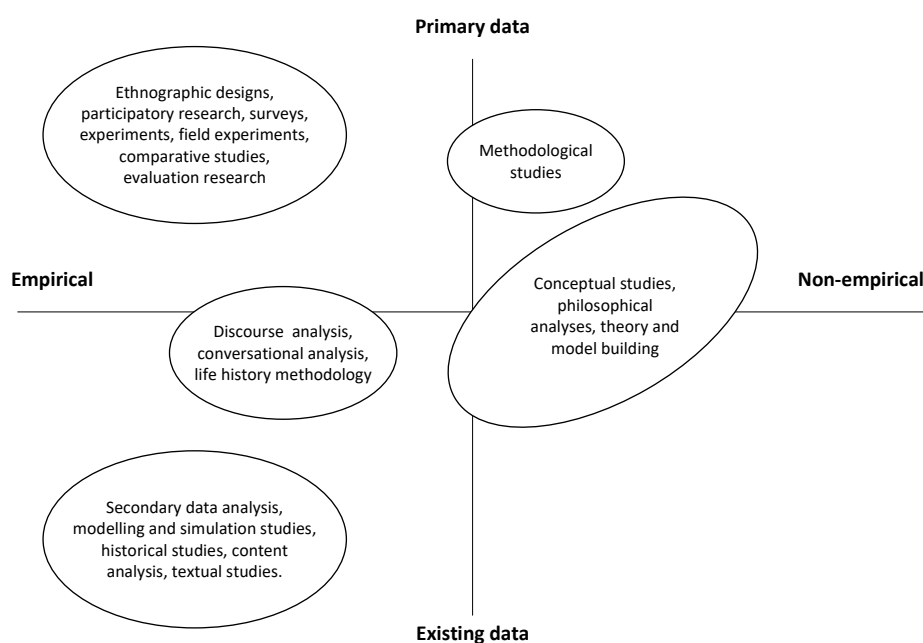
Figure 1.1: The research approach in this study, adapted to Mouton's (2001) Level 1 research design map

1.4.2 Research methodology

Figure 1.2 provides the research design and methodology for the development of the PoliVAN logic model. This study aims to address a real-world problem that encompasses practical and complex issues (Black, 1999). The first part of the study focuses on understanding the problem. Griffin *et al.* (2016) point out that in order to fully understand the problem, the system as a whole should be broken down into manageable parts. The research problem discussed earlier in this chapter can be categorised into three research topics, which will be covered throughout

Chapters 2, 3 and 4. Chapter 2 provides an overview of the VAN initiative. Chapter 3 identifies the link between policies and a VAN Operating Model, by investigating the operations of a pharmaceutical supply chain. Chapter 4 provides insight into different policy analysis methods and tools that exist.
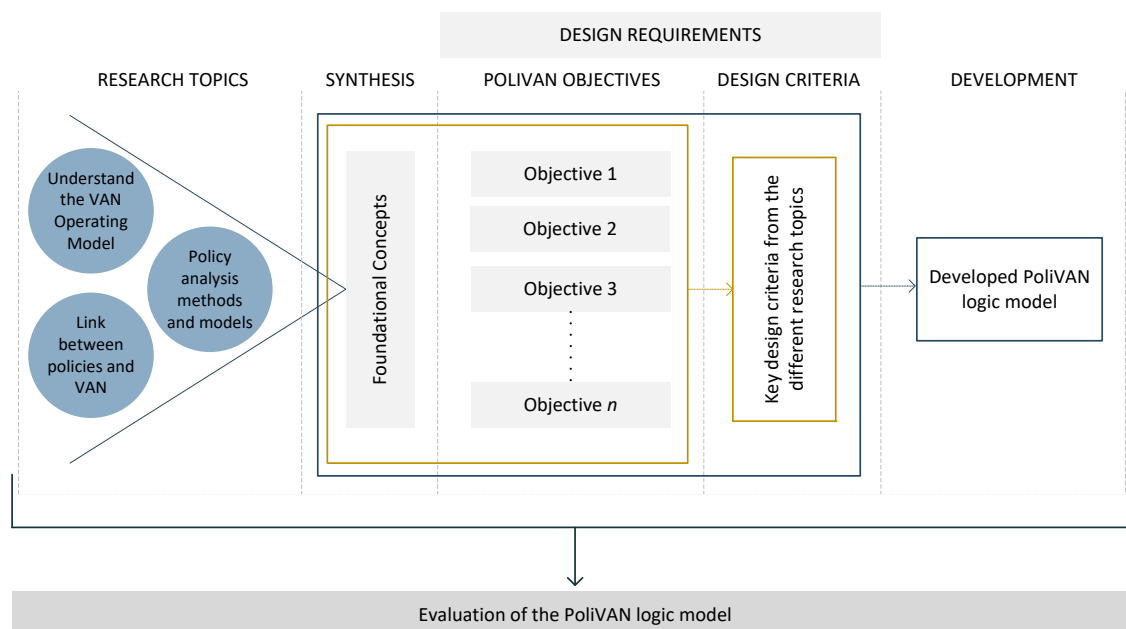
Figure 1.2: Research methodology for the development of the PoliVAN logic model

A literature review study is conducted for each research topic. Various resources that are used for the literature studies, namely: journal articles, papers, books, and secondary sources (i.e. grey literature). The literature analysis approaches used in this study are: (i) an extended literature review; and (ii) a narrative literature review. Extended literature reviews, according to Hofstee (2006), are undertaken to provide an overview of the study in a particular field, or the field in its entirety. A narrative review, according to Bryman (2014), "tend(s) to be less focused and more wide-ranging than systematic reviews." This is a particularly useful method when research and literature are the basis of the study.

The information gathered through the literature analysis is synthesised, to gather insight and identify the most relevant information required to develop the PoliVAN logic model. The synthesis is done by viewing the three mutually exclusive literature reviews as a whole in order to identify the interrelated parts among the three literature topics.

The next part in the research process focuses on the design requirements for the PoliVAN logic model. The design requirements are constituted of the PoliVAN objectives and the design criteria. The PoliVAN objectives set out what the PoliVAN logic model should be able to achieve. The PoliVAN objectives are identified from both the literature synthesis and

taking into account the overall aim of this research study. The foundational concepts from the literature synthesis, including the PoliVAN objectives, are reviewed to identify key design criteria required to develop the PoliVAN logic model at a systems level. The information from the literature synthesis, PoliVAN logic model and design criteria are systematically integrated to develop the PoliVAN logic model.

The development of the PoliVAN logic model takes on a systematic process that incorporates literature findings from the policy analysis literature chapter (Chapter 4) and adapts a preselected policy decision-making model to fit the PoliVAN objectives and design criteria. Then, a high-level PoliVAN logic model is developed, which is subsequently populated with best-practice decision-making tools that are adapted to fit the contexts of the VAN and a public pharmaceutical supply chain. The final steps in the research methodology are the evaluation of the PoliVAN logic model. The evaluation strategy and processes are further discussed in Subsection 1.4.3.

1.4.3 Evaluation strategy

This research study aims to develop a proposition that is able to assist VAN personnel, health authorities and government officials to develop policy-specific strategies (through policy analysis) that will enable the operationalisation of a country's VAN Operating model from a policy perspective. In this study, a proposed policy analysis method for a VAN Operating Model is developed, namely the PoliVAN logic model. In order to prove the accuracy and adequacy of the PoliVAN logic model, the body of research findings that supports the development, including the PoliVAN logic model and its intent must be evaluated. Evaluation is required to provide a judgment of the research findings and proposed PoliVAN logic model.

In this study, the process of evaluation is divided into two main categories, verification and validation, which are conducted over four progressive stages: (i) theoretical verification; (ii) subject matter expert (SME) validation; (iii) case study validation; and (iv) SSA transferability. Each stage in the evaluation process aims to incrementally improve the reliability and validity of the developed PoliVAN logic model. Figure 1.3 illustrates the evaluation roadmap. Each stage has an input type—the method used to perform the evaluation in each stage. Each stage also has one or two evaluation objectives to achieve throughout the evaluation process. A description of the evaluation objectives is shown in Table 1.1. Between the different stages the progression of the PoliVAN logic model is shown.

Stage 1: Theoretical verification

Following the research design depicted in Figure 1.2, the developed PoliVAN logic model takes into account the literature topics used to satisfy the research objectives of this study, the

Evaluation type	Evaluation process progression	Evaluation measuring outcomes

DEVELOPED POLIVAN

Structured questionnaire

Unstructured interviews

Literature cross-examination

STAGE 1:
Theoretical Verification

Theoretical verification

PROPOSED POLIVAN

SME workshop

Structured questionnaire

STAGE 2:
SME Validation

Relevance

Context appropriate

REFINED POLIVAN

Workshop case study

Desktop case study

STAGE 3:
Case Studies

Applicability

Flexibility

REFINED POLIVAN WITH
CONTEXT-SPECIFIC INSIGHT

IMPROVED POLIVAN FOR A
SOUTH AFRICAN CONTEXT

Structured questionnaire

Unstructured interviews

STAGE 4:
SSA Transferability

Transferability

FINAL POLIVAN WITH COUNTRY-
SPECIFIC PRE-REQUISITES

Figure 1.3: Evaluation strategy

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Table 1.1: A description of the evaluation objectives

EVALUATION MEASURING OUTCOMES
Theoretical verification The PoliVAN needs to be developed on sufficient, credible and valid literature findings.
Relevance The PoliVAN and the outcomes it produces need to be relevant to the objectives and needs of the VAN initiative.
Context appropriate The PoliVAN needs to be appropriate to the context in which the VAN Initiative is designed to operate.
Applicability The PoliVAN must be appropriate in terms of the level of difficulty of the tasks to be performed and the skills required for performing the task.
Flexibility The PoliVAN needs to be easy to adapt to change in a specific country setting.
Transferability The PoliVAN needs to be context-specific; however, transferable to other sub-Saharan African country-specific contexts.

PoliVAN objectives identified from the VAN literature research aim, as well as the design criteria. The developed PoliVAN logic model undergoes a thorough verification process. This process includes input from SMEs with the relevant experience in and knowledge[1] of the respective research areas, in order to assure that the PoliVAN logic model is developed based on valid, accurate and credible literature information and assumptions.

Stage 2: SME validation

Verifying the inputs that went into the development of the PoliVAN logic model provides assurance that the PoliVAN logic model has been 'built right' (Brade *et al.*, 2003). Once the updates from the verification process are incorporated, the PoliVAN logic model is proposed to relevant VAN experts—requiring their professional input and validation to ensure that the PoliVAN logic model is relevant and appropriate to the context of the VAN and the conditions of this study. The SME validation process makes use of structured questionnaires and semi-structured interviews (in the form of a workshop) in order to get the experts' opinions on the PoliVAN logic model proposed in this study. The SMEs only provide input based on their

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[1]Their knowledge specifically refers to their academic alignment with this research area.

knowledge and experience; therefore, to ensure that the policy analysis method is able to achieve its intended purpose, an additional validation approach is considered to further test the applicability of the PoliVAN logic model.

Stage 3: Case studies

Implementing the PoliVAN logic model is beyond the scope of this study, so a case study approach is undertaken. The PoliVAN logic model is applied to the South African VAN Operating Model in two case studies. The first case study focuses on testing the applicability of the PoliVAN logic model. The case study enables the implementation of the PoliVAN logic model to a small dataset or area to illustrate the ability of the design to achieve its intended purpose. The first case study applies the PoliVAN logic model to one of the operational functions in a pharmaceutical supply chain, medicine selection. This is done in a workshop setting with a number of SMEs.

The second case study aims to test the flexibility of the PoliVAN logic model—for example, whether the PoliVAN logic model can adapt to different elements of the VAN or pharmaceutical supply chain, and how flexible is it to such change. This case study applies the PoliVAN logic model to another operational function in the pharmaceutical supply chain, inventory management. This is done as a desktop exercise with SME-engagement where input was required.

Once both the case studies are completed, improvements (if necessary) will be made to the PoliVAN logic model for the South African context. This validation process, in addition to the applicability and flexibility objectives, allows insight into possible levels of effort required to utilise the PoliVAN logic model in South Africa and how the PoliVAN logic model should be adapted for different parts of the supply chain. The outcomes also provide insight into the efforts required to adapt the PoliVAN logic model to a specific context. The next step in the evaluation process is to investigate these context-specific factors for different SSA[1] countries, and discussed below.

Stage 4: SSA transferability

The final evaluation objective, transferability, aims to gain insight into the possible opportunities and restrictions for an SSA country to utilise the PoliVAN logic model. The validation process in Stage 4 consists of a questionnaire and unstructured interviews with relevant SSA VAN representatives in countries that have already developed a VAN Operating Model. The outcome of this validation stage will enable the construction of context-specific prerequisites for SSA countries that want to utilise the PoliVAN logic model.

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[1]SSA countries are selected, because the VAN initiative is specifically focused on these countries.

1.5   Document structure and outline

This section provides a layout of this document that reflects the logical course of this study. A graphical representation (Figure 1.4) is used to illustrate how the different chapters in this study align with one another. Additionally, the argument and motivation behind each chapter is summarised. Each chapter has an introductory paragraph, and concludes with a summary and a conclusion.
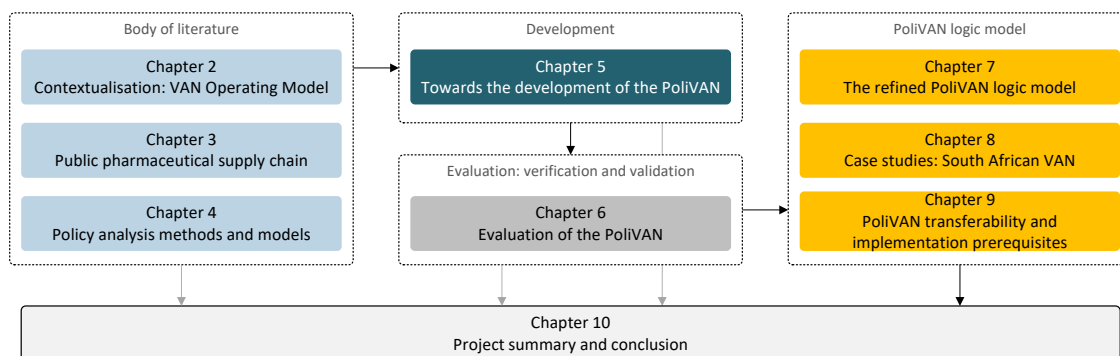
Figure 1.4: A schematic representation of the structure and layout of this study

Chapter 1

This chapter highlights the motivation behind the research problem in this study. It highlights the foundation from which the purpose and importance of this study is understood. It acts upon the notion that there are no existing, nor structured policy strategies available for medicine delivery in South Africa, especially in the face of implementing a VAN, and subsequently for any developing country aiming to implement a VAN strategy. The multiple aspects of this problem and a breakdown of the research objectives are discussed. This is supported by the research methodology and evaluation (verification and validation) strategy.

Chapter 2

The aim of this chapter is to provide context to this study by identifying the various elements and components a VAN Operating Model encompasses. This chapter discusses the guide that allows a country to develop a VAN Operating Model specifically for their country's context, including the VAN Operating Model that was developed for the South African context. This chapter provides insight into the different elements and components that the VAN encompasses and highlights the problem regarding the policy aspect of this model, which led to the birth of this study.

Chapter 3

In order to identify methods on how to develop policy strategies for an operating model such as VAN, it is necessary to understand the context in which a VAN is planned to be implemented. This chapter focuses on the operations of a pharmaceutical supply chain in a public sector. The different operational functions and components that allow a pharmaceutical supply chain to successfully operate are discussed, highlighting the fact that policies and legislations are the components that enable all the operations of a pharmaceutical supply chain—the enabling environment. This chapter also identifies different types of instruments in the enabling environment (i.e. policies, guidelines, standard operating procedures, etc.), broadening the scope of this study from policies alone, towards all the other legislative instruments as well.

Chapter 4

This chapter investigates various policy analysis methods and models that can be used to assist with the objectives of this study—to develop a proposition that allows health authorities, VAN personnel and government officials to develop policy-specific strategies for the VAN. This chapter identifies two different approaches to policy analysis models, and discusses some of the most prominent models and tools in literature within those two categories. This chapter concluded that there are multiple tools and models that can be used for policy analysis, and the choice of model and tool depends on the complexity of the problem, and whether the model or tool can be adapted to fit the objectives.

Chapter 5

In this chapter, key foundational concepts from Chapters 2, 3 and 4 are identified and used to develop a policy analysis method for a VAN—the PoliVAN logic model. Thereafter, the objectives of the PoliVAN are outlined, and based on the insights from the above-mentioned chapters, the key criteria are identified. Subsequently, the PoliVAN's development process is discussed with an overview of the high-level PoliVAN logic model that is developed.

Chapter 6

In this chapter, various verification and evaluation processes are executed to ensure that the PoliVAN logic model is correct, relevant and valid. The developed PoliVAN logic model is verified and validated by SMEs, utilising the following approaches: the use of expert interviews, questionnaires and workshops. All the possible aspects of the PoliVAN logic model are evaluated. The feedback from SMEs is interpreted and the necessary updates are made to the PoliVAN logic model.

Chapter 7

In this chapter, a detailed illustration and discussion of the PoliVAN logic model is presented and discussed. This is a practical approach that allows policy analysts, VAN personnel, government officials, and relevant stakeholders to analyse existing policies and legislations to develop policy-related strategies to enable the success of the VAN from a policy perspective. The version of the PoliVAN logic model presented in this chapter is refined from the first two stages of the evaluation processes, and is used for the third stage of the evaluation strategy, the case studies presented in Chapter 8.

Chapter 8

In this chapter, the third stage of the evaluation strategy is presented to illustrate the applicability and flexibility of the PoliVAN logic model. The scope of the case studies is defined, and a brief description of the SMEs who participated in each case study workshop, and who contributed towards the application of the case studies, is provided. Then, a short overview of the context of each of the case studies is given. The remainder of this chapter systematically proceeds as the PoliVAN logic model is applied to the described cases. Finally, the key findings from the case studies are highlighted with the adaption required for a South African-specific PoliVAN logic model. How the context-specific tools were adapted to fit the South African cases is summarised for the PoliVAN transferability process in Chapter 9

Chapter 9

The final validation stage is presented in this chapter. Here, the engagement with SSA VAN representatives and their feedback on the context-specific tools of the PoliVAN logic model is discussed. The conclusions drawn from the case studies and PoliVAN transferability questionnaires are highlighted and the context-specific prerequisites that are required before implementing the PoliVAN logic model are stipulated.

Chapter 10

This chapter provides a summary of the above-mentioned chapters, how they contributed towards the development of the PoliVAN logic model, and how they contributed towards the research aim and objectives of this study. Then, key findings from the application of the PoliVAN logic model are highlighted. This is followed by a reflection of this research study, whereby the unique contributions and the limitations of this study are discussed. Finally, possible future work is identified and discussed.

1.6   Chapter 1: Conclusion

This chapter gave an overview of the real-world problem and how an operating model such as the VAN is designed to solve the supply chain-related problems to improve the availability of essential medicines at the point of need in SSA countries. This chapter also gave an insight into the research gaps of the VAN initiative from a design and policy analysis perspective. Research objectives and methodologies were described, along with a detailed evaluation strategy, and the document structure and outline are discussed.

Chapter 2

Contextualisation: The VAN

This chapter provides a detailed description and overview of the generic Blueprint Reference Model (BPRM) that aims to improve the availability of essential medicines from a supply chain perspective. The BPRM was aligned to the South African context and a detailed account of South Africa's VAN Operating Model is discussed. Resultantly, this provides insight into how a VAN Operating Model can be developed from the BPRM. For the South African context, the discussion in this chapter considers the organisations involved in the supply and distribution of essential medicines, and each role player's responsibility within the VAN Operating Model. It illustrates the proposed planning activities to manage the pharmaceutical supply chain and briefly discusses the information technology landscape in which the VAN should ideally operate. Subsequent to the detailed description of the VAN, the lack of information about the role, influence and impact of policy from a design approach, is highlighted. Furthermore, this chapter briefly discusses the implementation plans for the VAN, along with the prerequisites and enabling factors that absolutely need to be in place before the VAN can be implemented. A limited number of documents that comprehensively describe the VAN concept and the proposed VAN operationalisation for a country's context are available. Consequently, this chapter is largely based on two key document, namely: (i) the *Blueprint Reference Model* released in March 2015 (Goel & Llewellyn, 2015); and (ii) the *VAN High Level Operating Model* released in October 2016 (Llewellyn, 2016). However, this chapter contributes towards the gap in literature, providing a comprehensive elaboration on the two existing documents.

2.1 Introduction to the VAN initiative

To address the issue of medicine shortages at primary healthcare (PHC) level, the National Department of Health (NDoH) in collaboration with the African Resource Centre (ARC)[1],

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[1] "ARC is an independent strategic advisor to African countries focused on improving the availability of medicines and health products" (African Resource Centre, n.a.)

designed an operational model (tailor-made for the current South African PHC context) to improve the current pharmaceutical supply chain. The operational model is derived from a generic model, known as the BPRM (Goel & Llewellyn, 2015), which can be used by developing countries that aim to strengthen their pharmaceutical supply chain. The following sections provide more detail about the BPRM, and how the operational model developed specifically for South Africa was designed, as well as in-depth discussion on the various elements of the South African VAN Operating Model.

2.1.1 The Blueprint Reference Model

Suboptimal supply chains are a significant contributor to underperforming health systems, especially in low- and middle-income countries (Goel & Llewellyn, 2015). To address these challenges discussed in Subsection 1.1.1, the Bill & Melinda Gates Foundation identified the concept of VANs as an area of focus when the strengthening of health systems is considered (Goel & Llewellyn, 2015). Leading supply chain organisations, such as Proctor & Gamble and Unilever, have implemented similar supply chain models to a VAN—often referred to as Control Towers—to improve product availability, and to facilitate end-to-end visibility along the supply chain (VillageReach, 2015).

According to the BPRM, the goal of the VAN initiative is to leverage private sector design approaches to improve end-to-end visibility across most relevant public health supply chains, and subsequently improve medicine availability. The BPRM describes the design of a VAN Operating Model at a level of detail that will enable countries to design and implement a VAN that is aligned to the specific pharmaceutical supply chain needs of the country. Even though the BPRM is not aimed at being a complete answer to underperforming supply chains, it aims to provide a generic framework (a guide) for developing countries looking to improve their pharmaceutical supply chain-related challenges (Goel & Llewellyn, 2015).

The BPRM provides the following information about the requirements for a VAN Operating Model (Goel & Llewellyn, 2015; Llewellyn, 2016):

i. Details regarding key VAN elements (defined in Table 2.1), i.e. people, process, technology and policy;

ii. Roles and responsibilities of VAN-related actors and stakeholders, as well as performance measures and indicators to sustain VAN capabilities;

iii. A common technical architecture of data requirements to enable a VAN, based on existing information systems and the maturity of such systems; and

iv. High-level operating processes and guiding principles concerning the overall governance of a VAN.

Table 2.1: Description of the design elements within VAN, excerpted from (Llewellyn, 2016).

ELEMENTS	THE VAN IS…	DETAILED DESCRIPTION
People	A team of dedicated professionals with defined roles and responsibilities, the right skills and knowledge, and a patient-centered, proactive approach to evidence-based quality improvement.	The highly skilled supply chain experts responsible for performing complex analytics to enable effective decision-making. The people element not only identifies the roles and responsibilities of the VAN experts, but also outlines the reporting structure within the VAN.
Process	Data-driven processes that use analytical methods to continually plan, pro-actively respond to, and recommend improvements.	The functional scope of the VAN is based on supply chain processes, and from subsequent workshops to design the BPRM, the four VAN services as they relate to the process element were identified—demand planning, supply planning, distribution planning, and cold-chain management—that consist of data-driven analytical processes performed by the people element.
Technology	The integration of multiple data systems, to generate alerts and actionable insight across the value chain with automation wherever possible.	This element refers to the data exchange between different existing systems, along with a list of the data required to run the processes, a mock dashboard that includes selected key performance indicators (KPIs) for the recommended processes.
Policy	A cross-cutting governance framework with clear responsibilities and accountability; and empowered decision makers with defined 'spans of control' across the medicine value chain.	Policy is the fourth element that governs the rest of the key elements. The BPRM provides policy assumptions and prerequisites, as well as governance considerations that need to be considered.

A VAN consists of a group of supply chain experts that can operate at any level of the system, empowered by the key VAN elements (each of these design elements contribute towards the objectives of the BPRM framework), geared towards improving the supply chain to ensure the availability of the right commodities when and where these are needed (Goel & Llewellyn, 2015). The supply chain experts are responsible for a majority of the supply chain-related work, and would require a shift in the roles and responsibilities of the current organisational structure.

As previously mentioned, the BPRM has been developed to aid developing countries in designing a VAN strategy specific to their current circumstances, and to address the specific needs of such a country. South Africa's NDoH, with input from multiple stakeholders, has designed a VAN to specifically fit the South African context, and defines how the different parts of the health system will function together in order to create improved performance in terms of medicine stock-outs at PHC facilities.

2.1.2   A VAN designed for the South African context

A VAN, in the context of South Africa, aims to transform the pharmaceutical supply chain from an uninformed pull system[1], to an informed push system[2]. The four stages of transitioning between these two modes of supply chain operation are illustrated in Figure 2.1. In a pull-based supply chain, the ordering and distribution are demand-driven, which is dependent on the customers' true demand; however, a push-based supply chain is dependent on the estimated demand by means of forecasting (Harrison *et al.*, 2004).

Stage 1: Uninformed Push	Stage 2: Uninformed Pull	Stage 3: Informed Push	Stage 4: Informed Pull
Most Basic: Higher levels of supply chain send stock to facilities based on assumptions and rough calculations. No supply chain training assumed.	**Trained Demanders:** Recipients make orders themselves. Training is available on how to calculate orders, but no analysis and upstream visibility possible.	**Trained and Informed Planners:** Technology is available to make current stock levels and consumption visible to specialist planners. Planners then make or recommend orders.	**Highly automated ordering:** Technology is available to automate much of the ordering process. Technology recommends orders to demanders who are only required to authorise spend

Figure 2.1: A description of the various pull and push systems, based on supply chain visibility (informed or uninformed). Excerpted from: Llewellyn (2016).

Forecasting is typically achieved through the use of an information system that ensures the stock levels and consumption data are accurate, available and visible to the necessary stakeholders. The transition between a pull- and push-based system (Stage 2 to Stage 3 in Figure 2.1) is achieved by adopting a cadre of supply chain experts (skilled in operating the technology information system) who are responsible for analysing the complex links in the supply chain, and optimising it; ultimately gearing it towards an informed push system. Therefore, to define in more detail, an informed push system follows a downward approach whereby informed experts (with data visibility) at either a national level or provincial level determine the type and quantities of products[3] to be supplied and distributed to the lower level (i.e. PHC facilities) (Management Science for Health, 2012).

The decision to implement an informed push model is due to the lack of supply chain competence from the current resources at public health facilities (Llewellyn, 2016). The current pull-based system of South Africa's public sector pharmaceutical supply chain is a complex

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[1]A pull system "follows an upward approach whereby health facilities determine the types and quantities of medicines required and place an order with the...supplier. This system is dependent on the demand of the facilities..." (Tema, 2014).

[2]A push system "follows a downward approach whereby the supplier at either a regional or national level determines the type and quantities of medicines to be supplied to the health facilities" (Tema, 2014).

[3]In this study, the term "products", "commodities", and "medicines" are used interchangeably.

system, requiring that scarce clinically trained staff members in the public sector to perform time-consuming supply chain-related tasks (Berger *et al.*, 2010). With the current resources, it is challenging to train PHC facility staff on the required supply chain skills to determine ordering quantities as the informed demanders of the system (Berger *et al.*, 2010). An informed push approach transfers the sophisticated supply chain work (such as the quantification of medicines to be ordered) from PHC facility staff who are not equipped to perform it, to the supply chain experts, enrolled by the VAN Operating Model. This process touches on the 'economies of skill' approach—the shift from low-skilled workers (or in this case, workers that may be highly skilled in terms of clinical work or healthcare provision, and who may therefore also be scarce resources, but who are not trained in supply chain management) towards high-skilled workers (or in this case, supply chain experts)—as part of technological improvements (Llewellyn, 2016).

2.2 The VAN Operating Model for South Africa

Llewellyn (2016) stated that "medicine access and availability are the outcome of a complex, multi-stakeholder value chain, with many related demand and supply functions interacting in a non-linear nature." Berger *et al.* (2010) conducted an in-depth review on access to medicines in South Africa and concluded that access to medicine barriers are interrelated, and that it occurs simultaneously at different levels of the health system, where multiple stakeholders operate. It is evident that a health supply system contains many interrelated components that need to function across the various levels of organisation that exist within a health system. Therefore, the combination of people, processes, technology, and policy should be organised coherently to ensure medicine availability (Llewellyn, 2016).

In the following sections, each of the four key VAN elements (defined in Table 2.1) are discussed (in light of the South African VAN Operating Model) to provide an understanding of how each element contributes towards medicine availability, as well as how these elements coordinate and interrelate with one another. The following sections follow the same order as how they were initially introduced: people, processes, technology, and policy.

2.2.1 People element: VAN organisational structure

The people element of the VAN consists of dedicated professionals with roles and responsibilities that are organised across different levels of the health system. This section provides detailed descriptions of the different role players and their responsibilities towards the VAN operationalisation. The roll-out of the VAN Operating Model is planned to be executed among three tiers of the public sector pharmaceutical organisational structure: national level, provincial level, and the district/facility level. These levels are considered to be the three levels of the

South African government structure (Tibane *et al.*, 2016). Each level has a set of actors and organisations that have specific roles and responsibilities within the VAN Operating Model.

In the context of South Africa, the VAN Operating Model builds on the existing split of responsibilities between the national and provincial levels. The VAN operates as a tactical centralised unit within each province, which is referred to as a Provincial Medicine Procurement Unit (PMPU). The PMPUs are responsible for managing the majority of the supply chain activities and administration for the district facilities in their respective provinces (Llewellyn, 2016), using modern delivery methods (Department of Health, 2017). The highly skilled supply chain analysts in each PMPU are encouraged to make or suggest ordering recommendations for facilities, rather than facilities being responsible for their own ordering.

The PMPU role in the planning activities consists of essential medicine consumption analysis, availability of stock, physical distribution constraints, and planning data for the national level. The data also contributes towards budget alignment and the resolution of possible issues. The national level will operate under the influence of the Affordable Medicines Directorate (AMD), which is a subset of the NDoH. The AMD is responsible for governing the processes and data from the provincial plans at an aggregated level, as well as facilitating communication along the supply chain, managing the national budget allocation, and resolving supplier issues (Llewellyn, 2016). Figure 2.2 summarises the VAN roles assigned to the different levels of the pharmaceutical supply chain: national, provincial, and district/facility. The absence of supply chain-specific roles at the district/facility level highlights one of the key VAN objectives: to place highly skilled supply chain specialists at provincial levels (PMPUs), to shift the responsibilities of supply chain related tasks away from the facilities.

Organisations	Selection/ Catalogue Master Data	Demand	Supply	Transportation
National: AMD	National Product Master Data Manager; EDP Lead	Demand Manager; Demand Analyst	Supply Manager; Supply Analyst	
Provincial: PMPU	Provincial Master Data Manager • Locations • Capacity • Lead Times	Demand Planner; S.C. Analyst	Supply Planner; Inventory Planner; S.C. Analyst	Transport Planner; S.C. Analyst
PMPU < > District Support		VAN Liaison to Budget Holders	VAN Liaison to Depot, X-Dock, Facilities	
District/Facility: Owners and Managers		District / Facility Budget Ownership Roles	Depot/Warehouse Operations Manager; Health Facility Representative / Stock Manager	Depot/Warehouse Operations Manager

Figure 2.2: The VAN roles at the different organisational levels (Llewellyn, 2016).

The non-PMPU roles (thus, AMD and district/facility roles) shown in Figure 2.3 are over-simplified for the South African context, and can be undertaken within the existing South African roles. The first column (Figure 2.3) states the VAN role; the second column describes the responsibilities associated with the role (from a VAN perspective); the third column defines the outcomes or KPIs that are expected from each role; and the fourth column defines the existing roles in South Africa that will need to undertake the corresponding VAN roles.

VAN Role	Responsibility	KPI	SA Roles	
MoH Budget Holders	1. Review Net requirement at country level and Supply Commitment 2. Review budget requested against allocated budget and previous budget utilisation 3. Approve or allocate budget against the forecasted demand to country/regions 4. Adds knowledge of healthcare to service level setting	Service Level Target to Patients	**Hospital:** Hospital CEO/ CFO/ Medical manager/ Pharmacist, **PHC:** (Sub) District manager/ Pharmacist/ Metro Pharmacist, **Depot** (non-allocated stock): Depot manager/ HOP, NB: National will check for aggregate affordability, and in instances where funds are held nationally	
Health Facility Representative	1. Share expected Demand data based on Usage & Health Trends 2. Sharing of On Hand Stock details, Cycle counting 3. Receipt & Delivery of Stocks 4. Storage and Handling of stocks 5. Transfer Rejected stocks to WH/CMS	FEFO Compliance Score ; Non-fulfilment of patient requirement;	**Data entry** PHC operational manager, Ward sister, Post basic pharmacy assistant	**Planning & oversight** District pharmacist, Hospital pharmacist, Metro pharmacist Programme / District Partners
Master Data Manager	1. Responsible for updating new product details into ERP / Other Related System 2. Responsible for updating new health facility, shipper , warehouse details into ERP / Other Related System 3. Resolving any system related issues by coordinating with experts/vendors.	Data Accuracy and Completeness	**National:** AMD should manage Product Master data. The **EDP lead** will be process owner and accountable for maintenance in a central repository, the **Demand Manager** will be responsible for promulgation to MPUs	
			Provincial: In a model where PMPU manages administrative and planning functions in provinces, the PMPU Master Data Management role is accountable for maintenance of Master Data for Locations, Capacity and Lead Times for distribution for Location>SKUs	
Warehouse / CMS Manager	1. Material receipt and dispatch 2. Storage and Handling of medical commodities 3. Writing off Rejected Stocks 4. Sharing Inventory details with Planners 5. Preventive maintenance of equipment and facility	FEFO Compliance Score; On Time Dispatches; In Full Dispatches;	**Warehouse / CMS Manager** (Similar to responsibilities column)	
			VAN Supply Chain Director 1. Responsible for Supply Chain Performance 2. Manage escalation handling process 3. Drive continuous improvement in supply chain processes	

Figure 2.3: Summary of the responsibilities of non-PMPU roles with allocation to possible existing South African roles, excerpted from (Llewellyn, 2016).

The aforementioned VAN roles (as shown in Figure 2.2 and 2.3), as well as their responsibilities across the different levels of the pharmaceutical supply chain (i.e. the national, provincial and district/facility levels), are coordinated by intricate sets of processes and communication

channels. Figure 2.4 clearly indicates the split responsibility between the national and provincial level as previously mentioned. Each PMPU is responsible for the majority of the supply chain processes as seen from the different delivery channels in Figure 2.4. These processes are organised according to the supply chain planning services (demand-, supply-, distribution-, and cold chain management) from the BPRM, which are discussed further in Subsection 2.2.2.
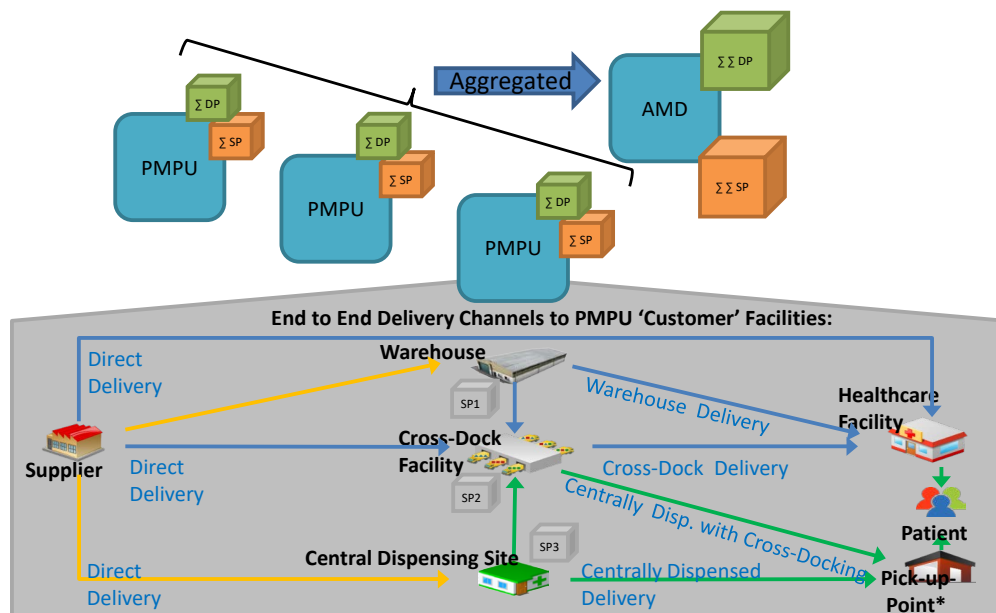
Figure 2.4: Illustration of the split role between the national and provincial level, as well as the supply chain channels governed by the PMPU. Excerpted from: (Llewellyn, 2016).

2.2.2 Process element: Supply chain planning processes

According to the APICS Dictionary, a supply chain is "a system of organisations, people, technologies, activities, information and resources involved in moving materials, products and service...from the supplier...to the end customer" (Wallace, 1984). Goel & Llewellyn (2015) describe a supply chain as "many overlapping things" and categorise the functions of a supply chain into three supply chain planning activities, namely: demand planning, supply planning, and distribution planning (note that the VAN Operating Model for South Africa does not incorporate cold chain management into the operational model). Demand planning is a multistep process to create a forecast, based on consumption patterns and inputs from health experts and facilities, in order to meet patient and customer needs. Supply planning is concerned with co-coordinating inventory and orders in the most optimised way to fulfil the demand plan. Distribution planning involves the shipment of products between the different warehouses and facilities, in response to the supply plans (Llewellyn, 2016).

Each supply chain planning process is discussed in the following sections. The activities within each supply chain planning category are illustrated by means of process maps. The process maps do not only illustrate the sequential activities, they also indicate the responsible actor for each activity, as well as provide insight on how data should be shared amongst the different organisational levels.

2.2.2.1 Demand planning

Demand planning activities apply trend analysis to historical data gathered from the various districts and facilities, and makes use of statistical modelling to determine the demand plan consensus across all facilities in the respective provinces (Llewellyn, 2016). A more detailed illustration of the VAN's proposed demand calculation approach can be found in Figure A.1. The objective of the calculation is to identify the future demand at each node of the health delivery system. A detailed representation of the key processes to determine the demand consensus is given in Figure 2.5.
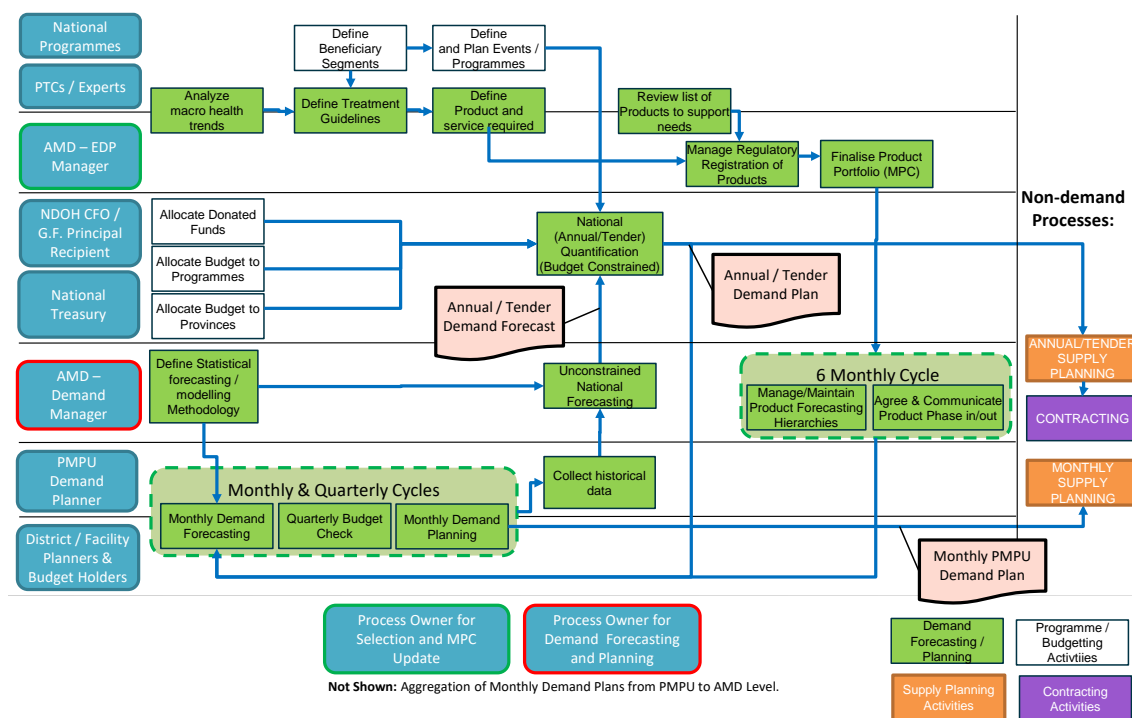
Figure 2.5: Integration of demand planning and other supply chain activities—horizontal swim-lanes show activity ownership (Llewellyn, 2016).

The selection of medicine is primarily programme-specific, i.e. the Essential Drugs Programme (EDP). Every six months, the selection and update of the master procurement catalogue (MPC) is reviewed by an AMD manager to ensure the best treatments and medicines are selected to improve a patient's outcome. This process includes the substitution and phase

in/out of new products. From a supply chain perspective, the substitution or change of a stock keeping unit (SKU) requires planning and forecasting in order to update the physical capacity plans and cycling of stock at the national warehouse (Llewellyn, 2016).

PMPUs are responsible for updating the monthly demand plans (forecasting plans) in order to track and reflect the actual consumption data received from respective district facilities. The granularity of the forecasts should ultimately be based on the facility and specific product level (Llewellyn, 2016). The monthly updates are aggregated to the national level; long-term (annual) forecasting processes take place with relevant and necessary experts and inputs from national statistical data, such as demographic trends, disease burdens, and seasonality.

The annual estimated demand plan determines the tenders of possible suppliers and annual budget allocations. It is the responsibility of the National Treasury and the NDoH's Chief Financial Officer (CFO) to review the annual forecast with budget holders and inform the annual budget allocation to each province for the procurement of pharmaceuticals. The consumption data and changes in budget allocation are subsequently aggregated and used at the national level to provide a baseline for annual or tender plans (Llewellyn, 2016). A change in the updated demand forecasts from the consumption data will have a direct effect on the budget, therefore a designated budget holder is responsible for executing quarterly updates and amending the budget allocation for supply planning according to the forecasted data (Llewellyn, 2016). These updates are used to inform monthly supply planning processes, which in turn are used to calculate supplier orders and replenishments (Llewellyn, 2016).

Due to the significant effort required to manage the demand-, supply-, and distribution planning processes, a hierarchy of plans is used to illustrate the interconnectedness of the planning activities. Figure 2.6 summarises the demand process map in Figure 2.5 into the process map hierarchy, which illustrates the planning activities discussed, the frequency at which the different processes are updated, as well as how the processes and activities interact between the national and provincial levels.

As previously mentioned, the supply chain planning categories are interlinked with one another—the output from the one process serves as an input to the next process. The outputs of the demand plan consist of the product demand according to the product type and geographical region (see Figure A.1), which is used as one of the inputs for the supply planning process calculations (see Figure A.2). The orange (supply planning) activities in Figure 2.5 also indicate that the demand plan is an input to the supply plan.

2.2.2.2 Supply planning

Supply planning activities within the VAN (shown in Figure 2.7) aim to optimally coordinate inventory levels, number of orders, and shipment plans, in order to ensure sufficient stock, and
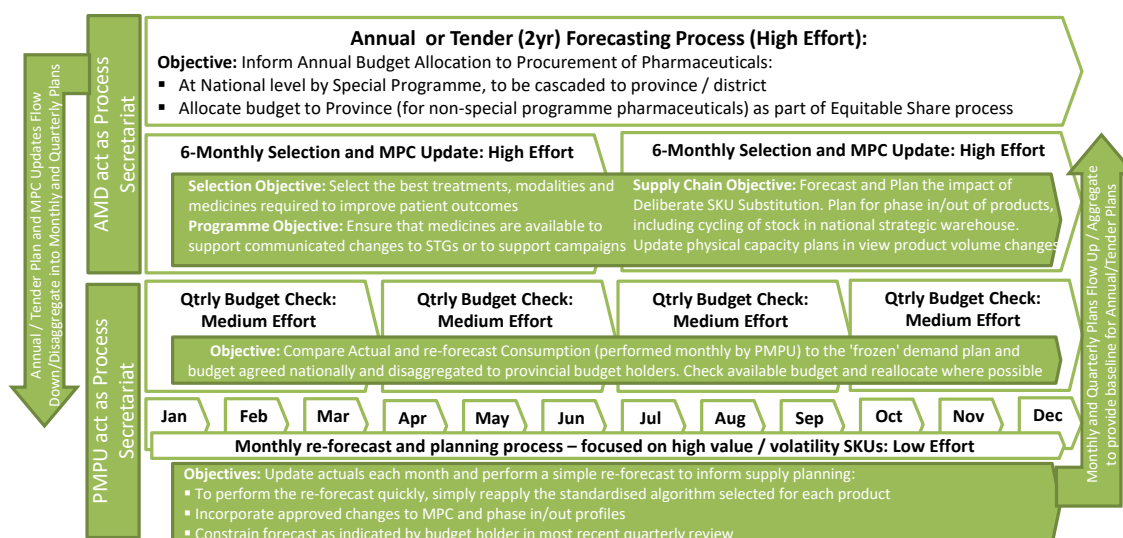
Figure 2.6: Hierarchical process cycles, with different actors, data granularity, and frequency for demand planning (Llewellyn, 2016).

to fulfil the demand plan, which is the input for the supply planning activities (Llewellyn, 2016). The objective of the supply planning process is to procure the ideal number of medicines as per the forecasted demand. Another objective is to maintain the right levels of inventory at the different nodes in the health system to ensure that there are ideally no stock-outs, and minimal wastage due to expired stock (Goel & Llewellyn, 2015).

The calculation of how the stock levels, supplier coordination and procurement are determined is illustrated in Figure A.2—in essence, the forecast data from the demand plan, along with multiple planning variables, are used to determine the following inputs for the supply plan: replenishment frequencies, demand variability, order cycles, lead time, stock on hand, sample rate, etc. (Llewellyn, 2016). Similar to the demand plan, a process map (Figure 2.7) illustrates the key activities for the supply planning process. The annual and monthly demand consensus are (as mentioned) the inputs for the supply planning process. The process map also indicates the roles responsible for each activity.

From the annual demand plan, the AMD supply manager is responsible for analysing the ordering quantities required to ensure stock availability to maintain the suggested inventory levels, based on the current stock holdings, and the fluctuation in stock as contracts are renewed and/or expire. The AMD supply manager works in collaboration with the AMD contract manager (activities are indicated by the purple process blocks in Figure 2.7), who is responsible for developing and managing the content of tenders (Llewellyn, 2016).

Six-monthly updates are performed by the demand planning actors that inform the supply planning actors about the timing of implementation of the Standard Treatment Guidelines
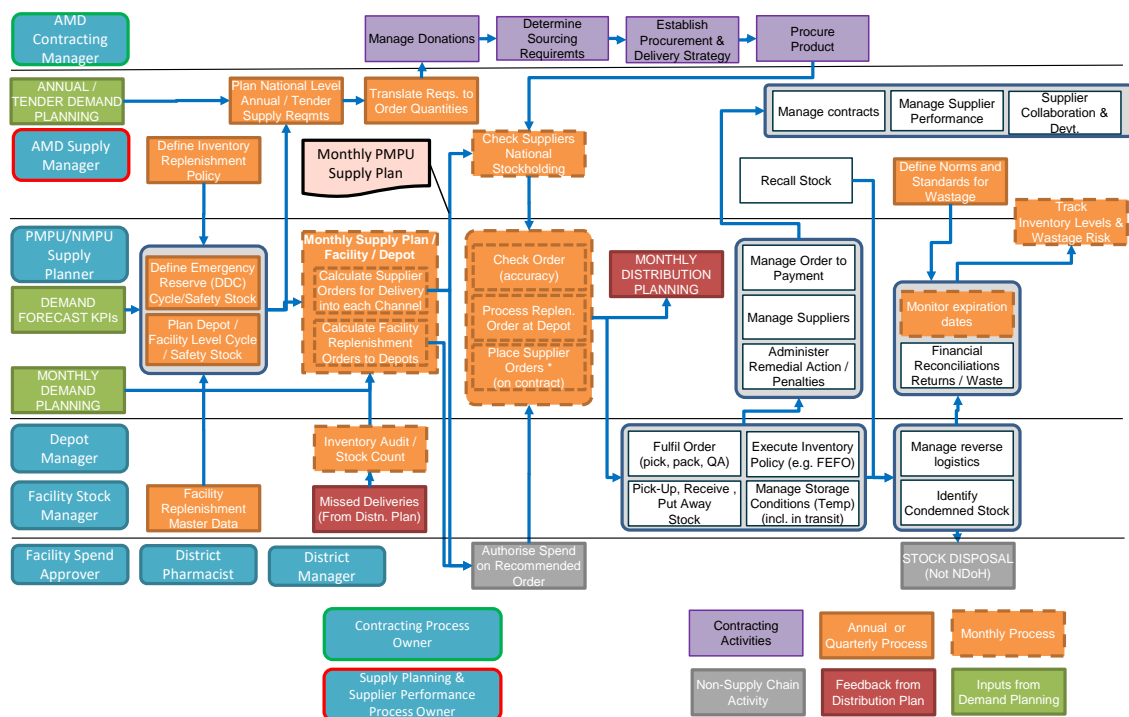
Figure 2.7: Integration of supply planning and other supply chain activities—horizontal swim-lanes show activity ownership (Llewellyn, 2016).

(STG) and new product selection. The AMD supply manager and EDP manager collaborate in order to create contracts and orders, based on the Essential Medicines List (EML) and STG, to achieve the required new product availability (Llewellyn, 2016).

As mentioned, the demand planning division is also responsible for the quarterly review of budget availability (Llewellyn, 2016). Evidently, this budget has an impact on the supply plan when the monthly process creates medicine order recommendations that need to be authorised by the spend approvers at district/facility level. The PMPUs are responsible for the monthly supply plan of orders required from the suppliers, as well as the replenishment plan for the movement of stock throughout the depots (Llewellyn, 2016). These monthly plans will be aggregated to the national level to confirm whether the suppliers have sufficient stock to meet the current (and future) demand (Llewellyn, 2016).

A summary (hierarchy) of the supply process map is given in Figure 2.8. The supply planning hierarchy is particularly similar to the demand planning hierarchy, due to the fact that the demand plan provides input for the calculation of the supply plan—the green demand planning activities within the supply plan hierarchy (Figure 2.8). The supply planning activities mainly operate at annual and monthly frequencies, and are reliant on the six-monthly and quarterly activities from the demand planning processes.
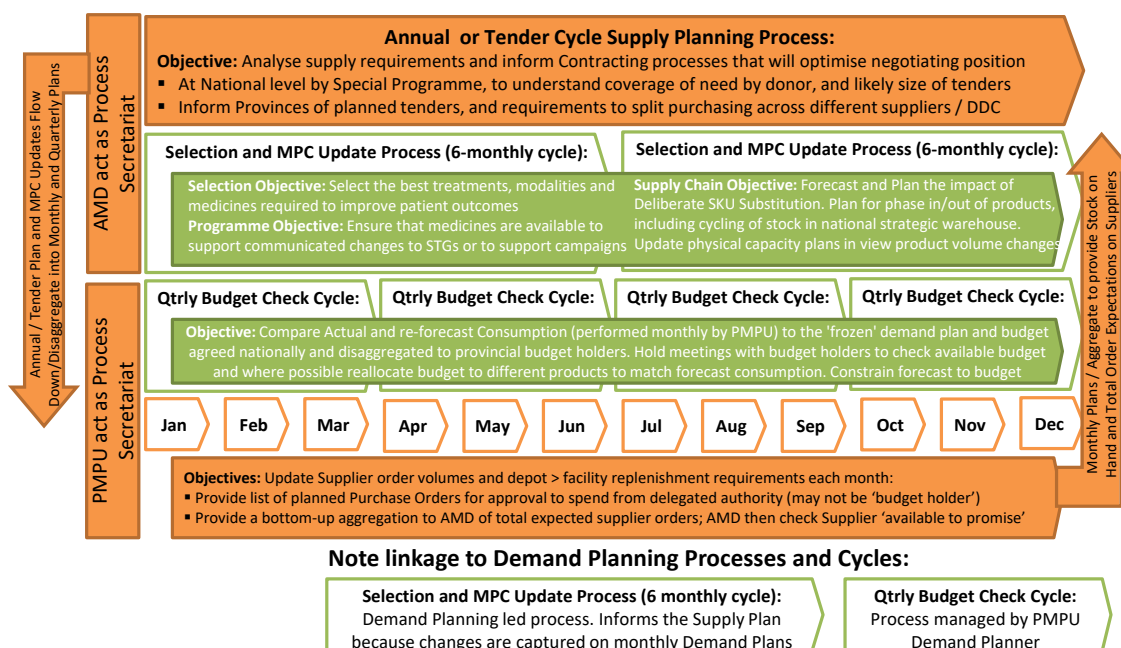
Figure 2.8: Hierarchical process cycles, with different actors, data granularity, and frequency for supply planning (Llewellyn, 2016).

2.2.2.3 Distribution planning

Distribution planning activities shown in Figure 2.9 are concerned with the scheduling of shipments and the distribution of products between the different warehouses and facilities, in response to the output from the monthly supply planning consensus (Llewellyn, 2016). Operations that are involved in both the supply- and distribution planning stages include: the execution of the physical delivery of material flow; the operations from the picking and packing; supplier management; stock logistics; and storage management.

The distribution plan determines the shipment and loads that are required by the respective depots and facilities in order to meet the replenishment plan. The distribution plan aims to use storage and available capacity as efficiently as possible, and feeds back information to the supply and replenishment plans respectively in the event that issues arise. Figure A.3 illustrates how the distribution plan is determined and calculated.

The hierarchy plan for the distribution processes is divided into two process levels. The first level consists of long term (1-3 year cycles) distribution trend analysis, done to calculate the capacity plans and to ensure network optimisations. This process generates data on order deliveries, shipment reliability, and costs of shipments (Llewellyn, 2016). The second level consists of short-term (weekly and daily cycle) planning that creates a distribution plan to schedule replenishment of drugs and medicine between the various government depots and facilities (Llewellyn, 2016). In the VAN operationalisation, the updates are done daily or weekly
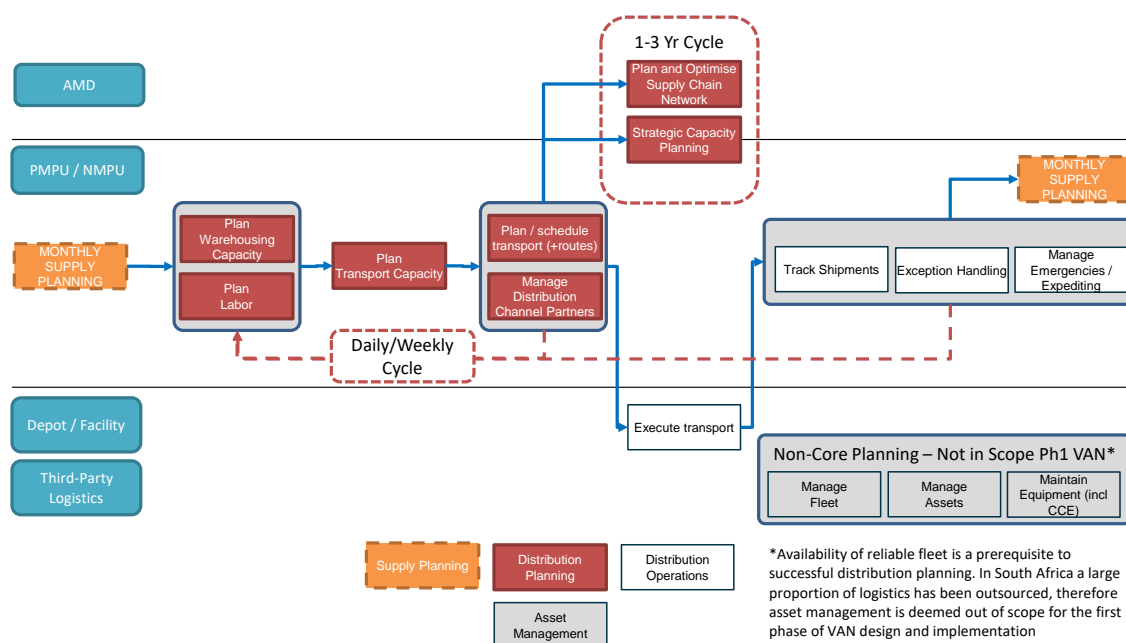
Figure 2.9: Integration of distribution planning and other supply chain activities—horizontal swimlanes show activity ownership (Llewellyn, 2016).

and will provide input on the available capacity, window for dispatch, and information on the delivery and receipt of stocks. The execution of the distribution plan is done by third-party logistics (3PL) companies—the activities in the white blocks (shown in Figure 2.9) represent such outsourced activities.

It is evident from the supply chain process maps that the VAN is a complex model with intricate processes that are interlinked at various levels of the pharmaceutical supply chain. It also indicates that there are many processes that demand data sharing among different levels of the organisational structure, as well as across the various supply chain categories. The following section discusses the technology element that encompasses the activities revolving around the end-to-end visibility objective of the VAN Operating Model.

2.2.3 Technology element: Integrated information technology and data sharing system

As previously mentioned, the VAN Operating Model for South Africa is designed to move the current pharmaceutical supply chain from an uninformed pull system, to an informed push system. The transition between the two systems not only requires supply chain experts, it also requires the technology that will enable the end-to-end visibility across the supply chain (Kleynhans *et al.*, 2018; Llewellyn, 2016).

The technology element of the VAN strategy aims for "an integrated network of multiple

data systems to generate alerts and provide accountable insight across the value chain with automation wherever possible" (Llewellyn, 2016). For this approach to work, it is critical that the supply chain planners have access to the following:

i Timely and accurate stock-on-hand data—accurate stock-on-hand data enables supply planning by ensuring accurate historical consumption for demand forecasting;

ii Up-to-date 'slow changing' data—accurate formularies per facility for the informed push of the correct medicines to the facility; and

iii Consistent product and location master data product nomenclature visibility for all planners, product and packaging specification for distribution planning, and accurate location and replenishment data to enable supply planning and inventory management optimisation.

From Table 2.1, the technology element is defined as the systems for data collection and aggregation that generate alerts and deliver actionable insight, with automation wherever possible. South Africa's public sector pharmaceutical supply chain operates on a fragmented and incomplete information system (Llewellyn, 2016). The use of different software technologies at different levels of the healthcare system make visibility within a supply chain difficult and cumbersome (Berger *et al.*, 2010). There are currently multiple software systems in use across the pharmaceutical supply chain in South Africa (e.g. MEDSAS, RFx, and Sourcelink) and these software systems are used inconsistently to perform the same function in different parts of the system, e.g. the tender and contract management system used in one province is different from the system used in another province (Berger *et al.*, 2010; Kleynhans *et al.*, 2018).

Of the multiple software systems being used, the two primary information systems proposed (by the VAN) for South Africa's public pharmaceutical supply chain—and currently the main focus for VAN implementation—are the Stock Visibility Solution (SVS)[1] and the RxSolution[2].

The use of different information systems across the healthcare system make data aggregation across provincial and national levels difficult or infeasible. Data aggregation is an important function for a VAN's information system in order to provide visibility across the supply chain (Kleynhans *et al.*, 2018).

Currently, the SVS and RxSolution systems are used in conjunction with one another and integration plans are in development to incorporate these two systems into a comprehensive

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[1] The SVS is a smartphone application, available for PHC dispensing facilities, to capture daily stock levels (Kleynhans *et al.*, 2018; Mezzanine, 2017). The data is automatically uploaded to a central, online repository or cloud (Kleynhans *et al.*, 2018; Mezzanine, 2017), which is available to district and provincial authorities in real time.

[2] The RxSolution is an integrated pharmaceutical management software package that supports best practices for procurement, storage, distribution and dispensing of pharmaceuticals (Berger *et al.*, 2010).

pharmaceutical information system. The future integration plan will allow the upstream system to automatically place replenishment orders for clinics in line with an informed push replenishment approach, a further modernisation of supply chain practices (National Department of Health, 2016b). The orders placed automatically will be based on monthly stock consumption determinations based on regularly reported medicine availability information uploaded into the SVS (Kleynhans *et al.*, 2018; Llewellyn, 2016).

For the South African VAN Operating Model, the existence of an integrated information system is still in the development phase; however, before a system can be developed, the system's criteria should be designed. The BPRM focuses on three sections for the planning and designing of a VAN information system (Goel & Llewellyn, 2015):

Data requirements: A list of data requirements to run the data-sharing processes suggested and for a VAN to operate smoothly.

Dashboard mockup: An example of a dashboard for a VAN with KPIs from recommended processes.

Technical and data architecture: Information on what data needs to be shared between the VAN and other existing systems.

At the time of implementation, it is recommended that a country should detail how the data for the information system would be collected. The BPRM provides an example (Figure 2.10—an extracted section from the data requirements table provided by the BPRM) of the minimum data requirements for VAN processes. The figure[1] also defines the frequency and level of granularity at which these data elements need to be captured, which helps define the resources required to perform the VAN activities.

Taking into account the VAN processes from the operational activities in Subsection 2.2.2, as well as the data requirements table from the BPRM (Section B.1), the VAN processes are analysed to determine what type of data elements are needed to support the visibility objective of the South African VAN model, and to determine for example, what data the various actors need to have access to, and who is responsible for generating this data. For the sake of interest, the data requirements for the South African VAN Operating Model are provided and discussed in Section B.2.

The data requirements (both from the BPRM and the South African version) clearly indicate that the data elements are dependent on one another, and that the information will only be able to successfully support the functioning of the VAN if data ownership that enforces the capturing of high-quality data is enforced (Kleynhans *et al.*, 2018). For the VAN's information system, there are not only multiple information channels, but there are different frequencies

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[1]For complete version, see Section B.1.

SI No.	Data Elements	Business Process	Used by (KPI /sub-process)	Frequency	Granularity
1	Historical consumption	DP	Statistical Forecasting	Monthly	At Storage Facility / Health Facility level
2	Forecasted Demand (unconstrained)	DP	Forecast accuracy/Forecast Bias/ Accuracy of statistical forecast/ Forecast Constrained	Monthly	By Health Facility / By SKU
3	Forecasted Demand (constrained)	DP	Forecast accuracy/Forecast Bias/ Accuracy of statistical forecast, Supply Plan	Monthly	By Health Facility / By SKU
4	% Waste	SPIM / DTM	SLOB / Write Off	Monthly	By health Facility / By SKU
5	Epidemiological data	DP	Statistical Forecasting	Annually	At Country / National / Regional level
6	Demographics	DP	Statistical Forecasting	Annually	At Country / National / Regional level
7	Seasonality data	DP	Statistical Forecasting	Annually	At Country / National / Regional level
8	Ordered quantity	DTM	In full dispatches/Order Processing	Monthly	By Health Facility /

Figure 2.10: Data requirements—extracted from the BPRM (Goel & Llewellyn, 2015).

at which the data should be generated. Because there are different frequencies at which data needs to be available, policies play an important role in formalising the frequency requirements and ensuring that the responsible actor complies with these.

This argument can be applied to all the data requirements, because the operating processes, such as demand forecasting, rely on consumption data from the facilities, but if the facility does not fulfil the responsibility of providing accurate and quality data, then the demand planning PMPU will not be able to provide the correct demand estimate to the supply planning PMPU. This will result in inaccurate order quantities at the suppliers, and probably lead to overstocking or understocking at the facilities.

Therefore, policies that stipulate and enforce the responsibilities of various actors in terms of the supply chain processes and data requirements are essential to ensure that the information system contains high-quality, comprehensive data to enable the effective functioning of the supply chain (Kleynhans *et al.*, 2018). As mentioned, the policy element governs all other elements within the VAN (Llewellyn, 2016), and is thus an important contributor towards its success. The contents regarding the policy element of the VAN are discussed in the next section.

2.2.4 Policy element: Governance framework

The policy element for the VAN Operating Model is defined as a "cross-cutting governance framework with clear responsibilities and accountability and empowered decision-makers with defined spans of control across the medicine supply chain" (Llewellyn, 2016). The VAN strategy for South Africa has well-planned roles and processes; however, the policy element is the least-

developed element, therefore special focus needs to be placed on the interaction between policy and the other VAN elements (Kleynhans *et al.*, 2018).

Even though there is a limited amount of information on the policy element for the South African VAN, the BPRM has provided generic assumptions to policy prerequisites and governance considerations for country VANs. Each country has different policies, regulations, and strategies that need to be acknowledged while designing a country-specific VAN (Kleynhans *et al.*, 2018). However, in order to successfully implement a VAN, each country must stay true to VAN design principles (Goel & Llewellyn, 2015).

A critical element of a VAN's success is the existence of an invigorating strategic vision of the change in the system (Goel & Llewellyn, 2015). Political will, policy enablers, and sponsorships are among the policy prerequisites, and the VAN Operating Model needs to be supported by the topmost tier of the respective political establishments and the Ministry of Health. Despite the policy enablers and engagement from political establishments, other policy requisites are also provided by the BPRM (Goel & Llewellyn, 2015):

i. The VAN is enabled with end-to-end visibility across the supply chain.

    a. Capturing and sharing accurate and timely data is required for end-to-end visibility, and policies that balance appropriate data protection with data between the political, supply chain, and health organisations should be introduced.

    b. Various organisational structures in the supply chain need to interconnect through collaboration and open communication in order to support information-sharing and building trust.

    c. To generate quality data, accountability for data gathering and the quality of the data needs to be defined, and resources at all levels need to be incentivised to share data and information.

ii. The VAN is empowered by performance measurement.

    a. Different layers of the organisation need to collaborate actively in the standardisation of supply chain performance management.

        * A common understanding of standardised KPI definitions and calculation methods. Reports produced should be interpreted the same way across all functions, geographies and programs, focusing on key outcomes in a synchronised manner.

        * A common understanding of what constitutes a measuring 'period', especially in instances where calendars differ across multiple organisations in the supply chain.

    b. Decision-making needs to be fact-based and supported by informed insights and business rules that explore trade-offs. Performance should be measured and fed back to the decision-makers to make informed decisions (e.g. establishing forecasting methods from historical data as opposed to only static demographic and consensus information).

    c. A low staff turnover should be embedded to enable continuous improvement–supporting resources (within and outside VAN roles) through performance-driven incentives and rewards, by measures against KPIs, accountability and ownership.

These policy prerequisites provide an oversight on how the objective of the VAN—to ensure end-to-end visibility across the supply chain and deliver supply chain services to all programmes and tiers—can be met if the above-mentioned examples are implemented. The end-to-end visibility is based upon the informed push model (Stage 2 in Figure 2.1). An uninformed pull model allows for medical staff to request orders based on the visibility of what is in stock locally and limited knowledge of the demand. Informed pull (Stage 4) is a relatively advanced system, which is highly dependent on technology, and is deemed as too sophisticated, and not applicable for low- and middle-income countries, where technological maturity, regulations and political structures may not allow for the VAN to take full control over stock replenishment down to the facilities (Goel & Llewellyn, 2015). Therefore, it is recommended that the VAN should base all policy assumptions on the informed push model approach.

The informed push model is only effective when it is subjected to strong governance structure to deliver supply chain services to all programmes and tiers. A VAN is a single governance unit that can exist in multiple organisation layers, which acts as an aggregator of information to all tiers of the supply chain, produces performance monitor plans, and interacts with non-VAN organisation layers (Goel & Llewellyn, 2015). In the context of South Africa, the AMD and PMPU take on the role of the VAN unit. For the VAN to deliver supply chain services to all programmes and tiers, the BPRM provided some governance considerations (Goel & Llewellyn, 2015):

   i. All organisational entities (including government authorities, supply chain organisations, healthcare bodies and programme staff) should have access to information on policies, roles and responsibilities, and accountabilities—exception handling procedures, escalation routes, approval processes and their role in each should be articulated and understood.

  ii. To implement a VAN, a change management process is required—changes in processes, roles, structures and technology need to be effectively communicated and implemented. The impact this change will have on stakeholders should be communicated, along with a

Change Impact Assessment subsequently, with the design of a training and communication plan.

iii. If a central decision-maker operates within a country with devolution of government to states, the autonomy of the state means that the authority cannot influence the entire supply chain. This means that their 'span of control' stops where the state's 'spans of control' starts. In this case, VAN liaison roles are required for each state to ensure that the VAN plans are enacted. For South Africa, a liaison role is situated between the PMPUs and the district level (depots, cross-dock and facilities), depending on the province or region, as well as a liaison role to the budget holders between the district and/or facility budget ownership role and the PMPU.

iv. The VAN process requires frequent interactions between the supply chain experts and the Ministry of Finance staff. The selection of the appropriate finance stakeholders depends on how the country delegates authority for spend on medical commodities from a Ministry of Health level to the specific programmes, as well as how frequently the budgeting is performed and updated.

v. The VAN information system needs to be able to create alerts to highlight exceptions. These will then need to produce recommended plans of action (exception handling plan) and ensure it is presented to the decision-maker to approve (or reject) and ensure the process is executed.

From the above consideration, it is evident that the VAN model for South Africa has taken into account most of these considerations. South Africa's VAN-design includes detailed processes on how the VAN will operate, with clearly defined roles and responsibilities of VAN personnel (including non-VAN personnel) executing these processes. The processes and roles are designed in mind of an integrated technology system that will provide end-to-end-visibility across the supply chain. However, the design of the South African VAN Operating Model does not provide any information regarding the effect current policies might have on the success of such an operational model. Neither does the VAN Operating Model plan on how to identify the impact of change on the stakeholders. This is a result of the lack of policy and governance insight provided in the BPRM. The BPRM does not, from a design perspective, provide the necessary guidance on how to plan for the impact of a country's current policies on the implementation of a VAN.

As mentioned, the policy element for the South African VAN is the least developed, and is required before a VAN can be fully implemented. The next section discusses the implementation plans, and what is required before the implementation of a VAN.

2.3   Implementation roadmap

The VAN is in line with the NDoH's strategy to improve medicine accessibility and availability. The AMD has created a strategic framework (Figure 2.11) that is derived from evidence-based problems and solutions. The strategy aims to steer the health delivery system from the current context towards integration with the National Health Insurance (NHI) landscape[1]. The supply chain functions, including the contracting and contract management functions, are the core functions in the VAN Operational Model for South Africa.
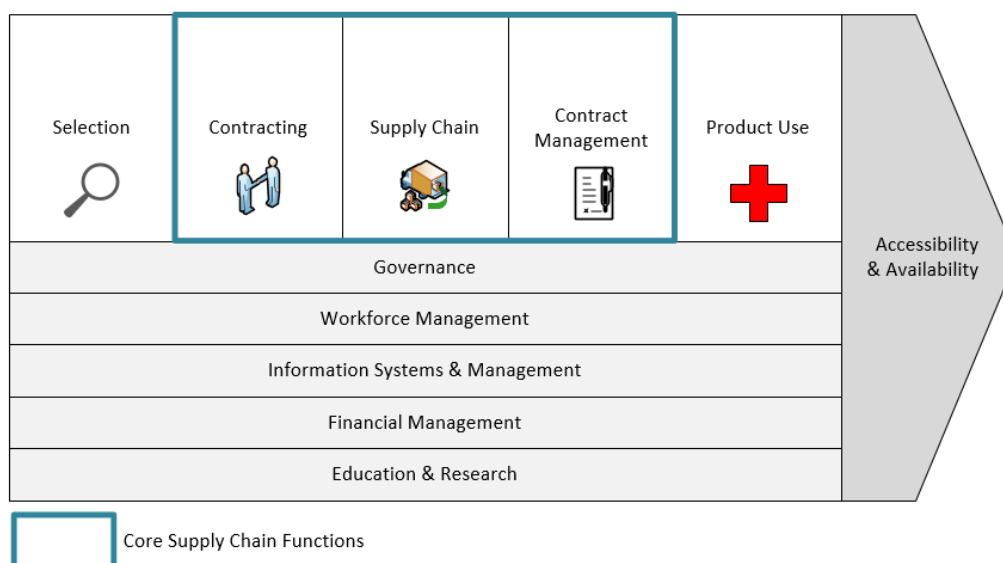
Figure 2.11: The Affordable Medicine Directorate (AMD) strategic framework to improve medicine availability (SIMA) (Llewellyn, 2016).

The selection and product use functions are equally as important as the core supply chain functions. The selection function influences the MPC, that has a knock-on effect on the supply chain functions—the product to be released into the system. The product use function provides not only consumption data to the system, but is part of ensuring that products are used rationally beyond the point of the facility. According to the context of the NHI, the relationship between the functions and their dependencies needs to be made clear, regardless of the current organisational structure. Implementing the VAN will, therefore, require stakeholder engagement across multiple organisations (Llewellyn, 2016).

The implementation plan of the VAN manages resource allocation across four phases of intervention (see Figure C.1), which might have complicated interdependencies (Llewellyn,

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[1] "National Health Insurance (NHI) is a health financing system that is designed to pool funds and actively purchase services with these funds to provide universal access to quality, affordable personal health services for all South Africans based on their health needs, irrespective of their socio-economic status" (Department of Health, 2017).

2016). For the sake of brevity, details regarding the implementation strategy for the South African VAN model, are available in Appendix C.

2.4 Chapter 2: Conclusion

This chapter provides background on the concept of the VAN approach and how South Africa has managed to adopt this approach and designed a country-specific VAN for the current South African context. The four design elements of the VAN, namely: people, process, technology, and policy are defined and thoroughly described in this chapter. The people element focuses on the split responsibility between the national (AMD) and provincial (PMPU) units, and describes the roles and responsibilities of other VAN, as well, as non-VAN roles.

Furthermore, the process element describes the three planning processes of the supply chain (demand, supply, and distribution planning), and how these processes interconnect with one another. The planning processes are illustrated by means of process maps containing the responsible actor for each activity. Moreover, the technology element is described with the aim of achieving the end-to-end visibility across the supply chain. Even though there is insufficient information provided on the actual data requirements, the BPRM and the process activities were used to determine the data requirements for the South African VAN.

The policy element is described with the aim of being a cross-cutting government framework; however, there is no information available on the policy plan for the South African VAN. Therefore, the BPRM is used to define some policy and governance guidelines a VAN Operating Model should consider. Although the BPRM is a thoroughly planned document, it lacks insight on how policies will support the VAN initiative. Therefore, further investigation into the policy landscape is required in order to identify the impact policies might have on the operationalisation of the VAN. Finally, a brief introduction to the implementation plan is provided, with a detailed discussion in Appendix C—emphasising the fact that enablers such as policies and governance structure should be intact before the VAN can successfully be implemented.

From this chapter, it is confirmed that the role of policy analysis should be investigated in order to identify country policies that might affect the VAN Operating Model (positively or negatively). The VAN Operating Model is designed to be implemented in a country's (public) pharmaceutical supply chain sector. In order to conduct a policy analysis approach, one first needs to understand the link between policies and the VAN (apart from what is discussed in this chapter). Therefore, further investigation of the link between policies and a pharmaceutical supply chain should be undergone.

The next chapter (Chapter 3) takes an in-depth look at the functions and operations of a pharmaceutical supply chain in the public sector, in order to understand the link between the pharmaceutical functions and country policies.

Chapter 3

Public pharmaceutical supply chains and the link to policy

The Visibility and Analytics Network (VAN) concept is designed to improve the availability of essential medicines in public pharmaceutical sectors. The VAN design elements (people, process, technology, and policies) should all be organised coherently to achieve this goal; however, the Blueprint Reference Model (BPRM) lacks understanding how policies might influence the operationalisation of a VAN Operating Model. The BPRM provides guidance on how to develop a VAN specific for a country's need, but the policy section only provides a few governance recommendations to consider.

From Chapter 2, it is concluded that the VAN is designed to operate in the public pharmaceutical supply chain context. This chapter aims to provide an understanding on how a pharmaceutical supply chain operates within a public sector, and the link it has with policies. This chapter start by defining the role of supply chain management in the pharmaceutical sector, leading towards the identification of the logistics framework. The logistics framework encompasses the functions and the elements that make a supply chain operate. Furthermore, the logistics framework is then used to identify and discuss the functions and elements in the context of a public pharmaceutical sector. The framework also identifies the link between policies and a pharmaceutical supply chain.

Finally, the information of the logistics framework in the pharmaceutical context is used to investigate the current operations of South Africa's[1] pharmaceutical supply chain, which is available in Appendix E—subsequently providing insight into the operations and obstacles that South Africa's pharmaceutical sector faces in terms of policies.

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[1]The reason behind this investigation is further discussed in Chapter 8, where the South African VAN Operating Model is used as the input for the case studies.

3.1 Supply chain management in public healthcare

In this section this section, term 'supply chain management' is defined (Subsection 3.1.1). The term 'logistics management', which is used interchangeably with ' supply chain management is defined, and the different operations within the scope logistics management are identified and discussed in Subsection 3.1.2.

3.1.1 Definition of supply chain management

The terms 'supply chain' and 'supply chain management' have come to prominence over the past decades (Cooper *et al.*, 1997). However, as these terminologies have been defined by multiple authors in both academia and in practice, overlapping and at times contradictory definitions of them exist. In response to the uncertainty caused by the existence of these multiple definitions, Croom *et al.* (2000) and Mentzer *et al.* (2001) conducted a critical systematic review of the topic. Table 3.1 shows a few definitions gathered from various sources with the goal of developing a comprehensive definition upon which the rest of this study can build.

Table 3.1: The definition of supply chain management by various authors

Authors (Source)	Definition
Jones & Riley (1985)	An integrative approach to dealing with the planning and control of the material flows from suppliers to end users.
Stevens (1989)	"The objective of managing the supply chain is to synchronize the requirements of the customer with the flow of materials from suppliers in order to effect a balance between what are often seen as conflicting goals of high customer service, low inventory management, and low unit cost."
Lee & Billington (1992)	Networks of manufacturing and distribution sites that procure raw materials, transform them into intermediate and finished products, and distribute the finished products to customers.
Christopher (1992)	Network of organisations that are involved, through upstream and downstream linkages, in the different processes and activities that produce value in the form of products and services in the hands of the ultimate consumer.
Lee & Ng (1997)	A network of entities that starts with the suppliers and ends with the customers through the production and delivery of goods and services.
Cooper *et al.* (1997)	"... an integrative philosophy to manage the total flow of a distribution channel from supplier to the ultimate user."

Table 3.1 continued from previous page

Authors (Source)	Definition
Kopczak (1997)	The set of entities, including suppliers, logistics services providers, manufacturers, distributors and resellers, through which materials, products and information flow.
Kopczak (1997)	Supply chain management encompasses materials/supply management from the supply of basic raw materials to final product (and possible recycling and reuse). Supply chain management focuses on how firms utilise their suppliers' processes, technology and capability to enhance competitive advantage. It is a management philosophy that extends traditional intra-enterprise activities by bringing trading partners together with the common goal of optimisation and efficiency.

Although the definitions in Table 3.1 differ from one another, there are partial overlaps found among the different definitions. For the purpose of formulating a definition of the term supply chain management, the following observations on the definitions provided in Table 3.1 are made:

- A majority of the authors agree that a supply chain consists of an integrated network of firms/entities/organisations, that includes coordination and collaboration.

- Lee & Billington (1992), and Kopczak (1997) state that these firms/entities include: manufacturers, suppliers, distributors, warehousing, and logistics services through which the product flows;

- Jones & Riley (1985), Lee & Ng (1997) and Cooper *et al.* (1997) argue that a supply chain flows from the supplier, as the starting point, to the end user. Thus these conceptualisations of the supply chain include the consumer as part of the supply chain (Mentzer *et al.*, 2001);

- Christopher (1992) defines the flow within the supply chain as upstream and downstream linkages of processes and activities; and

- According to Jones & Riley (1985), Stevens (1989) and Tan *et al.* (1998), the processes and activities of supply chain management include: the management of the supply and flow of material, by utilising the suppliers' processes and technology through planning and control; and ensuring competitive advantage; high customer services; low inventory management; and low unit costs.

Based on the preceding discussion, supply chain management is conceptualised as follows for the purpose of this research: a network of organisations (consisting of manufacturers, suppliers, warehouses, distributors, and customers), working in collaboration with one another,

that are directly involved in the upstream and downstream flows of processes and activities, logistics services, technology, material, information, and finances in order to achieve competitive advantage and customer satisfaction. This definition is similar to the 'supply chain' term given by the APICS Dictionary. However, Wallace (1984) provides a distinction between the term 'supply chain' and 'supply chain management'. Supply chain is referred to as a system comprising the organisations, technologies, processes and information involved in the flow of products to the end consumer, whereas supply chain management is referred to as the supply and demand management of these products across the multiple organisations (Wallace, 1984).

In some cases 'logistics management' is used interchangeably with 'supply chain management', while in other cases these two terms are distinguished from one another. The APICS Dictionary and the Council of Supply Chain Management Professionals (CSCMP), define logistics management as the part of supply chain management that deals with the management of the forward and reverse flow and storage of goods, services and information in an optimised way (Wallace, 1984). The term also refers to the functions that need to be carried out by the various supply chain partners (Raja & Mohammad, 2004), and are considered the operational component of supply chain management (Usaid Deliver Project, 2011).

3.1.2 Logistics cycle

These operational components form part of the main functions of a logistics cycle. The logistics cycle shows the activities and resources that are required to operate an effective supply chain and to ensure that the *right* goods are delivered in the *right* quantities, in the *right* conditions, to the *right* place, at the *right* time, for the *right* cost (Usaid Deliver Project, 2011). Over the past decades, logisticians have developed supply chain logistic models that illustrate the relationship between the various activities and resources within the system, each having a slightly different method of portraying the cycle. Four such portrayals of the logistics cycle are depicted in Figure 3.1.

As shown in Figure 3.1, each cycle starts with a 'selection' or 'product selection' function and ends with a 'use' function, the functions in-between are those that differ slightly between the different sources. Figures (b) and (d) refer to a process between selection and procurement, such as forecasting, quantification and pricing. According to literature, forecasting and quantification are similar concepts—forecasting methods are used to determine the order quantification (customer demand), which determines the demand of products to procure (Usaid Deliver Project, 2011). Figures (a) and (d) both combine the storage and distribution functions into a consolidated function, while Figures (b) and (c) separate storage from the distribution function. By identifying the similar identities and components within the remaining

(a) Management Science for Health (2012)

(b) WHO AIDS Medicines and Diagnostics Service (AMDS) (2011)

(c) Amenyah (2008)

(d) Usaid Deliver Project (2011)
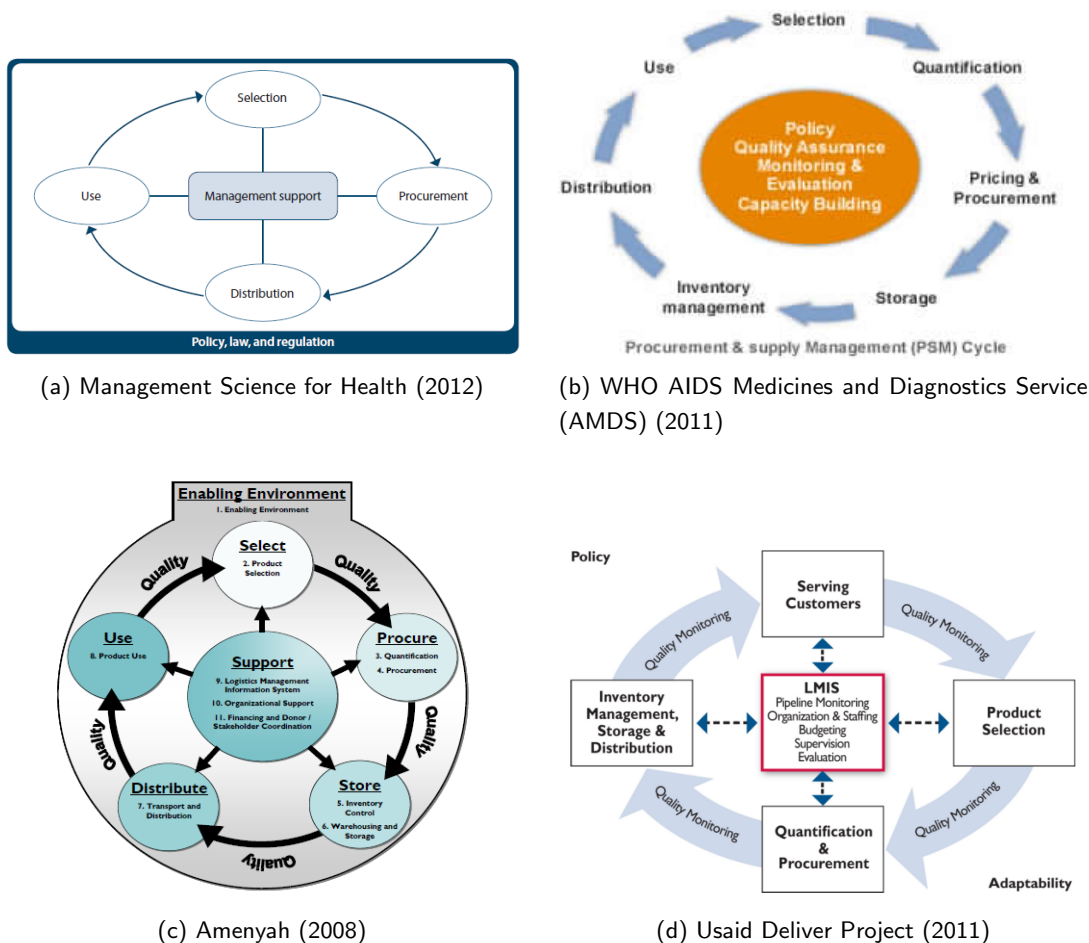
Figure 3.1: Various representations of the supply chain logistics cycle

cycles, a comprehensive logistics framework, illustrated in Figure 3.2, is selected and adjusted for use in the remainder of this study.

Figure 3.2 is organised around the four basic operational functions: selection, procurement, inventory & distribution, and product use. The circular cycle indicates a repetitive nature, meaning that each function depends on the other functions (Raja & Mohammad, 2004). Even though the operational functions occur in a cyclic nature, the activities within each function can occur at various levels in the system, and at different frequencies. At the core of the cycle are the supportive elements, which represent managerial functions that inform, support and impact the four operational functions within the cycle. Each function is a critical process in supply chain management, but none of them function in isolation (World Health Organization, 2007). Decisions and actions taken in each stage interact and depend on each other; therefore, customers will not be served if one of the stages fails in the execution phase (Raja & Mohammad, 2004).

The entire system (operational functions and supportive elements) requires policies, as

Figure 3.2: A comprehensive supply chain logistics framework used for this study

well as a political, legal and regulatory environment wherein these functions operate (Raja & Mohammad, 2004; World Health Organization, 2007), which is considered the enabling environment. The logistic functions can be incorporated into a medicine delivery system. This structure of the framework is considered the same for any level of a healthcare system; however, the processes within each function might vary between countries in accordance with local policies, laws and regulations (Usaid Deliver Project, 2011). The next section provides insight into how the logistics framework is applied within the healthcare context.

3.2 Applying the logistics framework to public healthcare

In healthcare, supply chain management is a set of practices aimed at ensuring the timely availability and appropriate use of safe, effective, quality medicines, health products, and services in any healthcare setting. Healthcare activities are organised according to functional components of a cyclic system (such as the logistics cycle mentioned in the previous section) and may take place at various levels of the healthcare system according to the design of the health system (Management Science for Health, 2012). The functions of the logistics cycle are the same for all health sector levels; however, the procedures and activities within each component may differ depending on the context (i.e. country-specific, or private versus public sector) (Management Science for Health, 2012).

In this section, the logistics framework (Figure 3.2) is described in the light of a public sector

pharmaceutical supply chain, each function within the logistic cycle being defined and described based on the activities within a public sector pharmaceutical supply chain. The framework in the context of a pharmaceutical healthcare system will be referred to as a pharmaceutical logistics framework (PLF) from here onward. The information described is not country-specific, but contains the activities within the functions that are considered generic for any public sector pharmaceutical supply chain.

3.2.1 Operational functions

The following subsections discuss the four operational functions of the logistics framework within the public healthcare context.

3.2.1.1 Product selection

Product selection is a key process in a healthcare logistics system, that identifies the product that needs to be procured to serve the customers and patients[1]. Because no public sector or health insurance system can afford to supply all available medicines on the market, the practice of selecting essential medicines[2] helps sets priorities for all aspects of the pharmaceutical system (World Health Organization, 2001). The products that are selected within a public sector pharmaceutical supply chain become part of a national essential medicines list (EML) (Usaid Deliver Project, 2011). Another term used in conjunction with the EML is a formulary list[3], that contains information on the approved products for use in a specific healthcare setting.

The selected products have a major impact on the supply chain system, therefore, supply chain requirements need to be considered during the selection process. The EML has a limited variety of products to ensure that the supply chain is more manageable and agile, ensuring: (i) cost reduction from suppliers (economies of scale) (Usaid Deliver Project, 2011); (ii) more focused training of the health workers; (iii) prescribers gaining more experience with the selected products; (iv) and rational prescribing (World Health Organization, 2001). The type and range of drugs that form part of the EML are selected according to health programmes (e.g. HIV and Aids, tuberculosis and chronic diseases), by a national formulary committee, therapeutic committee, or government-appointed group (Usaid Deliver Project, 2011).

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[1]In this study, 'customer' and 'patients' are used interchangeably as the end user in the pharmaceutical supply chain system.

[2]The World Health Organization (1999) defined essential medicine as drugs "that satisfy the needs of the majority of the population and therefore should be available at all times, in adequate amounts, in appropriate dosage forms and at a price the individual and the community can afford."

[3]It is a document that contains relevant information for the prescriber, dispenser, nurse or other health worker on a product's generic name, indications on dosage schedules, side effects, etc. Every country's formulary manual differs, depending on their context (Management Science for Health, 2012).

These committees are made up of members with clinical, process and methodological knowledge (Pharasi & Miot, 2012), such as doctors, pharmacists, and health ministry officials. In order to provide perspective on the supply chain systems, a supply chain manager should be included to determine the impact of a selected product on the supply chain (Usaid Deliver Project, 2011). The supply chain expert provides insight into the change in the system when new products are entered into or removed from the pharmaceutical supply chain.

The criteria for the selection of essential medicines is provided by WHO guidelines and drugs are selected according to evidence-based criteria and procedures (World Health Organisation Expert Committee, 2003). Countries develop EMLs at different levels of the system that target disease patterns commonly known to occur in a specific geographical region (Usaid Deliver Project, 2011), with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost (National Department of Health, 2015a). The pharmaceutical products that are selected for a specific facility should be based upon Standard Treatment Guidelines (STGs)[1].

The use of STGs have significant supply chain benefits, serving as a prerequisite for determining a base assumption in forecasting (Usaid Deliver Project, 2011). The STGs also play a vital role in the case of product substitution, because the supply chain has to adapt each time a product is added, substituted, or removed. For example: when a new product is added to the supply chain, a new stock keeping unit (SKU) has to be assigned and updated throughout the supply chain and the supplier management, to procure that specific product.

In order to use pharmaceutical products that are selected, evaluation and approval is necessary from a governing body, such as a regulatory authority. This is also known as the registration process, where products need to be proven to be safe, efficient, and of good quality. Because the evaluation of quality is a significant part of the registration process, different brands are registered separately, and in most cases, products of the same brand but that come in different types of packaging are also registered as separate products. It is important that registration protocols are adhered to with pharmaceutical products. This is mostly the responsibility of the manufacturers and not ministries of health nor supply chain managers; however, the supply chain managers need to ensure the products they procure are registered as required (Usaid Deliver Project, 2011).

In some cases, especially in the public sector, implementing donor partners (such as the Global Fund, USAID, or UNICEF) have specific disease programmes that require certain criteria to be met when using their funds (Usaid Deliver Project, 2011). Selecting a donor product that is not on the country's EML, registered, or in the STGs, may cause a delay with the registration of a new product, training of staff members, and the entering of a new product

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[1]STGs are "suggested treatment protocols for the most optimal treatment of a specific clinical problem, in a given setting, based on consensus by experts" (Usaid Deliver Project, 2011).

into the supply chain (Usaid Deliver Project, 2011). Therefore, when selecting products based on donations, the following should be adhered to: the product should appear on the EML list; it should be registered; it should appear in the STGs; and it should meet donor requirements (Usaid Deliver Project, 2011).

3.2.1.2 Quantification and procurement

The second operational function in the PLF, is quantification and procurement. In broad terms: after the selection process, forecasting is required to determine the estimated quantities of medicines needed to satisfy the demand, and financial analysis is required to determine the cost structures to coordinate available funds accordingly (Ripin *et al.*, 2014). A medicine procurement system ensures that the correct commodities are available for distribution from the suppliers to the designated health facilities. The activities flow according to the procurement cycle illustrated in Figure 3.3.
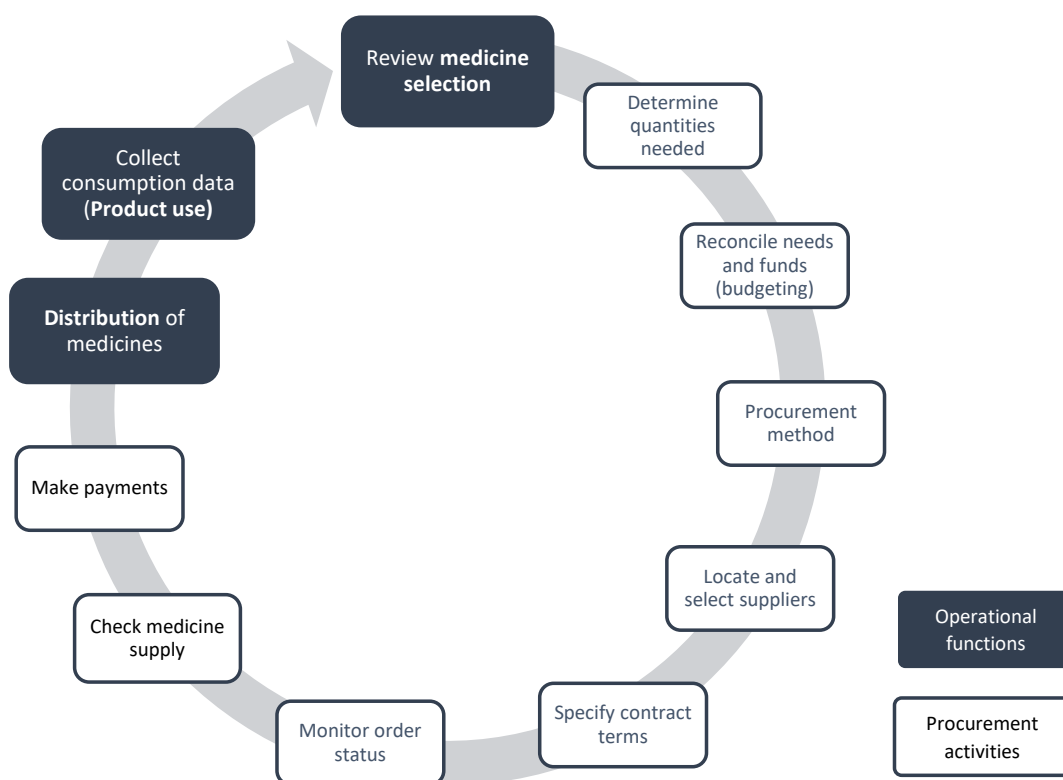
Figure 3.3: Illustration of the activities within the procurement function, adapted from (Management Science for Health, 2012).

The procurement cycle illustrates how the activities from the quantification and procurement function flow from and into the other logistic cycle functions (such as medicine selection, distribution, and product use)—highlighting the cyclic nature of the logistics cycle.

Quantification is the first step in the procurement cycle, and is defined as "the process of estimating quantities and cost of the products required for a specific health program, and determining when the products should be delivered to ensure uninterrupted supply for the program" (Usaid Deliver Project, 2011). In some cases, the terms 'quantification' and 'forecasting' are used interchangeably (Management Science for Health, 2012), however, for the purpose of this study, the term 'forecasting' will be used to describe the calculation method used to determine the product quantities. Thus, forecasting is a calculation method within the quantification function. Quantification is considered a critical activity within the pharmaceutical supply chain, that is responsible for the linkage between the consumption of commodities and services at the facility, and national policies and programs to determine the costs of the health programme (Usaid Deliver Project, 2011).

For each product within a healthcare pharmaceutical supply chain, a set of steps are followed to provide quantification data: preparation, forecasting, and supply planning. The preparation phase of the quantification process involves assembling quantification teams that are responsible for defining the policies relating to health programmes, strategies, as well as collecting the data that is necessary for the forecasting and supply planning phases (Usaid Deliver Project, 2011). As part of the preparation phase, the teams can collect the data from multiple sources, which can be categorised according to the following quantification data sources (Management Science for Health, 2012; Usaid Deliver Project, 2011):

i. Demographic: Demographic health surveys, census data, population growth and trends, and population characteristic (e.g. age, gender, and geography);

ii. Morbidity: Epidemiological data, percentage of population with specific disease, and standard treatments;

iii. Service: Number of services provided (i.e. health conditions treated), and daily registers; and

iv. Consumption Information system reports, consumption and inventory reports, and reported quantities dispensed.

Demographic data are based on population characteristics and are not always recommended for quantification, unless paired with other data sources, because the data are typically not regularly updated (Usaid Deliver Project, 2011). Quantification based on morbidity data is the most complex and time-consuming quantification method and is based on prevalence incidences or health conditions within a specific population group (Management Science for Health, 2012). As forecasting based on morbidity data tends to overestimate the amount of commodities needed, the data has to be expressed as a ratio—a percentage of the population with a specific disease (Usaid Deliver Project, 2011). A challenge that is frequently experienced

with this approach to forecasting, is that data are not available on all disease types, for all population groups.

The service-level forecasting data provides more insight into the financial needs and budget requirements for pharmaceutical procurement, rather than a product quantity estimation (Management Science for Health, 2012). The data used for this type of forecasting includes the number of service visits at which products are dispensed, diseases treated, and immunisations given (Management Science for Health, 2012). The most accurate method for forecasting the demand for pharmaceutical products, is consumption-based forecasting. This approach uses consumption data based on actual dispensed products (products given to patients). A challenge with utilising consumption data, is the possibility that facility level staff did not accurately capture the amount of dispensed products (Management Science for Health, 2012).

In the forecasting phase of the quantification process, the data that was collected in the preparation phase (such as the demographic data and morbidity data) is used to calculate an estimated quantity of each product to be procured for a predefined period (Usaid Deliver Project, 2011). Forecasting units are measured according to product quantities, therefore other data units, such as number of patients and number of treatments need to be converted to the number of products (Usaid Deliver Project, 2011). As discussed, forecasting based on historical consumption data is the best way to predict future needs; however, using historical data for a facility is not feasible if the facility has experienced stock-outs for a long period of time (Management Science for Health, 2012). These forecasts are then used to build a demand consensus (also referred to as a demand plan) among key stakeholders such as policy-makers, procurement units, programme managers, and healthcare providers. The consensus is conducted by forecasting the data captured, along with historical trends, projecting the trend forward—monthly, quarterly, annually—to calculate the future demand (Usaid Deliver Project, 2011).

The demand quantities for each product are then used to conduct a supply plan. The supply plan consists of shipment quantities and delivery schedules. The data needed for these plans differ from the data needed for forecasting. The main objective of the supply plan is to provide the programme managers with information to identify funding requirements, suppliers costs, forecasted consumption, etc. (Usaid Deliver Project, 2011). Ultimately, quantification is not a once-off process, it is an ongoing process of regular monitoring, reviewing and updating the data and assumptions, and recalculating the required cost and funds.

The calculation of the required cost and funds bridges the quantification activity with the rest of the procurement activities. During the last phase (the supply planning phase) of the quantification activity, the budget and funds necessary in order to supply the estimated quantities are calculated. Budgeting and financing for pharmaceuticals play a critical role

in the availability of medicines at healthcare facilities (Usaid Deliver Project, 2011). The budget is a plan by the government that outlines how the income generated by the national government, along with donor funds, will be distributed amongst the national, provincial, and district governments (Hassim & Heywood, 2007). Ensuring adequate financing for health care is becoming increasingly difficult in the face of economic pressures (World Health Organization, 2001). The primary sources of funds include government financing (i.e. taxes), health insurance schemes, and donor financing.

It is important for the procurement unit to communicate with the Ministry of Health and the funding agency to determine when the funds will be released to procure products (Usaid Deliver Project, 2011). Government and donor funds are released irregularly throughout a financial year (Management Science for Health, 2012), which makes proper procurement systems difficult to operate. Delays in releasing of funds are one of the major causes of stock-outs and procurement delays (Management Science for Health, 2012). It is advised that the quantification and budget requirements should be estimated for at least a 12-month to 24-month period, and updated regularly. These updates involve policy updates and inputs that might affect the demand for the products (Usaid Deliver Project, 2011).

The next step in the procurement cycle is to determine the procurement method. A procurement plan can be lengthy, because it involves the transfer of money, the availability of funds, and potential currency exchanges. The supply plan (the final plan from the quantification step) provides inputs for the procurement plan and, in addition, includes the identification of the procurement method to be used (e.g. centralised models or decentralised models). These models determine how and by whom the following steps, i.e. contracts and payments, are handled, and the choice of procurement method is determined in conjunction with the selection of either a pull- or a push-based system[1].

The success of a drug programme depends on the suppliers that will be able to deliver the right products, at an affordable cost, within the specified time frame, therefore, the selection of suppliers should be done in a manner that is as fair and transparent as possible. The selection of suppliers and contracts (the next step in the procurement cycle) is usually based on different tendering methods that can be used to solicit bids: open tender, restricted tender, competitive negotiation, and direct procurement (Management Science for Health, 2012; Usaid Deliver Project, 2011).

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[1]There are two types of procurement systems that a pharmaceutical supply chain can execute: pull-based and push-based. A pull system follows an upwards approach whereby the health facilities determine quantities of medicine required and place the order. A push system follows a downward approach whereby an expert at either a national level or provincial level determines the type and quantities of products to be supplied (Management Science for Health, 2012).

A description of each of these methods is provided in Table 3.2. Any of these methods can be used and the choice is informed by the national policies and regulations. Bids are offers for a quantity of goods, or service, at a stated price. The invitation for bids aims to reach a wide range of interested suppliers to ensure the selection of suppliers is fair and competitive (Usaid Deliver Project, 2011).

Table 3.2: Description of the different tender methods, excerpted from (Management Science for Health, 2012; Usaid Deliver Project, 2011).

Tender method	Description
Open tender	An open tender is a formal procedure whereby quotations are invited from a potential manufacturer or supplier locally or globally subject to the terms and conditions specified in the tender invitation.
Restricted tender	In a restricted tender, interested suppliers must be approved in advance, usually through a formal pre-qualification process that considers adherence to good manufacturing practices, past supply performance, financial viability and other related factors.
Competitive negotiation	Competitive negotiations involve approaching a few selected suppliers and requesting price quotations.
Direct procurement	This is the simplest but perhaps the most expensive procurement method of all as it involves direct purchase from a single supplier either at quoted prices or negotiated prices.

After the bids are evaluated, contracts are awarded to the best suppliers based upon set criteria. The contract is a document that legally binds the purchaser and supplier on agreements. The agreements include product specifications, delivery requirements, performance, payment obligation of both parties, and legal implications when one party does not comply with the agreements (Usaid Deliver Project, 2011). After contracts are awarded, these need to be monitored to ensure both parties comply with the agreements within the contract. A contract monitoring system or unit should be established to: monitor the health system compliance; monitor contractor's services, check invoices and certify payments; prepare assessment of supplier performance; and communicate during execution of the contract (Management Science for Health, 2012). Monitoring the products received from the supplier is also considered part of the monitoring system, and include steps such as: (i) visual inspection of the product; (ii) monitoring the delivery and transportation arrangement; (iii)packaging of products; and (iv) compliance with delivery schedules.

The next step in the procurement cycle is the payment for the products ordered from the suppliers. Payments are usually made to suppliers once the medicine received from the suppliers

is approved according to the description, quantities, and quality (Management Science for Health, 2012). By whom the payments are made depends on a country's legislative framework and policies (Usaid Deliver Project, 2011). The final steps within the procurement cycle, are the delivery and distribution of products, which flows directly into the next function of the logistics cycle: 'Inventory and distribution', as is indicated in Figure 3.3.

3.2.1.3 Inventory and distribution

The primary goal of distribution management is to maintain a steady supply of pharmaceutical products and ensure products are stocked and delivered according to the right procedures. There are at least five different strategies for distribution systems (type of stockholding and delivery method), containing different combinations of public and private roles, to improve the availability of essential drugs at the designated health facilities (Management Science for Health, 2012):

 i. Central medicine stores (CMS): Public sector pharmaceutical supply system, in which medicines are procured and distributed by a centralised government unit.

 ii. Autonomous supply agency: Alternatively to the CMS, managed by an autonomous pharmaceutical supply agency.

 iii. Direct delivery: Decentralised, non-CMS approach in which medicines are directly delivered to the facilities from the suppliers. The governmental pharmaceutical procurement unit selects supplier and price of each product, but does not store or distribute the products.

 iv. Prime vendor system: The government procurement unit selects primary distributors, who are responsible for receiving the products from the suppliers, then store and distribute the products to the facilities.

 v. Primarily private supply: Allowing private sector pharmacies, near a government health facility, to dispense medicines to public-sector patients.

After an item has been procured and received by the health system or programme, it must be transported to the patient-serving facilities (according to the preceding method(s) stipulated in the selected supply strategy) (Usaid Deliver Project, 2011). During this stage of the PLF, products need to be stored until being sent out to the next location (i.e. warehouse, depot or facility) (Usaid Deliver Project, 2011). For international shipments, the first activities in this function include the shipment of goods from the supplier's warehouse, through the port of entry, clearance through customs, receipt and inspection at the designated place of delivery, and resolution of any insurance or damage claims (Usaid Deliver Project, 2011). The rest of the activities within the distribution function are illustrated in Figure 3.4.
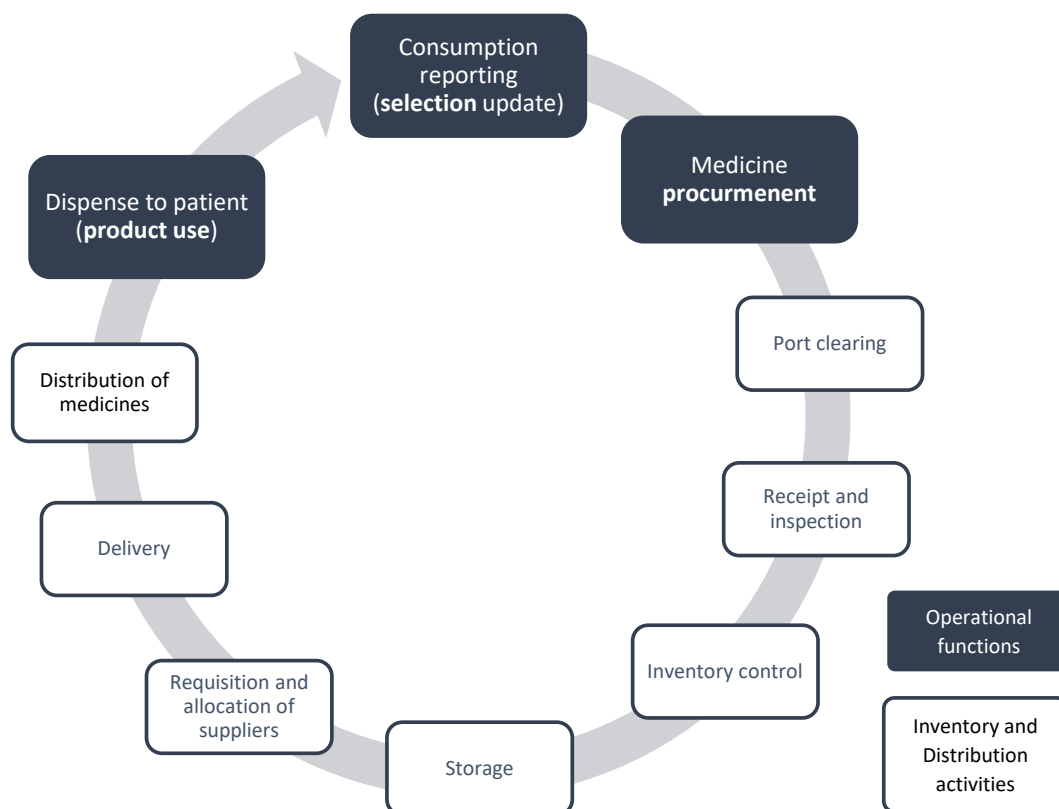
Figure 3.4: Illustration of the activities within the inventory and distribution function, adapted from (Management Science for Health, 2012).

In addition to distribution, the other major activity within this function of the PLF is inventory management (inventory control in Figure 3.4). An inventory management system is a system that informs users when to order or how much to order, based upon the stock levels and storage space availability, in order to replenish warehouses and depots of stock based on the demand plan. There are three types of inventory ordering systems (Raja & Mohammad, 2004): (i) forced-ordering system; (ii) continuous review system; and (iii) standard system.

For each pharmaceutical system, the same calculations are used to determine the quantities necessary to order; however, the difference between these systems is the trigger for the ordering. The forced-ordering system is triggered by the end of the review period, which is the routine interval of time between the assessment of stock levels. A continuous review system is triggered when the facility reaches the minimum stock level at which stock needs to be replenished. The stock levels are usually measured in terms of the amount of monthly stock left. The standard system is triggered when stock is at the minimum required level after the review period (Usaid Deliver Project, 2011). Each of these ordering systems is based upon the predefined minimum and maximum inventory levels, and are considered necessary to assist the budget plan, to prevent stock-outs, to avoid overstocking or understocking, to prevent expiration of products,

as well as to monitor stock levels (Tayob, 2012). To achieve this, there needs to be a minimum stock level high enough not to run out of stock, and a maximum level low enough to avoid stock from expiring (Usaid Deliver Project, 2011).

In order to enable adherence to the stock level requirements, the storage location (at facilities, depots and warehouses) needs to be able to accommodate the desired stock levels (Usaid Deliver Project, 2011). The key activities of storage include the inspection of incoming products, where the quantities are compared to the incoming delivery invoice; the allocation of storage area i.e. rack, shelf or floor; the picking and packing of orders prepared for shipment; and the shipping activities where quantities are checked according to the outgoing delivery orders (Usaid Deliver Project, 2011).

Each product has a defined shelf life—the length of time from the manufacturing date to the final date a product can be used. A product's shelf life is also defined as the length of time a product can be stored without affecting its safety, usability, or potency. The shelf life is usually specified by the manufacturers; however, a national formulary or therapeutic committee is normally responsible for approving the defined shelf life (Usaid Deliver Project, 2011). The shelf life of a product can be maximised by following defined procedures of storage guidelines. It is important to utilise the storage space, because an underutilised space wastes money, however, there is an increased risk of damage to products in an overutilised space. Usually, it is the responsibility of the warehouse manager to calculate and manage the required floor space. This is beneficial to the shipment and delivery planners, because the amount of floor space available in a warehouse or depot will determine the amount of delivering frequencies. It is therefore advisable to define allowable shipment sizes in the contract. (Management Science for Health, 2012).

As discussed previously, a pharmaceutical supply system can operate as either a push or pull system, and the requisition (also known as ordering) procedures that are governed by the pull or push approach are a key part of the inventory control system. Regardless of a country's choice of system (push or pull), the system should still be able to simplify the distribution and replenishment of medicines. This can be done by means of a product audit trail to trace the flow of the medicines through the supply chain—an intricate part of an information system (Management Science for Health, 2012).

Similar to storage and inventory management, the actual delivery of products plays a vital role in the distribution function of a pharmaceutical supply chain. The objective is to maintain a steady supply of pharmaceutical products, by ensuring resources are effectively used. The distribution process begins when medicines are dispatched at the supplier and ends when consumption data is reported back to the procurement unit (Management Science for Health, 2012). This includes the collection and delivery of products between warehouses, depots, and

facilities from a national level, to a provincial and facility level (Berger *et al.*, 2010), as well as the delivery schedules, waste management, and vehicle acquisition.

Delivery costs, including transportation and storage costs, are a significant expense of running a public pharmaceutical health supply system. Ensuring cost-effective and efficient delivery of pharmaceutical products are key functions of logistics management staff and require qualified logistic experts with the necessary operational and logistic skills. The key steps in planning a distribution system are: (i) to determine whether a pull or push system will be implemented; (ii) to determine whether distribution operations are carried out in the public or private sector; (iii) to plan the store location and delivery routes; and (iv) to determine the delivery schedules and transport infrastructure.

3.2.1.4   Product use

In the PLF, the selection, procurement, storage and distribution of products are done in order to meet patients' needs (Usaid Deliver Project, 2011). The aim of a pharmaceutical supply chain is to deliver the correct product to the patient who needs that medicine, and each step within the logistic cycle is a precursor to the rational use of medicines (Management Science for Health, 2012). Rational use of medicine "requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community" (World Health Organization, 1987). The use of medicines can be done rationally or irrationally, depending on how the medicines are used by both the health professionals and the public.

Figure 3.5 illustrates the key steps during the product use phase, from when the patient receives their diagnosis, until the patient uses the prescribed medication. The irrational use of medicines occurs in all countries and across all healthcare settings. It includes cases where medicines are prescribed when no medicine is actually needed; cases where unsafe and inefficient medicines are prescribed and dispensed; and cases where safe and effective medicine were prescribed but not used, or incorrectly used (Management Science for Health, 2012).

The irrational use of medicines has an adverse effect on the health system, especially on healthcare costs. The over- or underuse of prescribed medicines causes the system to spend excessively on pharmaceutical products and waste the available financial resources. Irrational prescribing also has an impact on the quality of patient care. For example, the likelihood of adverse drug reactions can increase when medicines are unnecessarily prescribed. Other effects such as antimicrobial resistance can occur through irrational prescribing or use of medicines (Management Science for Health, 2012).

In Figure 3.5, factors at each step within the product use function that contribute towards the irrational use of medicines are identified. As mentioned, other operational functions within
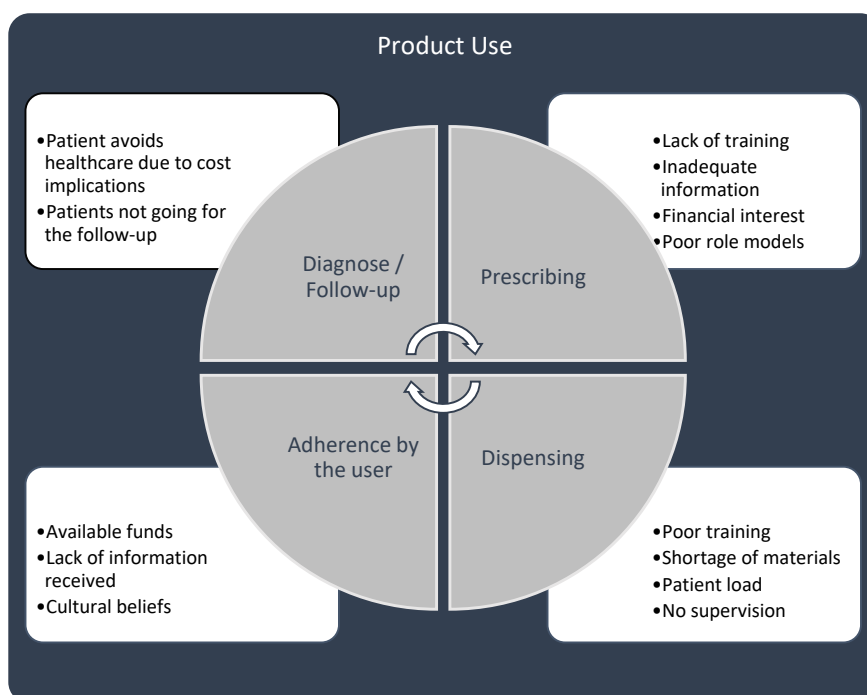
Figure 3.5: Illustration of the activities within the product use function, adapted from (Management Science for Health, 2012).

the health systems can affect the rational use of medicines. In a health system, the factors contributing towards the irrational use of medicines are: (i) the unreliable supply of medicine; (ii) medicine shortages; (iii) expired medicines, including counterfeited medicines; and (iv) inappropriately prescribed medicines (Management Science for Health, 2012). An aspect in the health system that influences these factors are the policies and regulations that enforce and promote the rational use of medicines.

The product use cycle starts when a patient is diagnosed, after which a medical practitioner will prescribe medicine according to STGs and treatment protocols. The medicines are then dispensed based on the prescription and medicine availability (Management Science for Health, 2012). Dispensing is the process of preparing and giving the prescribed medicine to the patient. There are multiple factors that determine the quality of dispensing: (i) the environment in which the dispensing occurs; (ii) the staff who perform the dispensing activities; (iii) the packaging and labelling of the medicines to be dispensed; and (iv) the patient's understanding of the medicine received (Management Science for Health, 2012). The dispensing environment includes the storage areas, the work surfaces, and the equipment used during dispensing and packaging. In addition to the organised system, a stock rotation process should be implemented, e.g. stock should selected from a shelf based on first-in-first-out (FIFO) or first-expiry-first-out (FEFO) principle.

In most countries, laws state that the dispensing of pharmaceutical products should be executed by a professional pharmacist; however, in developing countries, there is a lack of qualified and trained dispensers to provide quality services. It is required that dispensing personnel should receive the proper level of training based on the range of medicines to be dispensed at a facility (Management Science for Health, 2012).

The next factor that influences the rational use of medicines, is the patient. Knowledge regarding the use of medicines can influence a patient on whether to seek health care, where to access services, and whether to follow the proposed treatment. Effective communication between the dispenser and the patient is one of many factors that contributes towards the adherence to treatments. This includes the dispenser being informative as well as the labelling and instructions on treatment being clear to the patient. Not only does provider-patient communication play a role, but public communication as well, such as through education, posters, and flyers. Even after the dispenser provides the patient with the correct instruction, it is the responsibility of the facility to monitor the patient's adherence to the treatment. Some monitoring mechanisms include Pharmacovigilance—a system that detects, assess, understands and prevents adverse drug reactions (Management Science for Health, 2012; World Health Organisation Expert Committee, 2003).

As indicated in Figure 3.2, the PLF follows a closed loop system, and information from the product use functions are inputs for the product selection function. A dispensed product can be articulated as a consumed product, which is used for forecasting the demand within the product selection function. At the facilities, STGs are used by health workers to ensure that the right product is dispensed with the correct labelling and instructions.

The PLF is an interrelated process, based on the previous discussion on the operational functions and the activities each function encompasses. The next part of this section follows a discussion regarding the supporting elements (in the centre of the PLF in Figure 3.2).

3.2.2 Management support elements

The activities within the centre of the PLF (Figure 3.2) represent the management support elements that inform and impact the operational functions of the logistics framework. The management support elements consists of the following: (i) information system; (ii) organisational support and human resource management; (iii) financial and donor coordination; and (iv) a monitoring and evaluation system. A brief description of each element is provided.

3.2.2.1 Information system

Information is what drives the logistic cycle within a public pharmaceutical supply chain, and provides stakeholders with the necessary visibility and information of the last point in the

pharmaceutical supply chain. The information is used to make sound decisions and coordinate future actions (Management Science for Health, 2012; Usaid Deliver Project, 2011). A logistics management information system is a system that records, analyses, presents and reports data that is collected throughout the system—this is especially necessary when decision-makers want to be able to make informed decisions (such as an informed push model) for the supply chain (Usaid Deliver Project, 2011).

In a pharmaceutical supply chain, an effective information system synthesises a large volume of data generated by operations and healthcare providers to plan for the operational activities, demand estimation, product availability, inventory management, resource allocation, as well as monitoring and evaluation of the management operations (Usaid Deliver Project, 2011). The coordination of an information system requires accurate, quality, and timely information, therefore, key performance indicators (KPIs) are used to monitor facility level performances, and track accountability along the pharmaceutical supply chain (Management Science for Health, 2012).

3.2.2.2 Organisation and human resource management

The second element is the management of organisations and human resources—the coordination between the roles and responsibilities of healthcare workers, stakeholders, and logistics experts across various organisations (health facilities, warehouses and government) in order to execute the operations of the pharmaceutical supply chain system. Human resource management (HRM) is a cross-cutting activity, touching each function in the logistics framework from quantification to service delivery. HRM is "the integrated use of systems, policies, and management to recruit, train, and develop employees in order for an organisation to meet its goal" (Management Science for Health, 2012).

A HRM framework helps managers to plan, hire, deploy, motivate and retain employees. A HRM system not only consists of the hiring and firing of workers—robust policies and plans are critical elements to effectively strengthen HRM. These actions include: updating job descriptions to make sure that each resource in the supply chain knows their exact role in order to ensure accountability; updating manuals and procedures at PHC level to include SOPs for logistics tasks; and creating and enacting national-level strategic plans for human resources in supply chain management and budgeting. At a national level, HRM consists of developing strategies, policies and procedures to ensure that the workforce capacity is well-staffed, qualified, and competent. At a lower level, managers of district services and PHC facilities, as well as non-government organisations (NGOs) are needed to strengthen and execute these strategies (Management Science for Health, 2012)

3.2.2.3 Financial and donor coordination

The financial and donor management element directly affects all parts of the PLF, i.e. the product quantities that can be procured, the amount of storage space that may be available, the number of deliveries to be made, and the number of staff to work within the system. In order to successfully allocate the budget, the supply chain manager first needs to determine the expected cost at the different levels of the health system (Usaid Deliver Project, 2011). Financial allocations are usually done by a national body, and the allocation to the lower levels of the system depends on country regulations and legislation.

3.2.2.4 Monitoring and evaluation

Routine monitoring and periodic evaluation of the pipeline and logistics system activities help demonstrate how well the system is performing, the areas that can be improved, as well as the system's impact on service provision. This approach is conducted across all operational functions of a pharmaceutical system, depending on the decision of the country. Monitoring is the ongoing review of progress towards achieving an objective and evaluation is the periodic analysis of the progress towards achieving an objective (Management Science for Health, 2012). KPIs (predefined by stakeholders in policies) are used to track the progress of the system and are used for the evaluation process.

The description of the operational functions in the previous section, and the management support elements in the current section, served to highlight key aspects of a pharmaceutical supply chain, providing initial insights into policy options. The next section gives insight into the link between a supply chain model and the enabling environment in a healthcare context—focusing on the enabling effect the legal and policy environment has on a pharmaceutical supply chain system.

3.2.3 Policy, law and regulation

An effective pharmaceutical logistics system rests on a policy and legal framework that supports and enables the public commitment to essential medicine supply, therefore, a pharmaceutical logistics systems requires sound policies and legal frameworks that will provide a solid foundation for the systems (Usaid Deliver Project, 2011). It is equally important that these policies and regulations are periodically updated to ensure that they address the current health situation in the country and are in line with international standards (Management Science for Health, 2012). In addition, important decisions have to be made by regulatory authorities, governing bodies, health providers and committees in the oversight and performance of the key functions from the PLF (Management Science for Health, 2015). The role of governance is discussed in the second part of this section.

3.2.3.1 Legal framework

Seiter (2010) defines policy as "the conscious attempt of public officials or executives entrusted with public funds to achieve certain objectives through a set of laws, rules, procedures, and incentives." Legislation and regulations provide a legal basis for the policy and make it enforceable (Management Science for Health, 2012). Countries have different policies and legislation based on their context; however, the structure of a health legislation framework remains constant. Figure 3.6 illustrates the relationship between the various levels of legislation.
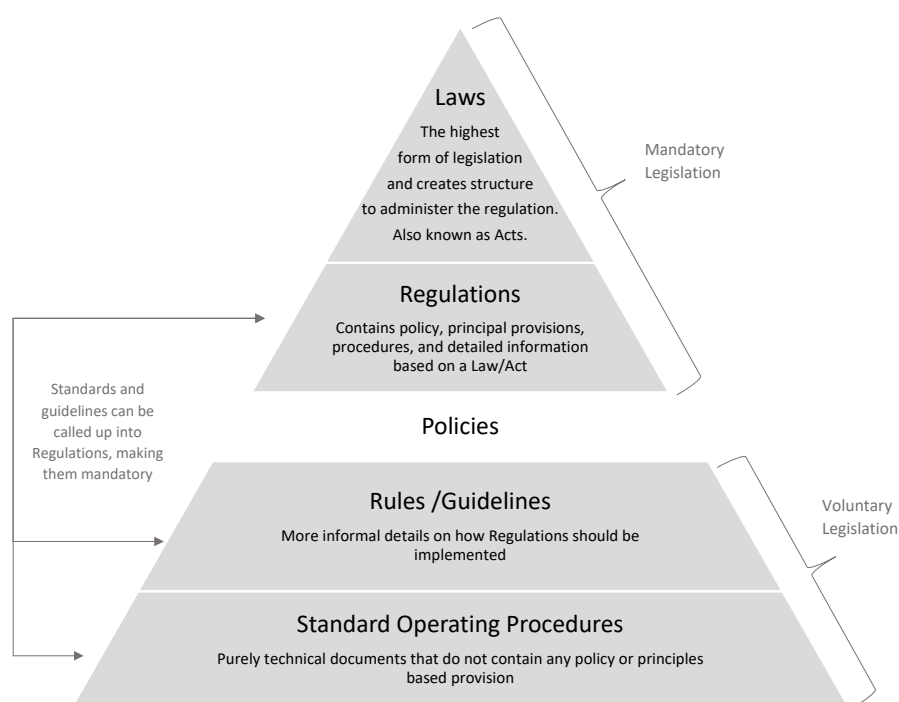
Figure 3.6: Illustration of the hierarchy in which legislations are categorised in (author's own representation based on multiple sources)

Laws and acts are passed by legislative bodies, and are formulated in general terms to meet the current and future needs of a country (World Health Organization, 2001). Regulations enable government authorities to set out in more detail how the acts should be interpreted, and how they will be implemented and enforced (World Health Organization, 2001). Passing new laws may require a lengthy process for final approval (Management Science for Health, 2012). Regulations are more flexible than laws, and provides details of the actors in the system and their responsibility. Laws and regulations are regarded as consequences of policy-making, but their implementation, or lack thereof, might lead to a process of further policy development. Guidelines do not carry any force of law, but offer informal information on how regulations should be implemented or executed (World Health Organization, 2010).

Government regulations and procedures affect all aspects of the pharmaceutical supply chain—in many countries, the government has created policies on the selection of medical products, how these items need to be procured, when items need to be distributed, how and where the items are stored, and the quantities customers receive (Usaid Deliver Project, 2011). Health programme managers and dedicated supply chain specialists have the influence to change policies (Usaid Deliver Project, 2011). Pharmaceutical policies have a significant impact on health system performance in low- and middle-income countries. It influences the health of the population, public satisfaction (and dissatisfaction) with the health sector, and the cost-effectiveness of the care provided. In this study, the term 'pharmaceutical policy' refers to the conscious efforts of national governments to influence the functioning of their country's PLF (Reich & Roberts, 2011).

In the 1980s, the concept of a national medicine policy came to light and the World Health Organisation (WHO) became active in developing the idea. A national medicine policy, also referred to as a national drug policy, is a political commitment and guide for action—a written document with medium- to long-term goals to guide the government on how to ensure accessibility to safe, efficient and affordable medicines of acceptable quality (Management Science for Health, 2012). Moreover, it provides a framework for the coordination of activities of the pharmaceutical sector, taking into account the public and private sector, donors, NGOs, and other related parties (Management Science for Health, 2012). Even though national drug policies serve similar purposes and therefore need to contain similar, necessary components, the specific goals and objectives of national medicine policies may differ between countries, depending on the context (Reich & Roberts, 2011). Table 3.3 illustrates the required key components of a national drug policy, and how these link (directly or indirectly) to pharmaceutical health objectives.

The WHO has developed a more detailed summary of the basic components (provided in Appendix D), that are considered necessary for a national drug policy, and these components include (Management Science for Health, 2012; World Health Organization, 2001): a legislative and regulatory framework; choice of essential medicines; supply strategies; rational use of medicines; affordability; financial strategies; human resource development; monitoring and evaluation; research; and technical cooperation amongst countries. These components align with the functional and supportive elements of the PLF, which is substantiated by the enactment of appropriate, and country-specific laws and regulations, allowing the policy to be enforceable (Management Science for Health, 2012). Thus, it can be argued that a pharmaceutical supply chain in the public pharmaceutical health sector (in its entirety) is enabled by policies, laws and regulations.

Table 3.3: The key components of a country's national drug policy, linked to the health objectives (World Health Organization, 2001).

Components	Objectives		
	Access	Quality	Rational use
Selection of essential drug	X	O	X
Affordability	X		
Drug financing	X		
Supply systems	X		O
Regulation and Quality assurance		X	X
Rational use			X
Research	X	X	X
Human resources	X	X	X
Monitoring and evaluation	X	X	X
Technical cooperation	X		O

X = direct link; O = indirect link

3.2.3.2   Good governance

Governing bodies (i.e. statutory bodies, governing boards and advisory councils) at the different levels of the health system (national, regional and local) are key in strengthening the governance at all steps of the pharmaceutical system (Management Science for Health, 2015). The strengthening of good governance practice focuses on the interventions in the following four areas (Management Science for Health, 2015):

  i. Developing policies and legislations that are supported by the rule of law;

 ii. Strengthening organisational structures for appropriate decision-making, authority, and oversight;

iii. Improving human resource management to promote effective performance and ethical practices; and

iv. Incorporating good governance practices to promote transparent, ethical, and accountable systems and processes.

Applying the following five governing practices can help strengthen the performance of pharmaceutical systems, and subsequently reduce the possibility of medicine stock-outs, loss in financial resources and wastage (Management Science for Health, 2015):

Accountability Governing bodies should insure that health institutions and organisations are accountable to stakeholders (patients, communities, elected politicians, purchasers, providers, etc.)

Stakeholder engagement: Engaging and coordinating stakeholders (donors, supply chain partners, etc.) to enable information sharing, resource mobilisation, procurement planning; and to improve the prospect that revised (or developed) policies, legislations, and strategic plans will be implemented successfully.

Setting strategic direction: A pharmaceutical strategic plan should be developed to provide a roadmap for achieving the national medicine policy—the priorities and objectives, funding requirements, timelines, and methods to measure performance.

Stewarding resources: Inadequate human, financial, and technology resources for managing medicines are leading causes of poor access and availability of medicines. Governing bodies play a role in mobilising these resources—allocating sufficient human resources to key responsibilities; and advocating for technology developments that allow real-time monitoring of procurement and distribution.

Continuously improving governance: Due to the complexity of a pharmaceutical system, it is critical to develop capacities for the governing bodies—responsible for decision-making and oversight—and empower them with tools, skills, and the information needed to make effective contributions.

Section 3.1 as a whole provided a detailed description of the functions of a pharmaceutical supply chain in general. Available in Appendix E, the pharmaceutical logistics framework, and the functions within this framework, are used to provide insight into the current pharmaceutical system of South Africa specifically.

3.3   Chapter 3: Conclusion

In order to analyse how an operational model such as a VAN can be influenced by country policies, it is necessary to understand how a pharmaceutical supply chain within a public healthcare setting operates, and how it is influenced by policies. This chapter provides an introduction into the terminology of supply chain and supply chain management, progressing towards the operations a logistics framework for a public pharmaceutical system (PLF). The PLF is divided into the following main components: (i) operational functions, which are the supply chain processes; (ii) the managerial supporting elements, which support the entire operationalisation of the pharmaceutical supply chain processes; and (iii) a policy and legislation framework that enables the entire pharmaceutical logistics framework. Subsequently, each component is discussed based on what is found in literature. The framework is then used as a guide to understand the current pharmaceutical supply chain context in South Africa (discussed in Appendix E).

This chapter also identified that not only policies affect (or enable) the pharmaceutical supply chain landscape, but other legislation (such as laws, regulations and standard operating procedures) as well. Therefore, in order for an operating model such as VAN to be implemented, the effect of current policies, including legislation, needs to be analysed to understand how these 'enablers' might affect a country's VAN Operating Model.

A pharmaceutical logistics framework is quite complex, and analysing policies and other governing legislations based on all of the framework's components can become long and tedious. Therefore, a policy analysis approach to this study should be applied to provide a method that assists with determining the enabling and limiting effect of country-specific policies and legislations specific to the VAN Operating Model.

Chapter 4

Policy analysis

The aim of this study is to support the Visibility and Analytics Network (VAN) project regarding the lack of planning strategies for the policy element, as concluded in Chapter 2. In Chapter 3, literature shows that a pharmaceutical supply chain and all its operational components sit within an enabling environment, meaning that the operationalisation of a public pharmaceutical supply chain is governed by laws, regulations and policies. According to Dunn (1981), policy analysis has proven its ability to support decision-making strategies through assessing future implications of current (or new) policies on a new (or current) system. Therefore, Chapter 4 focuses on the investigation of various policy analysis approaches to gain insight into the opportunities and constraints for the implementation of an operational model (such as VAN) in the public pharmaceutical sector.

This chapter starts with an introduction to policy analysis, and progresses into the identification of different policy analysis methods and models. Moreover, the chapter discusses some of the traditional methods, as well as some of the modern approaches to policy analysis. Finally, the link between policy analysis and the stakeholders involved is discussed and details on how to conduct a stakeholder analysis are provided.

4.1   Introduction to policy analysis

Policy analysis is a complex activity. It relates to a system that includes people, social structures, equipment and organisations, and the system being studied contains many variables, feedback loops and interactions, making it difficult to project the consequences of a policy implementation or change (Walker, 2000). Policy analysis is performed in government; in independent policy research institutions (both for-profit and not-for-profit); and in various consulting firms. It is not a way of solving a specific problem, but a general approach to problem-solving. This section focuses on defining the terms 'policy' and 'policy analysis' and the perception of these terminologies among different experts.

4.1.1   Definition of a policy

There are as many definitions of policies as there are authors that write on the topic, and policies are usually defined depending on the context in which a policy is viewed. As mentioned in Chapter 3, Seiter (2010) defines policy as "the conscious attempt of public officials or executives entrusted with public funds to achieve certain objectives through a set of laws, rules, procedures, and incentives." Similarly, Brook (1989) defined policy as the formulation of rules, norms and prescriptions intended to govern a broad framework of ideas and values within which decisions are taken and action is pursued by governments in relation to some issue or problem. Consequently, within this study, the term policy is considered to describe a broad framework of goals and objectives followed by public institutions to address a particular (set of) problem(s). These goals and objectives are translated into actions stipulated in rules, guidelines, or procedures in a policy, that will address the needs of the beneficiaries (World Health Organization, 2010). The contents of a policy are supported and enforced by country-specific laws and regulations as discussed in Subsection 3.2.3. Figure 3.6 highlights the different levels of legislation. Policies are supported by the mandatory legislations (i.e. Acts and regulations), whilst voluntary legislations (i.e. guidelines, rules and standard operating procedures (SOPs)) stipulate how the aims and objectives should be executed.

4.1.2   Policy analysis

A policy is based on a line of arguments that rationalise the course of action of a government, a social group or individual, which might eventually be adopted as a plan of action to address a specific need (Maluleke, 2010). Though policies are developed with an intended course of action in mind, they can in fact yield unintended consequences (Maluleke, 2010), an outcome of policy that is not a result of the intended objectives. This is caused when the environment in which a policy is implemented, is complex (Maluleke, 2010). It is not always possible to anticipate all the impacts and effects that a specific policy might have; however, the process of formulating policies should include attempts to evaluate the potential impact a policy might have on a system, whether it is intended or unintended. Therefore, policy-makers and public officials responsible for policies should facilitate the concept of policy analysis to clarify ambiguities that may occur (Maluleke, 2010).

Similar to the definition of policy, policy analysis is defined in many ways by multiple authors, each providing different models or methods to analyse policies, for example:

- MacRae & Wilde (1979), defined policy analysis as "the use of reason and evidence to select the best policy among a number of alternatives to address a particular problem."

- Dunn (1981), defined policy analysis as "an applied social science discipline which uses multiple methods of inquiry and arguments to produce and transform policy-relevant information that may be utilized in political settings."

- Paul *et al.* (1989), defined policy analysis as "the task of analysing, and evaluating public policy options in the context of given goals for choice by policy-makers or other relevant actors."

- Walker (2000), defined policy analysis as "a rational, systematic approach to making policy choices in the public sector. It is a process that generates information on the consequences that would follow the adoption of various policies. It uses a variety of tools to develop this information and to present it to the parties involved in the policy-making process in a manner that helps them come to a decision."

From these definitions, it is evident that policy analysis is a generic name for a range of problem-solving techniques and tools to study the characteristics of established policies, how policies are formulated, and what their consequences are towards the given context. Not all public problems are susceptible to policy analysis, but when they are, the analysis can support decision-makers to (Dunn, 1981):

i. Determine whether a new policy is required to address the problem;

ii. If a policy already exists, determine whether it needs to be modified or terminated;

iii. Analyse a policy (retrospectively or prospectively);

iv. Compare two or more policies that address the same or similar problem;

v. Assess future implications of current or new policies; and

vi. Explore stages in the development of particular policies.

Although it is an increasingly common topic in academic circles, according to Coveney (2010), policy analysis is not yet considered a unified field of study. There are different methodologies for policy analysis, and the approach towards policy analysis depends heavily on the disciplinary framework used and the purpose of the analysis (Coveney, 2010). For example, policy analysis can be described in two ways: first, it refers to the analysis *of* public policy—the study of public policy in an academic (descriptive) fashion. This form of policy analysis aims to achieve a generic understanding of public policy-making by means of social-scientific-political-historic research (Enserink *et al.*, 2013). The second type of policy analysis refers to analysis *for* public policy-making—the activities, methodology, and tools that are used to give aid and advice in a context for public policy-making (Enserink *et al.*, 2013). Most importantly, policy analysis is a process, each step of which is critical to the success of a study and must be

linked to the policymakers, to other stakeholders and to the policy-making process (Walker, 2000).

In policy analysis research, stakeholder analysis has been seen as a way of generating information on the "relevant actors to understand their behaviour, interests, agendas, and influence on the policy decision-making processes" (Reed *et al.*, 2009). In political science, stakeholder research is used to work more effectively with stakeholders, facilitate transparent implementation of decisions or objectives, understand the policy context, and assess the feasibility of future policy options (Reed *et al.*, 2009). In the next sections, the different models and methods used for a policy analysis (Section 4.2) and a stakeholder analysis (Section 4.3) is explored and discussed.

4.2 Exploring policy analysis methods and models

As mentioned, policy analysis can be done in two different ways: (i) the analysis *of* public policy—the study of the policy analysis decision-making process, and the method of how each process results in the formulation and implementation of policies; and (ii) the analysis *for* public policy—the use of analytical tools for specific types of analysis problems in order to make informed policy decisions (Enserink *et al.*, 2013). This section discusses existing policy analysis models in both of these cases. Section 4.2.1 starts off with the analysis *of* policies, highlighting models such as the rational model, political game, advocacy coalition, garbage can, and institutional process. Section 4.2.2, focuses on tools and methods for doing the analysis *for* policies, highlighting methods such as the health policy triangle, effect-implementation (impact) analysis, and different types of mathematical models.

Both of these types of analysis suit the objective of analysing policies; however, only from a different perspective. In practice, these two analysis approaches can be used either independently or in conjunction with one another. For example: the impact analysis tool (analysis *for* policies) can be used to analyse specific problems in the decision-making process of the garbage can model (analysis *of* policies).

4.2.1 The analysis of policies

Enserink *et al.* (2013) argues that policy analysis and the process of policy-making are isomorphic—mirror images of one another. The overarching decision-making process for the analysis of policies is built on the four building blocks: agenda-setting, policy formulation, implementation and evaluation (Lehmann, 2016). These building blocks of the policy analysis process are briefly defined and described (DeLeon, 2014; Lehmann, 2016):

i. Agenda-setting: The identification and recognition of problems, in order to set priorities (a policy-agenda) of the issues that need to be addressed, and in effect determining what policies are formulated.

ii. Policy formulation: Actors with policy-making authority make decisions regarding the policy content by means of various decision-making strategies.

iii. Policy implementation: The implementation of the policy content through various strategies involving various structures and people, which also includes the adaptation and/or non-implementation of the policy by these actors.

iv. Policy evaluation: The assessment of the success of the policy during the development of the policy (with a view to influence the process) or after the implementation, as a basis for further policy action.

Walker (2000) suggests that policy analysis "is not a way of solving a specific problem, but is a general approach to problem solving. It is not a specific methodology, but it makes use of a variety of methodologies in the context of a generic framework. Most important, it is a process, each step of which is critical to the success of a study and must be linked to the policy-makers, to other stakeholders and to the policy-making process" (Walker, 2000). Walker (2000) has developed a policy analysis map (Figure 4.1) that provides insight into the effect the building blocks have on one another.
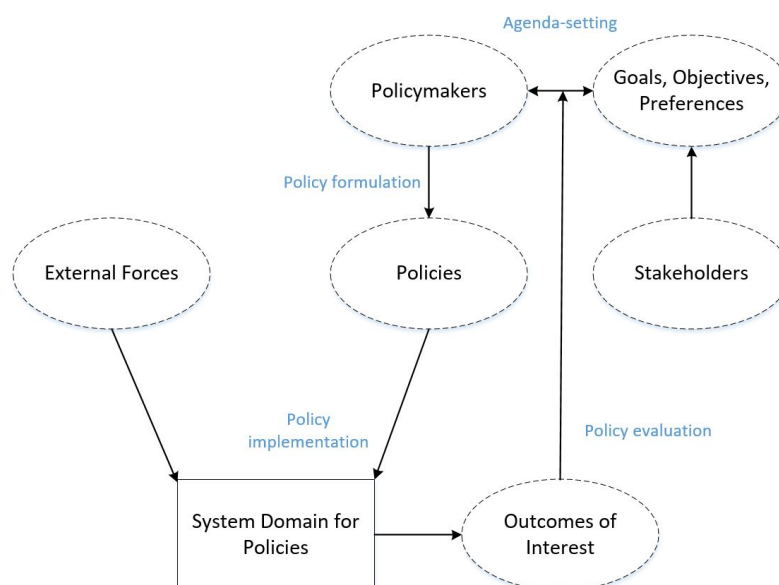
Figure 4.1: A policy analysis (decision-making process) map that illustrates the relationship between the policy analysis building blocks, adapted from Walker (2000).

The 'system domain for policies' is the heart of the analysis, illustrating the flow and relationships among the other building blocks of policy analysis. External forces have an impact on the policy domain. Walker (2000) identifies the first external force as the change in the economy, environment, technology, and people behaviour; and secondly, the change in policies—both causing high levels of uncertainty in the policy environment. The formulation or reform of policies and the implementation of those policies also have an impact on the policy domain.

The 'goals, objectives and preferences' are the generalised objective of the policy (e.g. 'ensure medicine availability') (Walker, 2000). Goals and objectives are set to determine the type of policy (or the content thereof) required to solve the problem identified, and subsequently implement. The policy choices are not solely dependent on relative policy goals and objective, but also on the preferences of various stakeholders (Walker, 2000). Policy evaluation contributes to ensuring that policies provide a desired outcome by providing insight into the impact the selected policies might have on the system. Each of the four building blocks of policy analysis is associated with a complex set of decisions and processes that are required for a policy to be put into effect (Lehmann, 2016). Various authors have provided their own take on this particular policy analysis decision-making process, which is described as a 'neat and rational' approach to policy analysis (Enserink *et al.*, 2013), and in some cases referred to as the rational or stages model (DeLeon, 2014).

The steps from the rational policy analysis models may vary among the authors, however, there are underlying similarities. Figure 4.2 illustrates how the steps within the different models are categorised into the four building blocks of policy analysis. This comparison indicates, that even though there are multiple approaches towards the rational policy analysis model, the core building blocks (agenda-setting, policy formulation, policy implementation, and policy evaluation) through which a policy is analysed, remain the same. Different approaches to the rational model are discussed in Appendix F.

There is some criticism of the 'neat' and 'ideal' nature of the rational policy analysis models. Enserink *et al.* (2013) suggest that there is a risk that rational models may be perceived as too neat in an environment that is renowned for its complexity (Enserink *et al.*, 2013). However, if policy development is assumed to be chaotic, this can pose a serious impediment to the analysis of the process. Some policy analysts have formulated policy analysis models to portray the increasingly complicated nature of policy decision-making. Five policy analysis models that are prominent in literature are compared in Table 4.1. Each model is discussed in the light of its normative implications for the policy process, the missions and role of the policy analyst, a toolbox for the analysis, as well as the skills the analyst should have. The following five
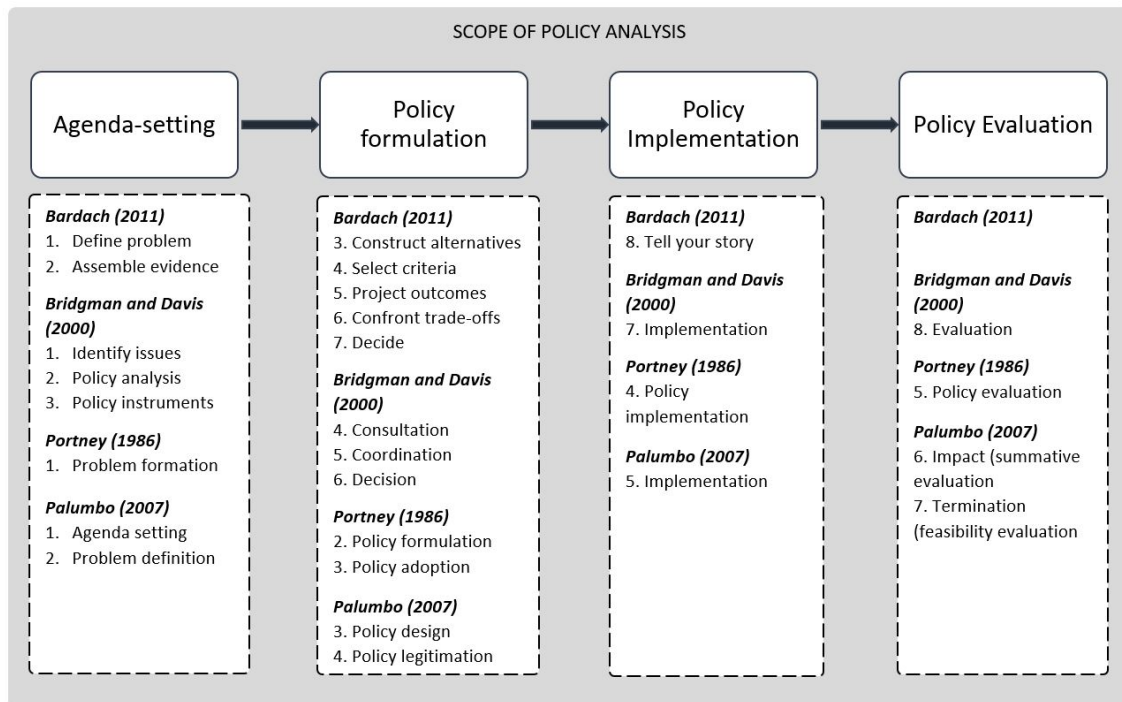
Figure 4.2: The building blocks of policy analysis and the rational steps

models are included in the comparison: (i) the rational process; (ii) a political game; (iii) the advocacy coalition (discourse); (iv) the garbage can model; and (v) the institutional process.

From the comparison in Table 4.1, it is evident that there are many different approaches to policy development and the origin and rationale behind each method is based upon the context and situation the analysts find themselves in. Enserink *et al.* (2013) suggest that the analysts' understanding of policy analysis should not be one-dimensional, because policy analysis constantly "faces boundary tensions and dilemmas, where conflicting demands on policy analysis and methods, the analyst, the outcomes and the process needs to be balanced" (Enserink *et al.*, 2013). However, Walker (2000) argues that the analyst should use the simplest model possible, because the analyst will have to explain the policy analysis methodology and results to the policymaker, who is generally not familiar with complex analysis models—"the simpler the model the easier it will be to explain and the better the chance that the policymaker will understand the analysis" (Walker, 2000). This section focuses on the policy process and the analysis that goes into the process of developing or reforming a policy based on a problem, and how the policy transcends through the policy process (rational or chaotic) towards the implementation and evaluation of that policy. In short, the focus is primarily on the decision-making process—the analysis *of* policies. The next section focuses on methods and tools that can assist the policy analyst with making decisions during the policy development, policy adoption, or policy evaluation stages—the analysis *for* policies.

Table 4.1: A summary of five prominent models based on the policy decision-making approaches, excerpted from (Enserink *et al.*, 2013).

TYPE OF POLICY FORMULATION / POLICY-MAKING MODELS					
	Rational Model	**Political Game**	**Advocacy Coalition (Discourse)**	**Garbage Can**	**Institutional Process**
Description	Policy-making is structured according to a set of sequential or cyclic steps: define problem; specify objectives; identify relevant policy options; determine policy consequences; and select the best option.	A bargaining process among different powerful interest groups, i.e. governmental agencies, NGOs, and bureaus. Decision-makers identify with own interest and avoid solutions that are unfavourable to them.	Policy-making regarded as 'conversations' in which actors exchange their arguments, aimed at influencing the perceptions of others and, eventually, the course and outcome of the overall debate.	The main idea is that the important activities in policy-making, such as problem formulation, design of a solution, participation, and decision-making, seem to develop independently of each other.	Focuses on the traditional organisation of government. This approach focuses on institutional structures, organisation, duties and function, without investigating their impact on public policy.
Normative implications	Failures can be caused by a lack of `intelligence' or `order' in the policy process.	Actors have conflicting perceptions and the process may result in poor decisions and compromises.	During a debate, asymmetrical arguments within a discourse can lead to information overload and ambiguity. Different perceptions can lead to different policy outcomes.	Policy failure and success in the garbage can perspective depends on the extent to which the problems, solutions, and political events are coupled.	Overlapping services with other organisations or actors occurs, wasting money and resources. Problems with understanding the institution can occur.
Mission of policy analysis	To reduce the complexities and uncertainties that policy-makers face.	To accommodate technical-scientific evidence and political rationality to prevent policy advocacy.	Following the logic of discourse perspective and overcoming asymmetrical debates among advocacy coalition.	Contribute to the development of good problem formulations, solutions, and enhance policy windows.	Support the development of integral, cross-sectoral, and interdisciplinary approaches to problem-solving.
Role of policy analyst	Doing systematic analysis, providing information and scientific insight for an informed decision and going through policy the sequential steps.	Systematic analysis and use of evidence to strengthen public policies; can take up role of process manager by arranging interface between political bargaining and analytical activities; stakeholder facilitator.	Discourse analysis, proposing argumentation strategies to overcome the `dead-ends' in debates and act as facilitator and mediator among advocacy coalition and belief systems.	``Go with the flow"---help with formulation in each stream, and be ready when opportunity arises.	Focus on clarifying the role of institutions and their impact on policy-making.
Toolbox for policy analyst	Collect information on problem (surveys, trend extrapolation); ranking option alternatives (cross impact analysis, cost-benefit analysis); and future-scenario analysis	In addition to the tools from the rational model: analyse political and multi-actor context (stakeholder analysis); make analytical tools interactive among stakeholders;	Analyse discourses and design new storylines to overcome asymmetrical debates. Reframe perceptions and pinpoint anomalies in belief systems of the actors.	Traditional policy analysis tools are needed to support the various streams.	Traditional policy analysis tools, with tools such as network analysis, stakeholder analysis, and agenda building research.
Skills of the policy analyst	Trained professional, fully skilled and equipped to operate the analysis techniques.	Political skills and strategic insights; develop sensitivity to understand the needs of stakeholders; and require skills in facilitation, mediation, and negotiation.	Be able to conduct discourse analysis, and develop sensitivity to understand each argument.	A combination of analytical tools and political skills should make an analyst professionally suitable.	Able to engage in institutional analysis and design, requiring insight of how stakeholders are affected by policies.

4.2.2   Analysis models for policies

There are multiple approaches to analysing *for* policies, this section only highlights a few methods in order to illustrate some of the different ways in which a policy analysis can be conducted. More specifically, the health policy analysis triangle, an approach which is specifically tailored to the healthcare context, is discussed. Furthermore, an impact evaluation model that measures policies against predefined dimensions in order to project the possible impact policies could have on the system, is discussed. And finally, a discussion of technical and mathematical tools that can be used for policy analysis is presented.

4.2.2.1   The health policy analysis triangle

The policy analysis triangle, developed by Walt & Gilson (1994), is used as a framework that illustrates the important factors to include in a policy analysis. The framework focuses on the content (the *what's*) of the policy, but stresses the importance of going beyond the content of a policy, focusing on the context (the *why's*) of a policy, the central role of actors in the policy process (the *who's*), as well as the processes of policy-making (the *how's*) (Buse *et al.*, 2005). The policy triangle in Figure 4.3 highlights the links between the actors and the other three factors that influence the decision-making (Lehmann, 2016). Even though the triangle may look simple, the complexity of the analysis results from the interaction between these factors (Lehmann, 2016), e.g. the actors are influenced by the context in which they live or work; and the context is influenced by factors such as history, culture and the process of policy-making (Buse *et al.*, 2005).

Context

Actors
- Individuals
- Groups
- Organisations

Content

Process
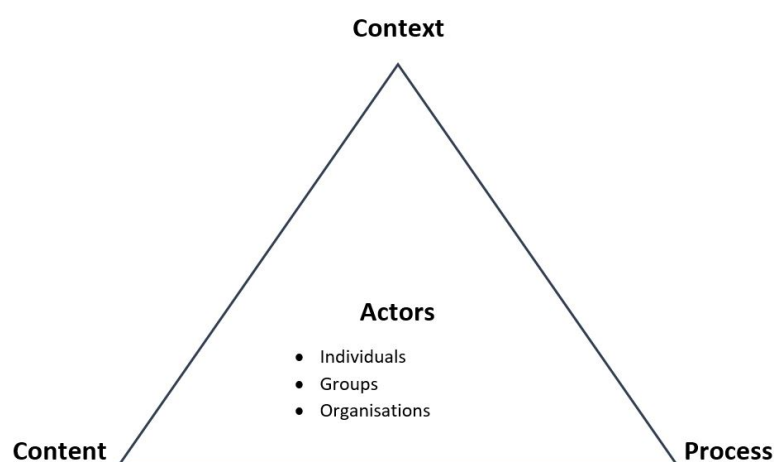
Figure 4.3: The health policy analysis triangle, excerpted from (Walt & Gilson, 1994).

Actors

Actors and stakeholders are terms that are used interchangeably, but the term 'stakeholders' does not take into account actors that may influence a policy decision, but have no 'stake' in the process (Lehmann, 2016). The actors are the centre of the policy triangle, therefore, it is important to understand who they are and what role they play in the policy decision-making process. Lehmann (2016) defined categories for policy actors, who can be individuals, groups, or organisations. These actors are among those who (Lehmann, 2016): formulate policies; try to influence policies; connect people, ideas, and problems to solutions; implement policies; and benefit from or resist policies.

Actors may try to influence the policy process at the local, regional, or national level, and it is considered necessary to differentiate among actors (group them) in order to analyse who has influence (power) over a policy. Lehmann (2016) and Buse *et al.* (2005) provide examples of the categories in which actors or stakeholders can be grouped:

  i. Government (e.g. Ministry of Health, Ministry of Education, Ministry of Finance);

 ii. Non-governmental Organisations (NGOs);

iii. Civil society;

 iv. Pressure/interest groups (e.g. Stop Stockout Project, HIV/AIDS campaign);

  v. International organisations (e.g. WHO, World Bank, UNICEF);

 vi. Funding organisations (e.g. USAID); or

vii. Private sector (e.g. Gavi, Imperial Logistics).

The behaviours and actions of these actors determine how a policy process plays out—what policies are identified, and how they are implemented (Lehmann, 2016). These behavioural characteristics are based upon an actor's judgement on whether they will lose or gain from the process, or whether policies are aligned with or against their values and beliefs (Lehmann, 2016). Values and beliefs are shaped according to the actors personality, education, religion, their organisational role, etc. Another characteristic that influences the actors judgement is their perception of whether they will lose or gain from a specific policy (see Section G.1 for a more detailed discussion).

An actor usually exercises power to support or oppose a policy consideration or policy implementation. In some cases power is deliberately exercised to 'prove a point' and consequently goes against policy objectives and undermines the achievement of public value (Lehmann, 2016). There have been many attempts in literature to try to understand power—who has it, and how it is exercised. A tool used to understand which actor has the power, which actor can

influence the policy process, and who has interest in a particular project or policy, is a stakeholder analysis tool. More about this particular form of analysis is discussed in Section 4.3. More information on forms of actor power is provided in (see Section G.2).

Content

The content of policy is made up of the problem that the policy seeks to address; the aim and objectives of the policy; and the intricate details of how the policy will be implemented and achieved (Lehmann, 2016). Appendix H provides a checklist, developed by Shung-King (2004), on the following: (i) implementation strategies to include to reduce the likelihood of poor implementation (Figure H.1); (ii) key factors to consider when defining a policy problem (Figure H.2); and (iii) key information required when drafting a policy document (Figure H.3)

According to Lehmann (2016), typical characteristics of a policy include: the gains and losses of the policy to the system; the administrative and technical resources needed for policy implementation; the level of complexity of the policy; the participation needed; and the resources needed (e.g. time frame and financial resources). The policy draft checklist (Figure H.3) referred to above, researched by Shung-King (2004), also includes most of these characteristics. Analysing these characteristics can help policymakers understand what the policy 'intends' to do and to conceive strategies for implementation in line with this intention (Lehmann, 2016).

Context

Policy content, policy processes, and how they interact with actors, are located within multiple contexts. 'Context' can be categorised into two dichotomous groups: macro level and micro level (Lehmann, 2016). Leichter (1979) has proposed four macro-level factors that have an impact on policies: (i) situational factors (i.e. irregular or impermanent situations); (ii) structural factors (i.e. permanent elements or characteristics of a country); (iii) cultural factors (i.e. values, gender relations, and trust in the government); and (iv) environmental factors (i.e. external or international factors) (Collins, 2005; Leichter, 1979).

Collins *et al.* (1999) argue that in policy analysis, macro-level contextual factors suggested by Leichter (1979) might be difficult to distinguish, and suggest that the macro-level factors should be based on the following factors (with an example):

  i. Demographic and epidemiological changes: percentage of elderly or young people in the population;

 ii. Process of socio-economic changes: conflict, or moves to free market economies;

iii. Economics and financial policies: restraint on government spending;

iv. External factors: international organisations;

v. Politics: new government with new ways of handling political instability; and/or

vi. Ideology, public policy, and the public sector: free market orientation in social policy (e.g. user fees for public services).

Micro-level context refers to the more immediate and local factors that may impact or influence a policy or the implementation of a policy (Lehmann, 2016). In summary, micro-level context includes primarily organisational and local contexts, which according to (Lehmann, 2016) may include some questions: (i) organisational capacity; (ii) organisational context and culture; (iii) previous policies and experiences; and (iv) social contexts surrounding the organisation. See Section G.3, where the aforementioned contextual factors are further discussed.

In order to understand the projected outcome of a policy, one has to take into account both the macro- and micro-level context in which the policy might be implemented. While it is important to understand the context in which a policy is developed and implemented, it is also important to take into account its relations with the actors, and its impact on the content (Lehmann, 2016).

Process

The policy process refers to the method according to which policies are developed, negotiated, implemented and evaluated. This refers back to the analysis *of* policy models (i.e. the policy- and decision-making processes) already discussed in Section 4.2.1. The process forms a critical part of the policy analysis triangle—the process of policy-making helps the analyst understand the development of a policy and how it evolves through the different building blocks of policy analysis (from agenda-setting to implementation and evaluation).

In summary, the policy process, the context in which the policy is made or changed, the content of the policy being developed or changed, and the actors involved in the development, implementations, and the operationalisation of the policy, are key components of policy. Thus, the policy triangle model argues that these are the critical components to focus on when developing or changing policies, and the components are guidelines on the different aspects of a policy that can be analysed. The next approach to policy analysis that is discussed focuses on the effect-implementation approach to policy analysis, where this model assesses the impact policy options or policy consideration have, based on different dimensions that fall within the 'effect' and 'implementation' categories.

4.2.2.2 Effect-implementation approach to policy analysis

Morestin (2012) developed an analytical framework that analyses the impact of public policies that improve the conditions people live in, i.e. policies that relate to education, child care, health services and housing (Morestin, 2012). This section discusses the types of public policy analysis this framework is useful for; the policy facets it is focused on; and how the analysis is carried out. Public health actors do not necessarily have the power to make public policy decisions, and their perspectives can be one-sided. Policies are influenced by numerous groups, individuals, and organisations with interests in the outcomes (Morestin, 2012). Therefore, it is important to take into consideration the public health perspectives, while remaining aware of other perspectives when conducting the analysis (Morestin, 2012). Given this context, the analysis of public policies for this framework is useful in the case of the following situations (Morestin, 2012):

i. Before the decision is made to adopt a policy:

   a. To **inform a decision-maker** on whether a particular public policy enables the desired outcome (or objective of the policy). The aim is only to provide the decision-maker with information, in order to make an informed decision.

   b. To **promote the adoption of a public policy**—playing the role of an advocate.

   c. To **compare public policies** that will inform the decision-making process on which policy the focus should be on.

ii. When a policy has already been implemented:

   a. It is required to **evaluate the public policy**, in order to identify weaknesses that can be addressed.

The framework is based on an evidence-informed approach to decision-making, which emphasises examining the effectiveness of the policies being considered, as well as understanding issues related to the implementation of a policy. Thus, this framework is considered to be a two-pronged analysis (Morestin, 2012); analysing two characteristics of a policy at once. Morestin (2012) has broken down the analysis into six analytical dimensions: (i) effectiveness; (ii) unintended effects; (iii) equity; (iv) cost; (v) feasibility; and (vi) acceptability, that influences the policy-making decisions (Morestin, 2012). The six dimensions are illustrated in Table 4.2, categorised according to the overruling dimension of either effect or implementation. A more detailed description of each dimension is available in Section I.1 (see Appendix I).

The six analytical dimensions discussed create the possibility of understanding the overall implications of the policy under study; however, the analyst may decide to document and analyse only one out of the six analytical dimensions (Morestin, 2012). The dimension(s)

Table 4.2: Six analytical dimensions to assess the impact of a policy (Morestin, 2012).

Effects	Effectiveness	What effects does the policy have on the targeted health problem?
	Unintended effects	What are the unintended effects of the policy?
	Equity	What are the effects of this policy on different groups?
Implementation	Cost	What is the financial cost of this policy?
	Feasibility	Is the policy technically feasible?
	Acceptability	Do the relevant stakeholders view the policy as acceptable?

selected for a policy analysis study can be determined based on the discretion of the analyst, taking into consideration whether the analysis is for strategic or practical purposes, but it is important to critically consider each dimension before setting the dimension aside (Morestin, 2012). The summary list found in Section I.2 can assist with deciding whether the dimension should be considered for the analysis.

Following the selection of the dimensions, the next step is to find the information that is necessary to support the analysis. Various potential data collection approaches exist and these differ in terms of the time required; the necessary competency required; the robustness of the analysis; and the relevance of the method to the context. (More information on this topic is presented in Section I.3). The appropriate data collection method depends on the situation the analyst is in, i.e. the time available to conduct the analysis or the availability of resources (Morestin, 2012). Once the information is gathered and analysed, the analysis can be presented in either a narrative form (the quantitative and/or qualitative data collected is synthesised in a text) or in the form of a scorecard (a visual representation). When conducting the analysis on multiple policies, a better overview of the analysis can be obtained by using the scorecard method. Table 4.3 provides an illustration of the scorecard approach.

Table 4.3: An illustration of the visual scorecard approach, adapted from (Morestin, 2012).

	Effect			**Implementation**		
	Effectiveness	**Unintended effects**	**Equity**	**Cost**	**Feasibility**	**Acceptability**
PP1	++	−	+++	−	−	− − −
PP2	+	++	−	+	+++	−
PP3	+++	− −	−	+	++	+
...						
PPn	++	−	+	−	− −	+++

The study by Morestin (2012) does not provide good instructions on how to utilise the scorecard tool; however, there are many studies available on how to do a scorecard analysis with multiple dimensions. Multi-criteria decision analysis (MCDA) is an example of a technique that can be used to identify a preferred option or to distinguish between acceptable and unacceptable possibilities (Department for Communities and Local Government: London, 2009). More details regarding this tool are discussed in Appendix I.

The effect-implementation approach to policy analysis is a structured and flexible tool that can assist policy analysts and policymakers on how to assess the impact of public policies (policies still to be adopted and policies that are already implemented), against a set of analytical dimensions, using either a narrative or scorecard approach. The framework is structured in a sense that it can analyse policy options to represent the public health perspective to policymakers (Morestin, 2012); however, it is flexible in a sense that it can be adapted according to the context and the resources available to conduct the analysis (Morestin, 2012). This method is a hands-on, however, subjective approach to identify the possible impact of policy options. The next section focuses on technical and mathematical approaches to analyse for policies.

4.2.2.3   Sophisticated analysis methods for policy

The purpose of this section is to provide an overview of sophisticated methods to analyse policies. Though a variety of quantitative[1], qualitative[2], and mixed methods are utilised to demonstrate policy impacts and propose potential solutions (Yang, 2006), only a select few quantitative techniques will be briefly described in this section to provide some insight into the numerous sophisticated analysis methods that are available.

As the environment in which policies are implemented become more complex, the policy problems becomes more turbulent, and time and budgets become more constrained, policy analysts must be able to deliver policy solutions to such problems (Peters & Pierre, 2006). Conducting an analysis *for* policies often requires sophisticated methods to assess how policy problems are effected, taking into account numerous variables, policy interventions and contextual factors simultaneously (Peters & Pierre, 2006). Quantitative methods can be used to

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[1] "Quantitative approaches make use of numerical data, usually gathered by means of surveys based on structured questionnaires with close-ended questions; or from other statistical sources (e.g. national statistical yearbooks, national accounts, custom data and international databases). They treat information by means of mathematical methods in order to derive expected responses to variables affected by policy interventions" (Bellù & Pansini, 2009).

[2] "Qualitative approaches for policy impact analysis essentially make use of non-numerical information. These include value judgements of key informants; non-structured interviews of stakeholders; focus groups, panel discussions etc. They can be also very detailed and context-specific, to feed the decision-making process" (Bellù & Pansini, 2009).

demonstrate relationships between policy design and policy outcomes, evaluate the effect policies might have on the social, political and economic factors of a system, and find alternative solutions (Peters & Pierre, 2006).

Systems analysis, also referred to as 'systems thinking', is an interdisciplinary field that investigates the nature of complex systems and hinges on the concept of non-linear dynamics through mathematical approaches (Atkinson *et al.*, 2015). Techniques such as modelling[1], descriptive statistics[2], quantification of inputs and outputs[3], operations research[4], cost-benefit analysis[5], and risk-benefit analysis[6] are some examples of mathematical approaches used in quantitative policy studies (Yang, 2006).

To select the most appropriate model for use in a specific operational context, the policy analyst should take its key features into consideration, such as (Bellù & Pansini, 2009):

i. Technical features: The explicit inclusion of specific dimensions, e.g. geographical region and their relationship; suitability—fitting the appropriate technical features to the situation and context;

ii. Human resources: Statistical modelling experts, including experts regarding the policy topic are required, and this can become complex when different policy areas need to be incorporated into the model;

iii. Flexibility: The statistical model should be able to adapt to different policy areas to reduce variables and costs relating to those variables;

iv. Data requirements: To develop a quantitative model, a sufficient amount of data (including secondary data) is required; and

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[1]A model is a representation of reality—a physical representation of a real-world problem, where 'reality' is represented by a series of equations (Richardson, 1979).

[2]Descriptive statistics, also referred to as exploratory data analysis, deals with gathering, classifying and computing large amounts of data. The data is simplified and presented in either tables or graphical form to visually have insight into the data (Jaggi, 2003).

[3]The input-output method is an adaptation of the theory of 'general equilibrium', which studies the quantitative interdependence between interrelated activities within a system (Kurz & Salvadori, 2000).

[4]According to Bradley *et al.* (2017), "operations research (OR) is a discipline that uses advanced analytical methods to better understand complex systems and aid in decision-making". OR makes use of various problem-solving techniques and computational methods to help improve the operations of a system (Bradley *et al.*, 2017).

[5]Cost benefit Analysis (CBA) is a tool used to rank projects and choose the most appropriate option (Department of Environmental Affairs and Tourism, 2002). The main purpose of CBA is to assist in social and policy decision-making—every decision presents different issues and implications for how policy analysts use CBA (Crouch, 2012). Therefore, there is not a 'one-method-fits-all' CBA, but an array of different CBA approaches (Crouch, 2012).

[6]Risk-benefit analysis (RBA) involves identifying and comparing the risk, as well as the benefits associated with a particular project, highlighting the trade-offs between the two in order to inform a policy decision (Richard Wilson, 2002).

v. Time required: Different models may require a different development and implementation lead time, depending on the preceding features.

System dynamics[1], agent-based modelling[2], and simulation modelling[3] are some of the most prominent systems science methods that are used to develop a tool for policy analysis (Atkinson *et al.*, 2015). Such a tool would allow virtual (desktop) experimentation of policy scenarios to test their comparative impact over different periods of time (short-, medium-, and long-term) (Atkinson *et al.*, 2015). These policy analysis tools could test the efficiency, effectiveness, and equity of policy responses, exposing unintended consequences in the system through computer modelling (Atkinson *et al.*, 2015). A typical area in the policy analysis process, where such models are utilised, is the 'system domain for policies' (Figure 4.1) (Walker & van Daalen, 2013). Computational modelling techniques can be used to test future scenarios based on different conditions (similar to the analytical dimensions discussed in Subsection 4.2.2.2). A good systems model should take into account the interest of relevant stakeholders, and the preferred choice of policy can be made by weighting the outcomes by their relative importance (Walker & van Daalen, 2013).

The advantage of quantitative methods, is that these:

i. Offer the ability to better operationalise and analyse research evidence to support decision-making for complex problems (Atkinson *et al.*, 2015);

ii. Provide valid, reliable and generalisable results to a larger population (Atkinson *et al.*, 2015);

iii. Allow policy-makers and interested stakeholders to have insight into possible policy choices with numbers, graphs, and tested relationships (Bellù & Pansini, 2009; Peters & Pierre, 2006); and

iv. Enable policy-makers and interested stakeholders to determine and prioritise the benefits and risk factors of different policy options through mathematical computation (Atkinson *et al.*, 2015; Wagle, 2000).

While these tools have provided valuable guidance to assist with the development of effective public policy, Atkinson *et al.* (2015) argue that "...their adequacy and accuracy are called

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[1]System Dynamics is "the study of information-feedback characteristics of industrial activity to show how organizational structure, amplification (in policies), and time delays (in decisions and actions) interact to influence the success of the enterprise" (Forrester, 1958).

[2]Agent-based modelling is the computational study of social agents interacting in an autonomous manner as evolving systems (Borshchev, 2013).

[3]According to Banks (1999), simulation modelling "is the imitation of the operation of a real-world process or system over time". It is used to analyse the behaviour of a system and aid in the design of real systems (Banks, 1999). Both existing and conceptual systems can be modelled with simulation (Banks, 1999).

into question when applied to complex problems". Atkinson *et al.* (2015) further elaborate: "the lack of literature available detailing practical applications of quantitative policy analysis methodologies to support health policy-making impede the understanding of the issues and limitations in the design of effective health policy."

The impact quantitative modelling has on the policy process is also limited because of the lead time to develop such modelling tools (Enserink *et al.*, 2013). According to Enserink *et al.* (2013), by the time the quantitative model is developed and the results are available, the stakeholders and interested parties may have other concerns, the urgency of the matter may have changed or disappeared, and/or the stakeholder may have been replaced (Enserink *et al.*, 2013).

4.2.3   Conclusion: Exploring policy analysis methods and models

In conclusion, a selection of prominent models and tools relating to the analysis *of* policies and the analysis *for* policies have been identified and discussed in this section. It is important to note that a number of models and tools that relate to policy analysis exist, but have been excluded from this discussion for the sake of brevity. The next section discusses the role of the stakeholder in the policy analysis process, along with a selection of stakeholder analysis tools.

4.3   Stakeholder analysis

As discussed in Subsection 4.2.2.1, actors form the core element of the policy analysis triangle framework. Therefore, it is important to understand who the actors and stakeholders are in the system—what drives them, what their role is in the policy process, as well as how they will influence policy decisions. This section focuses on analysing the stakeholders in a system. This section first discusses the difference (and similarities) between actors and stakeholders; the role of the stakeholders in the policy analysis process; and the methods for analysing these stakeholders.

4.3.1   What is an actor or stakeholder?

As mentioned in Subsection 3.2.3, the term 'actors' and 'stakeholders' are used interchangeably (Lehmann, 2016). Golder & Gawler (2005) defined a stakeholder as "any individual, group, or institution who has a vested interest in the natural resources of the project area and/or who potentially will be affected by project[1] activities and have something to gain or lose if conditions change or stay the same". This definition includes both the beneficiaries that are

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[1]A stakeholder analysis can be applied to any project, policy or programme.

involved and excluded from the decision-making process—in the case of this study, the policy-making process. A stakeholder is a crucial aspect to consider in order to achieve the policy goals (Golder & Gawler, 2005).

4.3.2 The role of actors and stakeholders in policy analysis

Policy analysis is influenced by policymakers and the affected parties, referred to as stakeholders. Stakeholders that are influenced by a certain decision or action usually respond to the decision, as they are those with the power to influence the policy result (Mulyaningrum *et al.*, 2013). A stakeholder analysis approach provides a means of understanding how stakeholders may affect policy change. A stakeholder analysis (SHA) is a process of systematically gathering and analysing qualitative information to determine whose interests should be taken into account when developing and/or implementing a policy or programme (Schmeer, 1999). A SHA gathers knowledge about actors and stakeholders, about their beliefs, behaviour, interest and the intentions they bear on the decision-making and implementation processes of policies (Schmeer, 1999).

4.3.3 Stakeholder analysis approach

The execution of a SHA is a recognised method used by researchers and policy analysts for understanding how stakeholders may influence the outcome of some policy considerations (Lehmann, 2016). Knowing how different stakeholders may affect the adoption or implementation of a policy can assist policy analysts, policymakers and project managers to manage and interact with key stakeholders to increase their co-operability for a given policy, and therefore prevent misunderstandings or mitigate opposition towards a specific policy (Golder & Gawler, 2005).

The information gathered from a stakeholder analysis can be used to develop action plans to increase the support for policy reform (Schmeer, 1999). Golder & Gawler (2005) believe that a policy is more likely to succeed if a stakeholder analysis (accompanied by other policy analysis tools) is used to guide implementation of a policy. In addition to what has been mentioned, the following can be identified with a SHA (Golder & Gawler, 2005):

i. Interests of all stakeholders who may affect or be affected by the policy;

ii. Risks that could jeopardise a policy or initiative;

iii. Appropriate strategies and approaches for stakeholder engagement; and

iv. Ways to reduce negative impacts on vulnerable and disadvantaged groups.

There are some limitations to consider when conducting a stakeholder analysis: (i) a SHA reflects experience at only one point in time—the analyst should decide the point in time which is most relevant to the policy; (ii) it is difficult to make assumptions about a stakeholders' position or power, and tailor different interpretations of their power and interests; and (iii) a SHA focuses primarily on power and interest, but those are not the only influences over time (Lehmann, 2016).

Different authors propose different methodologies and tools that can be used to conduct a SHA, however, many of these methodologies share the same underlying characteristics and follow a similar analysis approach that is represented by the framework researched by Luyet *et al.* (2012) for stakeholder participation (Figure 4.4). The framework is structured as a system with inputs (e.g. policies) and outputs (e.g. decision strategies) (Luyet *et al.*, 2012). Steps one to three encompass the activities for the analysis part of a SHA, and the rest are based upon strategic decisions on how to engage stakeholders based upon the findings from the analysis. The following subsection provides a discussion on the different tools and approaches towards a SHA.
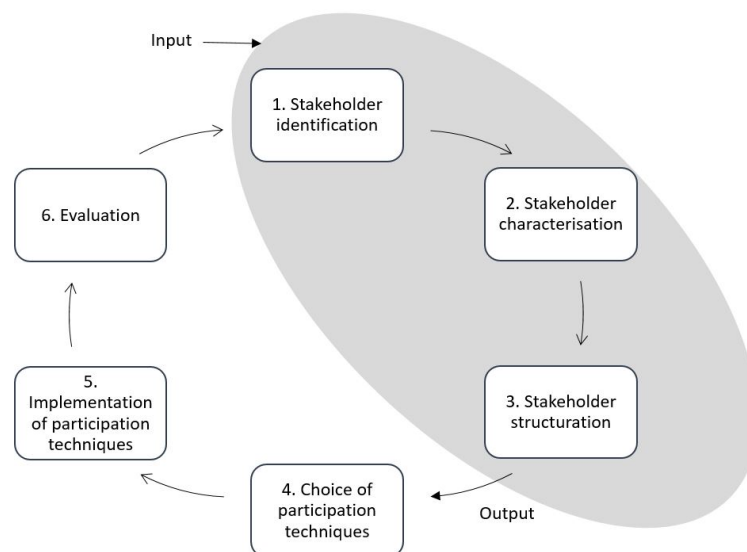
Figure 4.4: Stakeholder analysis process (core functions in the grey region), adapted from Luyet *et al.* (2012).

4.3.4 Stakeholder analysis tools and models

A SHA is conducted in a sequential manner as illustrated in Figure 4.4. The step-wise approach fits all contexts in which a stakeholder analysis can be conducted in (Mayers, 2005).

Step 1: Stakeholder identification

The first step in a SHA is to identify and list all the potential stakeholders related to the input (which is either a policy, programme or project) (Golder & Gawler, 2005; Lehmann, 2016; Schmeer, 1999). Schmeer (1999) suggests that the list should be developed with input from experts, due to the fact that time and resources for conducting a SHA are limited. Other methods for identifying relevant stakeholders includes brainstorming sessions, focus groups, semi-structured interviews, snow-ball sampling[1], or a combination of these mechanisms (Reed *et al.*, 2009).

As mentioned in Subsection 4.2.2.1, actors and stakeholders can be grouped into various categories (international, national, private, NGO, media and consumers). Islamy (2008) explains that these groups can be further grouped into either primary or secondary stakeholders. Primary stakeholders are those with high power and interest, as well as those who are affected the most, whether they benefit or are adversely affected by the intervention (Islamy, 2008). Secondary stakeholders are those with high interest and low power, or high power and low interest (Islamy, 2008). Key stakeholders have significant influence on the policy, and can both be a primary or secondary stakeholders (Islamy, 2008). The categorisation of stakeholders and the type of analysis that would be done should be determined at the discretion of the analyst(s).

Step 2: Stakeholder characteristics

Once stakeholders are identified (and grouped), their characteristics and actions towards a policy need to be understood (Mayers, 2005). The second step in the SHA (in Figure 4.4) is to select the stakeholder characteristics to be considered for the analysis. These are predefined variables set by the analyst. Some examples of these variables that are mentioned in other studies are the following (Lehmann, 2016; Luyet *et al.*, 2012; Mayers, 2005; Schmeer, 1999):

  i. Stakeholder's attitude towards a policy;

 ii. Potential conflicts between stakeholders;

iii. Access to resources, i.e. human, financial, and political;

iv. Degree of influence on the adoption, acceptance, or implementation of a policy; and

 v. The position (authority) of a stakeholder.

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[1]The snowball technique starts off with an initial list of stakeholders that have been developed within a brainstorming session, which is then given to one of the identified stakeholders, soliciting their opinion and allowing them to add to the list (Luyet *et al.*, 2012). When consulting experts (or the first identified stakeholder), they should be among those who know the content, as well as the context in which the particular SHA is conducted (Schmeer, 1999).

These characteristics can be used in tools such as tables, matrices, or influence maps to define, analyse, and illustrate how the characteristics of each stakeholder may affect a policy. There are a number of methods for illustrating the stakeholders' characteristics. Abdrabo & Hassaan (2007) and Lehmann (2016) use a tabular form to identify and list the relevant stakeholders and describe each stakeholder according to the analyst's preferred characteristics. Then the information is used to map the stakeholders (a stakeholder map) across the two characteristics. A detailed description on how the characteristics tabular form, provided in Section J.1, can be utilised to develop a stakeholder map.

Similar to the stakeholder map are the stakeholder analysis grids drawn up by Golder & Gawler (2005) and Mayers, also referred to as stakeholder analysis matrices (Figure 4.5(a) and 4.5(b)). Both of these methods use two characteristics to plot the positions of the identified stakeholders.
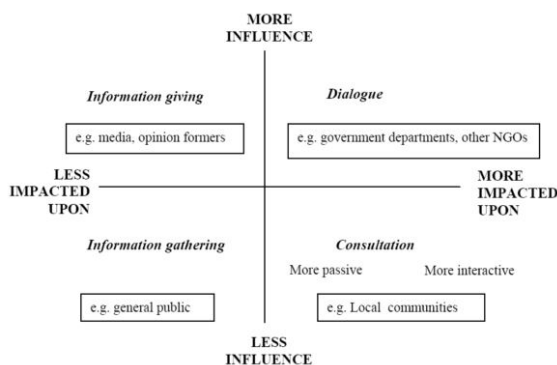
(a) Golder & Gawler (2005)
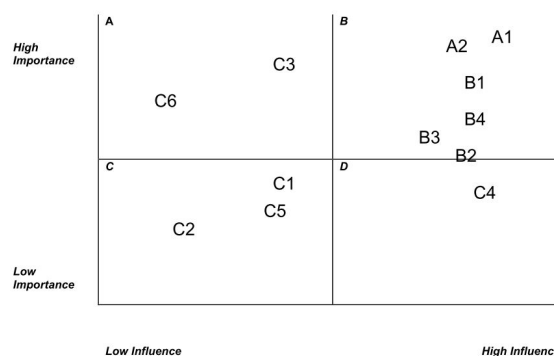
(b) Mayers (2005)
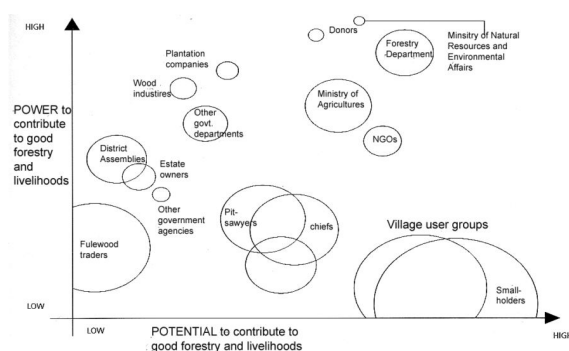
(c) Mayers (2005)
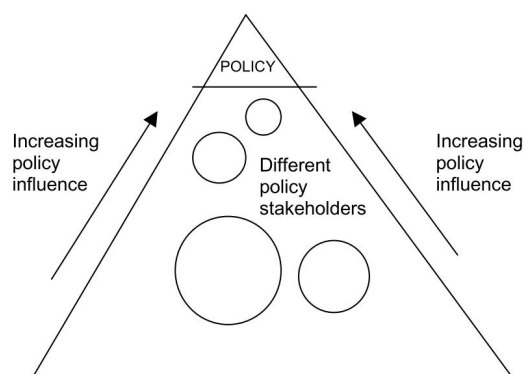
(d) Mayers & Vermeulen (2005)

Figure 4.5: Different types of stakeholder maps to plot stakeholder characteristics

It is up to the analyst or the purpose behind the analysis, which characteristic is used for the illustration. Mayers & Vermeulen (2005) included a third variable to the original matrix to illustrate the size of each stakeholder group. In Figure 4.5(c), three variables are used,

a characteristic on each axis, and one variable which illustrates the size of the stakeholder group. In Figure 4.5(d), the stakeholders are plotted according to the degree a certain variable influences the policy reform; the size of the stakeholder groups; and the relationship with each other (the distance plotted between stakeholder groups) (Mayers, 2005).

The matrices provide a visual approach towards the analysis, which illustrates where action can be taken and how stakeholders can be engaged. One limitation to this visual technique is that Mayers & Vermeulen (2005) and Mayers (2005) did not provide an explanation for plotting the group size of the stakeholders. However, some assumptions behind the rationale of the stakeholder group size are as follows: (i) the size of the group illustrates the effort that needs to be made regarding stakeholder engagement plans, due to the number of stakeholders within each group; and (ii) where stakeholder plots overlap, this indicates a strong relationship among the groups in terms of specific characteristics.

Another method used for a SHA, is the quantifying evaluation and analysis tool of Abdrabo & Hassaan (2007) which is illustrated in Figure 4.6. The tool makes use of quantifiable indicators to analyse the influence and power a stakeholder might have on a policy reform or policy. In the first column, a list of all the stakeholders is required. The second column is for the evaluation of the stakeholders' interest, attitude, power, and influence over a policy reform or policy. The third column uses the data from the second column to propose a stakeholder engagement action plan. A detailed description of how the table should be used is provided in Section J.2 in Appendix J.

Stakeholder	Criteria of evaluation							Decisions	
	Interests	Attitude	Power			Influence	Total	The need for involvement	Extent of involvement
			H	F	P				

Figure 4.6: An illustration of the table used for the quantifiable SHA approach by Abdrabo & Hassaan (2007).

Step 3: Stakeholder structuration

The third step in Figure 4.4 consists of structuring stakeholders into homogeneous groups in order to determine what their level of involvement needs to be in the policy or policy reform process (Luyet *et al.*, 2012). The quantifying evaluation tool discussed in Section J.2 incorporates the method of 'structuring'. Abdrabo & Hassaan (2007) define the following

four categories of stakeholder involvement: (i) to be informed; (ii) to be consulted; (iii) to be involved in decision-making processes; or (iv) to be disregarded from the decision-making process. Taking a slightly different approach, Luyet *et al.* (2012) use the following five categories in their framework:

i. Information: Explanation of policy to stakeholder;

ii. Consultation: Presentation of policy to stakeholders and collecting their suggestions (without taking them into account);

iii. Collaboration: Presentation of policy to stakeholders and collecting their suggestions (taking them into account);

iv. Co-decision: Cooperation with stakeholders towards agreement of solutions and implementations; and

v. Empowerment: Delegation of decision-making over policy development and implementation.

There is no single correct approach to mapping stakeholder characteristics (Luyet *et al.*, 2012), nor is there a correct way to categorise stakeholders according to their degree of involvement in a policy. The methods and tools that have been discussed in this section are provided to illustrate some of the different approaches that exist in literature and that have played a significant role in policy development strategies. An SHA model should be selected based on the context and objective of the study, as well as what the results of the SHA will be used for (Luyet *et al.*, 2012). It is important to take into account the analyst who will characterise each stakeholder, because the opinion and judgement from one person may be subjective (Luyet *et al.*, 2012).

4.3.5   Conclusion: Stakeholder analysis

In conclusion, a stakeholder analysis is a key analysis approach that is usually performed in conjunction with policy analysis. In literature, it is found that most policy analysis methodologies take into account the findings from the stakeholder analysis in order to form a better perception of what the policy plan and strategies for policy change, policy adoption and policy implementation should be.

4.4   Chapter 4: Conclusion

In this chapter, the concept and description of policy analysis is introduced, providing insight into the two distinctive views: the analysis *of* policies, and the analysis *for* policies. The two different ways of analysis are used to identify different tools and methods that can be used to

analyse policies. Some of the models discussed are traditional and have been used in literature for decades (e.g. the rational model and the garbage can model), while others are modern tools and methods (e.g. the effect-implementation model and system dynamics modelling) that are used for decision-making regarding policies and other fields where decision-making is required. Furthermore, the role of stakeholders and the inclusion of a stakeholder analysis in the policy analysis process is highlighted. The tools and methods used to conduct a stakeholder analysis are discussed in detail.

According to Bellù & Pansini (2009), "there is an array of models, frameworks, and theories to guide policy analysis". The information provided in this chapter highlights some of the most prominent policy analysis methods found in literature. For the majority of the models, methods and tools discussed in this chapter, the authors highlighted the fact that the models are adaptable, and should be adjusted to fit the problem rather than attempting to fit the problem to the model. Therefore, the information gathered in this chapter, along with critical information discussed in Chapter 2 and Chapter 3 needs to be combined to develop a policy analysis method for the VAN. As mentioned, models from the two distinctive views of policy analysis can be used in conjunction, if required.

Chapter 5

Towards the development of a policy analysis logic model for a VAN

In light of Subsection 1.1.3, the role of policy analysis is already an established discipline, but it has been overlooked when it comes to the healthcare sector in developing countries (Walt & Gilson, 1994). More specifically, as mentioned in Chapter 1, limited information is available on a comprehensive approach that analyses the effect of a country's existing legal framework on the change in design of its public pharmaceutical supply chain.

In this chapter, the development of a policy analysis method for a VAN Operating Model (PoliVAN logic model[1]) is outlined and discussed. As illustrated by the research design method (Figure 1.2), the chapter starts by highlighting the foundational concepts from Chapters 2, 3 and 4, which are critical to the development of the policy analysis method. Thereafter, the objectives for the PoliVAN logic model (hereafter referred to as PoliVAN) are outlined, and based on the insights gained from the preceding chapters, the key criteria needed from each chapter to develop the PoliVAN are presented.

The PoliVAN's development process is subsequently discussed, whereby the choice of methods and models selected to be used in both the development process as well as the final policy analysis method are justified. The chapter concludes with an overview of the high-level developed PoliVAN. The detailed PoliVAN is presented in Chapter 7. This detailed version incorporates changes that were made following the evaluation processes (discussed in Chapter 6).

5.1 Foundational concepts

As highlighted throughout the preceding chapters, prior to developing a policy analysis method for the VAN, information relevant to the key areas of interest (i.e. the VAN, a pharmaceutical

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[1]Details regarding the name of the policy analysis method is further discussed in Subsection 5.4.5.

supply chain, and policy analysis methods) is required. This is in order to have sufficient knowledge of what should be incorporated into the policy analysis method to effectively provide insight into the policy-specific opportunities and constraints regarding the implementation of a VAN in a country's pharmaceutical sector. The following concepts are therefore discussed in the earlier chapters of this study:

i. Chapter 2: The Blueprint Reference Model (BPRM) and VAN Operating Model for South Africa;

ii. Chapter 3: The operations of a pharmaceutical supply chain in the public sector and the link to policies; and

iii. Chapter 4: Various methods and approaches to analyse policies.

Chapters 2 to 4 provide insight into the requirements and objectives of a VAN, how policies influence and enable the operations of pharmaceutical supply chains in a public sector, and approaches on how to analyse policies. The VAN is a complex operating model with multiple interactions; however, it only provides one perspective of a pharmaceutical supply chain. The pharmaceutical logistics framework (discussed in Chapter 3) provides an overview of the entire supply chain, highlighting the fact that the different operations are interrelated and multiple policies and legislations can exist for a particular part of the supply chain. Finally, policy analysis models and tools (presented in Chapter 4) that are suited to the aim of the policy analysis method for a VAN Operating Model can be adapted in line with the specific objectives of the PoliVAN. The aforementioned aim and objectives are defined in the next section.

5.2 Aim and objectives of the PoliVAN

Identifying the aim and objective(s) that the PoliVAN aims to achieve, provides guidance on the key concepts that the policy analysis method should include. In Subsection 5.2.1, the aim of the PoliVAN is defined, and in Subsection 5.2.2, the objectives that the PoliVAN should seek to achieve are identified.

5.2.1 Aim of the PoliVAN

The overall aim of this study is to support the work of the Bill and Melinda Gates Foundation and VAN officials by developing a method that can provide useful insights into policy-related opportunities and constraints regarding the implementation of an operational model (such as the VAN) in the public pharmaceutical sector. Thus, as concluded in Chapter 2, the PoliVAN should be able to guide actors (such as policy analysts, government officials, VAN role players and relevant stakeholders) in a public pharmaceutical supply chain that operates

within the VAN framework (sub-Saharan African (SSA) countries that have adopted the VAN) on how to identify, analyse and envisage how country-specific policies will enable or hinder the implementation and operationalisation of the VAN model.

5.2.2   PoliVAN objectives

The success of a VAN Operating Model, discussed in Chapter 2, hinges on the relationships between the people, process, and technology elements, as well as the environment (referred to as the policy element) within which these elements operate (Llewellyn, 2016). An operating model such as the VAN is intended to be implemented across most of a country's public pharmaceutical supply chain, meaning that there are various levels, processes, people, technology, and components that the policy analysis model should take into consideration.

From Chapter 3, it is evident that policies are not the only governing element situated in the enabling environment, but that other legislation, e.g. regulations and guidelines, also govern the operations of a pharmaceutical supply chain. This indicates that multiple legislative instruments will need to be taken into account to comprehensively analyse the impact of policies (and other relevant legislation) on a pharmaceutical supply chain (relevant to the scope of the VAN model). Furthermore, the PoliVAN should ideally be transferable to other SSA countries that have, or plan to adopt and implement a VAN Operating Model. Hence, the PoliVAN, designed to support an operational model such as VAN from a number of perspectives, should aim to address the following objectives:

Objective 1: To identify and take into account multiple policy and legislative instruments that are relevant to the scope of the VAN Operating Model for the specific country;

Objective 2: To identify types of (or specific) policies and legislations that enable the implementation and operationalisation of the VAN Operating Model, as well as to identify those that do not support the country-specific VAN;

Objective 3: To propose a method that makes use of policy analysis processes to determine the impact policy options might have on the VAN Operating Model or the health system;

Objective 4: To take into account the influential factors, i.e. external/contextual factors, stakeholder engagement strategies, and decision-making strategies; and

Objective 5: To provide insight into possible policy decision and strategies for governance authorities to develop or make an informed policy decision.

The aforementioned PoliVAN objectives provide a high-level overview of what the PoliVAN should entail, and it builds on the content of the three preceding chapters that inform the development of the PoliVAN. In the next section, the aspects of each of these three chapters that should be incorporated into the development of the PoliVAN are identified.

5.3 Design criteria

In order to take into consideration country-specific policies (that are relevant to the scope of a country's VAN Operating Model) and determine or project the impact that such policies are likely to have on the operationalisation of the VAN that is specifically developed for the country, the PoliVAN should incorporate critical elements from: (i) the VAN; (ii) the pharmaceutical logistics framework; and (iii) 'policy analysis'-related models and other relevant analysis tools. These three key areas are illustrated in Figure 5.1.
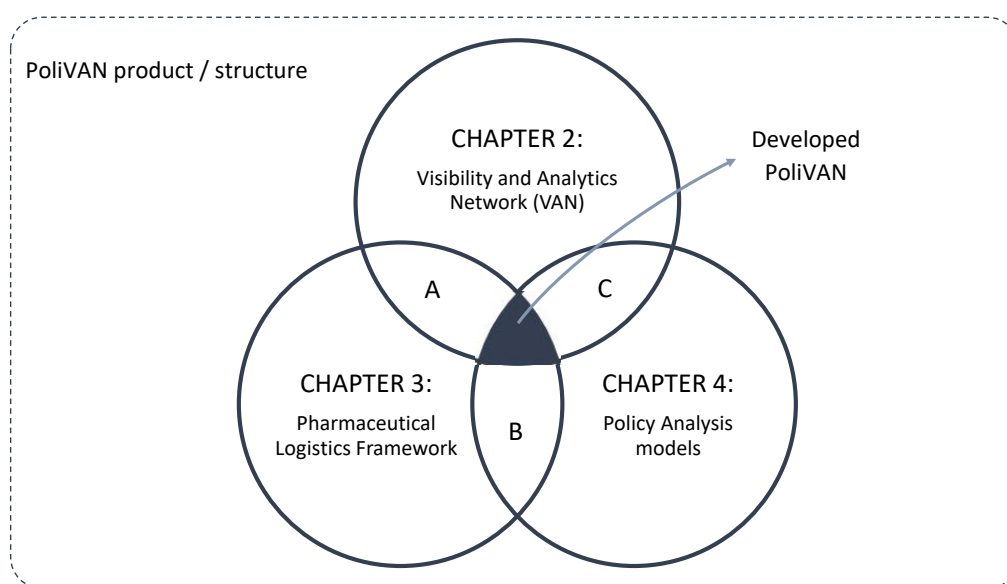
Figure 5.1: Key design areas for the PoliVAN

The integration between the three chapters comprises:

A: The VAN is developed for the public pharmaceutical supply chain context;

B: A pharmaceutical supply chain is governed and 'enabled' by country-specific policies and legislations; and

C: Policy analysis methods and models are studied in order to address the policy element gap (identified and discussed in Subsections 1.1.2, 1.1.3 and 2.2.4) of the VAN.

The development of the PoliVAN, pertaining the input from the three literature studies need to be embedded within a design product / structure[1]. The product should enable and support policy decision-making and guide the relevant analysts and stakeholders on approaches on how to identify, analyse and develop policy-specific strategies for the successful implementation and operationalisation of their country's VAN Operating Model. In the subsections that follow, the

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[1]As discussed in Chapter 1, the product refers to the development of either a framework, model, roadmap, process, business model canvas, logic model or maturity model.

actual content and criteria necessary from each chapter for the development of the PoliVAN are identified.

5.3.1 VAN Operating Model

The content from the BPRM and VAN Operating Model are important inputs into the PoliVAN. They inform the criteria used to determine whether country legislations and policies enable or hinder[1] the implementation of such a model. The success of a VAN hinges on the four key elements that allow the VAN to function: process, people, technology and policy. The following components from each element should be taken into consideration when developing the analysis model:

People element: The PoliVAN should facilitate the understanding of how the organisational structure of the VAN is designed (the responsibilities among the national, regional and district/facility levels), in order to measure the VAN or new roles and responsibilities against the current structure within a country. This includes the reporting lines and engagement structure among the different organisational levels and roles.

Process element: The PoliVAN should incorporate an understanding of how the different activities function within the different planning categories identified by the BPRM (demand, supply, distribution, and cold chain management). Additionally, the PoliVAN should understand who are the process owners (the VAN roles) for the different activities, the frequency at which these activities need to be executed, for whom (customer, role or level) the activity is produced, and how the activities link into the rest of the VAN Operating Model, and subsequently the pharmaceutical supply chain.

Technology element: The technology element for the VAN requires that the VAN Operational Model should have a system for data collection and aggregation that generates alerts and delivers insight, especially with regard to accountability (Goel & Llewellyn, 2015). The PoliVAN should take into account the software or system requirements for the VAN, i.e. the data requirements, the software tool to be used, and how the data visibility requirements are designed, in order to measure if data integration and visibility are enabled across the different regions in a country.

Policy element: The policy element aims to be a "cross-cutting governance framework with clear responsibilities and accountability and empowered decision-makers with defined 'spans of control' across the medicine supply chain" (Goel & Llewellyn, 2015). The BPRM identifies some policy considerations to take into account when designing a VAN. These considerations are discussed in Subsection 2.2.4. The key highlights are: (i) to

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[1]Throughout this chapter, the terms 'enable'/'support' and 'hinder'/'oppose' are used interchangeably.

enable end-to-end visibility; (ii) to develop key performance measuring outcomes; (iii) to include organisation-interaction through strategic collaboration; and (iv) to monitor the impact and change on relevant stakeholders. The PoliVAN should, therefore, incorporate all elements (people, process, and technology) into the analysis.

The aforementioned criteria from the VAN elements provide key areas to focus on and incorporate into the PoliVAN. However, the PoliVAN should be able to adapt to countries, with VAN Operating Models designed at different levels of detail; meaning, that it is possible that some countries might have more/less detailed VAN Operating Models than other countries. Nevertheless, the PoliVAN should not limit a country's opportunity to conduct the policy analysis.

5.3.2 Pharmaceutical logistics framework

For a policy analysis, it is important to understand the interactions between the operational functions and the supporting elements of a pharmaceutical supply chain. Thus, the key components of the pharmaceutical logistics framework (provided in Table 5.1) can act as a guide for a policy analyst to identify legislative instruments or assist with policy formulation by understanding how a pharmaceutical supply chain (both in literature and in a country context) operates. Furthermore, the policy hierarchy (shown in Figure 3.6) should be understood in order to understand the different types of legislative instruments that are available, and how policies fit between the mandatory and voluntary legislations.

Table 5.1: Key operational components from the pharmaceutical logistics framework

OPERATIONAL FUNCTIONS	
Medicine Selection	**Quantification and Procurement**
☐ Registration ☐ Essential medicines list ☐ Standard treatment guidelines ☐ Donor requirements	☐ Quantification and forecasting ☐ Funds and budgeting ☐ Procurement method ☐ Supplier selection and monitoring ☐ Contracting ☐ Order status and monitoring ☐ Product inspection (receive / check order) ☐ Payments
Inventory and Distribution Management	**Medicine Use**
☐ Port clearing ☐ Receipt and inspection (national warehouse/CMS) ☐ Inventory control ☐ Storage ☐ Requisition (ordering) and allocation of suppliers ☐ Delivery methods	☐ Diagnosis and follow-up ☐ Prescribing ☐ Dispensing ☐ Product use and adherence

Table 5.1 continued from previous page

MANAGEMENT SUPPORT ELEMENTS	
Information Systems	**Organisation and Human Resource Management**
☐ Pharmaceutical management information system ☐ Indicator-based monitoring system ☐ Integrated network	☐ Personnel management ☐ Education and training ☐ Accountability ☐ Reporting structures
Financial and Donor Coordination	**Monitoring and Evaluation**
☐ Financing and budget strategies ☐ Analyse and control expenditures ☐ Donor financing	☐ Programme planning, implementation, monitoring and evaluation

5.3.3 Policy analysis models

In Subsection 1.1.3, it is mentioned that there are no comprehensive methods available in literature on policy analysis that focus on analysing a complex system (such as a public pharmaceutical supply chain) in its entirety (and its individual components) taking into account existing country legislations. Therefore, investigation into policy analysis methods is required to develop a policy analysis method that can achieve the objectives of this study.

This chapter distinguishes between two types of policy analysis methods: (i) the analysis *of*[1] policies; and (ii) the analysis *for*[2] policies. The PoliVAN requires an approach to develop policy-specific strategies and decisions. Therefore, the PoliVAN should make use of a decision-making approach. A pharmaceutical supply chain is a complex system with intricate processes that are governed and enabled by many policies and legislations; therefore the decision-making model chosen for the policy analysis method needs to be easily adapted to aggregate a complex system into manageable steps, and to fit the objectives of the PoliVAN (from Subsection 5.2.2).

To achieve the other objectives (i.e. the identification of policies that enable or hinder the VAN; determine the impact policies might have in the VAN and the pharmaceutical supply chain; contextual influence; and the engagement of actors and stakeholders in the decision-making process), tools and analysis models that analyse *for* policies, and aim to achieve the PoliVAN objectives should be incorporated. Therefore, a combination of both types of analysis is required for this policy analysis method.

The key design criteria from Chapters 2 and 3 need to be used and adapted to the policy analysis models and tools discussed in Chapter 4. Integrating these three key design areas contributes towards a great portion of the PoliVAN. The design criteria from these three chapters are important components to be taken into account when developing a policy analysis

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[1]This type of analysis focuses on the policy decision-making process. From Chapter 4, the most prominent decision-making models identified from literature include: the rational process, the political game, advocacy coalition, garbage can model, and institutional process.

[2]This type of analysis focuses on different analysis tools that can be utilised within the different stages of the decision-making process.

model for the VAN. The next section uses these components, along with the objectives of the model outcomes, to develop the policy analysis model.

5.4 Development of the proposed policy analysis method for a VAN

In this section, a policy decision-making model is selected based on the PoliVAN objectives and design criteria mentioned in Section 5.2. The selected policy decision-making model is then adapted in order to align to the specific problem statement and research objectives of this research inquiry. Subsequently, the adapted decision-making model is combined with relevant analytical tools and processes, including the design criteria from the VAN and pharmaceutical supply chain chapters. This will ultimately develop the high-level policy analysis roadmap that will allow policy analysts to systematically analyse country-specific policies in order to develop policy-specific strategies that enable the operationalisation of the VAN.

5.4.1 Selecting a decision-making model

The different decision-making models (the most prominent models discussed in Chapter 4) are measured against criteria which are derived from the PoliVAN objectives for this study and assumptions made throughout the literature chapters. The comparison between these models is given in Table 5.2.

Table 5.2: A comparative analysis for the selection of a decision-making model

CRITERIA / OBJECTIVES	RATIONAL PROCESS	POLITICAL GAME	ADVOCACY COALITION	GARBAGE CAN	INSTITUTIONAL PROCESS
The process disaggregates a complex system into manageable steps.	X			X	
Allows for the adaption and inclusion of analytical policy tools.	X			X	X
Provides the ability to develop solutions to a problem.	X	X	X	X	X
Focuses on the analysis to determine the impact of policies on the system.	X				
Focuses on the actors and stakeholders in the system.		X	X		X
The process focuses on reaching policy decisions.	X	X	X	X	X

From Table 5.2, it is evident that the rational model adheres best to the objectives highlighted in Subsection 5.2.2. Walker (2000) points out that "the most convincing analysis is one that a non-technician can think through". The rational model is a simple and effective

decision-making process for the analysis of policies, especially given the complexity of the VAN. Based on further investigation on the rational model, some advantages the model offers are (Bridgeman & Davis, 2003):

   i. The model disaggregates a complex process into manageable steps;

  ii. It provides a description of policy-making, to assist with policy development;

 iii. It is an appropriate way to approach a problem;

 iv. It allows for modification and adjustments; and

  v. It allows for simple analytical tools to be used in each step.

Selecting a rational decision-making approach to this study provides room for adjustments to the model, as well as ensuring that the PoliVAN can be transferable to other contexts, due to its ability to adapt and include analytical tools to assist with the different stages of the decision-making model. Walker (2000) argues that an analyst should be able to "fit the model to the problem, not the problem to the model." The rational model also allows for simple analytical tools, meaning that tools that analyse *for* policies can be used in conjunction with the rational model. The next section takes into account the PoliVAN objectives and adapts the processes of the rational model to fit the 'problem'.

5.4.2   Adapting the decision-making model to the PoliVAN objectives

The rational model is discussed in detail in Subsection 4.2.1. As mentioned, this model is primarily concerned with a systematic analysis approach, providing information and insight for an informed decision by means of a structured process (which reduces the uncertainties most policymakers face) (Enserink *et al.*, 2013). The sequential steps from the rational model (proposed by various authors) are illustrated in Figure 4.2. The different approaches to the rational model are categorised under the four decision-making building blocks (agenda-setting, policy formulation, policy implementation, and policy evaluation) to identify key steps for each building block. Combining the various steps from Figure 4.2 into a comprehensive rational model, the sequential steps are the following:

1. Agenda setting: Problem definition;

2. Policy instruments;

3. Policy formulation;

4. Construct alternatives;

5. Projected outcomes;

6. Decision and adoption;

7. Policy implementation; and

8. Policy evaluation.

These steps provide guidance on how the logic of the policy analysis method for the VAN should be structured. To ensure that the PoliVAN encompasses the necessary factors to appropriately analyse policies, it needs to incorporate the four key factors from the policy triangle developed by Walt & Gilson (1994); the need to focus on the actors, the content, the context, as well as the process. The implications of each of these four key factors for the PoliVAN are defined in Table 5.3.

Table 5.3: Incorporating the policy analysis triangle factors into the selected policy decision-making model

POLICY TRIANGLE FACTORS	WHAT IT MEANS FOR THE VAN POLICY ANALYSIS METHOD
Process	The process refers to the decision-making model selected for the policy analysis method for a VAN Operating Model, which in this case is the rational model.
Content	When taking into account the 'content' factor, it means that the actual content from policies and legislative instruments, as well as the content from the VAN Operating Model, should be used in order to draw substantial conclusions on whether the various legislation enables or hinders the content of the VAN Operating Model.
Context	The context, in the case of this study refers to the 'environment' in which the VAN Operating Model operates. Thus, the macro- and micro-level contextual factors discussed in Subsection 3.1.2.3 need to be taken into consideration. The VAN Operating Model is designed to be implemented in a country's pharmaceutical supply chain, which operates within the public healthcare sector (micro level). A pharmaceutical supply chain is enabled by laws, regulations, and policies (as illustrated in Figure 3.2), which vary for different countries (macro level).
Actors	The final component from the policy triangle that needs to be included, is the actor component—identifying relevant actors, to evaluate their interests, authority, level of support, etc. when aiming to arrive at a policy decision. This analysis can be performed with a stakeholder analysis, which is thoroughly discussed in Section 4.3. The relevant actors/stakeholders are a core factor in the policy analysis triangle, and multiple studies have used a stakeholder analysis approach alongside policy analysis. The VAN Operating Model stipulates the role of multiple actors and stakeholders, making the inclusion of a stakeholder analysis beneficial for the VAN.

In Section 4.2.1, a schematic representation (Figure 4.1) is provided that shows the influence the building blocks from the policy decision-making process have on one another. This 'influence map' is used as an initial approach (in combination with the rational decision-making steps) to develop a logical flow of the PoliVAN. Figure 5.2 illustrates how that model is adapted (with consideration from the PoliVAN objectives in Subsection 5.2.2). The four key factors from the policy analysis triangle are added to the policy map. The process factor refers to

the selected decision-making model (the rational model) and the logic of the decision-making process.
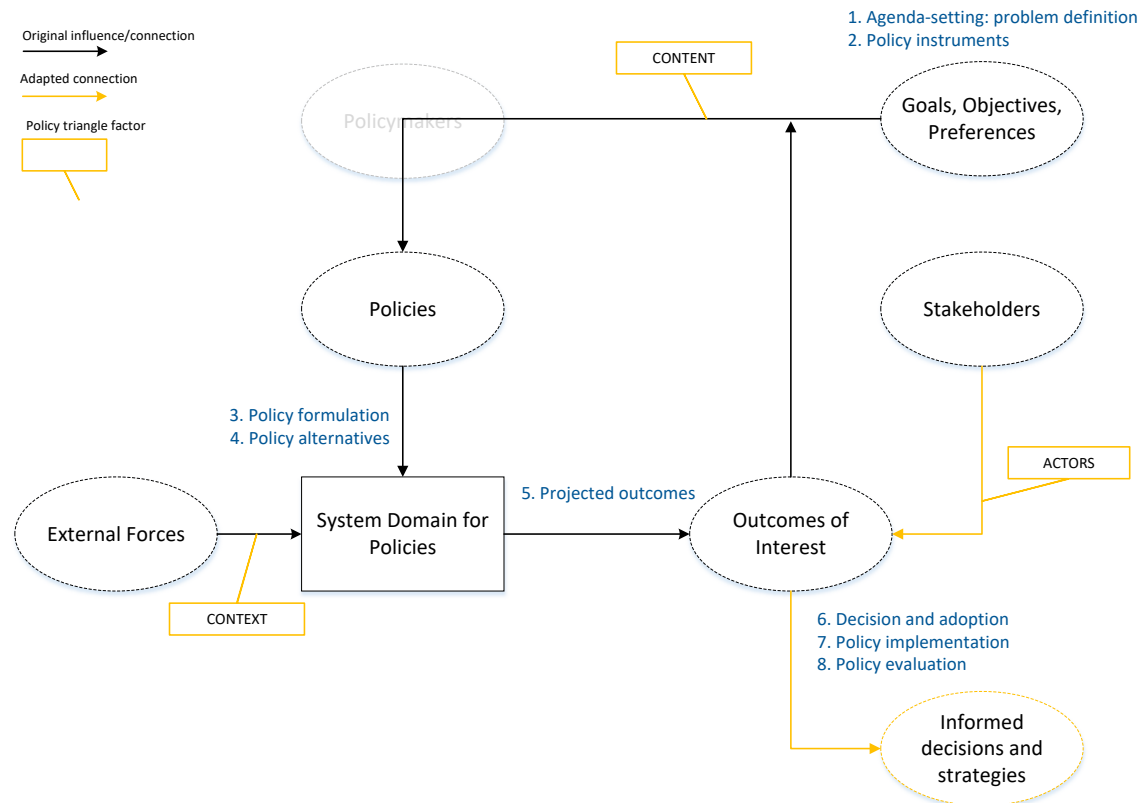
Figure 5.2: The influence between the policy building block (Figure 4.1) is used (in conjunction with the policy triangle and the rational model) as an initial approach to the development of the PoliVAN

In this study, the 'goals, objectives, preferences' (indicated in Figure 5.2) of the policy process are linked to the first step (agenda-setting) from the rational model—the identification and recognition of the problem. The problem, in this case, is where policies and/or legislations do not support the operations of the VAN Operating Model. The identification of such problems requires an analysis approach that assesses the current legislative environment (**Objective 1** from Subsection 5.2.2) in its ability to support the operations set out by a VAN Operating Model. For this analysis, an investigation of policy instruments relevant to the scope of the VAN is required, including an assessment of the degree to which the policies support the VAN Operating Model in a country (**Objective 2**). According to the original influence map, and the link between the building blocks, policymakers (or in this case the policy analyst) need to formulate and construct policy alternatives to provide a solution to the aforementioned identified problem. This process makes use of the goals and objectives required by the VAN to design alternative policies that can support the country's VAN Operating Model. The for-

mulated policy options (including those that exist) are all in an intangible 'system domain for policies'—an area of identified policies that either already exist and require analysis, or are developed to adhere to the VAN objectives, and such policies require analysis prior to being selected for implementation. The original policy map shown in Figure 4.1 indicates that the activity between the 'policies' and 'system domain for policies' component is 'implementation', but because the PoliVAN focuses on the analysis of policies for implementation (**Objective 5**) and not the evaluation of a policies after implementation, the 'system domain' environment will consist only of the policies found or formulated for the analysis.

The outcome of policies is influenced by external forces, which can result in an outcome that is either desired or not. Therefore, to ensure that the correct policy option is considered before it is implemented, an analysis should be included that determines the impact (projected outcomes) that the formulated policy options might have on the system (**Objective 3**). As mentioned, the inclusion of actors and stakeholders is considered beneficial for a policy analysis model. The extent of the influence that a stakeholder will have on the projected outcomes has to be evaluated, and was adapted from the original policy map and linked to the evaluation of the outcomes, because the design requirements indicated that the analysis of the policies for a VAN should be done prospectively. This constitutes **Objective 4**. Even though a stakeholder analysis is different from the actual policy outcome analysis, there is a level of interaction between these two. Combining the stakeholder analysis with the policy outcome analysis can provide sufficient information that can be used to assist with the decisions and strategies of how to plan, adopt and implement policies that facilitate an operating model such as VAN (**Objective 5**); hence, the addition of the 'informed decisions and strategies' component.

This section focused on the selection and adaption of a policy decision-making model for the PoliVAN, summarised in the schematic representation in Figure 5.2. The selection of analysis tools which can be used to deliver the analysis within the various steps of the policy decision-making model to achieve the objectives of the PoliVAN, is discussed in the next section.

5.4.3   Selecting analytical tools for decision-making steps

There are a considerable number of tools that can be useful during the execution of each of the decision-making steps (defined at the start of Section 5.4.2). In Table 5.4, different methods and tools from Chapter 4 that are relevant to the decision-making steps and the objectives of the PoliVAN are identified. When the tools identified in Chapter 4 (or more specifically Subsection 4.2.2) do not adequately fulfil the PoliVAN objective, or when a tool that can assist with the step or objective has not been identified; a description of the requirement is provided in the fourth column of the table.

Table 5.4: A summary of the tools identified in Chapter 4 that are applicable to the decision-making steps and the objectives for the PoliVAN

DECISION-MAKING PROCESS STEPS	POLICY ANALYSIS MODEL OBJECTIVES	ANALYSIS TOOLS IDENTIFIED IN CHAPTER 4 THAT ARE RELEVANT.	FURTHER INVESTIGATION REQUIRED
1. Agenda-setting: problem definition	1. To identify and take into account multiple policy and legislative instruments that are relevant to the scope of the VAN Operating Model for a specific country.	Figure 4.1: Policy and legislation hierarchy	Methods on how to identify relevant policies and legislations that are relevant to the scope of a country's VAN Operating Model, as well as methods to analyse the content of the policies and legislations against the objectives and content of the VAN.
2. Policy instrument	2. To identify types of specific policies that enable the operationalisation of the VAN Operating Model, as well as identify those that do not support the country-specific VAN.	Subsection 4.2.2.1: Content	
3. Policy formulation	3. To propose a method that makes use of policy analysis processes to determine the impact policy options might have on the VAN Operating Model or health system.	Appendix G: Bardach's eightfold path Policy analysis checklist by King (2004) Appendix H: Policy definition and formulation checklist	Methods to formulate policy alternatives for policies that are needed to achieve the objectives of the VAN.
4. Construct alternatives	4. To take into account the influential factors, i.e. external/contextual factors, stakeholder engagement strategies, and decision-making strategies.		
5. Projected outcomes		Subsection 4.2.2.2 and Appendix I: Effect-implementation approach to policy analysis.	-
5. Decision and adoption	5. To be able to provide insight into possible policy strategies for key stakeholders to develop or make an informed policy decision.	Subsection 4.2.2.3: Sophisticated modelling Subsection 4.2.2.1: Actors and context Section 4.3 and Appendix J: Stakeholder analysis	Implementation and evaluation methods and/or procedures that can be undertaken for a policy decision that is considered.
7. Policy implementation		-	
8. Policy evaluation		-	

In Chapter 4, it is mentioned that sophisticated quantitative modelling (e.g. system dynamics and simulation modelling) are evolving areas of focus, especially in the policy analysis field. They can be used to contribute towards addressing complex policy problems; however, the PoliVAN needs to be convenient and manageable for analysts in developing countries, where skilled resources in quantitative modelling are not always available. Most policy situations are complex, and designing a model can become overwhelming considering 'dimensionality' (Walker & van Daalen, 2013), especially for a pharmaceutical system with many interrelated components. Such modelling methods are best used in a specific part of the decision-making process (e.g. one of the building blocks), rather than for the entire decision-making process (Walker & van Daalen, 2013).

5.4.4   Constructing the PoliVAN

Based on the policy decision-making model (the rational model), the process of the analysis follows logical and sequential steps. The initial approach to construct the PoliVAN was to create the 'logic flow'. Thus, a high-level PoliVAN is derived by combining the steps from the rational policy analysis decision-making model and PoliVAN objectives (as illustrated in Table 5.4), with the influence between the building blocks illustrated by Figure 5.2. Figure 5.3 provides a schematic representation of how the process steps from the rational model and PoliVAN objectives are combined and grouped to construct the six high-level phases. The details of each phase and the tools envisaged in each phase to satisfy the objectives are discussed in Section 5.5.

These high-level phases provide a step-wise guide that allows the policy analysts and VAN stakeholders to follow a logical process. In the next subsection, the selection of a research product type is discussed. This provides more information on how the PoliVAN can further be developed and addressed.

5.4.5   Addressing the PoliVAN

In Appendix K, a characteristics table of various 'products', i.e. model, framework, logic model, etc. are summarised. Although the PoliVAN is based on the rational decision-making model, it cannot be addressed as a model—a model is defined as a human construct to help get a better understanding of the real world systems. From Table K.1, it is clear that the best possible 'product' for the PoliVAN is either a roadmap or a logic model approach. According to ProductPlan (2019), a roadmap is a plan or strategy intended to achieve a particular goal. A key characteristic of a roadmap is a high-level plan, defining the overarching strategic objective, and capturing the major steps (ProductPlan, 2019). Similarly, Petrick (2008) defined
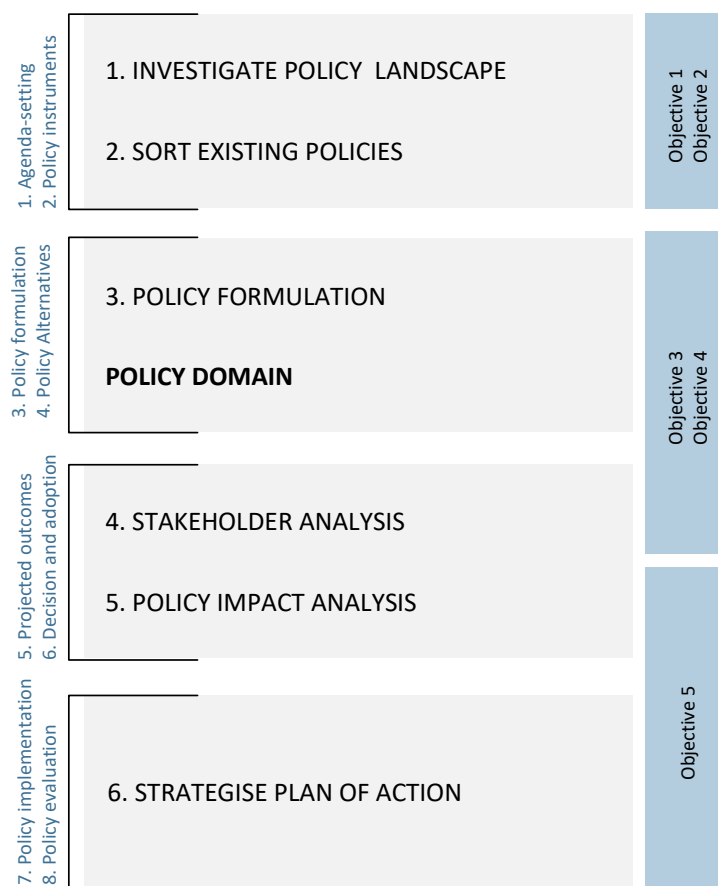
Figure 5.3: A schematic of the high-level PoliVAN phases that are constructed

a roadmap as a strategic plan that defines a goal or desired outcome, and includes the major steps or milestones needed to reach it.

A logic model is typically designed as a visual representation that helps organise programme development, implementation and/or evaluation (Monroe & Horm, 2012). According to Taylor-Powell *et al.* (2003), a logic model is often referred to as a roadmap. Taylor-Powell *et al.* (2003) also state that a logic model presents a picture of how an initiative is supposed to work. It explains why a specific strategy is a good solution to a problem at hand. Effective logic models make an explicit, often visual, statement of the activities from a roadmap (Taylor-Powell *et al.*, 2003).

Thus, the policy analysis method for the VAN is referred to as the PoliVAN logic model. Standard features of a logic model include (Monroe & Horm, 2012):

i. Inputs: Resources used, which can also include constraints;

ii. Activities: What you do with your inputs, which could include strategies, techniques, and interventions that direct actions;

iii. Outputs: The direct product of the outputs; and

iv. Outcomes: The short-, medium- and long-term outcomes / objectives of the outputs.

Currently the PoliVAN includes high-level activities and objectives; however, the inputs and outputs still need to be included. The inputs—resources required to perform the activities—can be identified from Table 5.4. The outputs are products from the activities and should be linked to the PoliVAN objectives. The high-level PoliVAN and the details regarding the various components are discussed in the next section.

5.5 The developed policy analysis logic model for the VAN: PoliVAN

This section provides an illustration of the high-level policy analysis method that is developed for a VAN Operating Model, and provides a brief description and discussion of each phase within the model.

5.5.1 Developed high-level PoliVAN logic model

Based on the discussion of the development and construction of the PoliVAN in Subsection 5.4.4, a high-level overview of the PoliVAN is illustrated in Figure 5.4. Each phase in the PoliVAN has an input, objective and an output. The inputs can take the following form: the output from a previous phase; key criteria or dimension from the Blueprint Reference Model (BPRM), VAN, or a pharmaceutical supply chain; and/or relevant information that is required to conduct the steps within each phase.

The outputs are the outcomes from each phase and are usually linked to the objective(s) of the phase. The objective of each phase is what the phase seeks to achieve—the objectives are achieved by the defined steps within each phase of the logic model. The steps within each phase require specific skills and tools to achieve the objective, for example: specific knowledge regarding a topic, brainstorming techniques or a specific analytical tool developed for the VAN context.

In summary, the PoliVAN aims to identify types of policies and/or legislative instruments relevant to the scope of a country's VAN Operating Model that could potentially affect the operationalisation of the VAN (identifying those enabling or hindering the VAN). Subsequently, the PoliVAN aims to develop a proposition that will enable both health system authorities and VAN personnel to develop policy-specific strategies to support the objectives of the VAN—formulating policy decisions to solve the policy problems, identifying stakeholder engagement, and analysing the impact of policy decisions on the pharmaceutical system. The next section provides more detail on how the different phases enable the logic model to achieve its aim and objectives.
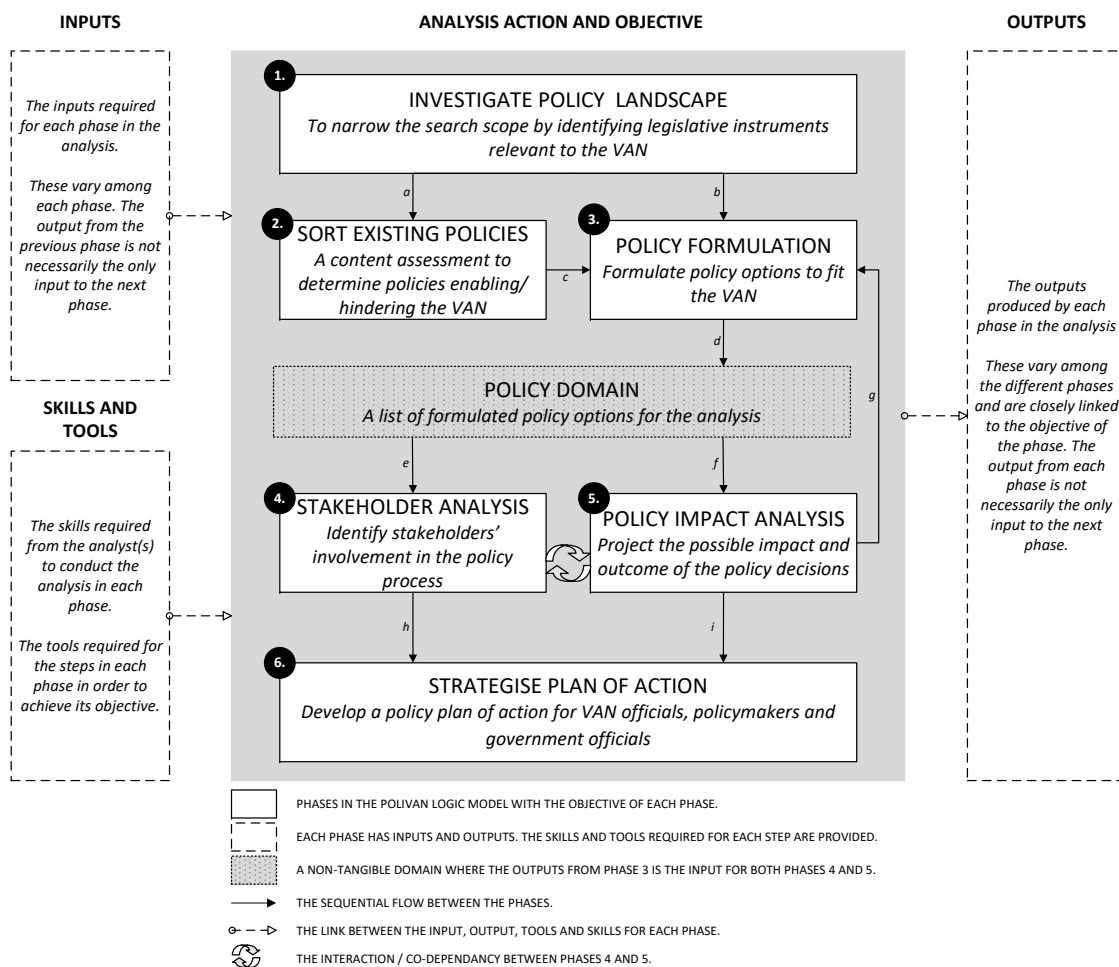
Figure 5.4: High-level developed PoliVAN logic model

5.5.2 Brief description of the high-level PoliVAN logic model phases

Here, a description of each phase within the PoliVAN is provided to explain the detail of each phase, and how it aims to achieve the objective of each phase respectively. The VAN Operating Model referred to in this section is the country-specific VAN for the country conducting the analysis.

PHASE 1: INVESTIGATE POLICY LANDSCAPE

The PoliVAN starts by investigating the policy landscape. The objective is to identify existing policies that are relevant to the scope of the VAN. This is achieved by taking into account a country's VAN Operating Model, as well as the operational functions and supportive elements defined in the pharmaceutical logistics framework (PLF). The output from this phase constitutes a categorised list of existing policies that are relevant to the scope of a country's VAN Operating Model. This phase could also have another output; insights on the parts of the

VAN Operating Model for which country policies do not exist, or have not been developed yet.

PHASE 2: SORT EXISTING POLICIES

From the first phase, in the case where policies exist, the policies are assessed against key VAN criteria—the critical elements (people, processes, and technology) of what makes up the VAN Operating Model. The objective is to distinguish between policies that enable the VAN and those that hinder it. This is achieved by using a content analysis matrix with assessment indicators to illustrate the effect of the various policies on the VAN Operating Model.

PHASE 3: POLICY FORMULATION

In this phase, a policy reform or policy formulation process is conducted to either: (i) design policy decisions for the reform of existing policies (from Phase 2); or (ii) formulate policy decisions for non-existing policies to support the objectives of the VAN (from Phase 1). This phase makes use of brainstorming techniques with subject matter experts (SMEs)—those who are familiar with the policy area under consideration. The output from this phase is multiple policy decisions designed for a specific policy problem area which requires analysis. The output from this phase is required for both the stakeholder analysis (Phase 4) and the policy impact analysis (Phase 5).

PHASE 4: STAKEHOLDER ANALYSIS

In this phase, the policy options from Phase 3 are used to identify stakeholders relevant to the policy area. This includes those likely to be affected or interested in the policy options. This phase identifies the relevant actors and selects characteristics according to which stakeholders can be evaluated. These characteristics include their level of influence, power and interests over the policy options under consideration. The output from the stakeholder analysis will provide a clear indication of which stakeholders to involve, consult, inform or exclude from the policy decision and adoption process. The output will also indicate the stakeholders' level of 'acceptability' towards different policy options (discussed in the next phase).

PHASE 5: POLICY IMPACT ANALYSIS

This phase takes the policy options from Phase 3 as an input, and analyses the policy options against analytical dimensions, such as cost, feasibility (operational, technical, environmental), acceptability (input from the stakeholder analysis) and unintended consequences. The objective is to determine the impact the different policy objectives might have in the system in order to select the best policy decision(s). The analysis makes use of a multi-criteria scorecard approach that either ranks the policy options according to the best overall score or provides

insight into the impact a policy decision could potentially have on a pharmaceutical supply chain. The analysis method can include a weighting dimension that can value one analytical dimension over another. The output from this phase will provide an indication of which policy decision has the best potential to successfully support the VAN in its operationalisation within the pharmaceutical context of a country.

PHASE 6: STRATEGISE PLAN OF ACTION

The final phase in the PoliVAN is where the outcomes from Phases 4 and 5 are used to make policy-specific decisions and develop strategies. This is where the policy decisions are selected, adopted and implemented. However, the following factors should be kept in mind: (i) a policy choice can only be made once the preceding five phases in the PoliVAN have been completed, and (ii) selecting a policy decision includes the possible input from many stakeholders, which emphasises the importance of the stakeholder analysis. Once a policy decision has been reached, the policy adoption and implementation plan needs to be set up. This includes selecting the type of implementation method (e.g. gradual, phased, or parallel); indicating the responsibilities for the stakeholders handling the implementation process; and generating training and education plans (if required).

The logical flow and routes explained

There are sequential phases that need to be undertaken to complete the different phases in the PoliVAN. The routes illustrate the flow of the logic model and subsequently illustrate the inputs and outputs among the different phases. Here, the routes illustrated in the PoliVAN are explained:

(a) Existing country legislative instruments that are relevant to the scope of the VAN Operating Model.

(b) Gaps where policies for a specific part of the pharmaceutical supply chain (relevant to the VAN) do not exist.

(c) Policies that require reform—those not enabling the successful operation of the VAN.

(d) The formulated and/or reformulated policy options (from Phase 3) as input to the analysis for Phases 4 and 5.

(e) The policy decisions from Phase 3 are used as an input for the stakeholder analysis.

(f) The policy decisions from Phase 3 are used as an input for the impact analysis.

(g) The outcome from Phase 5 will indicate whether policy options require reformulation.

(h),(i) The outcome from Phases 4 and 5 are used to develop a policy plan of action.

There is an interaction between Phases 4 and 5, as discussed in the aforementioned respective phases.

5.5.3   Section 5.5 conclusion

In this section, a brief overview of the high-level PoliVAN, a description of each phase in the logic model, and an explanation of each possible route in the PoliVAN are provided. In order to prevent duplication of information, only the high-level phases of the PoliVAN are discussed in Section 5.5. This is due to the fact that the full, detailed PoliVAN is subjected to an evaluation process, and the final, detailed and evaluated PoliVAN is presented in Chapter 7, which includes the updates and improvements after the evaluation.

5.6   Chapter 5: Conclusion

This chapter starts off by highlighting the foundational concepts found in literature that aim to provide insight into how a policy analysis method can be developed for a VAN. The key concepts from literature are used, and combined to develop a policy analysis method for a VAN, called the 'PoliVAN logic model'. The rational model is chosen as the decision-making process for the PoliVAN. Analysis tools (tools to analyse *for* policies) discussed in Chapter 4 are compared to the decision-making model phases and the objectives of the PoliVAN, in order to identify the appropriate tools to use in each phase of the PoliVAN. This led to the development and construction of a high-level PoliVAN. Next, the high-level PoliVAN is presented and discussed. Details of the PoliVAN are presented in Chapter 7, as the PoliVAN needs to go through verification and validation processes, which re further discussed in Chapter 6.

Chapter 6

Evaluation of the PoliVAN logic model

In this chapter, the evaluation strategy introduced in Section 1.4.3 is highlighted. The discussion provides insight into the progression of this chapter—the structure and sequence of the different evaluation processes which the PoliVAN underwent. In each of the following sections, the evaluation processes pertaining to the evaluation strategy, subject matter experts (SMEs) that participated and results from the evaluation, are discussed.

6.1 Highlights of the evaluation strategy

As discussed in the evaluation strategy in Section 1.4.3 and Figure 1.3, to prove the accuracy and adequacy of the developed PoliVAN, the development and the PoliVAN logic itself needs to be evaluated. Evaluation is categorised in two dimensions (Brade *et al.*, 2003): verification and validation. The following subsection discusses the distinction between verification and validation, followed by a breakdown of the verification and validation processes followed in this study.

6.1.1 Distinction between verification and validation

According to Morse *et al.* (2002), verification is "the process of checking, confirming, making sure, and being certain" that the product[1] has been developed according to credible and confirmable literature and specifications. They further argue that in qualitative research, verification refers to the mechanisms used during the process of research to incrementally contribute to ensuring reliability and validity and, thus, the rigour of a study. These mechanisms are woven

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[1]This refers to the research output—development of either a framework, model, roadmap, process, business model canvas, logic model, or maturity model. In this study, it refers to the PoliVAN logic model developed to achieve the aim of this study.

into every step of the inquiry to construct a solid 'product'—identifying and correcting errors before they are built into the final product (Creswell & Miller, 1997; Kvale, 1989; Morse *et al.*, 2002). It can thus be said that verification addresses the question as to whether something has been built right (Brade *et al.*, 2003).

On the other hand, validation deals with the suitability of the developed 'product' and addresses the question of whether "the right model has been built" (Brade *et al.*, 2003). These authors further argue that the process consists of identifying (through the opinions of SMEs and other validation techniques discussed below) whether the proposed method fits the real-world system and is able to perform its intended purpose. There exist four commonly utilised routes for validation as shown in Table 6.1 (Mouton, 2001). Each route exhibits its own set of strengths and weaknesses.

Table 6.1: Validation routes, their advantages and disadvantages by Mouton (2001).

VALIDATION ROUTES	DEFINITION	ADVANTAGE	DISADVANTAGE
Interviews with SMEs	Interviews are meetings in which information is gained from the interviewee to confirm or oppose the claims made by the researcher in their research study. There are four forms of interview methods, which include: (i) structured questionnaires; (ii) telephone interviews; (iii) semi-structured interviews; and (iv) free attitude interviews.	It provides a space to obtain knowledge from experts that either refute or support the research findings under consideration.	An interviewee can only answer based on their personal experience and/or the knowledge that has been conveyed to them. Another disadvantage, the information gained only covers an isolated part of the population, therefore interviewee selection requires special consideration.
Survey analysis	This is a quantitative approach to validating the proposed framework or model, and requires the model/framework's components to be deemed necessary and useful by those whom it is intended to assist.	Potential to generalise to large populations if appropriate sampling design has been implemented; and high measurement reliability if proper questionnaire construction has been implemented	Lack of depth and insider perspective sometimes leads to criticisms of "surface level" analyses; survey data is sometimes very simple and context specific—this is especially true of public opinion polls.
Application to a case study	A case study is an up-close, in-depth and detailed examination of an already existing case. A case study aims to provide explanatory, exploratory and descriptive findings.	A case study introduces a different perspective from which practical challenges and requirements are better understood. The proposed framework or model can be shown useful in real-world problems and/or scenarios.	Case studies are, however, susceptible to manipulation and they are very strongly rooted in the setting in which they take place. The combination of these factors makes it increasingly difficult to validate the framework's applicability across a wide range of different contexts.
Implementation	This is the truest test of the workability of a concept. Implementation denotes the review and validation of the correctness of a framework based on its practical application in an appropriate area.	The advantages are clear, as the results from the implementation of the framework are definitive.	The implementation of the framework is a resource-intensive process and requires repetition in various domains for the results to be deemed trustworthy.

6.1.2 Breakdown structure of the evaluation processes

A breakdown structure of the evaluation roadmap and strategy is illustrated in Figure 6.1. Each stage in the strategy is subsequently discussed in the following sections in this chapter. In each of these sections, a detailed discussion of the evaluation process followed and outcomes are discussed, as well as the changes that need to be made to the PoliVAN in order to satisfy the evaluation objectives given in Table 1.1. For each stage in the evaluation process, the SMEs were carefully and comprehensively selected.
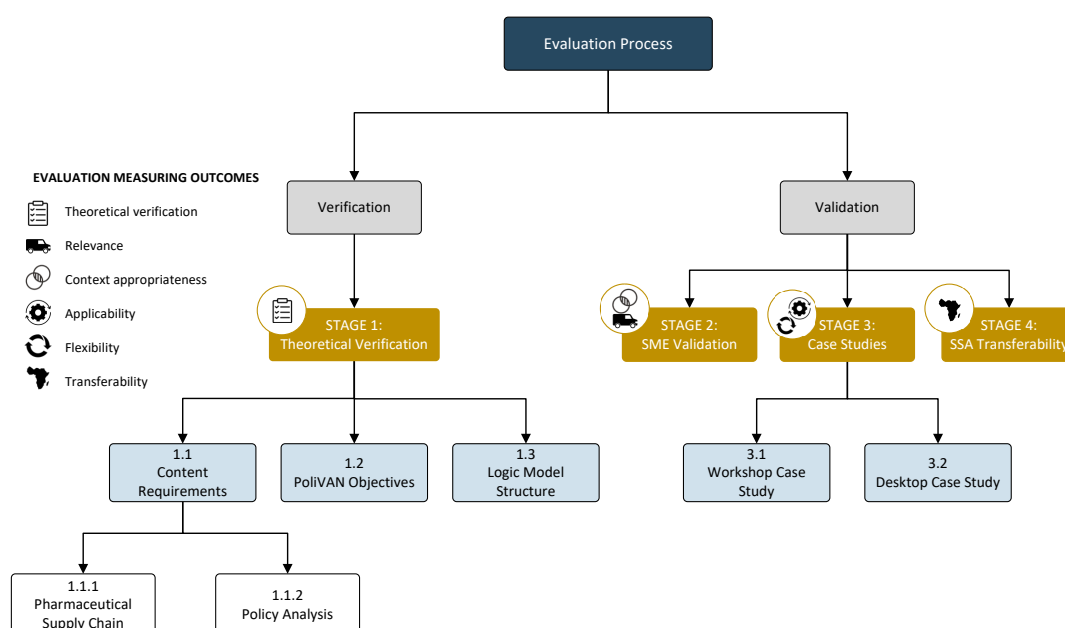
Figure 6.1: Breakdown structure of the evaluation process

A master table (available in Appendix L) provides the details of the SMEs that participated in the different evaluation stages. The table includes the academic and occupational background of each participant in order to assure their credibility and relevance to a specific evaluation stage. The table also indicates in which of the evaluation stages the different SMEs participated, showing that every possible evaluation stream for the PoliVAN has been considered. The personal details of the SMEs are hidden in order to protect the identity of the participants.

6.2 Verification of the PoliVAN logic model

Many doctoral studies, such as those of Kennon (2017); Ungerer (2015); Van der Merwe (2017), used similar techniques and strategies to verify their work. The techniques identified from these studies, including those from various literature sources, are used as a guideline to

define the verification process for the PoliVAN developed in this study. Verification strategies in this research study enable the ability to identify when to continue, stop or modify the PoliVAN to achieve reliability and validity and ensure rigour. Combining the above-mentioned methods, the verification techniques followed in this study, and discussed in the subsequent subsections, are respectively:

  i. Content requirement verification: Verifying the literature used and assumptions made (throughout Chapters 2 to 4) to develop and construct the PoliVAN.

 ii. PoliVAN objectives verification: To verify that the objectives set out for the PoliVAN (Section 5.3) are sufficient and will enable the PoliVAN to satisfy the aims and objectives of this study.

iii. Logic model structure verification: Verifying whether the PoliVAN is built according to the structure and characteristics of a logic model.

For (i) and (ii), a questionnaire and unstructured interview was conducted with each carefully selected SME. The selection of SMEs for these processes are also justified and discussed. During each of these processes, a pre-read document was provided pertaining to this study's background, problem statement, aim and relevant information. This allowed the participant to prepare for and understand the questions provided in the questionnaire. Each participant was asked to complete a questionnaire (the questionnaires are available in Appendix M). The recommended changes or improvements made by the SMEs were discussed during the unstructured interview.

For (iii), a short literature review process was undertaken to verify that the PoliVAN is built according to the specifications of a logic model. The various components and elements of a logic model were identified and cross-examined with components from the PoliVAN in order to ensure that the PoliVAN is structurally and logically correct. Where differences occurred during the cross-examination, the justification for the changes or non-changes are discussed.

6.2.1   Content requirement verification

The aim is to verify the literature and assumptions from the preceding chapters that were used to develop and construct the PoliVAN. The literature from this study forms a fundamental part of the development of the PoliVAN. The question is whether the key criteria identified from the literature chapters (Chapters 2 to 4) in Section 5.3 are credible and sufficient to be able to develop the PoliVAN. The literature used to construct the PoliVAN is verified by SMEs from each of the relevant literature fields: pharmaceutical supply chain practices and policy analysis practices. The literature regarding the VAN project is already considered credible and correct, as the information in Chapter 2 was provided by the developers of the VAN,

necessary to support this study. The following subsections discuss the questions and results of the respective literature fields. For the sake of brevity, in the following subsections the discussion regarding to the questionnaires will refer to Appendix M and is not presented in the main document, although the questions are highlighted and discussed here.

6.2.1.1 Pharmaceutical supply chain literature verification

Verifying the pharmaceutical supply chain literature requires SMEs that are academically qualified and have worked for a considerable length of time in this particular field. Table 6.2 provides an overview of the academic and occupational background of the three SMEs that participated in this part of the verification process. A more detailed table of the SMEs in this study is available in Appendix L. It is clear that the participants are qualified to make sound judgements on the questionnaire provided.

Table 6.2: Summary of SMEs that participated in the pharmaceutical supply chain content verification process

P#	OCCUPATIONAL BACKGROUND	ACADEMIC BACKGROUND	FAMILIAR WITH VAN
P1	Health supply chain programme officer at Bill and Melinda Gates Foundation.	Bachelor of Arts, Business Administration and Operation Management; MSc in Supply Chain and Operations Management.	Yes
P2	Senior pharmaceutical supply chain consultant; 9+ years of experience as supply chain consultant in pharmaceutical industry.	B.S. in Supply chain Management; MSc in Public Health; Certified Supply Chain Professional (CSCP).	Yes
P3	Public and Private Sector Supply Chain; Private Sector Pharmaceutical Distribution; Public Sector Technical Advisor - Medicine Supply Chain.	BSc (Pharm); MBA	Yes

The illustration and discussion of the questionnaire and results follows. For the sake of brevity, only a discussion is provided here, as the tables and figures in the questionnaire already exist in this document.

Question 1: The pharmaceutical logistics framework

The first question is directed to the pharmaceutical logistics framework (PLF), as depicted in Figure 3.2. The details of the PLF, captured in Table 5.1 were included in the questionnaire. The participants were asked to indicate the activities which they think make up the operational components of a public pharmaceutical supply chain. They were also given the opportunity to make suggested changes (add or remove activities), based on their expertise.

All of the participants suggested that 'donor requirements' from the medicine selection component can be removed. Two participants (P1 and P2), gave a similar argument; donor

requirements are criteria used when selecting the medicines or approving medicines to be on the essential medicines list or standard treatment guidelines; however, this is not an operational activity itself. All of the participants suggested removing 'port clearing' from the inventory and distribution component, as it is not an operational activity that directly affects the public healthcare supply chain. Two participants (P2 and P3), included the 'removal of expired medicine' to the inventory and distribution component, more specifically under inventory control.

The next part of this question is directed to the policy, law and legal framework (the legislation hierarchy illustrated by Figure 3.6). The following is asked of the participants: "Do you agree that the legal hierarchy depicted below provides a good generic representation of the relationship between the different levels of legislation?" All participants agreed to the question and illustration. The next part of the questionnaire refers to the importance of different governance techniques identified to strengthen the operations of a pharmaceutical supply chain. The participants were asked to indicate the level of importance of each identified practice. The results indicated that all of the practices (i.e. accountability, stakeholder engagement, setting strategic direction, stewarding resources and continuous improving governance) are either important or very important. No additional practices were recommended.

Question 2: Key role players in a public pharmaceutical system

The second question refers to the key role players identified in a public pharmaceutical supply chain summary. A list of stakeholders (individuals, groups and organisations) were listed and the participants had to indicate whether they agree with the role players identified and whether they had any changes or recommendations. Two participants agreed and had no changes, whereas the other participant (P2) recommended that "pharmaceutical manufacturers should explicitly be called out." From the stakeholder list provided in the questionnaire, manufacturers can be categorised under 'private sector entities'. The suggestion made by the participant is already embedded in the PoliVAN. The stakeholder list provided is a guide to ensure that all possible key role players can be considered during the application of the PoliVAN, based on the categories provided.

Question 3: Analysing pharmaceutical supply chain-related policies

The third, and final question refers to supply chain-related policies. Statements (constructed from assumptions made through the literature review) are presented and the participants had to indicate whether they agree or disagree with the statements. The following statements were given:

Statement 1: A pharmaceutical supply chain is governed by multiple policies and legislations that are intended for different operational functions and different levels of the health system.

Statement 2: Identifying and analysing various policies—that govern a country's pharmaceutical supply chain—can become long and tedious as multiple policies and legislations exist for a pharmaceutical supply chain. Therefore, categorising supply chain operations into major functions (as illustrated by the PLF), and analysing policies according to each function respectively can be more efficient.

Statement 3: The PLF structure is considered the same for any level of a healthcare system; however, the processes within each function might vary between countries in accordance with country-specific policies, laws and regulations. Do you agree that the operational functions are generic to the extent that any country can use the functions to identify the operations of their public pharmaceutical supply chain, and subsequently, to identify the relevant policies of those operations?

All of the participants agreed to all of the above-mentioned statements. This concludes the questionnaire on the public pharmaceutical supply chain literature topic. Based on the feedback from the participants, a great part of the pharmaceutical supply chain literature and assumptions are verified and only minor suggestions were required (as discussed above). This concludes that the information incorporated into the PoliVAN was proven to be credible and accurate.

6.2.1.2 Policy analysis literature verification

Verifying the literature and assumptions made regarding the policy analysis methods and models (especially how it is used to support the healthcare context), requires SMEs that are academically qualified and have worked for a considerable length of time in this particular field. Table 6.3 provides an overview of the academic and occupational background of the two SMEs that participated in this part of the verification process. As mentioned, a detailed table of the SMEs in this study is available in Appendix L. It is clear that the participants are qualified to make sound judgements on the questionnaire provided. One particular participant was contacted, because some of the policy analysis literature incorporated into the PoliVAN is their published work.

The illustration and discussion of the questionnaire and its results follows. The questions from this questionnaire are available in Appendix M. For the sake of brevity, only a discussion is provided here, as the tables and figures in the questionnaire already exist in this document. As mentioned, each participant received a pre-read document, pertaining to this study's

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Table 6.3: Summary of SMEs that participated in the policy analysis content verification process

P#	OCCUPATIONAL BACKGROUND	ACADEMIC BACKGROUND	FAMILIAR WITH VAN
P4	Medical doctor by training; 10 years Deputy Director at Children's Research Institute working on policies; Associate Professor at UCT (Health Policy and Systems Division)	MB ChB Medicine; PhD Social Policy	No
P5	Public Health Specialist; Senior lecturer and researcher at Stellenbosch University, Division of Public Health and Health Systems	Masters in Public Health Medicine; MBA	No

background, problem statement, aim and relevant information, prior to the questionnaire and unstructured interview.

Question 1: Policy analysis as a decision-making tool

In this question, it is highlighted that "policy analysis is able to support decision-making strategies through the following measures (to name a few): analysing public policies retrospectively or prospectively; assessing future implications of current (or new) policies on a new (or current) system; and determining if already existing policies need to be modified, or terminated." The aim of this question is to confirm the statement made in Subsection 1.1.3 whether policy analysis is a useful tool or method to use when approaching this study. Both participants indicated that they agree to this statement.

Question 2: Selecting an appropriate policy analysis approach

Selecting a policy analysis decision-making approach was one of the first steps during the development of the PoliVAN in Section 5.4. Various authors had different opinions on the choice of decision-making strategy—two conflicting views were prominent during this investigation. The one of Enserink *et al.* (2013), who suggests that the policy analysis model should incorporate its complex nature, where "conflicting demands on policy analysis and methods, the analyst and the process need to be balanced." The meaning of this is that policy analysis does not usually follow a rational or systematic approach. Walker (2000) argues that analysts should make use of the simplest approach, because the outcomes of the analysis need to be translated to policymakers.

After careful investigation and analysis (see Section 5.4), the rational model was chosen as the decision-making model for the PoliVAN. The participants are asked to indicate to what extent they agree with the choice of decision-making strategy for the intent and aim of the PoliVAN. Both participants agreed to the choice made in this study. P4 also provided additional

recommendations for the decision-making strategy. P4: "make sure that you appreciate the complexity and non-linearity of the policy process and that in the way that you engage with the data gathering, analysis and interpretation shows an understanding of the multi-faceted, complex and non-linearity of the policy process. So whilst I 'agree' there is a significant danger in choosing a rational model." During the unstructured interview, the details of the PoliVAN were discussed, i.e. the different tools and analysis techniques included; the inclusion of the health policy triangle; external factors; and stakeholder engagement. From this discussion, the participants agreed that the rational model is the best strategy when setting the foundational logic of the PoliVAN, because the analytical tools adds the necessary complexity to the decision-making process.

Question 3: Policy, law and legal framework hierarchy

Similar to Question 1 from the pharmaceutical supply chain verification questionnaire, the participants were asked to indicate to what extent they agree that the legal hierarchy depicted (Figure 3.6) provides a worthy generic representation of the relationship between the different levels of legislation. P5 agreed and P4 strongly agreed. P4 commented: "this diagram is representative of the tools guiding behaviour, interactions, process as they relate to the level of function i.e. strategic, tactical and operational."

Question 4: Policy formulation

This question refers to the policy formulation checklist developed by Shung-King (2004) (available in Appendix H). The question asks whether the checklist provides all the necessary components that need to be considered when (re)formulating policies. Both participants responded 'no' to this question. They did provide an explanation as to why the checklist needs more components.

P5 commented: "Where this checklist is ideal when considering the policy process (i.e. formulating policies); one objective of this study requires an evaluation of policies and this is the gap in the checklist. The NCCHPP framework analyses effects and implementation." After investigating the NCCHPP framework recommended by SME P5, it was discovered that it is exactly the same resource (Morestin (2012)) which contributed to the policy impact analysis tool in Phase 5 of the PoliVAN. This verifies that the inclusion of this tool in the PoliVAN can provide a valid analysis outcome. The comment from P5 also confirms that the checklist is ideal for policy formulation (which it is intended for in the PoliVAN).

P4 commented: "My own understanding of policy has evolved since. Whilst it still provides a useful guide for what to look out for, some of the sections lack a nuanced understanding of what to look out for in a policy document. Such as the variety of actors and their positions in

a policy process, for example." During the unstructured interview with this participant, it was made clear that the PoliVAN makes use of a stakeholder analysis tool to help manage the actors, as well as the components from the health policy triangle (discussed in Subsection 4.2.2.1) that was incorporated into the PoliVAN. Once this was made clear to the participant, the participant then agreed that the checklist (developed by Shung-King (2004)) is sufficient for policy formulation.

Question 5: Stakeholder analysis

This question refers to Phase 4 of the PoliVAN, as well as the literature used in Section 4.3 and Appendix J to develop this part of the PoliVAN. During the investigation of policy analysis methods and models, it became clear that the literature always referred to stakeholder analyses as well. In the questionnaire, the participants confirmed that a stakeholder analysis is a commonly used approach in policy analysis. Next, the participants were asked to indicate to what extent they agree that a stakeholder analysis is able to provide sufficient information on how to manage the development and implementation of a policy within the policy analysis process. Both participants responded with 'strongly agree' and gave supportive comments, i.e. P5: "The SHA is very important, but an aspect of what is required. A detailed understanding of context, content, and process are all crucial dimensions in helping to inform the management of policy development and implementation." This feedback supports the incorporation of both the SHA and policy analysis triangle into the PoliVAN. P4 added: a SHA "...adds value to the analysis and informs practical recommendations."

Question 6: Policy impact analysis

This question refers to Phase 5 of the PoliVAN, as well as the literature used in Subsection 4.2.2.2 and Appendix I to develop this part of the PoliVAN. In the questionnaire, the participants were provided with background on multi-criteria decision analysis approaches and the utilisation of this approach to analyse policies. The participants were asked to indicate to what extent they agree that a multi-criteria decision analysis (policy impact analysis) approach is a suitable evaluation tool that enables policy analysts to identify the impact of policy choices on a complex system such as a pharmaceutical supply chain. Both participants agreed to this method and gave supportive feedback. P5 suggested making use of qualitative data, which is being explored in an Industrial Engineering Bachelor's thesis project[1], as a supplementary project to this research study. P4 suggested that the analysis should be done while keeping the context in mind.

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[1] A summary of the project is available in Appendix U

The next part of this question focused on the interaction between the outcomes of a stakeholder analysis and the policy impact analysis. The question asks the participant whether they agree that stakeholders' opinions—their acceptance or disregard towards a policy should be considered in the multi-criteria decision analysis. Both participants agreed with 'yes'. P4 also commented: "If there is a way this can be done, then absolutely".

Question 7: Policy implementation

The final question in the policy analysis questionnaire is focused on the factors and strategies to include in the planning when adopting and implementing a policy. A number of components were given and the participants had to rank each component from 'very unimportant' to 'very important'. The following components were given: (i) policy (design) draft plan; (ii) stakeholder engagement plan; (iii) risk assessment (contingency) plan; and (iv) monitoring and evaluation. Both participants ranked each component as 'very important'. The participants were also given the opportunity to suggest additional components if they felt there were any missing aspects, but none was mentioned.

This concludes the questionnaire on the literature topic of policy analysis methods and models. Based on the feedback from the participants, no significant changes were required. This, however, verifies that the literature and assumptions on policy analysis, and the information incorporated into the PoliVAN is proven to be credible and accurate.

6.2.2 Verification of PoliVAN objectives

During the development process of the PoliVAN, a number of objectives were identified as design requirements to which the PoliVAN should be capable to perform (see Subsection 5.2.2). These objectives were attained through the knowledge gained from the literature studies and engagement with the VAN project. These objectives led the design and development of the PoliVAN. Therefore, the aim of this verification questionnaire was to ensure that assumptions based on problem statement, and those gathered through literature, are in fact a fair portrayal of what the VAN actually requires.

In this part of the verification stage, VAN-specific experts were contacted. All three participants (see Table 6.4) work closely with the VAN initiative: P3 is a supply chain technical advisor for the National Department of Health in South Africa, consulting on VAN-related projects; P6 is a VAN advisor for the Ministry of Health in Mozambique; and P6 is the technical lead for various VAN projects in SSA.

In the questionnaire, the participants were given an introduction and background to this study, including a description of the PoliVAN objectives. The participants were then asked to indicate whether they agree that the objectives encompass all the necessary elements in order

Table 6.4: Summary of SMEs that participated in the PoliVAN objectives verification process

P#	OCCUPATIONAL BACKGROUND	ACADEMIC BACKGROUND	FAMILIAR WITH VAN
P3	Public and Private Sector Supply Chain; Private Sector Pharmaceutical Distribution; Public Sector Technical Advisor - Medicine Supply Chain	BSc (Pharm); MBA	Yes
P6	VAN Advisor, Ministry of Health in Mozambique; Village Reach M&E Department; 7 years of experience working for NGOs in the public health sector.	Bachelor's degree in Computer Science for Management from A Politécnica University in Mozambique; Published multiple research articles.	Yes
P7	Health economist, Deputy Director within Affordable Medicines Directorate. Technical lead on many of the VAN initiatives and technology led supply chain reforms; Managing Executive: Health & Social Innovation at Mezzanine.	BA degree in Psychology, English; BA(Hons) in English Literature; MSc. In International Health Policy; Health economist; Multiple published articles.	Yes

for the PoliVAN to achieve the aim of this study. Thus, if the PoliVAN were to encompass these objectives (and achieve them), then the PoliVAN would carry out the aim of this study.

In the case where the participants do not agree with the objectives set out, they were asked to indicate which objective should be removed or changed and if an objective should be added to the PoliVAN objectives. From the responses, all of the participants agreed that the objectives identified are sufficient. P3 suggested for Objective 1[1] that the Constitution of the country should be considered. As this has already been considered in the policy and legislation hierarchy, the suggestion supports what has already been included into the PoliVAN and no changes to the PoliVAN objectives were required. This also concludes that the PoliVAN objectives can be accepted as accurate and credible.

6.2.3   Verification of the PoliVAN structure

During the development of the PoliVAN (Section 5.4), the design and the structure of the PoliVAN came into being as the development progressed through the different design sections. However, when it came to addressing the PoliVAN on which 'product'[2] it is, a literature study on different types of products was done to identify which one the PoliVAN coincides with. For the sake of brevity, the literature review regarding logic models is available in Appendix N and only the most important aspects are included here. As presented in Figure N.1, a logic model includes different components and specifications. These components were investigated individually and various subcomponents and specifications identified. To verify that the PoliVAN

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[1]The PoliVAN should be able "to identify and take into account multiple policy and legislative instruments that are relevant to the scope of the VAN Operating Model for the specific country."

[2]This is highlighted in Section 1.4.3. This refers to the development of either a framework, model, roadmap, process, business model canvas, maturity model, etc..

is correctly constructed according to the specifications of a logic model, a literature verification process was followed. This includes making use of the information gathered from the literature review, comparing it to elements from the PoliVAN.

The self-verification process of the PoliVAN structure as completed by the author is presented in Table 6.5. The specifications identified in each logic model component are compared to the various elements of the PoliVAN. In the first column, the components and their specifications were categorised. In the second column, a list of references was given to support the specifications provided. The third and fourth column provide an indication of the alignment between the PoliVAN and the structure of a logic model. In the fifth column is a description of the alignment. In the case of a 'yes', it describes the alignment and where it is incorporated into the PoliVAN structure. In the case of 'no', a discussion is given about either why it is not necessary to incorporate into the PoliVAN, or the changes that will be made to the PoliVAN to include this specification.

From Table 6.5, it is clear that the PoliVAN is largely aligned with the specifications of a logic model. The only change required is the inclusion of the level of effort to implement the PoliVAN. Given this comment, the details regarding the level of effort for each phase are assigned after the application of the PoliVAN to a country-specific case study. Details of the case study are discussed further in Section 6.4. To conclude the verification of the PoliVAN structure, it is confirmed that the PoliVAN is built according to the specifications of a logic model and can be addressed as the PoliVAN logic model.

Table 6.5: Cross-comparison between logic model specifications and the elements from the PoliVAN logic model

KEY COMPONENT OF A LOGIC MODEL	REFERENCE	ALLIGNED WITH POLIVAN?		COMMENTS ON THE ALIGNMENT
		YES	NO	
INPUTS				
Human Resources required for the activity, i.e. knowledge / skills / expertise.	a, b, c, d, e	X		The PoliVAN provides the recommended skills / expertise (an input to each activity) required from the analysts to conduct each activity.
Fiscal resources required for the activity, i.e. funds / donations / grants / guidelines.	a, b, c, d, e		X	In the context of this study, the PoliVAN does not require fiscal resources to perform the analysis. However, as part of the final recommendations and discussions of the PoliVAN, implementation prerequisites are developed for a country that plans on using the PoliVAN. It is possible that a country might require these funds to allocate the necessary resources to apply the PoliVAN.
Tangible resources required for the activity, i.e. technology / tools / material equipment.	b, f	X		The PoliVAN provides the tools and techniques (an input to each activity) required to perform each activity.
Intangible resources required for the activity, i.e. involvement / collaboration from relevant stakeholders.	b, c, d	X		The recommended expertise and techniques provide an indication of the collaboration and involvement required from various stakeholders.

Table 6.5 continued from previous page

KEY COMPONENT OF A LOGIC MODEL	REFERENCE	ALLIGNED WITH POLIVAN?		COMMENTS ON THE ALIGNMENT
		YES	YES	
ACTIVITIES				
Processes and techniques to direct action and ultimately provide a change / impact. These include: workshops (collaborating), training, educating, assessing, analysing, facilitating, demonstrations, etc.	b, c, d, e, f	X		The activities of the PoliVAN included workshops (collaboration of various stakeholders), tools to analyse and assess certain outcomes.
Activities are based on a programme and/or intervention that produces an output and ultimately support or create a desired outcome.	c, d	X		The PoliVAN is designed to support the VAN project and the successful implementation in a country's pharmaceutical supply chain landscape.
OUTPUTS				
Tangible artefacts (i.e. goods / products or documented information gathered) from activities. Service delivered, i.e. educational programming and/ or training, where knowledge and information is given / gained by relevant stakeholders.	a, b, c, e	X		The PoliVAN as projected outputs that are delivered from the activities. These include insightful information ("products / documented information") that provides insightful knowledge and (some of them) contributes towards an input for the next activity. Stakeholders are able to gain insight and knowledge from the outputs.
OUTCOMES				
The outcomes are based on detailed objectives set out to be achieved. The objectives and outputs aim to deliver the expected outcomes	a, b, c	X		The outcomes in the PoliVAN refer to the objectives discussed in Section 5.2.2. These objectives have also been verified as discussed in Section 6.2.2. In the PoliVAN, these objectives are translated and presented in the PoliVAN as the objective in each activity.
Expected benefits and changes that adhere to the situation (the bigger context / problem / picture). These **may** be categorised into: • Short-term outcomes: skills, knowledge, awareness, etc. • Medium-term outcomes: practices, policies, implementation, etc. • Long-term outcomes: systems change—political, economic and social conditions	a, c, e	X		The PoliVAN does not pertinently identify short-, medium- or long-term outcomes. However, it could be categorised as the following: • Short term: The techniques would be able to identify enabling and limiting effect policies on the VAN. • Medium term: The analysis would provide insight to enable informed decision-making for policies when implementing a VAN, and subsequently contribute towards the policy design element in the BPRM. • Long term: Enable countries to develop policy specific strategies to successfully implement a VAN.
EXTERNAL FACTORS / CONTEXT				
Narrative context (not part of the logic model structure and depiction) – the context or setting that the logic model is designed for.	a, b, c	X		This has been discussed throughout this document. The PoliVAN is designed for a public pharmaceutical supply chain (can be applied to private sector, although this will not be validated and confirmed). It is also recommended to make use of the PoliVAN before implementing the VAN, as it can aid in policy decision-making.
Contextual factors are included, i.e. geography, demography, economic-, social- and/ or political factors.	a, c, d	X		The PoliVAN did incorporate contextual factors. Some are presented in the high-level model, i.e. geography (country context) and others are included in tools of activities itself, i.e. demography, economic and political factors.
ASSUMPTIONS / CONDITIONS				
Narrative assumption (not part of the logic model structure and depiction) – things we assume to be in place in order to successfully implement the logic model.	b, c, f	X		The PoliVAN assumes that a country that has decided to implement the VAN concept has an already-designed VAN (people, process and technology), specific for their country context.

Table 6.5 continued from previous page

KEY COMPONENT OF A LOGIC MODEL	REFERENCE	ALLIGNED WITH POLIVAN?		COMMENTS ON THE ALIGNMENT
		YES	NO	
ASSUMPTIONS / CONDITIONS				
Possible limitations and barriers that needs to be considered before and when implementing the logic model.	c	X		The barriers / limitations are discussed for each activity of the PoliVAN in Chapter 7.
Level of effort that is required to implement the logic model.	d, f		X	Once the PoliVAN is validated and is proven to be applicable, the details of the level of efforts can be included. Currently, this cannot be given without knowing how each country would go about implementing the PoliVAN. However, an attempt at the possible low-, medium- and high-level effort is given in Chapter 8—the post-case study application.
DEVELOPMENT AND ILLUSTRATION				
The logic model has an underlying logic and objective / purpose / need for change.	a, b, c, d, e	X		The underlying logic and purpose is the aim of the study as discussed in Sections 1.3 and 5.2.1.
Has a clear situation that is the foundation of the logic model – clear priorities with desired outcomes	e, f	X		This is presented in the problem statement Section 1.2.
Evidence-based and relevant information is presented and used for the stakeholder to understand the logic.	c	X		The literature on which the PoliVAN is based and developed from have been verified, as discussed in Section 6.2.1.
The structure, i.e. "boxes" and "arrows" depict the underlying logic of the model.	c, e	X		The PoliVAN has clear "boxes" and "arrows" that depict the components and the logic flow of the model.
The components (i.e. inputs, outputs, activities and outcomes) are clearly illustrated and labelled.	a, c, d	X		The different components are clearly labelled and illustrated – a legend with an explanation of each component is provided as well.
Easy and straightforward language is used.	b, c	X		The aim is to make it easy to read and to understand for any sub-Saharan African country.
The narrative (and details) of the logic model is well explained and/or depicted: what is included in each component; the importance of each component; the rationale of the logic path; and an indication of the contributions towards the outcome and underlying purpose.	b, c, e	X		In Chapter 7, the details of the activities are discussed in a narrative form. The discussion includes the rationale of the activity, the tools used and how this contributes towards the objective and the underlying outcomes and logic.
The components of the logic model were developed according (or relatively close) to the following order: (1) impact / purpose; (2) outcome; (3) activities; (4) input; and (5) output	e	X		PoliVAN was developed in the following order (corresponding to the order recommended): (1) the aim of this study; (2) VAN objectives which were then translated to the outcomes/objectives in the high-level PoliVAN; (3) the activities and tools to be used (as seen in Table 5.4); (4) the inputs were identified by asking the question of who and what was needed to perform the activity – the tools are identified in (3); and (5) the outputs from activities were identified and consequently matched to see whether this could be possible inputs to the next activity as well.

[a](Centre on Knowledge Translation for Disability & Rehabilitation Research, n.d.). [b](Knowlton & Phillips, 2013). [c](Macdonald, 2018). [d](Milstein & Chapel, 2015). [e](W. K. Kellogg Foundation, 2004). [f](Taylor-Powell, Jones, & Henert, 2003).

6.3   Subject matter expert validation

From the evaluation strategy discussed in Section 1.4.3, the SME validation is the second stage of the evaluation process. Section 6.2 provided a detailed discussion about the verification process. At this stage the PoliVAN is considered verified, meaning that it is 'built right', thus upon sound and credible literature finding foundations. This part of the validation process is where the necessary changes and updates were made to the proposed PoliVAN (see Figure 1.3), based on the inputs and expertise of SMEs. The aim here is to shift the focus towards validation. This is achieved through SME engagement, to determine whether the PoliVAN is designed according to its intended purpose—to determine whether it is relevant to the problem discussed in Section 1.2 and appropriate for the context (the VAN and public pharmaceutical supply chain) which it is developed for.

The validation approach selected in this stage is a combination between interviews with SMEs and a workshop approach (see Table 6.1 for the different types of validation methods). According to the Oxford dictionary, a workshop is "a meeting at which a group of people engage in intensive discussion and activity on a particular subject or project" (Oxford English Dictionary, 2008). This mixed-method approach is used to gather a group of experts in the field of VAN and the public pharmaceutical supply chain, to engage in conversation regarding the proposed PoliVAN, and to provide feedback through a structured questionnaire.

The SMEs in this process were carefully selected to ensure that they encompass the knowledge that was required to develop the PoliVAN. Five SMEs participated in the validation workshop. Table 6.6 provides the academic and occupational background of the participants. A detailed table of the participants is available in Appendix L. It is clear that all the participants possess the knowledge and experience in the operations of a public pharmaceutical supply chain, whether this knowledge is based on working as a consultant for the Ministry of Health, or working on the technical areas of the health system (e.g. monitoring and evaluation of key performance indicators).

All participants are familiar with the VAN concept, with four participants currently working on a VAN-related project. Only two participants are familiar with policy analysis models; however, four participants are currently directly involved with formulating and drafting country policies and legislations, including the analysis of these. Each participant received a pre-read document that required their attention before attending the workshop. The pre-read document provided an overview of this study's aim and objectives, the literature used to develop the PoliVAN, an illustration of the high-level PoliVAN, and a brief description of the planned workshop structure. During the validation workshop, each participant received an activity workbook (provided in Appendix O). The activity workbook includes the details of the PoliVAN which have not yet been presented in this study—the activities and tools selected

Table 6.6: Summary of SMEs that participated in the SME validation workshop

P#	OCCUPATIONAL BACKGROUND	ACADEMIC BACKGROUND	FAMILIAR WITH VAN
P8	Cluster Manager: Governance, Monitoring and Evaluation at Systems for Improved Access to Pharmaceuticals and Services, Management Sciences for Health; Technical advisor for NDoH.	Diploma in Pharmacy, Master of Public Administration (M.P.A),	Yes
P9	Pharmacy Technical Assistance Manager: rational medicine use; Pharmacist; Member of South African Pharmacy Council.	BSc (Pharm)	Yes
P10	Public health consultant; National Health Service (NHS) Service Development, Governance, and Project Management; Managing Director at leading consulting companies in health advisory.	BSc Political Science and Law	Yes
P11	Senior business analyst at Imperial Logistics; Management Systems, Risk Management, Monitoring and Evaluation; Technical advisor at NDoH.	BSc (Hons) Microbiology	Yes
P12	Manager at PwC (health advisory); Technical advisor for NDoH; Hospital operations manager.	BSc (Pharm); Post-graduate diploma in Health Economics	Yes

and developed for each phase of the PoliVAN. Thus, in order to avoid duplication, the refined PoliVAN is presented in Chapter 7, which includes the adjustments made to the logic model, based on the feedback received during the SME validation workshop.

The activity workbook included a questionnaire. The questionnaire had 35 closed-ended questions, where participants had to reflect on the level[1] at which they agreed to a question or statement. The questionnaire also included open-ended questions, where the participants were able to add suggestions or additional information to the PoliVAN. The participants were asked to complete the questionnaire during the workshop. When participants did not agree with a statement, they were asked to provide a reason for their disagreement, which was discussed among the group of SMEs. They could also propose means by which the PoliVAN can be improved on these matters, if any. When the participants provided neutral answers, a discussion was conducted regarding the subject under consideration to clarify any uncertainties. The feedback from the questionnaire is discussed under the following subheadings and illustrated in Figures 6.2 and 6.3 using a stacked bar chart format. The figure also indicates which questions are concerned with the different phases in the PoliVAN.

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[1]A 5-point Likert scale is used. A Likert scale is a response scale primarily used in questionnaires to obtain participants' degree of agreement with a statement or set of statements (Bertram, 2006).
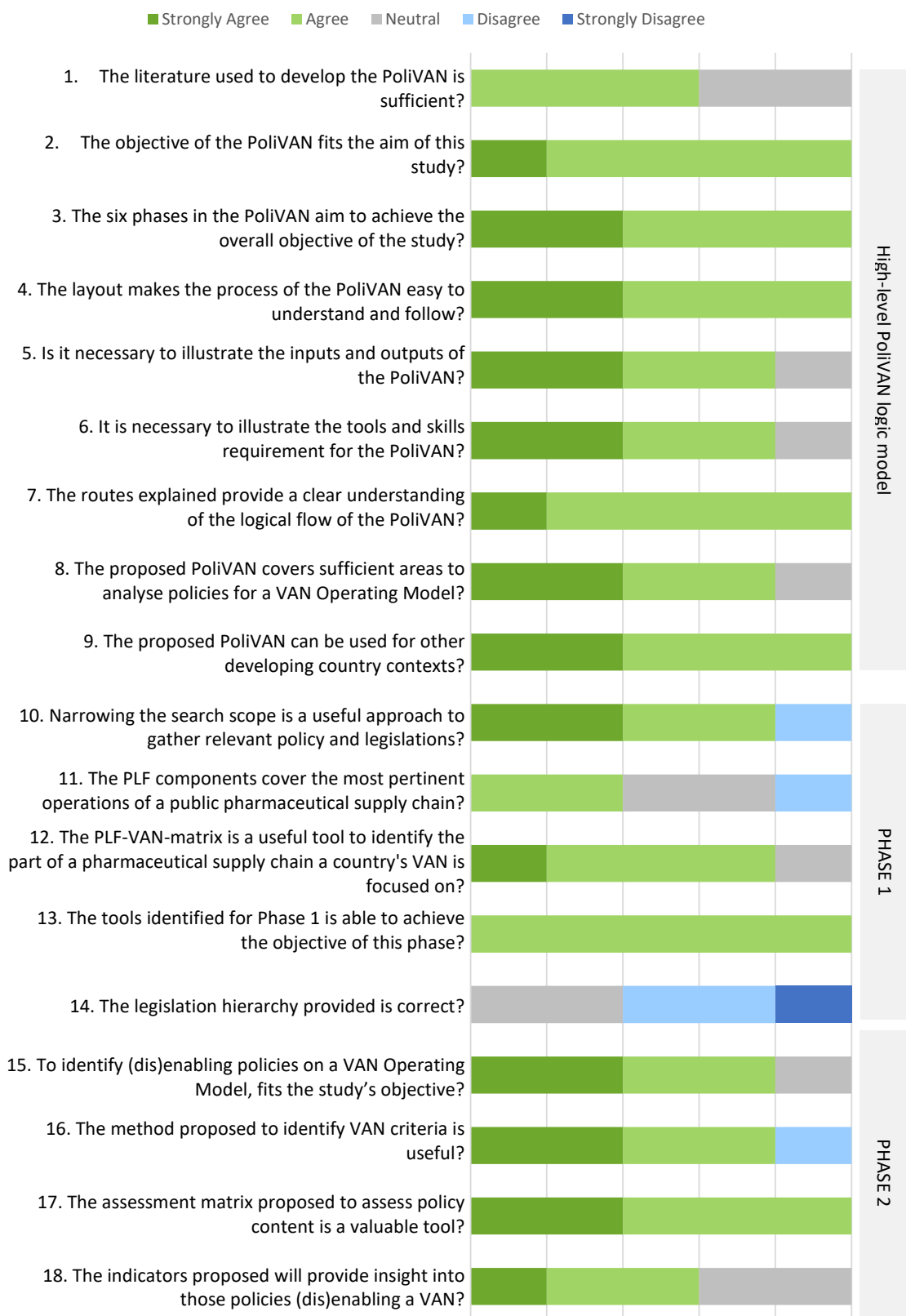
Figure 6.2: Results from the SME validation workshop: Questions 1 - 18

Questions 1 to 9: High-level PoliVAN logic model overview

The first set of questions was aimed at the high-level PoliVAN. Questions about the development of the PoliVAN, the flow of the processes, and whether the model is flexible were addressed. From the feedback, it is clear that most of the questions were answered with either 'strongly agree' or 'agree'. For Question 1, the participants had a difficult time responding to this question, as they have not read all the details of the literature used to develop the PoliVAN, but from what was given in the pre-read document, they agreed that it was sufficient. The verification process in Section 6.2 already verifies this question.

The participants were asked to complete Questions 8 and 9 at the end of the workshop. Although the feedback seems positive, this could only be proved with an actual application of the PoliVAN (further discussed in Sections 6.4 and 6.5). For the sake of brevity, the rest of the discussion about the questionnaire results will only focus on the questions where participants disagreed in the questionnaire or had made concerning comments.

Questions 10 to 14: Phase 1 overview

Questions 10 to 14 are concerned with Phase 1 of the PoliVAN. For Question 10, only P11 disagreed and recommended that the objective should be rephrased as: "To narrow the search range by identifying policy and legislative instruments relevant to the scope of the VAN." The participants also suggested splitting the terms 'policy' and 'legislation' from one another in the heading, due to them being different types of documents. However, due to limited space in the schematic representation, the term 'policy' will still remain, but the distinction between these two types of documents will be highlighted.

For Question 11, a range of responses was given; however, the participants recommended that the PLF should separate the inventory and distribution function from one another. P8 and P11 suggested to rename 'operational functions' (i.e. product selection, procurement, distribution, and product use) to 'operational components', and rather refer to the activities (i.e. quantification and forecasting, storage and contracting) within these components as the 'operational functions'. P9 and 10 suggested that 'formularies' should be added to the 'Product selection' component, as this is a separate operation from setting up the essential medicines list (EML) or standard treatment guidelines (STGs). These recommendations from the SMEs were included in the PLF (discussed further in Chapter 7).

The participants initially disagreed with Question 14—this question refers to the legislation hierarchy. Although they agreed that policies are situated between mandatory and voluntary legislations, they believe there are more up-to-date and relevant versions available for the South African context. However, since the legislation hierarchy in the PoliVAN is a generic schematic representation of how countries should be able to identify different legislative documents,

the participants subsequently agreed that the given schematic is well structured for a generic approach. The legislation hierarchy has also been verified as discussed in Subsection 6.2.1.

In conclusion, this phase should highlight that both the PLF functions and the legislation hierarchy provided is generic (based on the Management Science for Health publication[1]), and countries can either use it as a guide to identify the operational functions of their pharmaceutical supply chain, or use it (as-is) if they do not have an existing framework.

Questions 15 to 18: Phase 2 overview

The next set of questions is concerned with Phase 2 of the PoliVAN. The participants agreed to most of the questions. For Question 16, one participant raised the question about whether a country should already have an existing VAN Operating Model before using the PoliVAN. In this particular case, it is required, because the Blueprint Reference Model (BPRM) guides countries on how to design a VAN Operating Model based on the type of supply chain they would like to implement (see Figure 2.1). The PoliVAN aims to analyse the enabling and limiting effect of existing policies and impact of new policies when implementing the designed VAN Operating Model. If a VAN Operating Model is designed to fit a country's legal framework, a type of policy analysis should also be considered, but to what extent should a VAN Operating Model be designed to compensate for a country's policies and legislations. If so, the best possible VAN Operating Model for a country might not be designed and this contradicts the aim of the VAN project.

The only suggestion and update made to this phase is the addition of an alignment matrix, which assesses the relationship between different policy and legislation documents. This identifies which policies or legislations will be affected once one of them requires reform. However, this can only be determined for the policies and legislation that exist, not for those that do not exist. When policies for functions in the PLF do not exist, route (b) from the PoliVAN (Figure 5.4) should be taken.
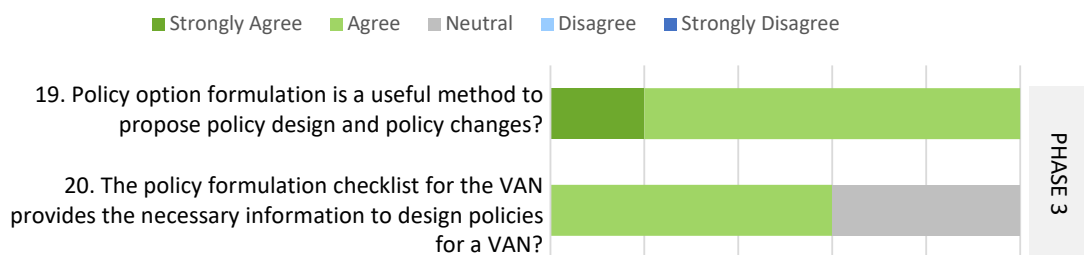
Figure 6.3: Results from the SME validation workshop: Questions 19 - 35

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[1]Management Science for Health (2012). MDS-3: Managing access to medicines and health technologies. Management Science for Health. Arlington, VA.
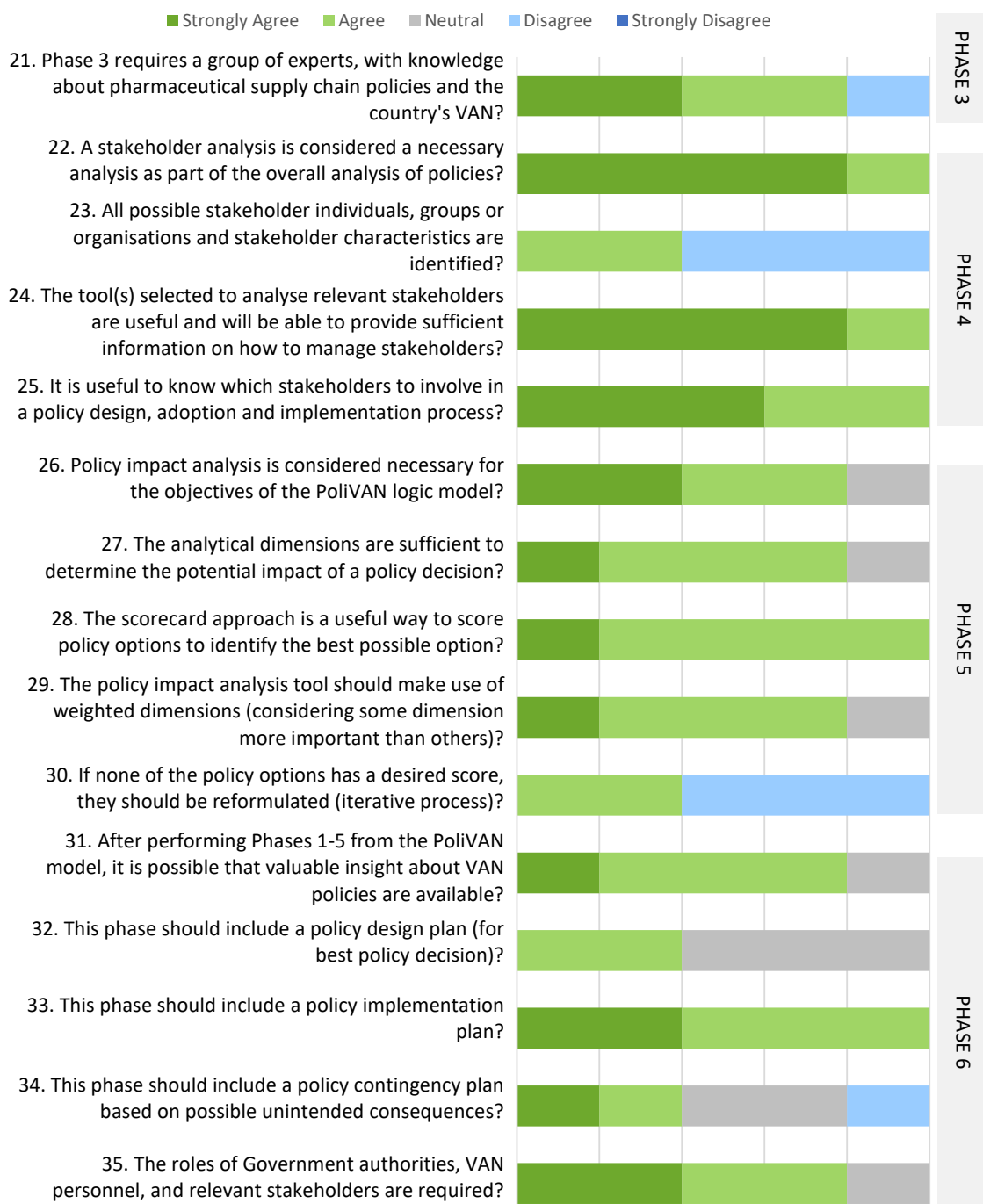
Figure 6.3 continued from previous page

Questions 19 to 21: Phase 3 overview

The fourth set of questions concerns Phase 3 of the PoliVAN. As mentioned, the questionnaire provided some open-ended questions. Question 20 refers to the policy checklist developed for the VAN which is derived from the policy checklist by Shung-King (2004) (available in Appendix H). This policy checklist can be used to ensure that the policy options are thoroughly

designed to fit the objectives of the VAN. According to the participants, the checklist that is provided to ensure that the policy options contain the necessary information, requires minor additions. The following suggestions were given and incorporated:

i. A policy option needs to define the scope of intended activities and objectives;

ii. The checklist needs to be generic in a sense that it can be used to facilitate a policy at any level (national, regional or local); and

iii. Management support elements need to be included in the policy checklist.

To formulate policy options, especially for an operating model such as VAN, the participants agreed (Question 21) that not only should those designing policy options require knowledge about the VAN or the operations of the pharmaceutical sector, but there should also be those who understand the specific part of the supply chain being focused on for the analysis. Thus, include SMEs and supply chain specialists (for specific parts of a supply chain and the supply chain as a whole), logisticians, policy experts, and pharmacists. This suggestion from the participants was added to the skill requirements for Phase 3 in the PoliVAN.

Questions 22 to 25: Phase 4 overview

The following set of questions concerns Phase 4 of the PoliVAN. As seen by the stack bar chart, the participants mostly agreed to the questions from this phase. Their only disagreement being concerned with the stakeholder groups and characteristics. Question 23 is an open-ended question, where the participants were able to add, remove or change stakeholder groups and characteristics gathered from literature. The stakeholder group list is aimed at being generic for any possible policy area. It is a guide for analysts to identify possible stakeholders. The proposed stakeholder groups and characteristics are based on what is provided in literature; however, the participants working in the public health environment might contribute significantly towards identifying other stakeholders missing from the current list. Tables 6.7 and 6.8 illustrate the original and suggested changes made to the list of stakeholders and characteristics.

Questions 26 to 30: Phase 5 overview

The sixth set of questions concerns Phase 5 of the PoliVAN. Question 27 refers to the analytical dimensions (Section F.2 in the activity workbook) identified to analyse the impact that the policy options could potentially have on the pharmaceutical system. The participants had the opportunity to make recommended changes to the analytical dimensions (see Table 6.9), and agreed that the tool can be useful to compare different policy options with one another.

Table 6.7: Suggestions and updates made to the stakeholder lists

INDIVIDUALS, GROUPS, ORGANISATION	EXAMPLE OF POSSIBLE STAKEHOLDERS
Government	Ministry of Health, Ministry of Finance, Departments, etc.
Health sector level	National, regional, local levels of the healthcare sector
NGO (Non-governmental organisations)	Funding Agencies, donor organisations, health programmes, etc.
Media	Newspapers, news, social media, etc.
~~Consumers~~ *Beneficiaries*	Patients
VAN ~~specific~~ *roles*	Process planners, supply chain analysts, budget holders, facility representative, liaisons, etc.
~~Private~~ *Third party services*	Transport services, IS services, suppliers, etc.
Private sector	*Distributors, wholesaler, clinics, pharmacies, hospitals, etc.*
Public sector	*Primary healthcare facilities, hospitals, central medicine stores, etc.*
Ministerial appointed committee	*Task teams appointed by the Government to investigate health issues.*
International influencers	*World Health Organisation (WHO)*
Societies	*Politicians, councils, academia, etc.*

Table 6.8: Suggestions and updates made to the characteristics lists

CHARACTERISTICS	DESCRIPTION
Position and organisation	Position the stakeholder has and the organization that he/she works for.
Knowledge of policy *scope*	The level of accurate knowledge the stakeholder has regarding the policy under analysis.
Level of support	Support refers to the level of degree a stakeholder is ~~affected~~ *impacted* by a policy decision, ~~and how he would respond to it~~ (positively or negatively).
Interest	The interest the stakeholder has in the policy, regardless of whether he/she is affected by the policy or not.
Resources	Resources can be of many types—human, financial, technological, political, and other. The analysts should consider the stakeholder's access to all of these resources.
Power	Power refers to the ability of the stakeholder to affect the implementation of the health reform policy due to the strength or force the stakeholder possesses.
~~Leadership~~	~~Leadership is specifically defined here as the willingness and ability to initiate, convoke, or lead an action for or against the health reform policy.~~
Attitude	A stakeholder's attitude is determined by the level of interest he/she has in a policy area combined with how they are impacted by the policy (positively or negatively).
Opinion leaders	*The leadership ability to initiate, convoke, or lead an action—for, or against—the health reform policy.*

For Question 30, there is a combination of both 'agree' and 'disagree' responses. The participants who disagreed with the iterative process, suggested that instead of the policy impact score determining when to reiterate (and subsequently redesign policy options), it should rather look at why none of the policy options reaches a desired score, and focus on that specific analytical dimension(s). After considering both options, it is realised that policy problems and alternatives were already explored in Phase 3, therefore reiterating would be a redundant process and thus the suggestion by the disagreeing participants should be considered; rather focusing on the analytical dimensions and possible trade-offs to consider and manage.

Table 6.9: Suggestions and updates made to the analytical dimensions

POLICY IMPACT ANALYTICAL DIMENSIONS		
CATEGORY	DIMENSIONS	DESCRIPTION
EFFECT	Relevance	Does it support or oppose the content and objectives of the VAN? To what extend is the policy appropriate for the objectives of the VAN?
	Unintended effects	What is the probability of unforeseen consequences of this policy?
	Contextual factors	These are factors relating to macro (i.e. social, environmental and political) and micro (i.e. health outcomes and organisational structure) contexts.
	Criticality	*What is the impact the policy option has on the pharmaceutical supply chain landscape?*
IMPLEMENTATION	Feasibility	The feasibility of a policy in terms of technical and operational factors. How feasible is the policy option for the country's infrastructure?
	Cost	The availability of funds for the adoption, implementation, and execution of the policy.
	Time	*What is the expected time to implement such a policy option?*
GOVERNANCE	*Acceptability*	*The input gathered from relevant stakeholders on whether they support or oppose the policy option.*
	Legal coherence	*Do other governing legislative instruments support the policy? How well do policies within the same landscape (i.e. health) support the policy option? Does it require a mandatory legislation to change?*

Questions 31 to 36: Phase 6 overview

The final set of questions concerns Phase 6 of the PoliVAN. This phase suggests that the following strategies should be utilised when a new policy for a VAN Operating Model is considered for implementation: a policy design plan, implementation plan, contingency plan, and a stakeholder plan. For Question 34, two participants were neutral in a sense that they believe that a policy contingency plan is only necessary as this depends on the level of the policy under consideration. The participant who disagreed, suggested including monitoring and evaluation plans which track and react to unintended consequences. After a discussion among the SMEs regarding this question and the outcomes of Question 36, it was decided that a risk management plan should take the place of the contingency plan.

Question 36 is an open-ended question that allows the participants to suggest strategies to be undertaken. Their suggestions (besides what was already proposed) are the following:

  i. Risk mitigation plan

 ii. Communication / stakeholder engagement plan

iii. Strategy and objectives

 iv. Success criteria / key performance indicators (KPIs)

From the validation workshop and the questionnaire responses, there are no major or high-level (structural) changes to be made to the PoliVAN. However, there are minor details

that require some attention and refinement given the feedback received during the validation workshop. The inputs provided by the SMEs frequently relate to their experience in practice, and this therefore adds a depth to the PoliVAN which could not be achieved based solely on literature studies. This confirms that the PoliVAN is relevant, context appropriate and has been designed with the correct intent. At this stage of the evaluation process, only one form of validation method has been applied. This method confirms that theoretically the PoliVAN should be able to work as indicated. To further prove that the PoliVAN can be utilised, a second validation method was considered. The means and details of this method are discussed in the next section.

6.4 Case study validation

Section 1.4.3 provides a detailed account of the evaluation strategy used in this study. The first two stages of the evaluation strategy are concerned with the theoretical verification and SME validation of the developed and proposed PoliVAN respectively. The refined PoliVAN (which is comprehensively discussed in Chapter 7) is used for the next stage in the evaluation process; the application of the PoliVAN to real-world case studies to showcase the PoliVAN's applicability and flexibility (see Table 1.1 for a description of the evaluation objectives).

6.4.1 Satisfying the evaluation objectives

The applicability of the PoliVAN can be validated by the outcomes produced from the case studies; testing whether the inputs and tools provided in each phase (see Chapter 7) help to achieve the intended and expected purpose. The flexibility outcome evaluates the PoliVAN's ability to perform an analysis when the environment of the application changes, i.e. changes in the pharmaceutical supply chain environment, changes in the VAN Operating Model (especially if different countries aim to use this), and the granularity at which the analyses are done. Thus, to test both evaluation objectives, two case studies are conducted in this study.

6.4.2 Designing the case study methods

Many authors who have contributed towards the development of the case study phenomena (i.e. Houghton *et al.* (2015), Merriam (1988), Yazan (2015) and Yin (2013)), agree to some extent to what constitutes a case study. Every case study must have a 'case', which is the object of study (Yin, 2013). The features of a case are the following: (i) the 'case' is a complex functioning unit; (ii) a 'case' should be investigated in its natural context; and (iii) a 'case' can be purposefully selected Yin (2013). When it comes to designing the case study, Yin (2013)

identifies four types of case study design methods with a 2 x 2 matrix (Figure 6.4). All these designs[1] show the desire to analyse the case within its contextual framework Yin (2013).
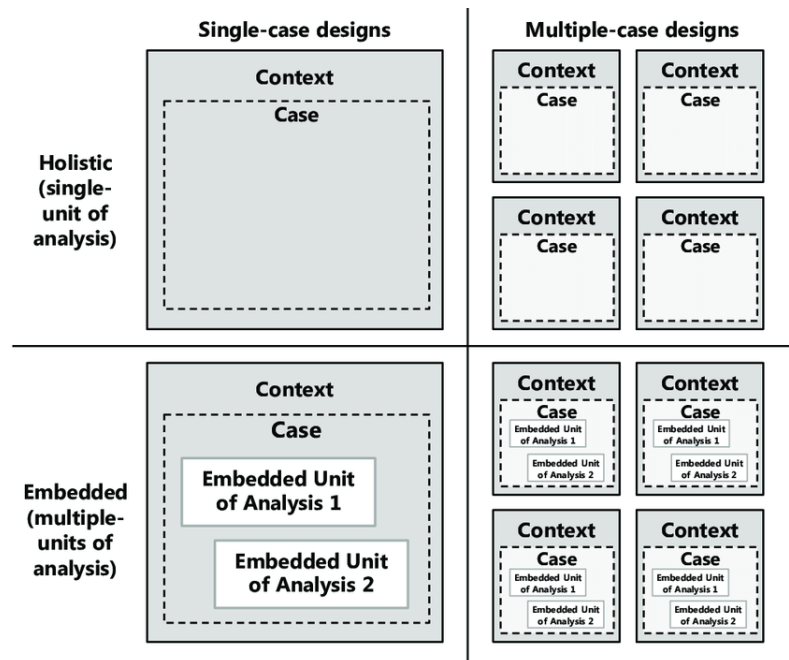
Figure 6.4: Case study design types by Yin (2013)

This study takes on a multi-case embedded design approach, Type 4. A multiple case design refers to a study that contains more than one single-case to explore the differences between two or more cases Yin (2013). Each case takes on an exploratory approach to investigate the embedded units of analysis—the different outputs produced— within each particular case. The applicability of the PoliVAN is tested by the outcomes produced in each case from the embedded units of analysis. The flexibility is tested from the differences in the outcomes produced by the two cases. These cases are applied within the same pharmaceutical supply chain and country context. Figure 6.5 illustrates the case study design applied in this study.

As mentioned, the context of the case studies will be focused on the South African VAN Operating Model. Only two case studies are applied in this study, which provides the necessary level of detail to satisfy the research enquiry. In each case the PoliVAN is applied, and the embedded analysis refers to the different outputs produced by the respective phases in the logic model. The 'cases' for the case studies are two operational components from the pharmaceutical logistics framework: medicine selection and inventory management.

The first case study is focused on the selection of medicines component. The case study is done in a workshop environment with multiple SMEs that contribute towards the different

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[1]Type 1 is a single-case, holistic design. Type 2 is a single-case embedded design. Type 3 is a multiple-case, holistic design. Type 4 is a multiple-case, embedded design.

Figure 6.5: The case study design for the PoliVAN logic model

analyses, based on their knowledge and expertise in this specific field. The second case study is focused on the inventory management component and is done as a combination of desktop exercise, SME interaction and a workshop with two SMEs, where the content details for the different phases of the PoliVAN are discussed. More details regarding the scope of the case studies and the reasons behind the two case study cases, the application of the case studies including the outcomes and findings, are presented in Chapter 8.

6.5 PoliVAN transferability validation

The final stage in the evaluation process is the transferability validation process of the PoliVAN, through sub-Saharan African (SSA) SME engagement. The aim is to investigate the transferability component proposed by the research aim in this study. The validation process will include interaction with SSA VAN representatives to gain insight into the possible opportunities and restrictions for SSA countries to utilise the PoliVAN. This validation process is done through a structured questionnaire, followed by an unstructured interview to gain an understanding on the feedback received from the questionnaire. The unstructured interview also allowed for the settlement of any unclear feedback or discrepancies. Chapter 9 discusses the PoliVAN transferability validation outcomes, which includes the SMEs who participated, the questionnaire results and an interpretation of the feedback received from both the questionnaires and unstructured interviews.

6.6 Chapter 6: Conclusion

Chapter 6 consists of an amalgamation of the different evaluation processes—both verification and validation—applied to the PoliVAN. For each of the four evaluation stages (see Figure 6.1), the outcome and how it contributes towards a refined PoliVAN is discussed; however, the outcomes from Stages 3 and 4 are discussed in Chapters 8 and 9 respectively.

Based on the feedback received in Stages 1 and 2 of the evaluation process, minor changes had to be made to the PoliVAN. In this chapter, the PoliVAN was evaluated with three evaluation objectives. In the verification stage (Stage 1), the literature and assumptions made in this study and the information incorporated into the PoliVAN was proven to be credible and accurate. The PoliVAN was found to be relevant to the VAN initiative and appropriate to the pharmaceutical supply chain context (Stage 2). The evaluation objectives from Stages 3 and 4, and how this is aimed at being achieved, are discussed in the following chapters.

Chapter 7

Policy analysis logic model for a VAN: PoliVAN

In this chapter the policy analysis logic model that is developed for a VAN, the PoliVAN, is presented. The PoliVAN is developed based on literature findings from Chapters 2, 3 and 4, and refined after a verification and validation process conducted with input from subject matter experts (SMEs). This chapter thus presents the verified and SME validated version and provides a generic guide on how to interpret the different element in the PoliVAN. The PoliVAN is a practical method that allows policy analysts, government officials, VAN role players and relevant stakeholders to analyse existing policy and legislations in order to develop policy-related strategies to enable effective and efficient operation of a VAN Operating Model. This chapter starts with an overview of the high-level PoliVAN, followed by a detailed description of each phase in the logic model and how the tools within each phase can be utilised to achieve the PoliVAN's objectives.

7.1 High-level PoliVAN logic model

To provide a revision from the previous chapters, Figure 7.1 represents the high-level PoliVAN, but with the minor changes, based on the feedback received during the validation workshop conducted with SMEs. Subsection 7.1.1 provides detailed insight into the operations of each phase in the PoliVAN—illustrating the steps in each phase, the inputs and outputs of each phase, the skills and tools required for the different steps, and a detailed discussion of how to use the tools for the analysis. The key refinements that were made to the high-level PoliVAN include:

   i. In Phase 1, refinements are made to the generic pharmaceutical logistics framework (PLF);

ii. In Phase 2, an alignment matrix tool is included to illustrate the relationship between the different policies and legislations identified;

iii. In Phase 4, stakeholder individuals, groups, and organisations, as well as stakeholder characteristics are added to the initial lists developed from literature. These changes are based on the expertise and experience of the SMEs; and

iv. In Phase 5, minor additions to the analytical dimensions are included; and the route that linked back to Phase 3 is removed (reasons behind this are discussed in Section 6.3).
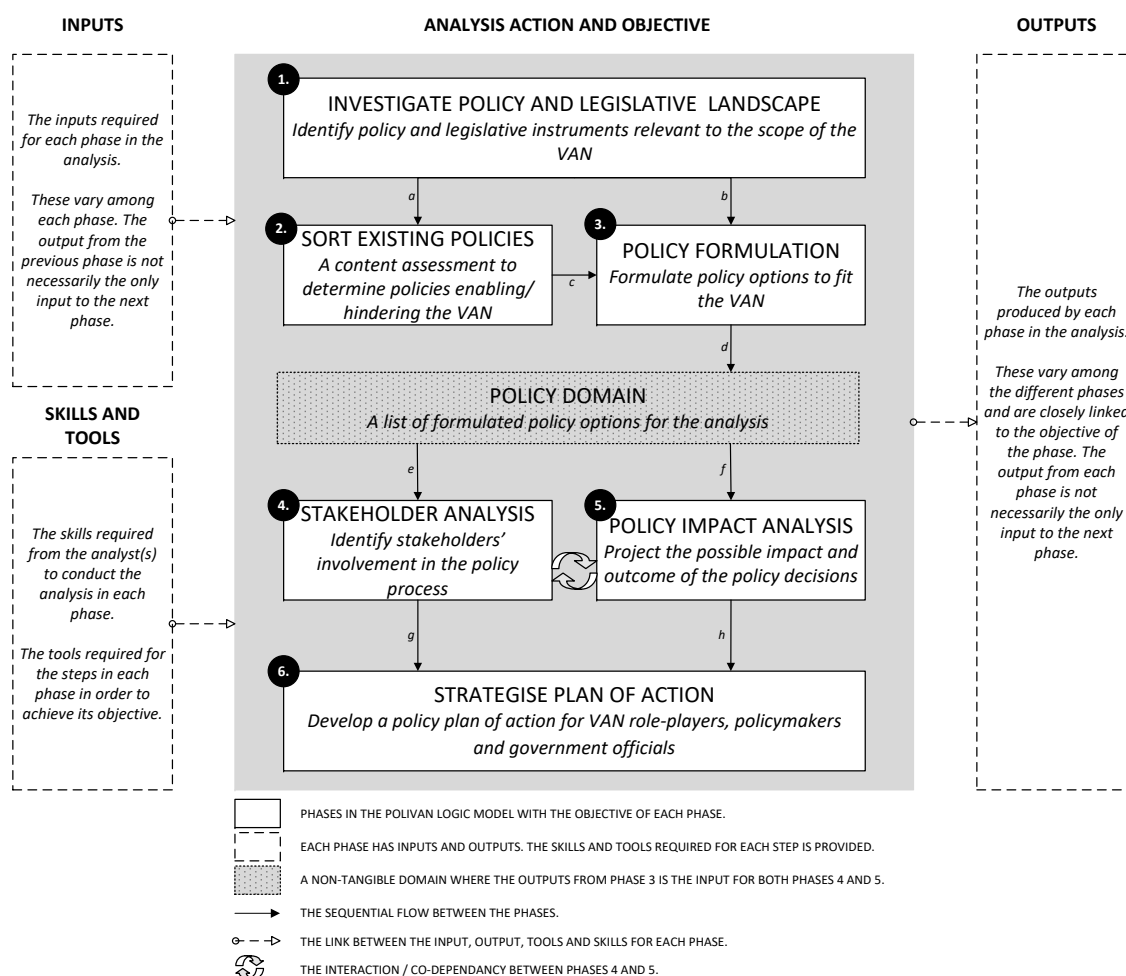
Figure 7.1: High-level policy analysis logic model for the VAN: PoliVAN

7.1.1 A guide to understanding the PoliVAN logic model

The PoliVAN is designed to support the VAN Operating Model to make informed policy decisions and is presented in the form of a logic model. Figure 7.2 illustrates each phase of the PoliVAN generically; the illustration indicates the name and objective of a phase, the inputs,

the outputs, including the tools and criteria used to perform the steps within each phase. Each phase is formulated according to this framework shown in Figure 7.2. This generic structure allows the analyst to follow the progression of the analysis, with clear indication as to the tool(s) and skills required by the analysts for each step in the phase. As mentioned, the PoliVAN is developed in such manner that any developing country (specifically sub-Saharan African countries) that plans on implementing a VAN can utilise it. When specific tools or criteria have to be adapted according to a country's specifications, an asterisk (*) is shown next to the identified tool.
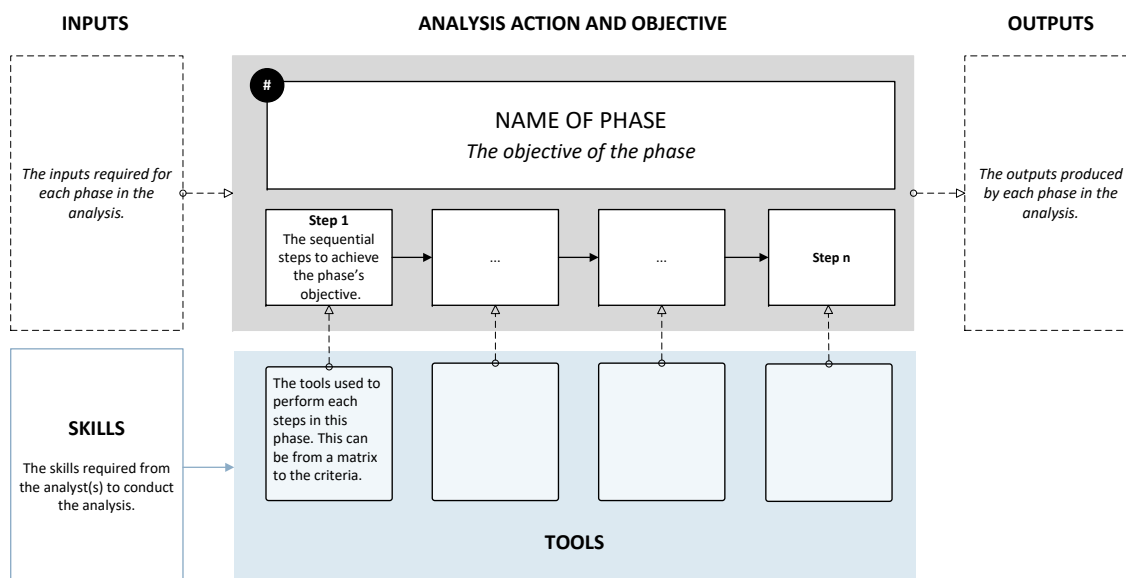
Figure 7.2: An analyst's guide to understanding the illustration of the PoliVAN phases

Further, the discussion of each phase (see Sections 7.2 - 7.8), consists of a number of steps with a detailed description of the tools and how they can be applied, including indications of how the tools can be adapted to a specific context, should this be required.

7.2 Phase 1: Investigate policy and legislative landscape

In order to analyse policies, and understand whether they support or hinder (to some extent) the implementation and operations of the VAN Operating Model, it is necessary to identify the policies that are relevant to the VAN Operating Model, and thus need to be analysed within the context of the country implementing the VAN. Due to the complexity of a pharmaceutical supply chain, the number of policies and legislations that might exist to govern these operations could potentially be significant, and the time it takes to identify these documents can become

tedious. Therefore, the first phase in the PoliVAN is to investigate the policy and legislation[1] landscape to gather legislative instruments that are relevant to a country's VAN Operating Model. The objective of this step is thus to narrow the 'search range' for the legislative instruments. Figure 7.3 illustrates the steps within Phase 1 to achieve its objective.
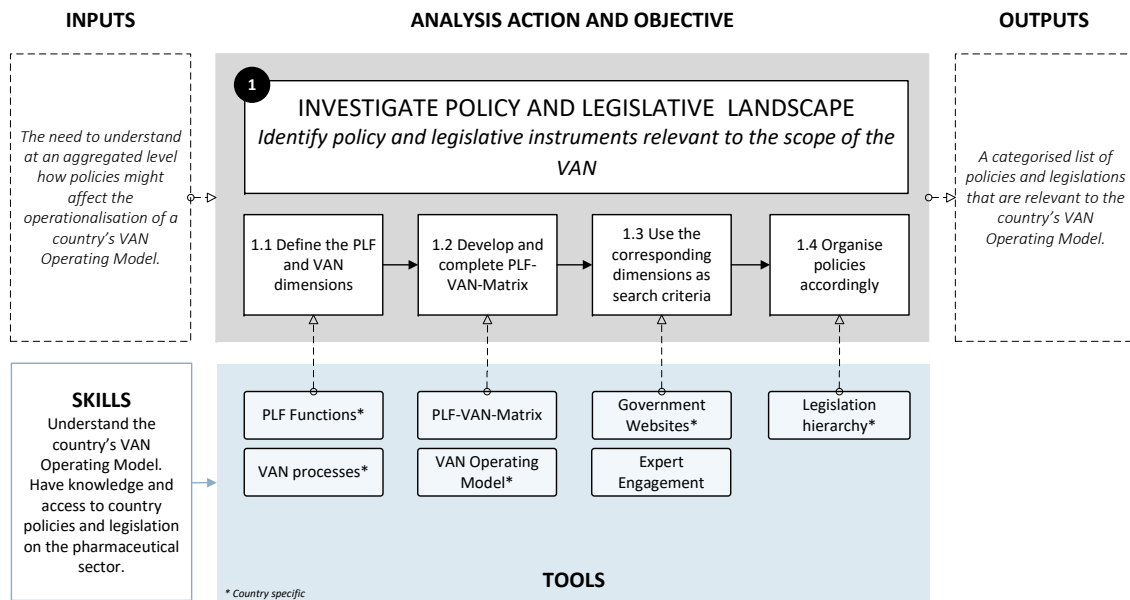
Figure 7.3: Phase 1: Investigating the policy landscape

The input for the first phase of the PoliVAN is the need for a country to understand how their existing policies and legislations are most likely to affect the operationalisation of the VAN, at an aggregate level, in order to make the required policy decisions and develop the required strategies for the implementation of the VAN. The steps in this phase are performed by taking into account a country's VAN Operating Model, and cross-examining the elements within the VAN Operating Model against the operational functions and supportive elements of a pharmaceutical logistics framework (PLF). Due to the fact that the VAN is designed to operate within a pharmaceutical supply chain, it is useful to understand the elements of a pharmaceutical supply chain that the country's VAN focuses on. This allows the analyst to gain an understanding of the type of policies and legislations to be included in the analysis. The output from this phase is a categorised list of country-specific policies and legislations relevant to the scope of a country's VAN. A detailed account of the steps in Phase 1 is provided.

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[1] For this step, policies and legislations are identified as two separate types of documents. Even though the rest of the PoliVAN logic uses the term 'policy' alone, the analysis process still takes other legislations into consideration as part of the analysis.

Step 1.1: Define the PLF and VAN dimensions

The main components from a PLF encompasses the functions and activities of a pharmaceutical supply chain. Even though these functions can be generically defined, as illustrated in Chapter 3, it is possible that countries might have a different framework that specifically depicts the operations of their pharmaceutical supply chain. Therefore, for this step, the PLF functions (which can be country-specific, but are not necessitated) and a country's VAN processes are defined. The VAN processes include the following: demand-, supply-, distribution planning and cold chain management (as identified in the Blueprint Reference Model). In Figure 7.4, the PLF is shown; this provides a generic framework of the operational component of a pharmaceutical supply chain, the functions within each component, and the management elements supporting these functions. Countries can either use the provided PLF as is or use it as a guide to define their own framework for pharmaceutical logistics.
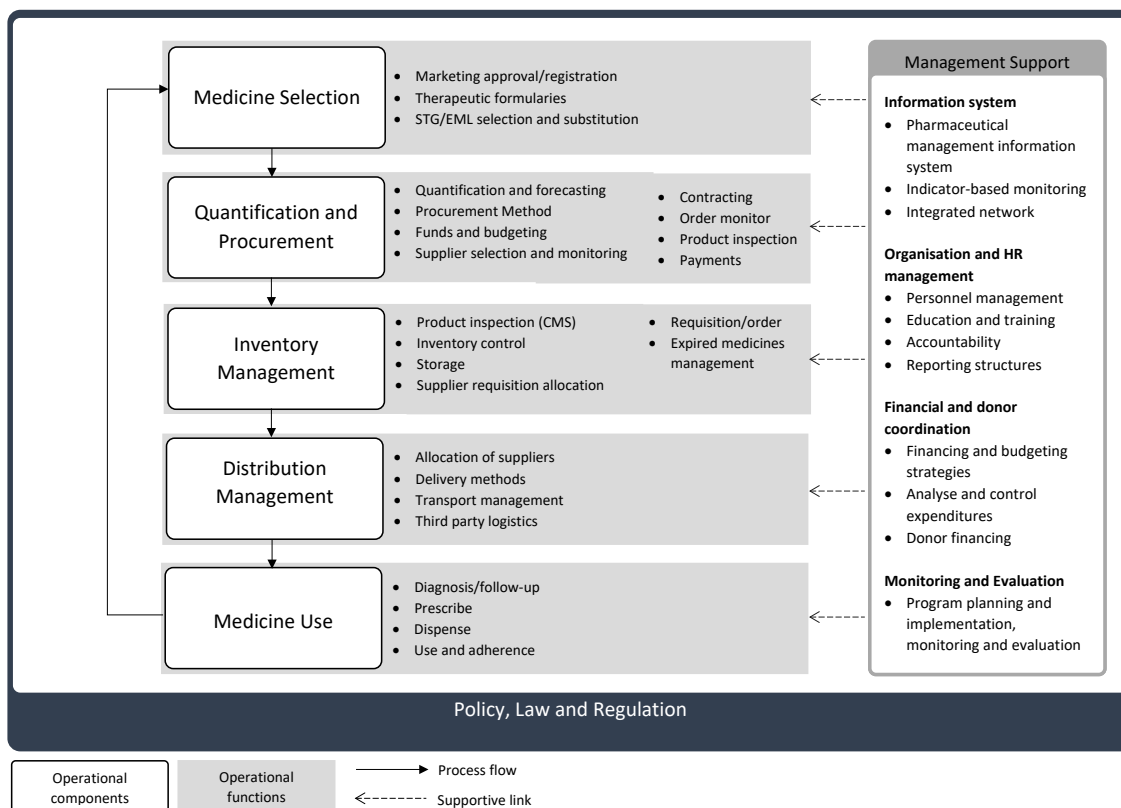
Figure 7.4: Pharmaceutical logistics framework for the PoliVAN

Step 1.2: Develop and complete the PLF-VAN-matrix

Identifying the components of a country's pharmaceutical supply chain that their VAN is designed to operate in, can facilitate the process of identifying the relevant policies and legislations

that are likely to affect the operations of a county's VAN Operating Model. Therefore, for this step, the PLF components (including its functions and supportive elements) are compared against the VAN processes from a country's VAN Operating Model. The PLF-VAN-matrix (PLF components on the vertical axis, and the VAN dimensions on the horizontal axis) is a simple tool, developed to identify the components of a pharmaceutical supply chain that a country's VAN is focused on. In order to populate the PLF-VAN-matrix, the content from a country's VAN Operating Model are used to complete the matrix. Table 7.1 provides an illustration of the PLF-VAN-matrix.

Table 7.1: PLF-VAN-matrix tool (this table provides an example for illustrative purposes)

Pharmaceutical Logistics Framework	VAN Planning processes			
Operational Components	DEMAND PLANNING	SUPPLY PLANNING	DISTRIBUTION PLANNING	COLD CHAIN MANAGEMENT
Medicine Selection				
Market approval/Registration				
Therapeutic formularies	X			
STGs / EML select and update	X			
Quantification and Procurement				
Quantification and Forecasting	X			
Procurement method		X		
Funds and budgeting	X			
Supplier selection and monitor		X	X	
Contracting		X		X
Order monitor				
Product inspection (depots/facilities)				
Payments				
Inventory Management				
Requisition / ordering		X		
Product inspection (CMS)				
Inventory control		X		X
//				
Management Support elements	DEMAND PLANNING	SUPPLY PLANNING	DISTRIBUTION PLANNING	COLD CHAIN MANAGEMENT
Information System	X	X		
Organisation and HR management	X	X	X	X
Financial and donor coordination		X	X	X
Monitoring and evaluation				

As an example, if the country's VAN is focused on the estimation of medicine quantities, and the quantification and forecasting is performed by the demand planning processes, then an indicator (such as 'X') can be placed in the cell corresponding to this specific PLF component. This indicates that the policies and legislations regarding the forecasting and quantification of medicine need to be investigated, as they might affect the VAN positively or negatively. Ultimately, the completed PLF-VAN-matrix provides the analysts with an overview of the PLF functions the country's VAN are concerned with.

Step 1.3: Use the corresponding dimensions as search criteria

In the populated PLF-VAN-matrix, each 'X' is an indicator of the types of policies and legislations to search and identify—the PLF operational functions can be used as search criteria. For example: activities within the supply and distribution planning processes (from the VAN) focus on the selection of suppliers, and this usually includes the requests for bids and awards of tenders. Certain criteria need to be met in order to identify and subsequently select the right supplier, therefore, 'supplier selection policies in medicine procurement','contract management', and 'bids and tenders' can be examples of such search suggestions (specifically for the pharmaceutical supply chain). Another example is the registration of medicines—from the example in Table 7.1, there is no process or element from the VAN that focuses on the registration of drugs, therefore, there is no need to identify policies and legislation regarding the registration processes for the selection of medicines. The types of methods that analyst(s) may use to identify, select and retrieve policies and legislation may differ, due to the access to such policies and legislation often being restricted, or not being available in the public domain. However, some common approaches to find policies are from government websites, and inputs from policy experts in the field.

Step 1.4: Organise policies accordingly

Once all the policies and legislations are identified and gathered, the next step is to categorise the legislative instruments into their legislation hierarchies. The hierarchy (shown in Figure 7.5) is a generic example of how a country's policies and legislations can be categorised (even though the structure and names of the legislations may vary between different countries and contexts). It is important to distinguish between mandatory and voluntary documents, because this has an impact on the ability for the policy to change, for example policies sit between mandatory and voluntary legislations. Voluntary legislations are much more prone to change, whereas mandatory legislation are more reluctant to change. From these steps, the objective of Phase 1 is realised; a list of categorised policies and legislations that are relevant to the country's VAN Operating Model for the different operational functions are identified.

7.3   Phase 2: Sort existing policies

The second phase in the PoliVAN is to distinguish between the policies and legislations that enable the VAN and those hindering the VAN. The goal of this phase is to assess the ability of the policy and legislative instruments—whether positive or negative, direct or indirect—to enable the operations of a country's VAN Operating Model.
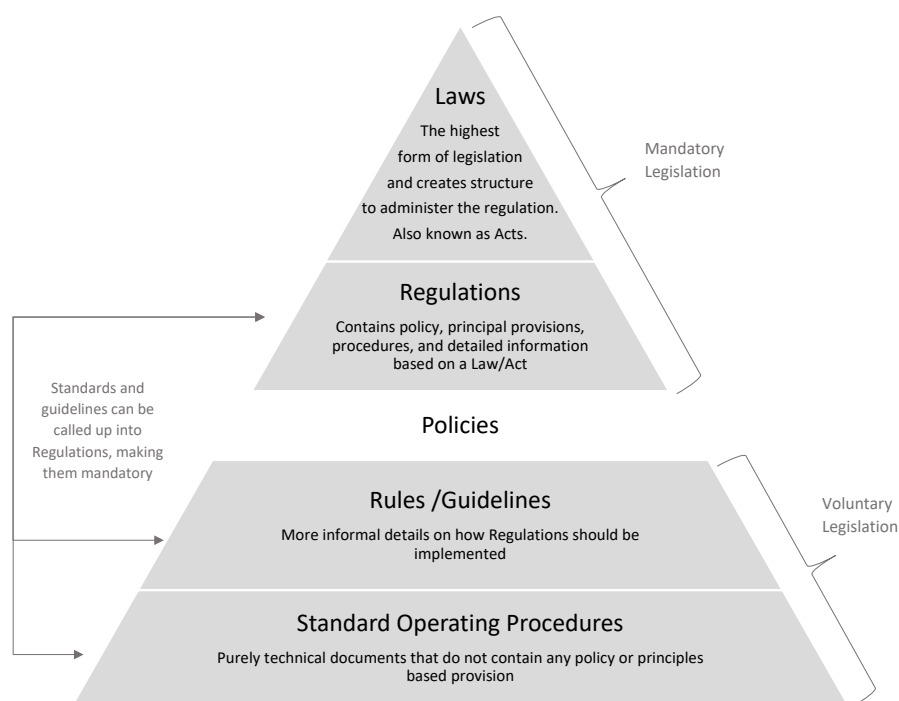
Figure 7.5: The generic policy and legislation categorisation and hierarchy

This phase uses the list of identified and selected existing country policies from Phase 1, and evaluates them against the VAN objectives and criteria in line with the country-specific VAN Operating Model. This allows for the classification of the different policies and legislations categories, and to subsequently identify policies that could potentially affect the success of the VAN. Figure 7.6 outlines the inputs, detailed steps, tools, and outputs of Phase 2. A detailed account of the steps in Phase 2 is provided. It is advised to apply this phase (following in the sequence of the next phases) of the PoliVAN in groups[1] of the operational components (i.e. medicine selection, quantification and procurement, and inventory management) in order to make the analysis manageable.

Step 2.1: Identify VAN criteria

The first step in Phase 2 is to identify VAN criteria. In order to evaluate and analyse the policies and legislations effectively, the analysis needs to be conducted according to the VAN design elements: people, process and technology. Each of these elements is designed to support the objective of a country's VAN Operating Model. Therefore, providing an exact approach according to which this method needs to be executed (for every country) can become complex and cumbersome. However, the example provided in Table 7.2 is an approach from the BPRM that can be used to assist with identifying a country's VAN criteria, and this is proposed as

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[1]This is showcased through the case study applications in Chapter 8.
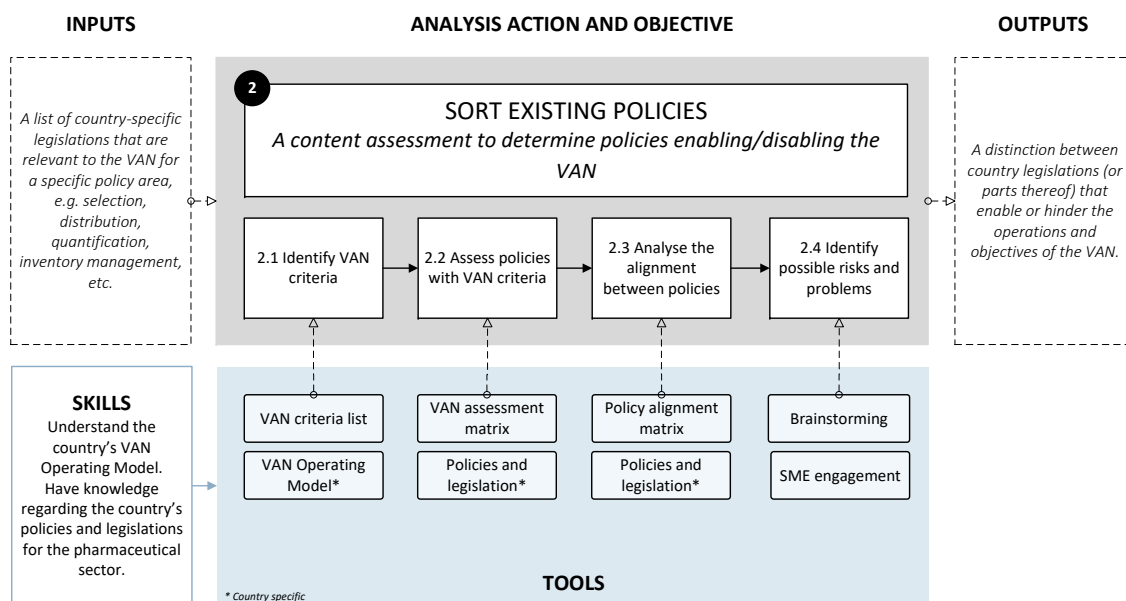
Figure 7.6: Phase 2: Sort existing policies

guidelines for this step. The approach makes use of the process name, the role responsible for the process, the frequency at which these processes must be executed, the level (location granularity, i.e. national, regional or local level) that governs these processes, and the customer of the process (those using the process as an input).

Table 7.2: Example from the BPRM regarding the details of the VAN processes

Process ID	Process name	Process description	Frequency	Locations (scale of granularity)	Responsibility	Customer
DP 1.1.1	Review previous performance	Compare data received from healthcare facility with historical trends a (make changes if required)	Monthly	Regional level	Supply chain analyst	Supply chain analyst/ country demand planner
DP 1.1.2	Update Expected demand data	Healthcare experts/facility representatives need to update expected demand data in a system or excel-based tool	Monthly	Regional/local level	Healthcare experts/facility representatives	Supply chain analysts
DP 1.1.3	Non receipt of expected data and consider historical data	In case of trend data not updated by health facilities, escalate to MoH and consider historical demand for statistical forecasting	Monthly	Regional level	Supply chain analysts	MoH
...	...	...	...	...	...	...

When the example in Table 7.2 is considered for a VAN Operating Model, that is designed to be an analytics network with end-to-end visibility across the supply chain, it is clear that the technology element (the information system) plays a critical role in achieving this objective. Therefore, the technology system, tool, or software to be used for the different processes can be included in the 'criteria list'. Table 7.3 provides a generic table that can be used to populate a country's VAN process, and to subsequently formulate the VAN criteria. The content in each list will vary between different countries. In the case where a list does not already exist for the

country, the headings can be used as a guide to develop such a list. The outcome of this step is a list of VAN criteria that can be used in Step 2.2 to assess whether country policies and legislations enable or hinder the country's VAN Operating Model.

Table 7.3: Adapted approach to the generic VAN criteria list

Process ID	Process name	Process description	Frequency	Locations (scale of granularity)	Responsibility	Customer	Software/Tool
ID for the activities in the planning process maps, e.g. DM1.1 for the first sub-component in Demand Planning.	The name of the process / sub-process indicated by the process ID.	A description of the activity.	The frequency at which the process is updated or performed, i.e.: - Annually - Monthly - Weekly - Daily	The scale of the application (national, regional, district, or local).	The role responsible and / or accountable for the process activity (process owner).	The role that needs to be informed and / or consulted by the process.	The system software or tool planned to be used for the process activity (if any).

Step 2.2 Assess policies with VAN criteria

Given the list of VAN criteria developed in the preceding step, Figure 7.7 illustrates a matrix tool developed for the content assessment between a country's VAN and the policies identified in Phase 1. On the vertical axis are the VAN criteria developed to assess whether current policies from a country support or oppose the VAN operationalisation, and on the horizontal axis are the existing policies and legislations from Phase 1 (categorised according to the legislative hierarchy, shown in Figure 7.5). This content assessment approach is based on a study done by Barant *et al.* (2016), that used a correlation approach to represent the links (complementary and conflicting) between policy instruments and their objective in matrices (similar to Figure 7.7), as part of the Regional Land Use Project[1].

There are various approaches to assess how well the content of the legislations align with the criteria from the VAN. The study by Barant *et al.* (2016) developed four categories of how the policies could support the RLUP project: (1) directly supportive; (2) indirectly supportive; (3) ambiguous; and (4) very indirect or neutral. Each category is assigned a unique symbol to be used in the matrix to identify the specific relationship. The four categories presented by Barant *et al.* (2016) are used as a guideline on how to categorise the alignment between country-specific policies and legislations, and the VAN criteria. The outcome of this step is to determine which policies enable or hinder the country's VAN Operating Model; however, this analysis of policies could be complex in some instances as the impacts of policies and legislation instruments are not always easily identifiable or categorical—in some cases a policy can support the initiative, e.g. VAN, but parts of the policy do not in their entirety support the VAN. Therefore, another category is added to the content assessment matrix, namely

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[1]The Regional Land Use Project (RLUP) is an attempt to translate the Scottish Government's Land Use Strategy to the regional level (Barant *et al.*, 2016).

←——— Existing legislations relevant to the scope of a country's VAN Operating Model for a specific policy area. ———→

Policy Area This is the area (from the PLF) on which the policy analysis is focused.	Legislative instruments													
	SOPs/Guidelines			Policies			Regulations			Acts /laws				
	Legislative instrument 1	Legislative instrument 2												Legislative instrument n
			⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮			
Group the VAN criteria into individual process activities, or into operational functions; however, the assessment should focus on the process objective, frequency, scale (location granularity), responsibility, customer, and/or the system tools.														

Figure 7.7: The VAN content assessment matrix

'facilitate'. This category designates legislations that does, on the whole, support the VAN criteria, but which also contains little detail that require reform. The proposed categories are illustrated in Figure 7.8.

E	**Enabling the VAN operationalisation :** The legilsation support the VAN model, and no reform is required.
F	**Facilitating the VAN operationalisation :** The legislation supports the VAN model, however there are aspects that requires reform.
—	**Hindering the VAN operationalisation :** The legislation does not support the VAN model, and the implementation of the VAN model could have consequences.
?	**Ambiguous:** The impact of the legislation on the VAN model cannot be determined because it depends on too many factors.
0	**No impact on the VAN operationalisation:** The legislation has either no relationship or too much of an indirect relationship with the VAN.

Figure 7.8: The VAN content assessment indicators

According to Barant *et al.* (2016), "the aim of this analysis is...to reflect the intentions of the policies." Therefore, it is important to stick to the policy and not to go too far in the reasoning even if everything is intertwined (Barant *et al.*, 2016). Once the policies and legislations are assessed and categorised according to their 'supporting' category, a clear indication of the policies that could potentially influence the operation of the VAN are identified, as well as the nature of their influence on the operationalisation of the VAN. This allows the analyst to gain an understanding of which policies should undergo analysis and possible reformula-

tion. However, changing the content of one policy or legislation might impact other policies or legislations. Therefore, in the next step an approach to understanding the influence different policy and legislation documents have on one another is presented.

Step 2.3: Analyse the alignment between policies

This step highlights the synergy, and level of synergy between policies and legislation. This is done by comparing all the policies and legislation documents identified in the analysis in Phase 1 with each other. Policy and legislation documents usually identify the regulatory framework in which the policy or legislation is developed (i.e. the regulation or law). This type of analysis can assist with the identification of complementary and conflicting interests when the reformulation of a policy or legislation is considered. The developed alignment matrix that has been developed to facilitate this analysis allows for the listing of each document on both axes, and then a scoring indicator (similar to the approach in Step 2.2) is used to identify and define the relationship. In Figure 7.9, a generic example of the alignment, with the scoring indicators, is shown.

	Policy 1	Policy 2	Policy 3	⋮	⋮	Policy n
Policy 1		S	L/N	L/N	S	S
Policy 2	S		A	A	A	S
Policy 3	S	S		A	A	S
...	A	A	S		L/N	A
...	S	A	L/N	L/N		A
Policy n	S	L/N	A	A	A	

S	**Strong Alignment** The two policies are synergistic as their objectives, targets, or the influence on the pharmaceutical supply chain are perfectly aligned.
A	**Alignment** The objectives, targets, or the influence on the pharmaceutical supply chain of the two policies under consideration are moderately aligned.
L/N	**Little to No Alignment** The objectives, targets, or the influence on the pharmaceutical supply chain of the two policies under consideration are not aligned or are only marginally aligned.

Figure 7.9: The VAN alignment matrix and alignment indicators

It should be kept in mind that the alignment matrix is not a mirror image, due to the hierarchy and levels in which different policies and legislations are embedded. For example, a policy can be called upon within a regulation or higher law, i.e. an Act. Therefore, if some changes are required to be made, it is most likely possible that it is regulated by one or more legislation and has a strong alignment. However, if a regulation is in need of a reform, then it is less likely to have an effect on standard operating procedures (SOPs) or guidelines, because regulations govern at a higher level. Ultimately, the alignment matrix should also be populated with the context of the analysis in mind; meaning, if the focus is on distribution

management, then the alignment factors should be focused on the content of the distribution functions within the policy or legislation documents.

Step 2.4: Identify possible risks and problems

The analysis of the content assessment matrix (Step 2.2) and the analysis of the alignment matrix (Step 2.3) both provide insight into: (i) policies supporting and not-supporting a country's VAN operations; and (ii) the effect that (re)formulating policies might have on other policies or legislations. From this, possible risks or unintended consequences can be identified to determine the specific policy problem areas.

7.4 Phase 3: Policy formulation

Phase 3 of the PoliVAN concerns the formulation of policy options (drafts) and their alignment with a country's VAN Operating Model and the objectives of the VAN initiative. This phase is triggered by two conditions: (i) policies or legislations for a specific part of the VAN model do not exist in the country's policy and legislation landscape (route *b* from Figure 7.1); or (ii) policies and legislations exist, however, they require reform based on the outcome from Phase 2 (route *c* from Figure 7.1). Policy (re)formulation is one of the four main building blocks of the policy analysis process, and assumes that participants in the policy analyses and/or (re)formulation process have already identified and defined a policy-related problem (Peters & Pierre, 2006); the problem is identified, as mentioned above, in Phase 2.

As discussed in Section 4.2.1, policy formulation requires both policy design and policy tools (Peters & Pierre, 2006). Policy design is considered a process preceded by multiple policy choices, the design of new policy alternatives, and selecting the best policy for adoption. Policy tools are the models used to enact the policy design concept (Peters & Pierre, 2006), and examples of such tools include: scenario planning to predict future problems; tools to identify and recommend policies such as cost-benefit analysis, cost-effectiveness analysis, and multi-criteria decision analysis; and problem structuring tools, e.g. brainstorming.

Figure 7.10 presents the third phase in the PoliVAN. There is no universally accepted method for policy formulation, due to country-specific and problem-specific contexts; however, policy formulation steps proposed by Bryan & Jones (2006); Hanzl *et al.* (2003); Sidney (2006); and Turnpenny *et al.* (2015) are combined and used in the PoliVAN (Phase 3 steps) as a guide on how to identify and formulate policy options, given a certain problem.

Based on the formulation methods and tools from the studies of the aforementioned authors, the steps for Phase 3 include: problem analysis; specification of policy objectives; policy option development; and policy design. The policy option development step, i.e. formulated and/or reformulated policy options for a specific policy area that required analysis are used as
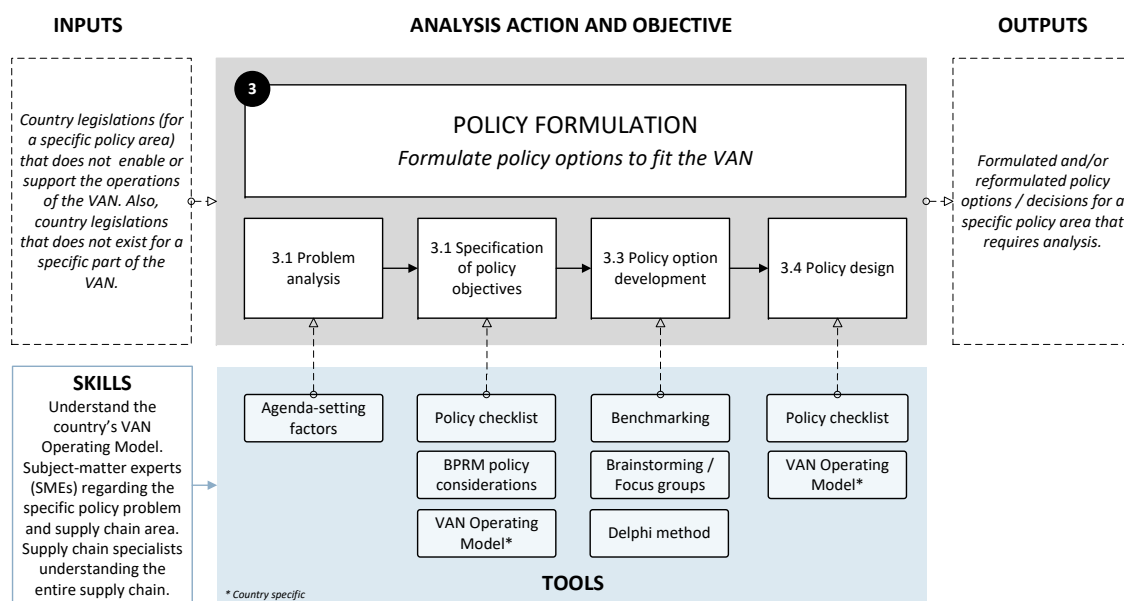
Figure 7.10: Phase 3: Policy formulation

input into the stakeholder analysis (Phase 4) and policy impact analysis (Phase 5), to identify the most appropriate and applicable policy decision. The policy design step makes use of a policy formulation checklist to design the details of each policy option for the analyses in Phases 4 and 5. The policy checklist is then used to rigorously design the details of the policy decision to subsequently strategise policy adoption, implementation and evaluation (Phase 6).

Step 3.1: Problem analysis

The first step of Phase 3 is the analysis of the policy-related problem—using evidence-based information gathered from Chapters 1, 2 and 3, regarding the cause of the problem. In this case, 'problem' refers to the fact that current country legislations do not entirely enable, or otherwise hinder the VAN model (output from Phase 2). The problem analysis step is an extension from the agenda-setting process discussed in Section 4.2.1 (Turnpenny *et al.*, 2015), which provides an indication of conditions that give rise to the policy problem. Insight into the cause (conditions) of the problem can be gained through understanding the following factors: (i) the context of a country and its pharmaceutical supply chain processes; (ii) a comprehensive understanding of the VAN and its objectives for the country's pharmaceutical supply chain; and (iii) the operational functions[1] that are inputs or outputs of the function(s) relating to the problem. Understanding the context of the country, and how the pharmaceutical supply chain operates for the specific policy area, can contribute towards understanding the problem.

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[1] Referring to the pharmaceutical logistics framework (PLF).

Step 3.2: Specification of policy objectives

To develop policy options for either a policy reform or to formulate a new policy, the policy objectives need to be specified. Essentially, this entails setting out desired outcomes or objectives that the specific policy, legislation, or part thereof, aims to achieve. Therefore, the analyst requires a comprehensive and in-depth understanding of the country's VAN Operating Model, and the context and circumstances in which the country operates. Setting out the objectives is country-specific and policy problem-specific. Ideally, from a VAN perspective, the objectives should be in line with the visibility[1], analytics[2] and network[3] objectives of the VAN initiative.

Step 3.3: Policy option development

The previous step serves as foundational input into this step, where problem objectives are required to formulate policy options that aim to solve the problems identified in Phase 2. In this step, the analyst(s) needs to formulate different policy options and decisions. Benchmarking, brainstorming, the Delphi[4] method, and expert engagement techniques are examples of tools and techniques that can be used to define the problem objectives as well as develop policy solutions to the policy-related problem. The BPRM provides a high-level overview of governance considerations for a VAN, as discussed in Subsection 2.2.4, which can be used, in combination with the policy objective, for the development of policy alternatives.

Step 3.4: Policy design

Shung-King (2004) developed a policy checklist that enables policy analysts to ensure that the correct information is provided in a policy design and subsequently, a policy document. Shung-King's (2004) policy checklist is available in Appendix H. This policy checklist is adapted for the VAN context and the nature of the analysis at hand, and subsequently included as part of the PoliVAN. Figure 7.11 provides the policy formulation checklist for the PoliVAN that assesses the important aspects of what is required in a policy, adapted for a VAN Operating Model.

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[1]Provide end-to-end visibility of what happens and how well it happens in the entire pharmaceutical supply chain network (Goel & Llewellyn, 2015)

[2]Utilise highly skilled supply chain experts to perform analytical processes and operational plans to optimise the system.

[3]Continuous improvement of problem resolution processes, conditional actions and standard operating procedures (SOPs) (Goel & Llewellyn, 2015).

[4]The Delphi method uses the opinions of a limited group of experts or people who have knowledge of the subject from their experience by means of anonymous questionnaires. The group of experts work towards a consensus, through step-by-step feedback of information, by repeating the question and providing feedback on each other's answers (Hsu & Sandford, 2007).

A VAN POLICY OBJECTIVE AND FORMULATION CHECKLIST

The policy option aims to support either of the VAN objectives:

- ☐ End-to-end visibility: data aggregation from multiple sources bringing end-to-end visibility across health commodities and programs, and ultimately the entire value chain.
- ☐ Analysis and insight: analytical processes to create operational plans, and optimise the system.
- ☐ Continuous improvement: standardised problem resolution processes, conditional actions, and SOPs used to solve challenges and implement ongoing improvements.

Operational functions (process element):

- ☐ Scope of intended activities
- ☐ How it fits into the planning process category in which it operates (demand-, supply-, distribution planning, and cold chain management)
- ☐ The link to the rest of the supply chain
- ☐ Level of frequency of intended activities

Organisational structure (people element):

- ☐ Process owner of intended activities (VAN role)
- ☐ Stakeholder roles and responsibilities
- ☐ Location granularity (national, regional, or local)
- ☐ The link to existing country roles (non-VAN roles)
- ☐ Reporting lines among the different roles and levels

Information system (technology element):

- ☐ Data requirement for intended activity
- ☐ Software/tool to be implemented/used
- ☐ Interoperability
- ☐ Data transparency

Monitoring and evaluation:

- ☐ Strategical outcomes
- ☐ Continuous improvement plans
- ☐ Key performance indicators (KPIs)

Human resource development:

- ☐ Education, training and/or skill development
- ☐ Workforce capacity (hire, deploy, retain, motivate, etc.)

Financial and donor coordination:

- ☐ Financial sources
- ☐ Budget allocation and update
- ☐ Disbursement (release of funds)

Figure 7.11: A VAN objective and policy formulation checklist

Once the policy options are formulated, the best policy option needs to be considered for the final policy design, adoption and implementation. Selecting the best policy option from a set of possible solutions, involves applying some set of criteria to the policy alternatives, for example judging their feasibility, political acceptability, costs and benefits, to determine the impact the different options might have on the system. It has become evident (as discussed in Section 4.3) that stakeholders have a great deal of influence when it comes to the adoption and implementation of a policy. Therefore, before selecting the best policy option, a stakeholder analysis is required. Before the best policy option is considered in this analysis, a stakeholder analysis (Phase 4), and a policy impact analysis (Phase 5) need to be conducted. Once the outcome of these two analyses have provided insight into what the best policy option is, then the policy option needs to be developed through a policy design process (making use of the tools provided in Phase 3), and subsequently a process of developing an implementation plan (Phase 6).

7.5   Policy domain

The policy domain indicates a transitional phase between policy formulation and the stakeholder- and impact analysis (Phases 4 and 5). The policy domain is an indication that the policy options developed in Step 3.4 are inputs to both Phases 4 and 5. In the case when the analysis does not provide any desired outcomes from the policy choices (Phase 3), then either the dimensions used in the analysis (Phase 5) need reconsideration, or the condition under which the policy options were formulated (Phase 3) requires adjustment (referring to the objectives chosen for the policies, or the actors involved in the formulation and analysis process). Once the stakeholder analysis (Phase 4) and policy impact analysis (Phase 5) provides promising outputs for a (re)formulated policy, the policy checklist can be revisited to thoroughly design and complete the (re)formulated policy content.

7.6   Phase 4: Stakeholder analysis

The SHA is a key part in the policy analysis process, that allows policy analysts, government officials, VAN role players, and relevant key stakeholders to gain insight into how different actors and stakeholders in the system might react to policies. The process for conducting the SHA in the PoliVAN is a combination of the best practices SHA models discussed in Section 4.3. Figure 7.12 illustrates the process for the stakeholder analysis in the PoliVAN. The inputs for this step are the (re)formulated policy options (Phase 3) that have been identified as relevant from the policy domain. Once the SHA is complete, stakeholders to involve or exclude from the policy development and implementation processes, including those that need to be monitored

whom might be opposed to the policy ideas, will be identified. A detailed account of the steps in Phase 4 is provided in the following sections.
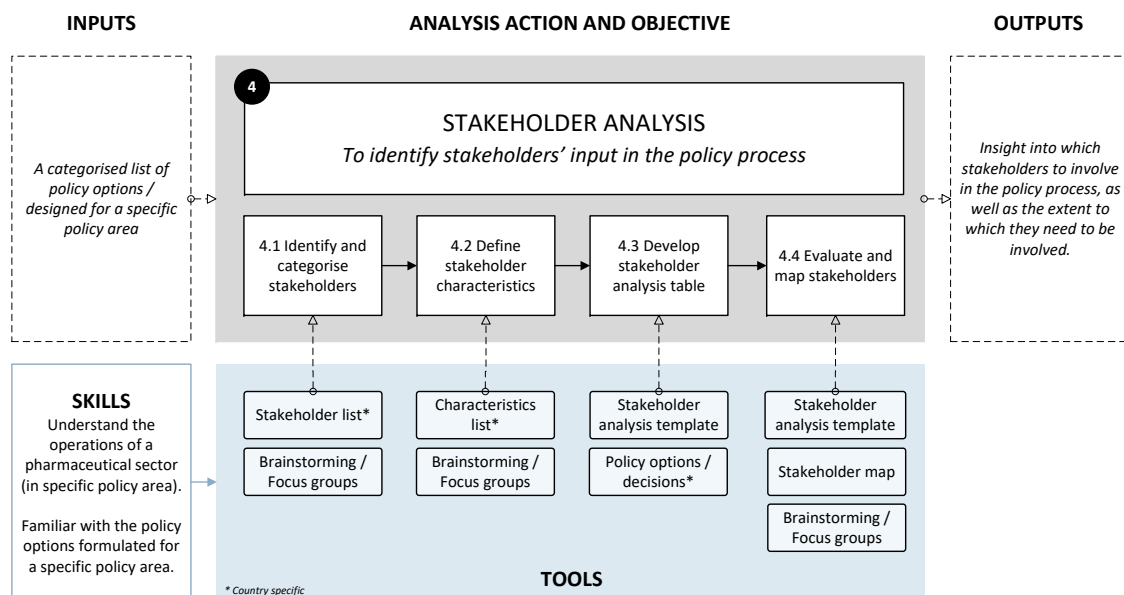
Figure 7.12: Phase 4: Stakeholder analysis

Step 4.1: Identify and categorise stakeholders

The first step of the SHA is to identify and categorise the possible stakeholders[1] with a vested interest in the policy being proposed. The identification and categorisation of stakeholders can be done by means of the following techniques: brainstorming; individual research; focus groups; semi-structured interviews; and snowball-sampling. These methods on how to gather data are mentioned and described in Appendix I. A generic list of possible stakeholders is presented in Table 7.4—these are either individuals, groups or organisations.

This list of stakeholders presented in Table 7.4 is a guide that facilitates the selection of relevant stakeholders to consider in the analysis. These can be actors who could possibly be interested in the policy, but have nothing at 'stake' in the process (Lehmann, 2016). The stakeholders can also be among those formulating the policies; those that influence policies; implements policies; and/or benefit from the policies. However, stakeholders have to be selected according to their relevance to the policies under consideration, within the context of the country applying the PoliVAN.

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[1]All references to 'stakeholders' in the remainder of Section 6.6, should be understood to also include 'actors'. (The distinction between these terms, as used in this research was set out in Subsection 4.2.2.1)

Table 7.4: Stakeholder identification and categorisation list

STAKEHOLDER IDENTIFICATION	
INDIVIDUALS, GROUPS, ORGANISATIONS	EXAMPLE OF POSSIBLE STAKEHOLDERS
International influencers	World Health Organisation (WHO), United Nations (UN), etc.
NGO (non-government organisation)	Funding agencies, donor organisations, health programmes, etc.
Government	Ministry of Health, Ministry of Finance, and other relevant departments.
Ministerial appointed committee	Task teams appointed by the Government to analyse and investigate healthcare sector or pharmaceutical-related issued.
Health sector level	National, regional, district, and local levels of the healthcare sector.
VAN roles	Process planners, supply chain analysts, budget holders, liaisons, etc.
Public sector	Primary healthcare facilities, hospitals, central medicines stores, etc.
Private sector	Distributors, wholesalers, clinics, pharmacies, hospitals, etc.
Third party services	Transport services, non-government owned information system services, suppliers, etc.
Beneficiaries	Patients
Media	Newspapers, television news, radio, social media, etc.
Societies	Politicians, councils, academia, etc.

Step 4.2: Define stakeholder characteristics

Once the stakeholders are identified, the characteristics that will be used to evaluate their effect and/or influence on a specific policy have to be ascertained. A list of possible, but not exhaustive, characteristics and descriptions that can be used to facilitate the evaluation is provided in Table 7.5. The selection of characteristics depends on what the analyst wants to analyse about each stakeholder. The list is based on previous studies, including recommendations from the expert engagement workshop (discussed in Subsection 6.3); however, the list can still be elaborated on as the PoliVAN is applied over time. To assist with this evaluation step, each stakeholder is listed against the characteristics selected (similar to the table in Appendix J) and described according to these characteristics (Table 7.6). This allows the analysts to get a better understanding of the stakeholders' characteristics within a specific policy context (i.e. their skills, knowledge, personality, occupational position, reputation, political status, etc. (Lehmann, 2016)). It is suggested that a table similar to Figure 7.6 be completed in a focus group or brainstorming session, in order to have comprehensive descriptions of each stakeholder that are as unbiased as possible.

Step 4.3: Develop a stakeholder evaluation table

This step consists of developing the evaluation table for the analysis. The most prominent method for a stakeholder analysis is discussed in Section 4.3. This is the quantifiable SHA model developed by Abdrabo & Hassaan (2007) (refer to Appendix J for a comprehensive explanation of this model). The SHA model measures the characteristics in quantifiable units

Table 7.5: Stakeholder characteristics

STAKEHOLDER CHARACTERISTICS	
CHARACTERISTIC	DESCRIPTION
Position and organisation	Position the stakeholder has and the organization that he/she works for, e.g. director, manager, head of department, etc.
Knowledge of policy scope	The level of accurate knowledge the stakeholder has regarding the policy under analysis.
Interest	The interest the stakeholder has in the policy, regardless of whether he/she is impacted by the policy or not.
Level of support	Determined by how the stakeholder is impacted by the policy (positively or negatively).
Attitude	A stakeholder's attitude is determined by the level of interest he/she has in a policy area combined with how they are impacted by the policy (positively or negatively). This is a combination of the level of support and the interest of a stakeholder.
Resources	Resources can be of many types—human, financial, technological, political, and other. The analysts should consider the stakeholder's access to all of these resources.
Power (influence)	Power refers to the ability of the stakeholder to affect the implementation of the health reform policy due to the strength or force the stakeholder possesses.
Opinion leaders	The leadership ability to initiate, convoke, or lead an action for or against the health reform policy. A leader (group) that is held in high esteem by a cultural setting who accepts their opinions.

Table 7.6: Illustration of the table to list stakeholders and discuss their characteristics

STAKEHOLDERS (Relevant to the policy analysis area)	CHARACTERISTICS					
	C1	C2	C3	...	...	Cn
Stakeholder 1						
Stakeholder 2						
Stakeholder 3						
⋮						
⋮						
Stakeholder n						

in order to understand which stakeholders to involve (or deliberately exclude) in the policy development and implementation processes. The SHA model is adjusted to fit the objectives of PoliVAN, meaning, factors regarding a VAN Operating Model are included in this specific analysis. Table 7.7 presents an example of what the PoliVAN SHA model could entail, with the measuring scale to be used. The characteristics chosen for this example do not indicate the only characteristics that can be selected for a stakeholder analysis. It should be noted that, given the specific context and objectives of a VAN Operating Model, the SHA could vary; and thus Table 7.7 can be used as a guide to develop a case-specific SHA model.

Figure 7.13 provides instructions on how to develop a measuring scale from the different stakeholder characteristics. The proposed range (a 3-point or 5-point Likert scale) of the

Table 7.7: Stakeholder analysis evaluation table

POLICY CLASSIFICATION		EVALUATION CRITERIA							DECISION STRATEGY	
Policy Typology	Stakeholders	Position	Attitude (A)	Resources			Power	Opinion leader	Map stakeholders	
				H	F	P				
Policy area under analysis	S1	Internal / External	= (Knowledge + Interest) * Support	= sum(human + financial + political)			Score based on given criteria	Yes / No	Challenging factors	
	S2								Attitude vs. Power	Attitude vs. Opinion Leaders
	S3								Complimenting factors	
	…								Power and position	Power and Resources
	…									
	Sn									

measuring criteria can be altered based on the analysts' preferences; however, the proposed scale provides a guideline for how stakeholder characteristics can be evaluated. The outcome of this step is to set up an SHA evaluation table that is subsequently used in Step 4.4 to analyse the stakeholders' reaction towards the policy options formulated in Phase 3.

INSTRUCTIONS TO EVALUATE STAKEHOLDER CHARACTERISTICS

POSITION IN ORGANISATION

Identifying the position of stakeholders in the organisation is useful when developing a stakeholder position map for policy-makers and government officials. The position of a stakeholder can either be:

- Internal: Stakeholders that participate in the operations of the pharmaceutical supply chain
- External: the rest are external stakeholders, e.g. the media, who is able to support in terms of their knowledge or opinions.

Different levels to consider:
- Directorate (Ministry of Health, Ministry of Finance, etc.)
- Department head (national, regional, or local government)
- Managerial position (warehouse, hospital, depot, etc.)
- Facility representative
- Staff level

KNOWLEDGE OF POLICY SCOPE

This is the level of knowledge a stakeholder—whom is involved, interested, or impacted by the policy—has on the scope of the policy area under analysis. This also refers to the level of knowledge regarding the VAN Operating Model and its intentions. The level of knowledge has two parts to consider:
- Knowledge regarding the policy under analysis: 3 = high; 2 = moderate/some; 1 = none.
- Knowledge regarding the country's VAN Operating Model: 3 = a lot; 2 = some; 1 = none.

Figure 7.13: Instructions to evaluate stakeholder characteristics

INTEREST

This refers to the level of interest the stakeholder might have on the policy area, regardless of whether he/she is impacted. The level of interest follows the following scale:

0 = neutral/not interested; 1 = slightly interested; 2 = moderately interested; 3 = interested; and 4 = very interested.

LEVEL OF SUPPORT

The level of support is determined by how the policy under consideration would affect/impact the stakeholder when implemented, such as positively/support (+), or negatively/oppose (-).

ATTITUDE

The attitude characteristic is a combination of the stakeholder's interest in the policy area and the level of support. Multiplying the interest scale with the (+)- and (-)-factor gives the following scale:

Highly oppose		Moderately oppose		Neutral		Moderately support		Highly support
-4	-3	-2	-1	0	1	2	3	4
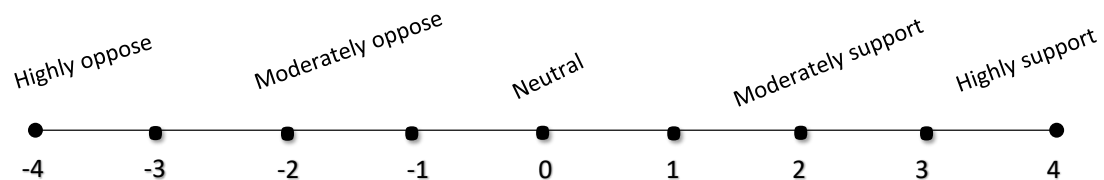
RESOURCES

This characteristic refers to the stakeholder's access to resources, which can be of many types—financial, political, human, technology, etc. The **quantity** of resources can be scaled according to the following:

- 3 = many resources
- 2 = some resources
- 1 = few resources
- 0 = none

POWER

The power of a stakeholder is his/her ability to affect the implementation of the policy under consideration. The power can be measured as: 3 = high power; 2 = medium power; 1 = little power; 0 = no power.

OPINION LEADERS

The ability to change the opinion of those valuing his/her opinion. This can be indicated by either `yes' or `no'.

The above characteristics and evaluation instruction, is provided to give the analyst the best possible idea of how to analyse stakeholders. If the analyst choose to change the scale, it is possible; however, the analyst should keep in mind the consistency of the evaluation. The characteristics affecting one another.

Figure 7.13 continued from previous page

Step 4.4: Evaluate and map stakeholders

In this step, the analyst need to complete the SHA table and give a score to the stakeholders accordingly. This can either be a comprehensive score discussed in, for example, a brainstorming environment, or an average score from multiple analysts. Once the score for each stakeholder is determined, the analyst will have insight into which stakeholders to involve or exclude from the policy development and implementation process. The score should also indicate the extent of involvement for each stakeholder, i.e. who to include in the decision-making process, who to consult (take opinion into consideration), and who to inform (but not take their opinion into consideration). Another way[1] to indicate the extent of the involvement is through the stakeholder decision strategy map illustrated in Figure 7.14.
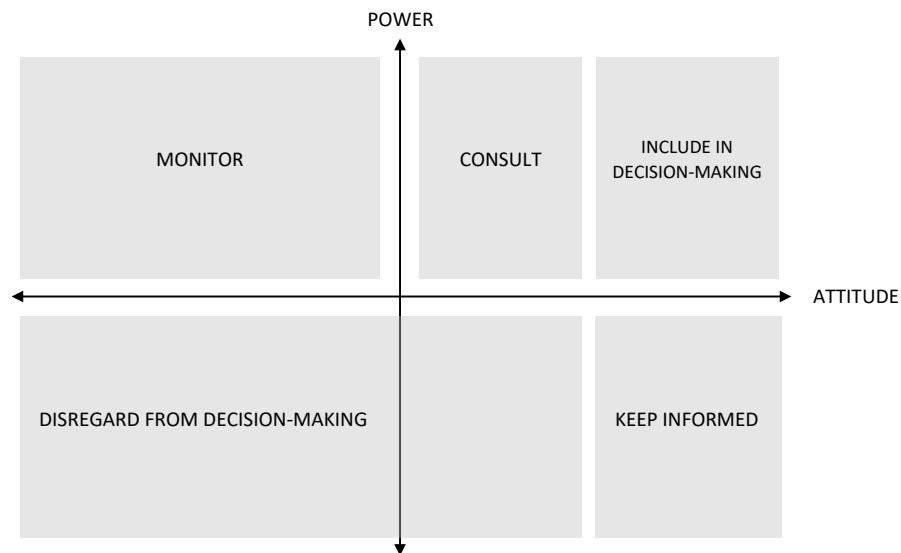
Figure 7.14: The stakeholder decision strategy map

The decision strategy map illustrates the relationship between, for example, the attitude and power of a stakeholder, with the extent of involvement (as shown in in the shaded sections in Figure 7.14). The decision strategy map is divided into quadrants, similar to the methods from other studies (Islamy, 2008; Mayers & Vermeulen, 2005) that aim to map stakeholders relative to their characteristics. The extent of involvement is defined within each quadrant. In the top right quadrant, the extent of involvement is described to engage stakeholders in the decision-making process—either to include the stakeholders or just to consult them for their opinion. Therefore, this decision strategy map provides the analyst with a range of options, indicating that there are still decisions the analyst has to make regarding stakeholder engagement.

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[1]There are a number of methods that can be used to analyse stakeholders; it is dependent on what the analyst wants to know (Islamy, 2008; Mayers & Vermeulen, 2005).

In some cases, a stakeholder has high power or authority to influence a policy decision, but has a negative attitude towards a policy being considered. On the stakeholder map, this stakeholder will be placed in the top left quadrant; meaning, that a strategy should be considered to keep this stakeholder satisfied through means of consultation, to avoid unforeseen consequences when adopting a policy. Thus, the stakeholder map provides an informative visual approach to include in a policy plan for analysts who partake in the design, development and implementation the policy. In conclusion, Phase 4 of the PoliVAN will provide the analyst with insight into which stakeholders to involve in the decision-making process for the adoption and implementation of new policies. It also provides insight into the power, interests and influence that a stakeholder might have on a certain aspect of the VAN Operating Model and the policy relative to that part. The results and outcome from this step (combined with the results from Phase 5) can then be used to construct decision strategies for the purpose of policies regarding the VAN project and operational model.

7.7   Phase 5: Policy impact analysis

The final analysis phase in the PoliVAN is a policy impact analysis. This is a multi-criteria decision analysis that takes into account the policy considerations from Phase 3, as well as the stakeholders' perception of those policies from Phase 4, and uses analytical dimensions to determine the impact these policies might have on the pharmaceutical supply chain. The analysis can be used to: inform decision-makers; promote the adoption of a policy; or compare policy options. Figure 7.15 illustrates the steps, the inputs and the outputs for Phase 5.
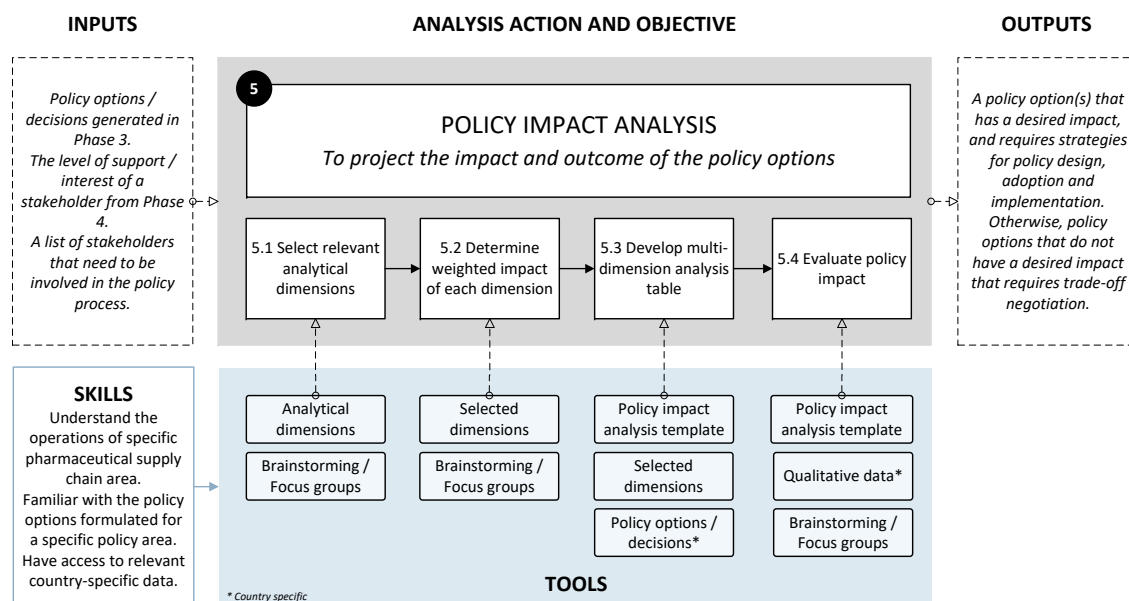
Figure 7.15: Phase 5: Policy impact analysis

Step 5.1: Select appropriate analytical dimensions

Analytical dimensions are used to determine the impact the policy options might have on the pharmaceutical supply chain. In Subsection 4.2.2.2, Morestin (2012) provides six analytical dimensions against which policies should be assessed, and groups them in two categories: 'effects' and 'implementation'. The analytical dimensions are adapted and modified (according to feedback from the validation workshop) to fit the objectives of the PoliVAN. Table 7.8 identifies and describes the analytical dimensions that can be used to analyse policy options. Methods on how the information regarding the different dimensions can be gathered are summarised in Appendix I, which includes individual research, brainstorming, expert engagement and literature review.

Table 7.8: Analytical dimensions

POLICY IMPACT ANALYTICAL DIMENSIONS		
CATEGORY	DIMENSIONS	DESCRIPTION
EFFECT	Relevance	Does it support or oppose the content and objectives of the VAN? To what extend is the policy appropriate for the objectives of the VAN?
	Unintended effects	What is the probability of unforeseen consequences of this policy?
	Contextual factors	These are factors relating to macro (i.e. social, environmental and political) and micro (i.e. health outcomes and organisational structure) contexts.
	Criticality	What is the impact the policy option has on the pharmaceutical supply chain landscape?
IMPLEMENTATION	Feasibility	The feasibility of a policy in terms of technical and operational factors. How feasible is the policy option for the country's infrastructure?
	Cost	The availability of funds for the adoption, implementation, and execution of the policy.
	Time	What is the expected time to implement such a policy option?
GOVERNANCE	Acceptability	The input gathered from relevant stakeholders on whether they support or oppose the policy option.
	Legal coherence	Do other governing legislative instruments support the policy? How well do policies within the same landscape (i.e. health) support the policy option? Does it require a mandatory legislation to extensively change?

Step 5.2: Determine weighted impact of each dimension

The multi-criteria decision analysis approach uses the analytical dimensions selected from Table 7.8 and scores the policy options, using the predefined measuring scale (Figure 7.9). It consists of attributing a weight to each analytical dimension and then calculating the entire score across all dimensions for the specific policy option (Larsson & Ibrahim, 2015). A weight in the form of a percentage is given to the analytical dimension based on its importance (according to the decision-maker's preferences).

Table 7.9: A policy impact scoring example

METRICS AND SCORES FOR POLICY IMPACT ANALYTICAL DIMENSIONS				
CATEGORY	DIMENSIONS		METRIC UNIT	DIRECTION OF PREFERENCE	WEIGHTED SCORE
EFFECT	Relevance	Is it relevant to the VAN objectives?	☐ Yes ☐ No	Yes	*W1*
	Unintended effects	Probability that the policy will produce unintended effects	$0 \rightarrow 1$	↓	*W2*
	Contextual factors	To what extent do these factors (social, economic, or political) influence the policy options?	4 = High 3 = Moderate 2 = Low 1 = No influence	↓	*W3*
	Criticality	How much does the policy affect the rest of the supply chain?	3 = A lot 2 = Some 1 - None	↓	*W4*
IMPLEMENTATION	Feasibility	The level of feasibility from a technical, operational, and/ or workforce perspective?	5 = Very high 4 = High 3 = Moderate 2 = Low 1 = Very low	↑	*W5*
	Cost	The cost implications the policy option might have.	3 = Costly 2 = Moderate 1 = Cost- effective 0 = No cost	↓	*W6*
	Time	The time before the policy is implemented.	3 = years 2 = months 1 = weeks	↓	*W7*
GOVERNANCE	Acceptability	The level of support from stakeholders	5 = Very high 4 = High 3 = Moderate 2 = Low 1 = Very low	↑	*W8*
	Legal coherence	Is the policy supported by other health policies and legislation?	☐ Yes ☐ No	Yes	*W9*

The global score for each policy option is calculated by multiplying each score given to a policy option score by its weighting and by adding the multiplied scores per policy option. The global score expresses a score that is realistic, based on the most important dimensions. The weight selected for each dimension may vary for countries conducting the analysis, and can be chosen by means of brainstorming, focus groups, or SMEs. Each analytical dimension needs to be converted into a measurable unit—a score. Table 7.9 provides an example of how the metrics for the analytical dimensions can be constructed, including the Likert scale, scores, and direction of preference to be given for each dimension. This can be adapted according to the analysts' preferences; however, the consistency of the scores needs to be kept in mind.

Step 5.3: Develop the multi-dimension analysis table

The next step is to develop the multi-criteria decision analysis table by incorporating multiple dimensions, and Table 7.10 provides the layout of how to construct such a table. The first column is the list of policy options that are compared to one another to select the best possible policy option. The rest of the columns are the selected criteria used for the analysis—each identifying the weight of importance chosen, as well as the direction of preference. Each dimension has a preference of outcomes, for example, the cost needs to be as low as possible, where the acceptability should be as high possible. This is indicated by a direction of preference which is incorporated into the global score. The last column is the weighted total score (the global score) calculated for each dimension. This will give an indication of which policy option is considered favourable in terms of the impact analysis outcome.

The interaction between Phase 4 and Phase 5 is the 'acceptability' dimension that is scored based on the outcome from the stakeholder analysis. The score can be seen as the percentage of stakeholders in support of the policy option.

Table 7.10: Policy impact analysis tool structure

Decision Factors	Dimensions	D_1	D_2	D_3	...	D_n	Weighted Total Score
	Weight	w_1	w_2	w_3	...	w_n	
	Direction	$d1$	$d2$	$d3$	...	dn	
Policy consideration 1		score 1	score 2	score 3	...	score n	= SUMPRODUCT(Weight, score)
Policy consideration 2							
Policy consideration 3							
...							
Policy consideration n							

Step 5.4: Complete table and select best policy option

The final step from Phase 5, is to complete the table and interpret the outcome. Brainstorming, focus groups, Delphi-techniques, literature review studies and stakeholder engagement methods can be used to complete the table. The multi-dimension decision approach should thus provide the analyst(s) with a relative insight into the possible impact the policy considerations might have, whether it is problems with implementation feasibility, contextual factors, or stakeholder acceptability factors. The impact analysis also identifies the best policy option to consider. The outputs from Phases 4 and 5 are used to identify the best policy option for the problem identified in Phase 2. Phase 6 takes into account the analysis from the preceding phases to develop and strategise a plan of action.

7.8   Phase 6: Strategise plan of action

In this phase, the best policy option selected from the analysis in the preceding phases is used to design a policy plan of action—the plan to get the policy adopted and implemented. Each country will have different outputs from the policy analysis model and it is up to policy analysts, government officials, VAN role players and key stakeholders to plan the next steps. Phases 4 and 5 provide insight into the best policy option for consideration, including how stakeholders relevant to the policy area under analysis might react to the policy options. How this step is conducted, depends on how a country sets up policy and/or legislative documents, and how they implement a policy or legislation. This also refers to the amendments made to legislations.

The following key policy plans are proposed to be included in this phase of the analysis:

Policy draft: The policy draft or amendments to legislation should incorporate the policy draft checklist (Figure H.3) developed by Shung-King (2004). The checklist includes all the necessary factors that need to be included in a policy draft document. The policy objective and formulation checklist developed for the VAN (Figure 7.11) can be used to refine the design of the policy in consideration.

Implementation plan: Passing policies for adoption does not guarantee success if policies are not well implemented (Cerna, 2013). Hasenfeld & Brock (1991) said that implementation should involve processes that make decisions and actions that put policies into action. Implementation revolves around three theories: top-down, bottom-up, or hybrid (Peters & Pierre, 2006). Top-down implementation is where decisions are made by a national/central body, which are then translated into operating instructions at a lower level (Lehmann, 2016). Bottom-up implementation is described as a process of interaction and negotiation between those seeking to put a policy into effect and those upon whom action depends (Lehmann, 2016). Increasing focus is placed on a combination (hybrid) of these two models in order to benefit from the strengths of both processes and enable different levels of the system to interact (Lehmann, 2016).

Stakeholder engagement and communication plan: This plan is developed based on the outcome of the SHA. The results from the SHA should provide an indication of which stakeholders to include in the decision-making strategy (include in the impact analysis process and include in selecting the best policy option); who to consult on matters regarding the policy decision, and who to inform about the decisions. The stakeholder engagement and communication plan can be incorporated into the implementation plan. The plan should be able to identify which stakeholders to engage at which stage of the policy development, adoption and/or implementation plans.

Risk management plan: As for any policy, some outcomes can have unforeseen consequences, which could have risks associated with them. The risk management plan should make use of the most common risk management framework, which includes the identification, analysis, treatment, monitoring and reporting of risks (Shenkir & Walker, 2007). The risk can be identified from the policy impact analysis outcome (Phase 5). The analytical scores for the desired policy option(s) can be investigated to determine the possible risks associated.

This phase in the PoliVAN provides key policy plans that should be incorporated into the final policy strategy, to ensure the effective adoption and implementation of the policy selected from the analysis. This phase can be the most time consuming, and the outputs of the analyses conducted in the previous phases of the PoliVAN, should be taken into consideration when developing the various policy plans. The development and implementation of policy is a time consuming process, particularly due to the time it takes for a problem to be presented, and the different pathways a policy goes through before it is accepted by the Ministry of Health or President. Therefore, the PoliVAN facilitates a thorough, yet systematic analyses to identify the problem and provide the best possible policy solution to the problem, as efficiently as possible in order to contribute to reducing the time required to arrive at a final policy strategy. Without thorough analysis, important policy problems and choices are based on hunches and guesses, which can lead to regrettable results (Walker, 2000).

7.9 Chapter 7: Conclusion

This chapter presents the policy analysis logic model for a VAN, named PoliVAN. The PoliVAN, discussed in this chapter, is the refined PoliVAN that includes the suggestions provided by the subject matter experts (SMEs) during the validation workshop, discussed in Section 6.3. This chapter starts by highlighting the high-level PoliVAN introduced in Chapter 5, and provides a generic guide on how each phase of the PoliVAN is presented. Then, each phase from the PoliVAN is discussed throughout the different sections. For each phase, the inputs, outputs, objectives, and tools required to complete each step are discussed, including a description of how to complete the steps.

The PoliVAN presented aims to explore how a country's existing policies and legislations are likely to affect the implementation of a Visibility and Analytics Network (VAN) Operating Model. The logic model is intended to be a practical framework that will allow developing countries in sub-Saharan Africa to develop policy-related strategies and decisions when thinking of implementing the VAN concept.

The PoliVAN presented is structured according to logic model specifications and a logical policy decision-making process adapted for the VAN. The tools, dimensions and criteria proposed in the different phases of the PoliVAN, are based on evidence found in literature with refinements from SMEs. However, there are other tools available to conduct some of the analysis, e.g. in Phase 5, sophisticated modelling can be used for the impact analysis, but this is not always the best option when the model is aimed at developing countries, hence the exclusion of sophisticated modelling from the policy impact analysis model. The PoliVAN indicates areas where the tools provided need to be adapted to fit the country specification, and it is up to the analyst(s) conducting the analysis to determine the criteria and dimensions to be used

The evaluation objectives discussed in Table 1.1 for the refined PoliVAN have been ascertained by SMEs, discussed in Chapter 6. The next stage in the evaluation strategy (Figure 1.3) is to determine (validate) whether the PoliVAN is applicable and flexible. These evaluation objectives are tested by means of two case studies provided in the next chapter.

Chapter 8

Case study: South African VAN Operating Model

In this chapter, the third stage of the validation strategy—the case studies—is presented to illustrate the applicability and flexibility of the PoliVAN. This chapter starts with an overview of the validation approach used for the case studies in this research inquiry. The scope of the case studies is defined, and a brief description of the subject matter experts (SMEs) who participated in the respective case studies, is provided. Then, a short overview of the case study contexts are provided, including the updated VAN supply chain processes that were used for the respective case studies. The remainder of this chapter is concerned with the processes and outcomes of each case study, concluding with the key findings of the practicability of the PoliVAN and how the applicability and flexibility evaluation objectives have been achieved.

8.1 Details of the PoliVAN logic model case studies

In this section, the validation strategies; the refined scope of the application of the case study; and the SMEs who contributed to the application of each case study are discussed.

8.1.1 Highlights from the case study validation strategy

Sections 1.4.3 and 6.4 provide a detailed account of the validation strategy used in this chapter. The first two stages of the evaluation strategy are concerned with the verification and subject matter experts' (SME) validation of the developed and proposed PoliVAN respectively. The refined PoliVAN (comprehensively discussed in Chapter 7) is used for the next stage in the evaluation strategy; an illustration of the application of the PoliVAN to real-world case studies. This is done to showcase the PoliVAN's applicability and flexibility through the evaluation objectives defined in Table 1.1.

As discussed in Section 6.4, the two case studies are approached differently; however, the processes of the PoliVAN are executed similarly. The first case study was conducted in a full-day workshop setting, where a group of SMEs dedicated their time and expertise to apply the PoliVAN to a case (the South African VAN Operating Model). The content excerpted from the workshop setting was sufficient to conduct the analysis and proceed sequentially through the six phases of the PoliVAN. The second case study was done as a combination between a desktop exercise, SME interaction and a workshop with two SMEs, where the content details for the different phases in the PoliVAN were discussed. The information was used to progress through the six phases as a desktop study, with a number of SMEs providing inputs and validation of the information produced from the case study as and when required.

The aim of the first case study was to illustrate the applicability of the PoliVAN. The aim of the second case study was to illustrate the flexibility of the PoliVAN, in addition to showcasing its applicability. The flexibility was examined by considering how well the PoliVAN accommodated changes between the two cases presented. The scope of the case studies and the details of each case study are presented in the following subsection.

8.1.2 Scope and focus area of the case studies

The scope of the case studies is limited according to the level of detail necessary to address the questions surrounding the applicability and flexibility as set out in the evaluation strategy. Therefore, efforts are geared towards achieving a balance between demonstrating the applicability and flexibility of the PoliVAN as comprehensively and thoroughly as possible whilst confining the case studies to a feasible scope. The PoliVAN aims to enable actors (i.e. government authorities, policymakers and VAN role players) to conduct an analysis of their country's entire pharmaceutical supply chain. Applying the PoliVAN to such an extensive and comprehensive system is beyond the scope of this study. Hence, Figure 8.1 provides a schematic overview of the PoliVAN application and the scope of these case studies. The table in Figure 8.1, which is the PLF-VAN-Matrix[1], highlights the PoliVAN application coverage in this study: two operational components (medicine selection and inventory management) and two VAN supply chain planning categories (demand and supply planning) were analysed for the South African context. Two case studies that focused on specific logistical components provided sufficient insight into the applicability and flexibility of the PoliVAN to support the evaluation objectives.

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[1]The details of the 'Xs' are discussed in Phase 1 of the respective case studies.

1. INVESTIGATE POLICY AND LEGISLATIVE LANDSCAPE

PHARMACEUTICAL LOGISTICS FRAMEWORK	VAN PLANNING PROCESSES		
OPERATIONAL COMPONENTS	DEMAND PLAN [1]	SUPPLY PLAN [2]	DISTRIBUTION PLAN [3]
Medicine selection			
Market approval/Registration	X		
Therapeutic formularies	X		
STGs/EML selection and substitution	X		
Quantification and procurement			
Quantification and Forecasting	X	X	
Funds and budgeting	X	X	
Procurement method		X	
Supplier selection and monitor		X	
Contracting	X	X	
Order monitor		X	
Product inspection (depots/facilities)		X	
Payments		X	
Inventory management			
Product inspection (CMS)			
Inventory control		X	X
Storage			X
Supplier requisition allocation		X	
Requisition/ordering		X	
Expired medicine management		X	
Distribution management			
Allocation of suppliers			X
Delivery methods			X
Transport management			X
Third party logistics			X
Medicine use			
Diagnosis/follow-up			
Prescribing	X		
Dispensing	X		
Use and adherence			
MANAGEMENT SUPPORT ELEMENTS	DEMAND PLAN [1]	SUPPLY PLAN [2]	DISTRIBUTION PLAN [3]
Information System			
Pharmaceutical management information system	X	X	
Indicator-based monitoring	X	X	X
Integrated network	X	X	X
Organisation and HR management			
Personnel management	X	X	
Education and training		X	
Accountability	X	X	X
Reporting and organisational structures	X	X	X
Financial and donor coordination			
Financing and budgeting strategies			
Analyse and control expenditures	X	X	
Donor financing			
Monitoring and evaluation			
Programme planning and implementation	X		
Monitoring and evaluation (key performance indicators.)		X	X

[1] Demand plan version 2, September 2018.
[2] Supply plan version 2, July 2018/2019. The latest version is currently being updated.
[3] Distribution planning version 1, October 2016.

2. SORT EXISTING POLICIES

High-level policy Problem

Subproblem 1
Subproblem 2
⋮
Subproblem n

3. POLICY FORMULATION

Policy subproblem 1

P1 P2 … Pn

·(Re)formulated policy options·

POLICY DOMAIN

P1 P2 … Pn

4. STAKEHOLDER ANALYSIS

Stakeholder characteristic outputs

C1 C2 … Cn

Acceptability

5. POLICY IMPACT ANALYSIS

Policy impact outputs

P1 P2 … Pn

Best policy option(s)

6. STRATEGISE PLAN OF ACTION

To provide a policy plan of action for VAN role players, policymakers and government officials

Figure 8.1: Case study application scope and coverage

The specific focus areas were selected through consultation with relevant VAN SMEs. The motivation for selecting 'medicine selection' and 'inventory management' as the two focus areas is:

i. Achievability: From a research perspective, a majority of the policy and legislation documents that govern the specific functions of medicine selection and inventory management are accessible and available in the public domain;

ii. Practicality: The SMEs that are available to participate in the case studies, have extensive knowledge of these two particular pharmaceutical supply chain processes, policies, and legislations in South Africa, making these focus areas a practical choice; and

iii. Relevance: The VAN Operating Model for South Africa was continuously updated and changed during the progression of this study. At the time of each case study, the particular VAN processes for the respective operational components were updated and available.

The first case study is focused on the medicine selection operational component and demand planning VAN processes. The second case study is focused on the inventory management component and the supply planning VAN processes. Although different application approaches[1] were operationalised in these case studies, the process of each application followed the same sequential phases presented by the PoliVAN in Chapter 7. Even though the case study was limited to two operational components, these components were evaluated across the breadth of the PoliVAN (i.e. the application of each case to all of the PoliVAN phases) and the depth of the PoliVAN (i.e. focusing on one subproblem but in comprehensive and extensive detail within each phase). In Phase 2, as shown in Figure 8.1, a single subproblem stream is followed for the remainder of each case study, in order to showcase the depth of the remaining phases. However, the case study application processes illustrated in Figure 8.1 also show the level of detail the PoliVAN is advised to be applied to.

8.1.3 Summary of the case study participants

Due to the specific nature of the case under analysis, it is required that specific SMEs[2] partake in the case study application of the PoliVAN. The SMEs are able to provide insight into the contextual background (country-specific operations) where the VAN Operating Model is intended to be implemented. The SMEs were also able to contribute significantly towards

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[1]The application processes refer to the case study methods in Subsection 8.1.1. The main reason for the two different approaches was based on the location and personal timelines of the SMEs available (and skills required) for the case studies.

[2]In this instance, individuals with sufficient knowledge about South Africa's pharmaceutical supply chain operational aspects and South Africa's VAN Operating Model were viewed as SMEs.

the quality of the case study application, as their inputs were representative of the real-world situation.

A total of seven SMEs participated in the respective case studies. A breakdown of the participants, including their relevant background information and the case study in which they participated, is presented in Table 8.1. A detailed description of their involvement in this study is available in Appendix L. For the second case study, participants P13 and P15 were present during the inventory management case study workshop, whereas participants P3, P10 and P15 were contacted after the case study, during the desktop exercise, regarding secondary inputs and validation of the information used in the analysis. From the information presented in Table 8.1, the SMEs for the particular case studies are considered to have the required knowledge on the operational aspects of South Africa's pharmaceutical supply chain to provide the technical and contextual information for the case studies. All of the participants are well-informed on the VAN operations and six of them are currently working on projects in line with the VAN.

Table 8.1: A list of the SMEs that participated in the two respective case studies

P#	OCCUPATIONAL BACKGROUND	ACADEMIC BACKGROUND	CASE STUDY 1	CASE STUDY 2
P3	Public and Private Sector Supply Chain; Private Sector Pharmaceutical Distribution; Public Sector Technical Advisor - Medicine Supply Chain	BSc (Pharm); MBA		X
P8	Cluster Manager: Governance, Monitoring and Evaluation at Systems for Improved Access to Pharmaceuticals and Services, Management Sciences for Health; Technical advisor for NDoH.	Diploma in Pharmacy, Master of Public Administration (M.P.A),	X	
P9	Pharmacy Technical Assistance Manager: rational medicine use; Pharmacist; Member of South African Pharmacy Council.	BSc (Pharm)	X	
P10	Public health consultant; National Health Service (NHS) Service Development, Governance, and Project Management; Managing Director at leading consulting companies in health advisory.	BSc Political Science and Law	X	X
P13	VAN Programme Manager for NDoH; Supply Chain Operations Manager for Healthcare; Supply Chain Development Lead at African Resource Centre (ARC)	MEng Aeronautical Engineering; Masters in Supply Chain management	X	X
P14	Clinical pharmacist for 6+ years; Technical advisor for NDoH; Health Policy Specialist for NDoH.	BSc (Pharm)	X	
P15	USAID Supply Chain Consultant for NDoH; 20 years' experience in supply chain management; Business process re-engineering	BEng (Industrial Engineering); MBA		X

8.2 Context-specific information for the case study: South Africa

In order to apply the case study to the South African VAN Operating Model, relevant information within the South African context is required. Figure 8.2 provides an illustration of context-specific information that should be known before applying the PoliVAN (this applies for any country). In order to gain a thorough understanding of South Africa's pharmaceutical supply chain, a literature review was conducted on the required topics to gain the necessary knowledge for the case studies and in order to have the ability to engage with SMEs on topic-specific matters. The following subsections provide a description of the required information identified in Figure 8.2.
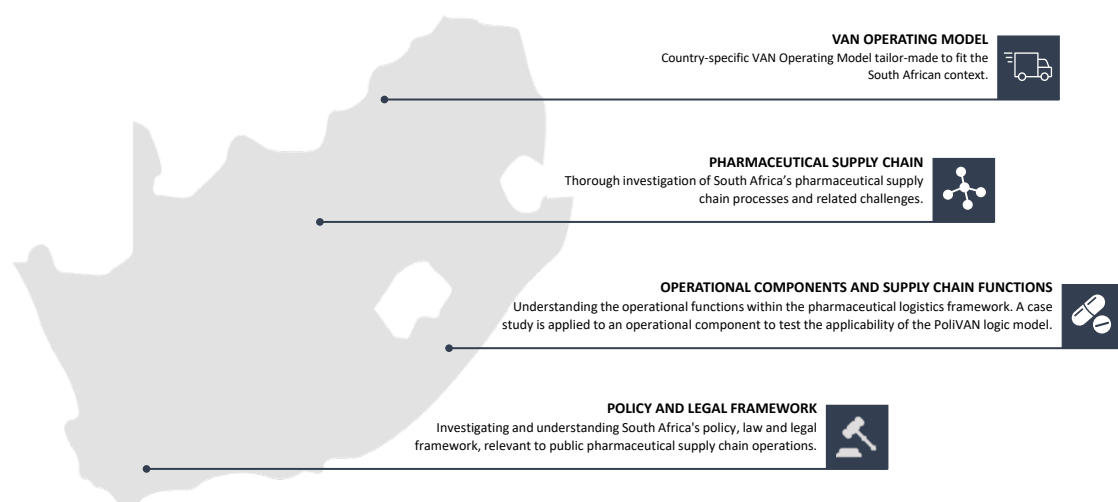
Figure 8.2: Country-specific information required for the application of the case study: South Africa

8.2.1 South Africa's VAN Operating Model

In Chapter 2, the Blueprint Reference Model (BPRM), including the VAN Operating Model[1] for South Africa and how it was developed from the BPRM was discussed. During the progression of the study, details of the VAN Operating Model for South Africa have been updated. An updated version of the VAN demand planning processes was developed late 2017 and into 2018 by the National Department of Health (NDoH). The updated demand planning processes (see Appendix P) were provided by the NDoH at the commencement of the first case study, and were subsequently applied to the medicine selection case study in Section 8.3. The information in Appendix P is used when referring to the demand plan for the South African VAN Operating Model. The VAN supply planning processes for South Africa were also updated late 2018 and

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[1]In the beginning of this study, the 2016 version of South Africa's VAN Operating Model is used in Chapter 2

into 2019. The updated version (in Appendix Q) was provided by the African Resource Centre and NDoH at the commencement of the second case study and are discussed in Section 8.4. The information in Appendix Q is used when referring to the supply plan for the South African VAN Operating Model.

8.2.2 South Africa's public pharmaceutical supply chain system

For the sake of brevity, a detailed discussion of South Africa's pharmaceutical supply chain operations is included in Appendix E. The details regarding South Africa's pharmaceutical supply chain were not used to develop the PoliVAN; however, they are provided as additional information in order to understand the context of the case study better. Additionally, during the progression of the case studies, the SMEs provided insight into operations of the South African healthcare supply chain (not specified in the literature in Appendix E) that were incorporated into the case study applications.

8.2.3 Operational components and supply chain functions

Knowledge regarding the operational functions is required, especially those on which the case studies were focused: i.e. medicine selection and inventory management. In South Africa, prescribed health systems processes are based on best-practice methods. Most of the best-practice methods are presented in the *Managing Access to Medicines* book by Management Science for Health (2012). The operational aspects of the different operational functions were discussed in Chapter 3. Knowledge regarding best practices becomes an integral part of the PoliVAN application. This allows analysts to incorporate these best-practice methods into the policies designed for the VAN.

8.2.4 South Africa's policy and legal framework

Details about South Africa's governance framework within the pharmaceutical sector is discussed in Appendix E. Furthermore, during the application of the PoliVAN, a list of policies, regulations, guidelines, and Acts was compiled to support the analysis in the respective case studies (Sections 8.3 and 8.4). Understanding the country's policy and legal framework is of high importance, as this contributes to a significant part of the analysis. Thus, it is critical for the SMEs involved in the case study to have the relevant policy knowledge and background.

8.3 PoliVAN logic model case study: medicine selection

In this section, the six phases of the PoliVAN are applied to the South African VAN Operating Model, specifically to the area of medicine selection. An explanation of the logical steps within

each phase will not be repeated in this section (please refer to Chapter 7 for a comprehensive account of the phases and steps in the PoliVAN). For the sake of brevity, only the key outcomes, findings and interpretations of the processes and application of the case study are discussed in the remainder of this section. A detailed account of the case study's content (such as the 'how's' and the 'why's') are provided in Appendix R. All assumptions made during the application of the case study are based on the available data and are described in the discussion of the case provided in Appendix R.

8.3.1 PoliVAN Phase 1: Policy landscape for medicine selection

In Phase 1, the PoliVAN aims to investigate the policy and legislation landscape of policies relevant to South Africa's VAN. The steps in this phase aim to narrow the search scope, in order to identify policies relevant to the specific VAN Operating Model within a country. South Africa's pharmaceutical framework is supported by the framework for the Strategy to Improve Medicine Availability (SIMA). An illustration of the SIMA framework was shown in Figure 2.11. Details regarding this framework are not available within the public domain; however, the case study participants agreed that the pharmaceutical logistics framework (PLF) components (and the operational functions) provide a comprehensive view that considers all the functions within the SIMA framework. Taking into account the PLF components and the VAN Operating Model for South Africa[1], the PLF-VAN-Matrix for the South African VAN Operating Model is presented in the table in Figure 8.1.

For the medicine selection case study, the respective functions were used in conjunction with the management support elements to identify existing South African policies that are relevant to the VAN Operating model (the demand plan). The search process also considered the following factors for each function:

  i. Contextual background: The current process in the country regarding the functions (see Appendix E);

 ii. Laws, Acts and regulations in which these functions are stipulated (mandatory legislation as indicated by the legal hierarchy in Figure 7.5);

iii. The roles (i.e. health authorities, committees, and health establishment) and their responsibilities regarding these functions; and

 iv. Whether other functions might generate input to/or use output from a particular function.

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[1]The distribution planning processes are concerned with the original VAN Operational Model of 2016 (presented in Chapter 2); the demand planning processes are concerned with the updated version of 2018 (presented in Appendix P); and the supply planning processes are concerned with the updated version of 2018 / 2019 (presented in Appendix S).

Given the above investigation, a total of 19 policy documents (available in the public domain) were identified for the selection of medicines. These include Acts, regulations, policies, guidelines and standard operating procedures (SOPs). The list of policies was validated by the SMEs during the case study workshop. The title and description of each policy document is provided in Section R.1.2. The policies and legislations identified and categorised in this phase were used to assess their effect on the VAN Operating Model (Phase 2).

8.3.2 PoliVAN Phase 2: Sort policies for medicine selection

The aim of Phase 2 in the PoliVAN is to identify the enabling, facilitating and hindering policies[1] respectively, from the VAN Operational Model. In this part of the workshop, the relevant demand planning processes were listed in the VAN criteria list[2], (see the case study outcomes in Table 8.2). The demand planning document for South Africa provided clear processes (as suggested by the BPRM), that made the population of this table relatively easy. A discussion of these processes is available in Section R.2.

Table 8.2: Demand planning process steps to identify VAN criteria for medicine selection only

ID	Process name/ Process description	Frequency	Locations (scale of granularity)	Responsibility	Customer	Software/Tool
4.	Enrichment baseline forecast with national and provincial inputs					
4.1	Review changes to EML and all Provincial formularies.	Quarterly	National and provincial	Triggered by AMD, and feedback provided by national programmes, PMPUs	AMD Demand Manager	(as-is tools) EML spreadsheet, EML clinical guide, STG books, MPC/MHPL.
4.2	Create and incorporate any data relating to campaigns that may cause changes in demand.	Quarterly	National	National programmes, EDP, EDI	Provincial Demand Planner	Forecast Pro
4.3	Receive input from Provincial Pharmaceutical and Therapeutics Committee (PPTC) including provincial programmes that may influence the demand.	Quarterly	National	PPTCs, Provincial programmes, EDP, EPI	PMPU	Forecast Pro
4.4	Review notifications regarding health establishments in the province to include any that have opened or closed, or changed status.	Quarterly	Provincial	PMPU	Provincial Demand Planner	Not identified
4.5	Receive input of macro forecasted epidemiology and populations statistics from national programmes, Statistics SA and National Health Laboratory Services (NHLS).	Annually	Provincial	StatsSA, NHLS, National programmes	Provincial Supply Chain Team (PMPU)	Statistics SA, the rest not identified

The details around the discussion have shaped the number of VAN criteria identified by the SMEs during the workshop. The developed VAN criteria were then used to assess the effect the policies (from Phase 1) have on these criteria. Figure 8.3 provides a formulated overview

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[1]For the sake of brevity, the term 'policy' is used, but encompasses legislations, i.e. regulations, guidelines and SOPs as well.

[2]This is a generic table illustrated in Table 7.3, which details the VAN processes according to their frequency of occurrence, location of granularity, relevant stakeholders, and the technology tools or software to be used.

of the VAN content assessment matrix and alignment matrix. For the VAN content assessment matrix, the indicators were used to illustrate the enabling, facilitating and hindering effects. The indicators were provided after critically considering all of the identified policy documents, and the SMEs subsequently provided the necessary insights to thoroughly populate the VAN content assessment matrix. The complete VAN content assessment matrix is discussed and made available in Table R.3.
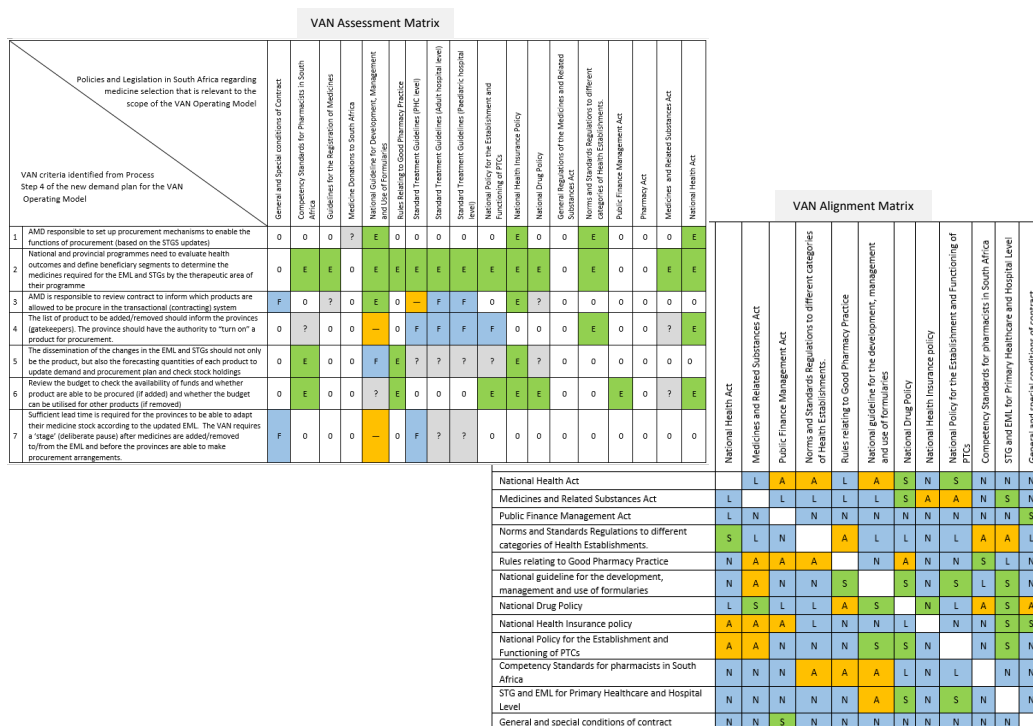
Figure 8.3: A formulated overview of the VAN assessment matrix and VAN alignment matrix for medicine selection

South Africa's Constitution was identified as a relevant legislation in Phase 1. Due to the nature of the Constitution to govern at a higher level than the criteria stipulated in Table R.3 and the fact that it does not have a direct effect on operational criteria, it was decided not to include the Constitution in the content assessment matrix. However, it does provide the necessary context in order to understand the other policies and legislations. For example, according to the Constitution, no patient may be refused healthcare treatment (Parliament of the Republic of South Africa, 2005). In the event of a stock-out, where the budget has already been exceeded, the system should still procure medicine to provide for patients in need. Another important clause in the South African Constitution, relates to the establishment of provincial governments (each with their own head of department and treasury), which are autonomous (Parliament of the Republic of South Africa, 2005). For the VAN to be integrated and operate as intended, this is probably one of the most salient obstacles regarding policy-making. Every

province has the authority to pass and enforce legislation, as long as it is enabled by national legislation (Parliament of the Republic of South Africa, 2005). Therefore, these sections in the Constitution should be kept in mind when making policy decisions.

After the assessment, two types of methods were deduced from the VAN content assessment matrix, which could be utilised to identify policy problems. Both of these methods were used in this case study:

i. The grouping of policies and legislation based on their enabling, facilitating or hindering effect; or

ii. The identification of VAN criteria not completely supported or enabled by policies and legislation.

In applying the first method, the policy documents were grouped according to the assessment indicators[1]. Four documents were categorised as 'facilitating' and two as 'hindering'. It was interesting to find that all of the Acts identified either have no effect, enabled the criteria or were ambiguous. In a discussion with the SMEs, an assumption was made that this is possibly a result of the level within the legislation hierarchy where an Act is situated. Acts do not necessarily provide details on the specific roles, processes or procedures, but they do give effect to regulations and guidelines that provide more guidance at an increased level of detail. This assumption will be validated after the second case study is completed.

The second method was considered the best option for this specific case study, because there were only a small number of hindering and facilitating policies[2] identified in the analysis. This made the identification of policy problems easier to manage. Table 8.3 summarises the VAN criteria that are grouped in the hindering and facilitating categories. The following short discussion, excerpted from Subsection R.2.3, provides the content details to showcase how the hindering effects and potential policy problems were identified:

From the VAN criteria (the third criterion), contractual commitments need to be reviewed in order to identify whether the selected medicines can be procured in the system. Contracts in South Africa usually comprise a two- to three-year agreement and the Essential Medicines List (EML) and Standard Treatment Guidelines (STGs) (PHC- and hospital level) are each reviewed at different times. This constrains the ability to align the procurement of products with the selection of medicines. The VAN requires the relevant provincial authority to start procuring a product—within a reasonable amount of time—once the supply chain is ready for the changes that need to happen (the fourth criterion). Within the formulary guideline

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[1]The assessment indicators include: enabling effect, facilitating effect, hindering effect, ambiguous to the VAN criteria, or no-effect.

[2]The hindering category comprises the policies that prohibit the operationalisation of the VAN criteria, whereas the facilitating policies require attention to the detail of the policy specified in the assessment matrix.

Table 8.3: The VAN criteria that are not enabled[1] by the policies or legislation.

Policies and Legislation in South Africa regarding medicine selection that is relevant to the scope of the VAN Operating Model / VAN criteria identified from Process Step 4 of the new demand plan for the VAN Operating Model	General and Special conditions of Contract	Competency Standards for Pharmacists in South Africa	Guidelines for the Registration of Medicines	Medicine Donations to South Africa	National Guideline for Development, Management and Use of Formularies	Rules Relating to Good Pharmacy Practice	Standard Treatment Guidelines (PHC level)	Standard Treatment Guidelines (Adult hospital level)	Standard Treatment Guidelines (Paediatric hospital level)	National Policy for the Establishment and Functioning of PTCs	National Health Insurance Policy	National Drug Policy	General Regulations of the Medicines and Related Substances Act	Norms and Standards Regulations to different categories of Health Establishments.	Public Finance Management Act	Pharmacy Act	Medicines and Related Substances Act	National Health Act
3 AMD is responsible to review contract to inform which products are allowed to be procure in the transactional (contracting) system	F	0	?	0	E	0	—	F	F	0	E	?	0	0	0	0	0	0
4 The list of products to be added/removed should inform the provinces (gatekeepers). The province should have the authority to "turn on" a product for procurement.	0	?	0	0	—	0	F	F	F	F	0	0	0	E	0	0	?	E
7 Sufficient lead time is required for the provinces to be able to adapt their medicine stock according to the updated EML. The VAN requires a 'stage' (deliberate pause) after medicines are added/removed to/from the EML and before the provinces are able to make procurement arrangements.	F	0	0	0	—	0	F	?	?	0	0	0	0	0	0	0	0	0

(National Department of Health, 2018b), it states that medicines should be immediately available for the public once they have been approved by the National Essential Medicines List Committee (NEMLC). This does not allow the provinces to adapt the supply chain to ensure that the medicines approved by NEMLC can be readily available.

The seventh criterion (which can operate in conjunction with the fourth criterion) requires that sufficient lead time is made available for the pharmaceutical supply chain to adjust the current stock-holding (phasing in/out of products) when a new product is added or removed from the EML. This criterion is also strongly affected by the formulary guidelines (National Department of Health, 2018b). Additionally, if a supplier does not adhere to contract terms, strict penalties are issued against them, but when the buyer (in this case the government) needs to buy out or terminate the contract due to the removal of medicines from the EML, no consequences are applied to the government within the contract—thus the general conditions of contract are one-sided.

The previous discussion has highlighted the problems regarding formulary updates and contractual agreements with the suppliers. During the workshop a high-level problem was identified, which was subsequently categorised into three subproblems. The high-level policy problem is identified as: '*there are currently no prescriptive details within policy or legislation that provide for the link between the selection of medicines and the procurement of medicines*'. The following three subproblems were formulated from the high-level problem (details of each problem are available in SubsectionR.3.1):

- Policy subproblem 1: The phase in/out of medicines added to the national EML and the link to procurement.

- Policy subproblem 2: The alignment between the selection processes and the contracting processes—linking the timing of these processes.

- Policy subproblem 3: Unfair contractual agreements between the government and the suppliers.

For the sake of obtaining depth within the case study during the available time with the SMEs in the workshop, only one policy subproblem was selected for the remainder of this case study. The SMEs chose to further investigate the second policy subproblem, because during the workshop session (while identifying the subproblems) possible policy solutions were highlighted for this subproblem. The next section discussed the third phase of the PoliVAN application.

8.3.3 PoliVAN Phase 3: Policy formulation for medicine selection

Policy options were formulated during the case study workshop in order to address the problem of the temporal misalignment between medicine selection and contracting. These policy options contribute towards an overarching integration between the selection, planning and procurement functions in the pharmaceutical supply chain for the VAN Operating Model. The different policies were formulated by means of brainstorming among the SMEs. The details of the policy options were developed by utilising the VAN policy objective and formulation checklist (Figure 7.11). Four policy options were identified:

i. Policy option 1: To view contracts by therapeutic type;

ii. Policy option 2: To enable strategic collaboration with potential suppliers;

iii. Policy option 3: Therapeutic reference pricing; and

iv. Policy option 4: A procurement card / government 'credit card'.

The details of each of the four policy options that were conceptualised are available in Section R.3. Utilising the policy checklist in a workshop setting enabled the SMEs to create dialogue around the policy options to ensure the formulation of rigorous policy options. Figure 8.4 provides a sectional view of the policy formulation table developed to detail the different policy options.

A draft policy formulation table was initially developed during the workshop. After the workshop further refinements were made to the table with inputs from participants P10 and P13. These four policy options were then used as the inputs for the next two phases of the PoliVAN, namely the stakeholder analysis (Phase 4) and the policy impact analysis (Phase 5).

Figure 8.4: A formulated sectional view of the policy formulation table presented in Section R.3

8.3.4   PoliVAN Phase 4: Stakeholder analysis for medicine selection

During the case study workshop, the stakeholder identification list was used to identify the stakeholders that are relevant to the policy problem area focused on in the analysis. The SMEs also decided to make use of all the proposed stakeholder characteristics for the analysis in this phase. The stakeholder evaluation table/tool was applied to each of the four policy options (see Figure 8.5). Section R.4.1 provides the detail of each stakeholder analysis table. The SMEs that participated in the case study workshop were asked to score each of the stakeholders based on their relevant experience within the policy field, where they work with relevant stakeholders on a regular basis (using the scoring instructions in Figure 7.13). The scoring of the stakeholders was done after the case study workshop and the average of the scores from the participants was used to conduct the analysis.

For each policy option, three types of stakeholder analysis were performed from the stakeholder evaluation table: (i) determining the extent of stakeholder involvement; (ii) determining the ability of an opposing stakeholder to influence the decisions; and (iii) determining the ratio of power between the internal and external stakeholders. The three types of analysis are explained:

Power-attitude map: For each policy option, the stakeholder's opinion of the policy option was plotted on a power-attitude-map. The attitude[1] takes into account a stakeholder's

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[1] The attitude is calculated as the combined sum of the knowledge and interest of a stakeholder, multiplied by their level of support (positive or negative).
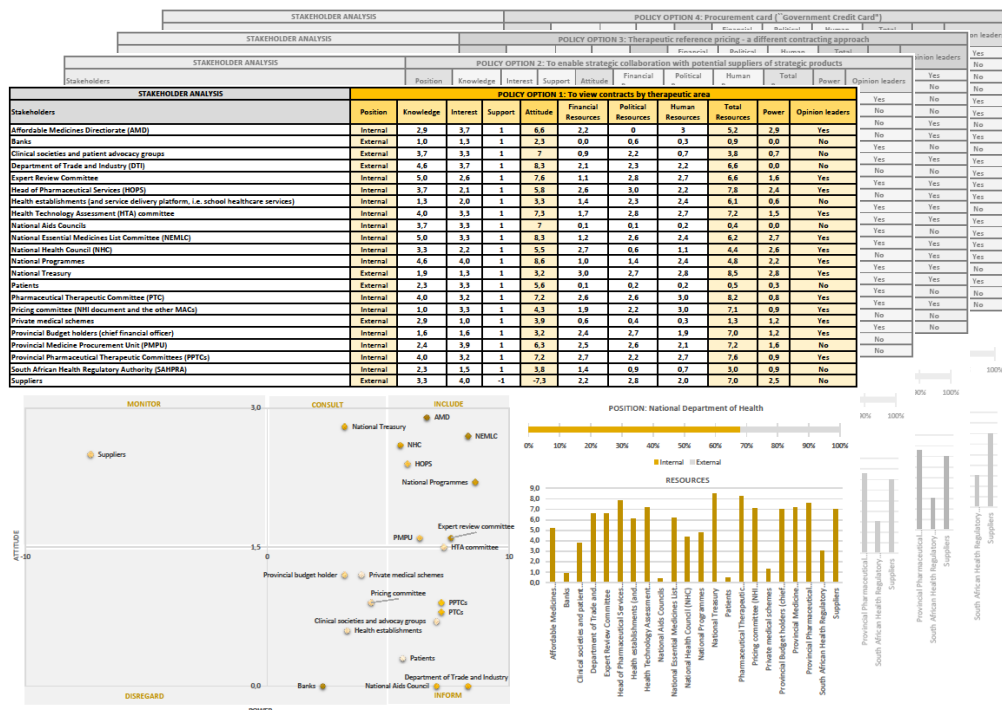
Figure 8.5: A formulated overview of the four stakeholder analysis evaluation tables in Section R.4.1

knowledge about the policy option, the interest the stakeholder might have towards the policy option (regardless of whether they are impacted by the policy), and the stakeholder's level of support (positive or negative, which is determined by how they are impacted). The power characteristic is the possible level of power that a stakeholder can exert over a policy option. The power-attitude map was used to categorise the stakeholders according to their suggested degree of involvement in the policy process, which is based on the stakeholder map presented in Figure 7.14.

Stakeholder influence and access to resources: The degree of the stakeholders' access to resources (financial, political or human) was summarised in a bar diagram. The outcome of the power-attitude map was investigated and when an outlier was identified— stakeholders not supportive of the policy option—their access to resources was investigated to determine the influence they could potentially have. This information was then utilised to decide whether the SMEs wanted to change a stakeholder's involvement status. The resources could also be combined with the 'opinion leader' attribute, which are complementing characteristics. Their level of access to resources and their ability to persuade the political or human resources provided useful insight to manage these stakeholders.

Stakeholder position analysis: For this analysis the percentage of internal vs. external stakeholders was considered. The type of position-analysis considered for a case is at the discretion of the analyst, based on the policy problem under analysis. In this case study, the position relative to the NDoH was used to identify which department would be responsible for the policy implementation. Three government departments (i.e. Health, Trade and Industry, and Treasury) had stakeholders involved in the policy options.

These three analysis methods were used for the development of the stakeholder management and engagement plan in Phase 6. For the sake of brevity, the three analysis methods were only applied to the best policy option in this case study when a policy decision was reached after Phase 5. The high-level PoliVAN illustrates an interaction between Phases 4 and 5. This is because one of the characteristic outcomes in Phase 4 is used as an input in Phase 5. The stakeholder characteristic, 'attitude', is determined as the extent to which a stakeholder will support the policy option. This attribute is used as an input into the 'acceptability' dimension in Phase 5, because the attitude of a stakeholder could potentially have an impact on the successful implementation of a policy. The details regarding the policy impact analysis are discussed in the next section.

8.3.5 PoliVAN Phase 5: Impact analysis for medicine selection

The fifth phase in the PoliVAN is where the policy options are assessed against analytical dimensions to determine the likely impact of the policy on the pharmaceutical landscape (and vice versa) and also to determine the feasibility of implementing the policy, with specific reference to whether it can function within the current governance structure. The analysis not only gives insight into the best policy option but also gives insight into potential strategies to ensure successful adoption and implementation of the various policy options.

The SMEs were asked to score the policy options based on the pre-defined analytical dimensions. In line with the discussion during the workshop, the SMEs suggested that all of the analytical dimensions needed to be included in the analysis. As mentioned during the development of the PoliVAN, the decision to include or remove dimensions from the analysis is at the discretion of the analysts responsible for applying the PoliVAN to their specific VAN case, but it is recommended that careful thought be given to the inclusion or exclusion of analytical dimensions. The dimensions were broken down to subdimensions (and in some cases sub-subdimensions) according to the description provided in Table 7.8. The breakdown structure is available in Figure R.5.

Given that each country has a different context and objective with regards to the VAN Operating Model, it is recommended that the weighting factors be included whenever the PoliVAN is applied. The weighting factor for each dimension was assigned during the workshop.

The 'criticality' and 'feasibility' dimensions were given the highest weighting preference of 30% and 25% respectively. The reason for this was because the policy options are designed to enable the link between medicine selection and the procurement functions. The third-highest weighting preference of 15% was given to the 'acceptability' dimension. The reason for this was because the policy option sits within the legislation of three departments: the NDoH, National Treasury and the Department of Trade and Industry. Thus, numerous different stakeholders are involved. The rest of the dimensions were given either 5% or 10% preference. Details of the construction of the policy impact analysis table and the scores provided by the SMEs, as well as details relating to the analysis tool itself are available in Section R.5. Figure 8.6 provides an overview of how the impact analysis table was constructed.

Categories	
Weight	5%
Dimensions	RELEVANCE
	End-to-end visibility
Policy Option 1	5
Policy Option 2	5
Policy Option 3	1
Policy Option 4	2
Scoring Metrics	5 - Highly relevant 4 - Relevant 3 - Moderately relevant 2 - Slightly relevant 1 - Little/no relevance
Categories	IMPLEMENTATION
Weight	20%
Dimensions	FEASIBILITY
	Technical
Policy Option 1	2
Policy Option 2	3
Policy Option 3	2
Policy Option 4	3
Scoring Metrics	3 - Feasible 2 - Moderately feasibly 1 - Slightly feasible 0 - Not feasible

EFFECT			
5%			30%
CONTEXTUAL FACTORS			CRITICALITY
Macro	Micro		
Economical	Organisational	Cultural	
3	2	3	4
2	1	3	4
2	2	3	2
1	2	2	2
3 - Low impact 2 - Moderate impact 1 - High impact			0 - Very high affect 1 - High affect 2 - Moderate affect 3 - Slight affect 4 - Little affect 5 - No affect

GOVERNANCE			
15%	5%		
ACCEPTABILITY	LEGAL COHERENCE	TOTAL SCORE	TOTAL WEIGHTED SCORE
5	5	61	53,10
5	3	48	45,90
5	2	46	41,40
5	5	53	46,35
5 - 80% → 100% 4 - 70% → 80% 3 - 50% → 70% 2 - 30% → 50% 1 - 20% → 30%	5 - No effort 4 - Low effort 3 - Moderate effort 2 - High effort 1 - very high effort		

Figure 8.6: A formulated sectional view of the policy impact analysis for medicine selection policies

In Figure 8.6, the total score[1] and the total weighted score[2] were calculated for each policy option. Both methods provided different outputs in terms of the best policy option. The argument for considering the weighted rather than the unweighted score is that the country applying the analysis is likely to have specific preferences as a result of its specific contextual factors. For example, South Africa is focused on the feasibility of implementing the policy option and the criticality of the changes it proposes towards the rest of the supply

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[1]The total score is calculated by the total sum of all the scores given.
[2]The total weighted score is calculated by the sum of the weighted averages.

chain, whereas another country could, for example, prefer to focus on the expected cost of implementing the policy option.

A seen by the evaluation scores, Policy Option 1 has the best overall weighted outcome among the four policy options—the option with the least impact on the pharmaceutical supply chain. Using the information from Table R.6, the following excerpt from the case study discusses the conclusions that were drawn (this is also a description of how the analysis can be understood):

- *The policy option is relevant to the three main objectives of the VAN, which provides a level of analysis to inform decision-making for both the AMD and programmes by providing visibility by therapeutic programme.*

- *The probability of the policy option to produce unintended effects is very low.*

- *The probability for contextual factors to influence the success of the policy option is very low.*

- *The criticality of the policy option is high as this will impact the selection, contracting, and potentially the rational use of medicines[1].*

- *For the technical feasibility, the policy option is dependent on the ePrescribing tool which is currently in development. Access is required to the warehouse management system for procurement and contracting. The vision is that all the systems should be interoperable, but these systems are at the moment working in isolation. For the operational feasibility, the majority of the operations remain the same, because therapeutic classes have already been established; however, slight operational changes might need to occur within the contracting of medicines. For the workforce feasibility, this policy only requires initial training, but no additional workforce is required.*

- *From the alignment matrix done in Phase 2, there are no hindering possibilities from a policy or legislation perspective; however, a prescriptive policy might be considered.*

Taking into account the analyses done in both Phases 4 and 5, the information and insights gathered from these were combined to develop rigorous policy-decision strategies that support the operations of the VAN Operating Model. The next section highlights the insights from this case study and showcases how the stakeholder analysis can be utilised to develop stakeholder management plans.

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[1]Monitoring medicines and the contracts differently might change how medicines are used.

8.3.6   PoliVAN Phase 6: Policy decisions for medicine selection

The final phase of the PoliVAN is where the outputs and analysis outcomes from the preceding phases are used to make informed policy decisions and provide strategic direction. The policy option that was considered the best approach for the policy problem according to the policy impact analysis, is to change contracting clustering to contracting of medicines by therapeutic categories, such as HIV, TB, antibiotics and cardiovascular. This is Policy Option 1. The details of this policy option are available in Section R.3.

Therefore, the first step is to identify the type of legislation and the level at which it will govern. A recommendation made during the workshop, would be to make it a policy state-ment, where it stipulates within specific guidelines such as the formulary guidelines (National Department of Health, 2018b) the development and management of formularies according to therapeutic area. However, the policy should be supported through mandatory legislations, such as the Medicines and Related Substances Act 72 of 2008 and Act 14 of 2015, that govern the management of the medicines and a regulation from the Department of Trade and Indus-try regarding contracts or contract terms. The alignment matrix from Phase 2 was useful to identify the degree of alignment between other policies or legislation. Figure 8.7 illustrates an overview of the alignment between the National Formulary Guideline, and the other legislation.

Figure 8.7: A formulated overview of the alignment between the National Formulary Guideline and other legislations

These insights provided guidance on which of the other policies or legislations should be

taken into consideration. To comprehensively design the policy is beyond the scope of this study; however, the details in the policy formulation table (Table R.5) can be used to further update and refine the policy—incorporating the insights from the stakeholder analysis and policy impact analysis.

One of the key design plans in Phase 6 is a stakeholder communication and engagement plan. To include this stakeholder management plan in the policy design, the SMEs analysed the stakeholder evaluation table (for Policy Option 1) to develop a strategy on how to engage with the stakeholders during the final decisions, adoption and implementation of the policy option. As discussed, three types of analysis can be done. The details of each analysis are provided in Section R.6. Here, an overview of the first analysis is given. Figure 8.8 illustrates the power-attitude map for Policy Option 1, populated with the scores given by the SMEs during the analysis, with a discussion excerpted from Appendix R.
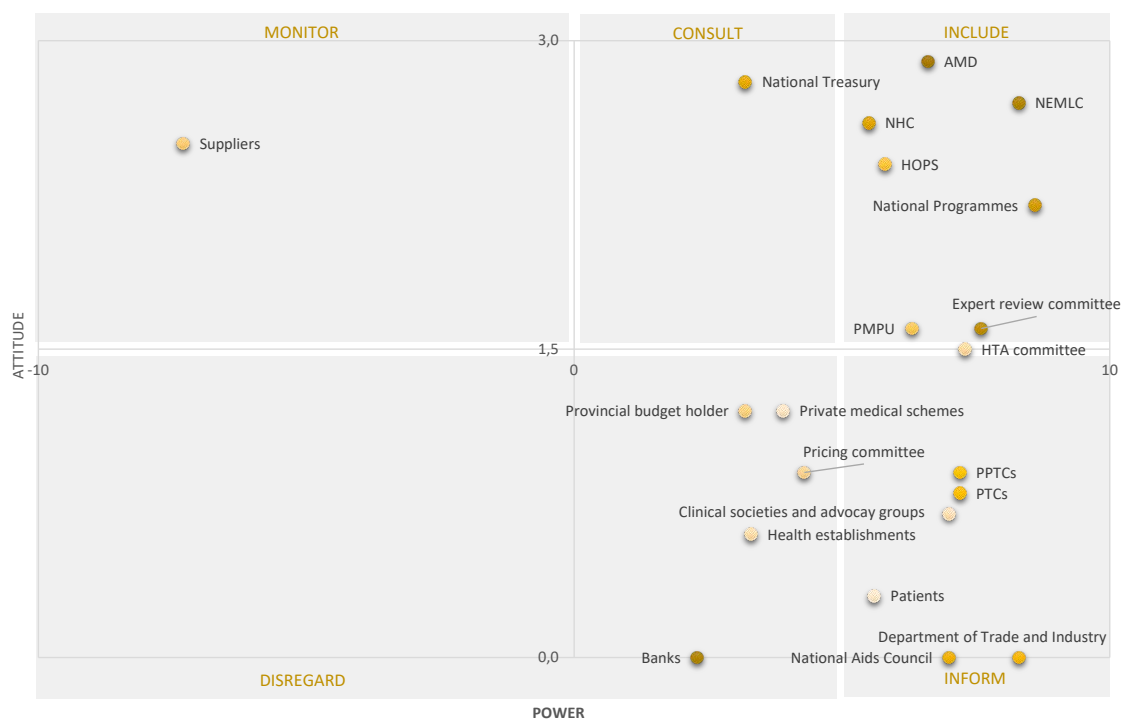
Figure 8.8: Power-attitude map for Policy Option 1

From the schematic [shown in Figure 8.8], *only the National Treasury needs to be consulted during the policy process. The difference between consulting a stakeholder and including the stakeholder, is that stakeholders are consulted to gather their opinions (because they have high power), but their opinions may not necessarily be incorporated because of their attitude score, which includes the 'knowledge'*[1] *attribute. However, it is clear the National Treasury has access to many resources (meaning that they have the capacity and ability to access*

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[1]The level of knowledge that a stakeholder has regarding a specific policy option.

financial, political and human/workforce resources), therefore, it is recommended that the National Treasury should be included in the decision-making process.

The map [in Figure 8.8] provides a clear distinction between the stakeholders to keep informed in the policy process, and those to disregard from the policy process. From the way in which the stakeholders are grouped, and taking into account who they are and their relevance to the policy option, it is clear that the policy map provided relatively accurate outputs; however, some minor changes are recommended based on the stakeholders' 'resource' characteristics (the second type of analysis). The highest plot on the map (in the middle of the horizontal axis) is the HTA committee, which is a committee established by the National Health Insurance (NHI) policy, responsible for reviewing the health interventions within functional areas such as medicine selection (National Department of Health, 2017e). Because the VAN is intended to be implemented in the context of the NHI policy (Llewellyn, 2016), it is recommended that the HTA committee should be included in the decision-making process. Another change that is recommended, is to move the patients from the 'keep informed list' to the 'disregarded list', because although they are interested and impacted (positively) by the policy option, they do not have access to many resources as previously mentioned.

Phase 6 of the PoliVAN also suggests that other plans, such as an implementation plan and risk management plan, need to be included in the policy strategy process. However, due to the analysis being done only to illustrate the application of the PoliVAN, the development of such a plan is deemed beyond the scope of the case study. In this subsection of the case study (Phase 6), a short discussion about the policy design strategy was mentioned as well as an overview of the stakeholders (with recommendations) that can be used to develop a stakeholder communication and engagement plan.

8.3.7 Conclusion: medicine selection case study

In this section, the PoliVAN has been applied to the medicine selection component of the PLF. The medicine selection functions were detailed in the demand planning processes of South Africa's VAN Operating Model. As discussed in Chapter 7, the PoliVAN was sequentially applied during the workshop. Based on the one workshop conducted, the outcomes from the PoliVAN in this case study presented valuable insights. Although the content and details of the case study are grounded on the available policies and legislations within the public domain, the practicality of the PoliVAN was clearly illustrated. The case study showed that the different steps and tools within the different phases have managed to provide the output required by each phase, and subsequently achieved the overall aim of the PoliVAN. The next section applies the PoliVAN to another component of the PLF, inventory management.

8.4 PoliVAN logic model case study: inventory management

In light of the scope of this research, the aim of conducting a second case study is to validate the flexibility of the PoliVAN; the ability to adapt to changes in the pharmaceutical system or VAN Operating Model of a country under consideration. The case study was conducted in a full-day workshop setting with participants P13 and P15. P13 is part of the VAN design project and P15 is currently focusing on the development of inventory management policies for the VAN. The remainder of the case study was done as a desktop exercise, with input from SMEs as and when required. The detail pertaining to this case study is available in Appendix S, which includes the processes followed during the workshop and the work done as a desktop exercise.

Key aspects of the case study, including the findings, are discussed in this section to showcase the outputs from a process perspective. However, to avoid repetition, some processes that were similar to the previous case study will not be explained in detail, instead referring to previous sections where these have already been described. The rest of this section flows logically according to the different phases of the PoliVAN.

8.4.1 Phase 1: Policy landscape for inventory management

The identification of relevant policies and legislations made use of the same PLF-VAN-Matrix developed in the table in Figure 8.1. From the PLF-VAN-Matrix, it is evident that the inventory management functions are all documented in the supply plan (2018 version) of South Africa's VAN Operating Model. The relevant functions, including those of the management support elements, subsequently highlight the governing policies and legislations which need to be identified and these were gathered prior to the workshop with SMEs P13 and P15.

A total of 23 relevant policies and legislations were identified in the public domain, which were validated by SMEs P3 and P10. The title and description of each policy document is provided in Section S.1.2. These policy[1] documents were used to analyse the effect (Phase 2) they have on the supply planning processes of the South African VAN.

8.4.2 Phase 2: Sort policies for inventory management

From the updated supply planning document (provided in Appendix Q), a list of key VAN criteria was identified. These criteria should be met by the system in order for the VAN to function as desired (from an inventory management perspective). The number of criteria identified by the SMEs was three times greater than those identified for the medicine selection functions. This could be because a majority of South Africa's VAN processes are focused on the

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[1]Again, the term 'policy' is used further in this study, but refers to all policies and legislations, i.e. Acts, regulations, guidelines and SOPs.

procurement and inventory management components of the PLF (see the table in Figure 8.1). Similar to the first case study, the VAN criteria were developed using the criteria list (shown in Table 7.3). However, this first had to be populated using the supply planning process map, the key supply planning enablers, and the process level table from the supply plan document (shown in Appendix Q). Figure 8.9 provides a sectional overview of the VAN assessment matrix and the VAN alignment matrix for inventory management policies and criteria as developed during the SME workshop. For similar reasons to those mentioned in the first case study, the Constitution was not included in the VAN assessment matrix. Due to the number of criteria identified, it made the assessment (see the VAN assessment matrix depicted) manageable when the criteria were categorised into relevant themes.
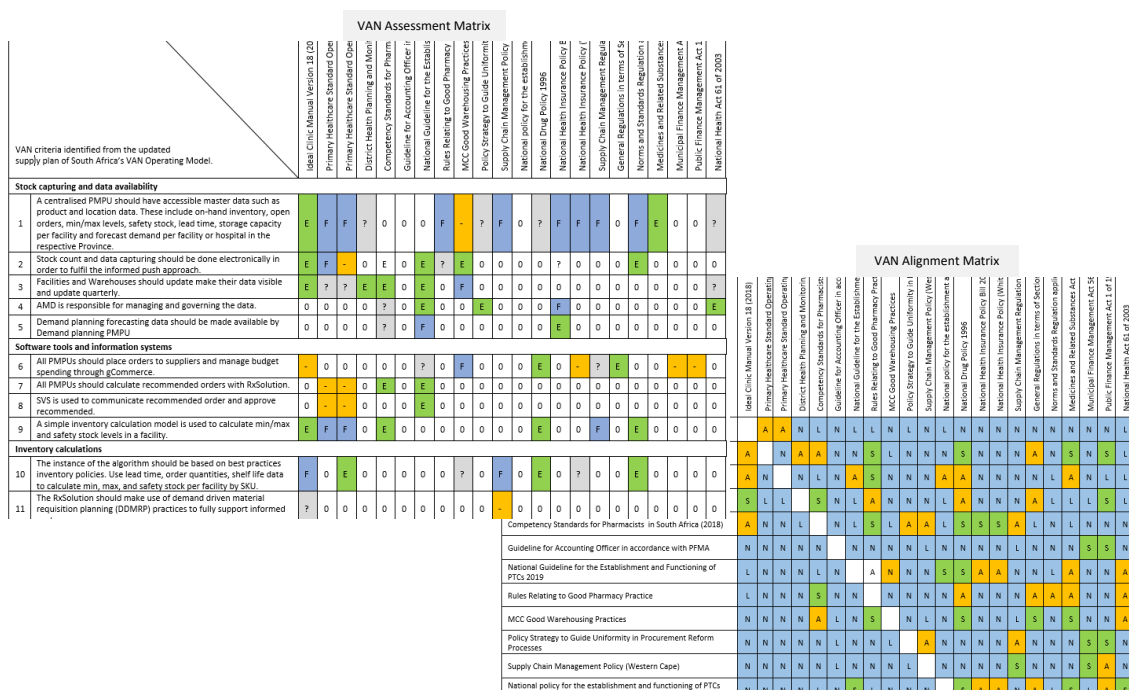
Figure 8.9: A formulated sectional view of the VAN assessment matrix and alignment matrix for inventory management

In the case study for the selection of medicines, two methods of categorisation were listed for identifying the policy problems: (i) the grouping of policies and legislation based on their enabling, facilitating or hindering effect; or (ii) the identification of VAN criteria not completely supported or enabled by policies and legislation. In the assessment matrix, altogether 14 policies were categorised as either facilitating or hindering. Due to the high number of hindering and facilitating policies, the first categorisation type was used. From the hindering category, it is clear that a majority of the policies govern at an operational level— such as SOPs

and guidelines. Only two Acts, the MFMA[1] and PFMA[2]—concerned with the financial and budgeting operations—have hindering effects on the VAN Operating Model for South Africa. These policies were linked to the VAN criteria (specifically the themes in which they were categorised) to identify the policy problems concerned. The problem was defined by four subproblem areas:

- Policy subproblem 1: Inventory calculation and stock integration system.

- Policy subproblem 2: Replenishment according to VEN[3] and ABC categorisation.

- Policy subproblem 3: Best-practices KPIs for stock monitoring across the supply chain.

- Policy subproblem 4: Integration of the VAN budget holder role with current South African finance roles.

It should be noted that this is not necessarily an exhaustive list of the policy problems that exist. It is possible that alternative policy problems may have been identified if more policies and legislations were included in the analysis. However, for the purpose of validation, only policies and legislations in the public domain were used. Similar to the first case study, only one policy subproblem from the aforementioned list was used for the remainder of this analysis. The SMEs decided to focus on policy subproblem 1. SMEs, P13 and P15 chose this option, based on the policy problem that was frequently emphasised during the workshop discussions. The information gathered during the workshop also provided the necessary information required to develop policy options and populate the policy formulation checklist table in Phase 3.

8.4.3   Phase 3: Policy formulation inventory management

For this phase a desktop exercise was performed to formulate the policy options. The information gathered in the workshop was sufficient to be able to formulate policy options. SMEs P3 and P10 were contacted during the policy formulation stage to get their input and further refine the populated table (the policy option table is shown in Table S.4). Similar to the first case study, the VAN objective and formulation checklist was utilised.

The policies formulated in this stage were different from the case study and what was proposed by the PoliVAN. The original steps in the phase requires the analyst(s) to develop policy *alternatives* to address the policy problem. In this case, the VAN criteria clearly defined what was required from a policy to enable the VAN specific to the policy subproblem. Therefore, three *complementing* policy options were developed to address the policy subproblem:

i. Policy option 1: A national policy for provincial demand-driven inventory management;

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[1]Municipal Finance Management Act 56 of 2003 National Treasury (2003a)
[2]Public Finance Management Act 1 of 1999 (National Treasury, 2017)
[3]Vital, essential and non-essential medicine classification.

ii. Policy option 2: Standardised stock management SOPs for all health establishments; and

iii. Policy option 3: A national policy for the transition to an electronic stock management system.

The policy options formulated were used as the input for Phases 4 and 5. These are further discussed in the following subsections.

8.4.4 Phase 4: Stakeholder analysis for inventory management

For each policy option, a different[1] stakeholder evaluation table was developed (see Figure 8.10). Some of the relevant stakeholders were identified during the workshop session, while others were identified through the investigation of other policy documents aligned[2] with the hindering policy documents relevant to this problem, using the stakeholder list from Table 7.4. The population of each evaluation table was done with input from SMEs, P3 and P10. They had the relevant experience and knowledge to propose the necessary scores. Similar to the previous case study, all three types of analysis were performed for each stakeholder evaluation table. The interpretation of this is discussed in Subsection 8.4.6.
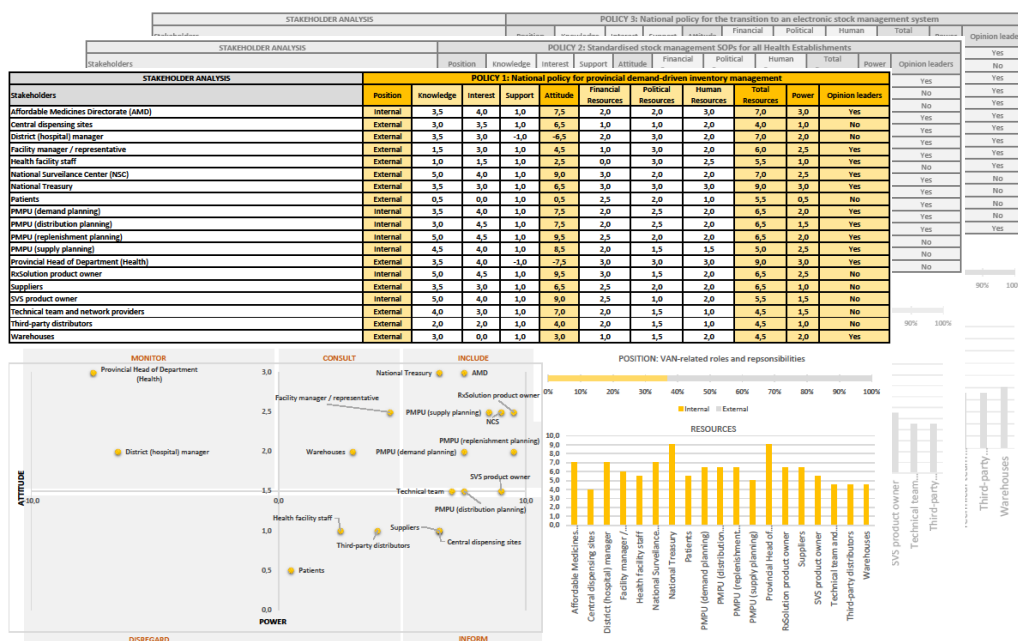
Figure 8.10: A formulated overview of the stakeholder evaluation table for the three complementing policy options

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[1] In the first case study, where policy alternatives were developed for a policy problem, the same stakeholders were used for each evaluation table.

[2] The alignment matrix from Phase 5, available in Table S.3

8.4.5   Phase 5: Impact analysis for inventory management

Similar to the first case study, a policy impact analysis table was developed to determine the possible impact of the policy options on the pharmaceutical supply chain in South Africa. Figure 8.11 provides a formulated overview of the policy impact outcomes for this case study (the comprehensive policy impact analysis table is shown in Table S.5). The SMEs selected the analytical dimensions during the workshop based on the policy problem under analysis. The same breakdown structure was used for the analytical dimensions, but the SMEs decided to leave the 'unintended effects' and 'contextual factors' dimensions out of the analysis. They wanted the analysis to focus on the technical and operational aspects of the policy options. For each dimension, a weighted factor was assigned–'feasibility' and 'criticality' received the highest preference. The 'acceptability' function was the input gathered from the stakeholder analysis[1]. It is the percentage of stakeholders that support the specific policy being addressed.

Figure 8.11: Sectional view formulated from the policy impact analysis for inventory management policies

The data in the policy impact evaluation table was populated after a background research on past policies and their impact on the South African system; however, little information was available. As this was part of the desktop exercise, fewer SMEs participated in this phase. The impact scores were proposed by SME P3 and these were afterwards reviewed by SME P15 for additional input and validation. The outcomes from the evaluation table were then

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[1]This is recommended by the PoliVAN discussed by the metric scores in Figure 7.9. This was also included in the first case study for medicine selection.

used to illustrate how the results can be interpreted and how the complementing policies were analysed.

In the first case study, the competing policy options were ranked according to their impact score. For this case study, the weighted score of each policy option was presented as a percentage of the maximum score. In literature, it was found that a weighted score is not required when options are not purposefully analysed to outrank each other, but rather to analyse the impact of each option individually (Dodgson *et al.*, 2009). Therefore, in this analysis, the weighted score was not used for further interpretation. The analytical dimensions which impose a possible risk were rather investigated and are highlighted in Table S.5. The outputs and insight produced by the preceding phases were then used to develop policy-decision plans and strategies. The strategies identified in this case study are discussed in the next subsection.

8.4.6 Phase 6: inventory management

From the outcomes in Table S.5, Policy 2 and 3 were both given high scores, meaning their impact is relatively low on the pharmaceutical supply chain. They also do not pose any risks as seen on the impact analysis table. However, Policy 1 holds potential risks from a number of analytical dimensions. As proposed by the PoliVAN, these risks need to be included in a risk management plan, to mitigate the possible outcomes that can be produced from this policy. Because in this study the policy options do not outrank each other, this policy option cannot be discarded. Because the VAN requires a system such as RxSolution to enable the end-to-end visibility and informed push supply chain approach, it is considered necessary to have this policy implemented in order to enable the above-mentioned VAN requirements. Details of the possible risks are discussed in Section S.6 .

In addition to these strategies, a stakeholder engagement plan needs to be designed for each policy (because all three policies are planned to be implemented). However, to avoid redundant information and repetitive analyses, only one policy was selected for the illustration of the analysis, which is presented in Section S.6. Figure 8.12 shows the power-attitude map for Policy 3 with an example excerpted from the case study in Appendix S for one stakeholder group.

[A] number of stakeholders will need to be involved in this policy process; facility managers and representatives should be monitored; health facility staff and third-party distributions can be disregarded from the policy process; and four stakeholder (groups) are equally distributed on the 'attitude' (horizontal) axis. The decision to manage the Pharmaceutical Therapeutic Committees (PTCs) was discussed: *they are responsible for ensuring that the national for-mularies and provincial formularies should be updated accordingly. This will then need to be*
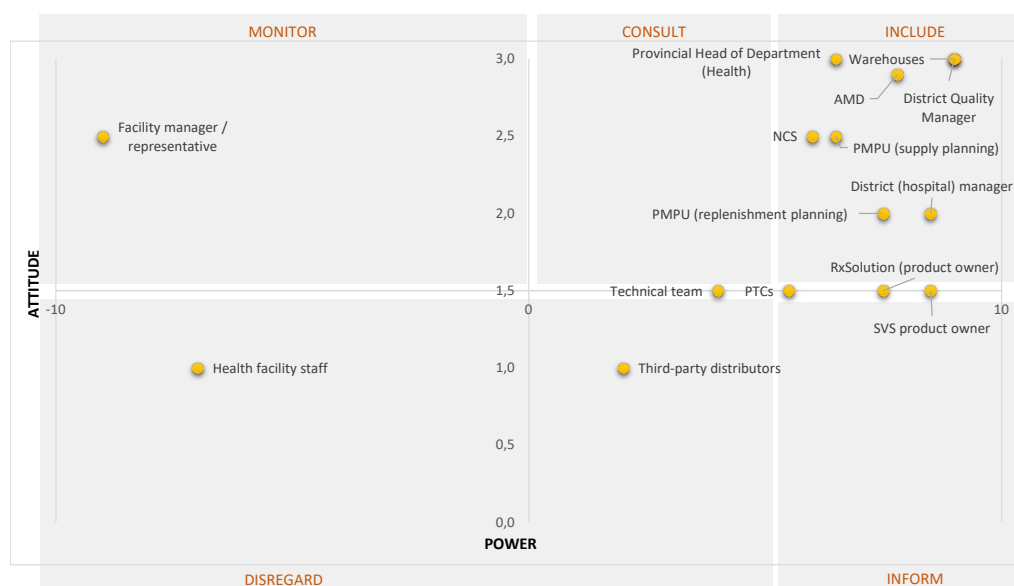
Figure 8.12: Power-attitude map for Policy 3 from the inventory management case study

embedded into the electronic system. The PTCs have a role to play in the operations; however, they are not negatively impacted by this and can thus be moved down to the 'keep informed' category. They will need to be kept updated on policy decisions, but do not necessarily need to provide input.

The final plan to include in this phase is a policy implementation plan. A gradual or phased-in approach would be ideal in this case, as Policies 1 and 3 are disruptive to the current system. Also, the three policies should not be implemented at the same time; it is suggested that Policy 2 should be implemented first. The reasons for this are: (i) Policy 2 is expected to have a less disruptive impact on the pharmaceutical system; and (ii) the foundational SOPs required to be able to accommodate the information systems proposed by the other two policies, are formulated as part of Policy 2's implementation. Policy 2 should be followed with the implementation of Policy 3, because the SVS tool is utilised at a facility level, which fits in with the SOPs from Policy 2. Then, Policy 1 should be implemented because the RxSolution requires input from the SVS system, making this implementation order the logical choice. The details of these aforementioned plans should be developed within the National Department of Health.

8.4.7 Conclusion: inventory management case study

In this section, the PoliVAN has been applied to the inventory management component of the PLF. The operational functions were detailed in the supply planning processes of South Africa's VAN Operating Model. The PoliVAN was sequentially applied, as discussed in Chapter 7, as a combination between a desktop exercise, SME interaction and a workshop with two

SMEs, where the content details for the different phases in the PoliVAN were discussed. The applicability of the PoliVAN has already been illustrated in the medicine selection case study. The purpose of the second case study was to test the flexibility of the PoliVAN. The case study showed that the different steps and tools within the different phases have managed to provide the output required by each phase, even though they were applied to a different component of a pharmaceutical supply chain and a different planning process in the VAN Operating Model. Changes that were made to the PoliVAN included both context-specific and country preference-specific factors. These two types of changes are further discussed in the next section.

8.5   PoliVAN logic model findings and recommendations

The execution of both case studies was systematic, progressing through the phases and steps of the PoliVAN. Each high-level phase was able to provide the intended and expected outputs for the next phase. The steps within each phase (as well as the tools provided by the PoliVAN model logic) were able to achieve the objective stipulated in each phase. In Chapter 7, an asterisk (*) is placed next to the PoliVAN tools that require a country to make adaptions according to their country's specifications. These specifications can be categorised as:

i. Context-specific: This is based on the context of the country utilising the PoliVAN, for example, their VAN Operating Model and planning processes and pharmaceutical supply chain structure.

ii. Preference-specific: This is the preference of the analyst in a specific country applying the PoliVAN. The preferences are based on the type of policy under analysis and the needs of the analyst. These include, for example, the decision as to which stakeholder characteristics to use in the stakeholder evaluation table and which analytical dimensions to use in the policy impact analysis. Although these dimensions are given based on the best practices identified, the type of policy under analysis could still influence the decision of the analyst.

Table 8.4 discusses the findings from the two case studies. The first column shows how the PoliVAN was adapted to South Africa's context and preferences of the SMEs. In the second column, the context-specific adaptions are highlighted to identify the validation required from the SSA countries. The third column provides recommendations for future evolvement and continuous improvement strategies for the PoliVAN (for South Africa and any country that utilises the PoliVAN). The findings for South Africa are specifically focused on the application processes and flexibility factors identified from the two case studies. The recommendations are not linked directly to the findings in the first two columns.

Table 8.4: A summary of the findings and recommendations for each phase in the PoliVAN logic model

POLIVAN	FINDINGS		RECOMMMENDATIONS FOR CONTINUOUS IMPROVEMENT IN THE POLIVAN LOGIC MODEL
	SOUTH AFRICA CASE-SPECIFIC FINDINGS	COUNTRY CONTEXT-SPECIFIC FINDINGS	
PHASE 1	• South Africa's pharmaceutical supply chain framework (SIMA) is similar to the PLF, according to the SMEs. Therefore the PLF was sufficient to use in these two case studies. • When looking up the relevant policies and legislations, the following factors should be considered: contextual background, all other legislations in the legal hierarchy, roles and responsibilities for each function, and functions that might influence or be influenced by the specific function. • It is possible that policies and legislations are not always governed by a country's Ministry of Health. As in this study, some policies and legislations were identified from other departments as well	• It is required that a country should have a VAN Operating Model, or at least one planning category (demand, supply, distribution or cold chain management) completely developed before applying the PoliVAN logic model. • The PLF was initially developed from literature and has been verified and validated a number of times in this study. The PLF was applied in the South African case studies, because their SIMA framework is not available to the public. The PLF framework worked for the South African context; however, it should be validated whether the PLF will work for SSA countries, and what possible changes will need to be made. • The policy and legislation hierarchy was developed from interpreting literature, because a comprehensive schematic was not available. South Africa's legal framework is structured similarly.	• Developing the PLF-VAN-matrix can be a once-off process. Refinements can be made if a country's VAN changes. • The PoliVAN logic model should be applied to one operational component (i.e. medicine selection, procurement, inventory management, distribution management, and medicine use) per instance. This is because the content and context within which the problems are identified and analysed are specific to an operational component.

PHASE 2	• Two different methods can be used to identify policy problems from the VAN content assessment matrix:
	   i. Grouping of policies based on their enabling/hindering effect. This method is recommended when many policies are grouped in the facility and or hindering categories.
	   ii. Identifying the VAN criteria not completely supported or enabled by the policies. This is recommended when little policies are categorised in the facilitating and or hindering category.
	
	• Mandatory legislations high up in the legal framework hierarchy, i.e. a Constitution or Act could potentially have ambiguous to no effect on VAN criteria that are focused on operational activities; however, they should not be left out of the rest of the analysis. They should be used to understand the legal environment and context within which the other policies govern. Therefore, unlike the VAN alignment matrix in the first case study, the acts that had an ambiguous effect on the VAN criteria—
			• From the two case studies, it was found that Acts and regulations can govern more than one operational component in the pharmaceutical supply chain, whereas, policies, guidelines and SOPs are more likely to focus on specific functions. Countries can utilise the information from the VAN assessment criteria to develop a policy typology. This will guide future analysis when the PoliVAN logic model, or other policy methods are applied to the pharmaceutical supply chain.

Table 8.4 continued from previous page

	but are still relevant to the pharmaceutical function—need to be included in the VAN alignment matrix.		
	• The more VAN processes that are linked to the operational functions of a PLF, the more VAN criteria are created. The VAN criteria should be categorised in the relevant themes in order to make the analysis manageable. Subsequently, this will make the policy problems easier to identify.		
PHASE 3	• Although the start of the analysis in Phase 1 focuses on one component, it has been found that the root causes of problems identified in the policy component under analysis sit within another operational component. This can be understood, because all pharmaceutical supply chain functions are interconnected to some extent. • The VAN objective and policy formulation checklist provided the necessary components to consider when formulating policy options, to make rigorous policy options, stakeholder analyses and policy impact analyses. • It was found from the second case study that the policy options being formulated do not have to be competing policies that are considered for a policy problem, but if the objectives and criteria for the VAN are specific in such manner that policies can be formulated accordingly, then the option to formulate complementing policies should be included in the PoliVAN logic model. The processes of the stakeholder analysis and policy impact analysis will need to adjust accordingly (as done in the second case study).		• It is recommended that a policy problem set (with its policy options formulated) should be taken through to Phases 4 and 5 of the PoliVAN logic model, meaning that for three policy problems, three streams of analysis will be done. This places the emphasis on the policy domain between Phase 3 and Phases 4 and 5— the intangible domain where policy problems have been identified and policy options have been formulated, ready to undergo the analysis. See Figure 8.1 for a schematic of the above-mentioned description.
PHASE 4	• The stakeholder identification list was able to assist the SMEs with identifying all the relevant stakeholders for the policy analyses. • It was discovered that all the stakeholder characteristics should be used in the stakeholder analysis, as these characteristics provided valuable insights for three types of analysis set out by the SMEs during the case studies: (i) to identify the extent of a stakeholder's involvement; (ii) to use of the 'resources' information in order to identify the ability of an opposing stakeholder to influence the policy decision; and (iii) to determine the ratio of power between internal and external stakeholders for a specific organisational group. • It was found that the 'resources' and 'power' characteristics for a stakeholder will remain the same for an analysis within a specific problem context.	• The stakeholder identification list was initially developed from literature findings. The list was then validated by SMEs from South Africa; however, the updates which these SMEs made, were not focused on the South African context. The identification list has been applied in the South African context in the case studies and has proven its ability to assist with identifying all the necessary stakeholders relevant to the policy problem. However, the list still needs validation to determine if it is generic for SSA countries as well.	• It is recommended that the stakeholder identification list should evolve within a country and that countries can use the current list provided by the PoliVAN logic model, yet begin to update the list as more analyses are done. This will make the identification of stakeholders per functional area more manageable and efficient. During the second case study, it was much easier to identify stakeholders, based on the knowledge already gained from the previous case study.

Table 8.4 continued from previous page

	• The best manner to populate the stakeholder evaluation table is through brainstorming techniques. Between the two case studies, more input from SMEs was available for the medicine selection case study. From a process perspective and analyst perspective, the scores given to each stakeholder seemed more accurate than the scores in the second case study, where less SMEs were involved (and were not brainstorming).		
PHASE 5	• Between the two case studies different analytical dimensions were used (or not all of the dimensions were used in the second case study). Both analyses provided valuable insights on the possible impacts of the policy options. What the analysts want to analyse is problem-specific. For example, in the second case study, the policies were designed for operational processes and technology; therefore, dimensions such as demographic or political contexts did not matter to the SMEs for the analysis. Therefore, the policy impact analysis and the dimensions selected for the analysis are based on the preference and policy type under analysis. • Assigning weights to the analytical dimensions is only required if the policy options need to outrank each other, based on the preference of the analyst(s). Thus, for complementing policies, evaluations are based on the score calculated as percentage of the max score.		• The current policy impact analysis is scored subjectively. Countries should make use of the analytical hierarchy process (AHP[1]) to transform the subjective scores into objective scores. In line with this study, a research project[2] is focused on developing a policy impact analysis approach that steers away from subjective scoring and incorporates best-practice methods to score the policy options for the VAN. See Appendix U for a description of this project.
PHASE 6	• The VAN alignment matrix should be used when the level at which the policy will govern is decided. The information from the alignment matrix will provide the inputs of policies and legislations to keep in mind when designing the final policy. • The VAN policy objective and formulation table should be revisited to refine the policy option(s) selected for implementation is refined. • The stakeholder evaluation table and the three analysis outputs (identified by the SMEs) should be used to develop a stakeholder engagement plan. • The scores in the policy impact analysis table (especially the dimensions given a low score) should be incorporated into a risk management plan, to develop mitigation plans for expected or unexpected outcomes. • The implementation plan should include the phase-in of the policy option(s). When more than one policy needs to be implemented (complementing policies), the plan should include the order in which the policy will be phased into the system.	• In this phase, the policy analyst will need to select the best policy option and develop policy strategies. In South Africa, the supply chain technical advisers (who reports to the Ministry of health) will most likely take the responsibility for the PoliVAN logic model as the majority of the SMEs from the two case studies are among these advisers. This role should be clarified for SSA countries before implementation.	• It is recommended that countries should develop a risk management framework (if they do not already have one) that can easily be used to identify possible outcomes of policies. This framework will be able to evolve and could even be used in the future for the implementation of policies (non VAN-related).

[1] AHP uses mathematical and psychology techniques to rank complex decisions and has been used for policy impact analyses (Saaty, 1987).
[2] This forms part of a final year project which develops a multi-criteria decision analysis to objectively analyse the impact policy options could potentially have on the system.

8.5 PoliVAN logic model findings and recommendations

8.6   Chapter 8: Conclusion

At the start of this chapter, the context-specific information required before applying the PoliVAN to the VAN Operating model was highlighted. The pre-requisites were specifically required as part of the research effort. The application of the PoliVAN to two case studies was presented with the details of the case study contents presented in Appendices R and S. The aim was to illustrate (and subsequently test) the applicability and flexibility of the PoliVAN—two of the evaluation objectives identified in Section 1.4.3.

The application of the PoliVAN systematically proceeded through the six phases, providing sufficient insight into the policy problems and relevant strategies that can be followed to resolve the policy issues—thus validating the applicability of the PoliVAN. In both case studies, the PoliVAN provided insightful information that will allow the relevant policy analysts to make informed decisions. The PoliVAN illustrated its flexibility through the following measures: (i) it can be applied to different operational functions within a pharmaceutical supply chain; (ii) it is able to adapt when changes are made to a VAN Operating Model; and (iii) it is able to perform the analyses on different granularities and levels of detail.

Finally, the key findings, and recommendations on possible future improvements for the PoliVAN were discussed for the South African context. The next chapter aims to gain insight on the transferability of the PoliVAN to other countries, where engagement with sub-Saharan African SSA VAN representatives was undertaken to investigate this outcome.

Chapter 9

PoliVAN transferability and implementation prerequisites

In this chapter, the transferability of the PoliVAN to other country contexts is investigated, through engagement with sub-Saharan African (SSA) country VAN representatives. An amalgamation of the context-specific outcomes highlighted from Chapter 8 are discussed with SSA VAN representatives to develop an understanding of the changes to the PoliVAN that are required in order for it to be applicable in their countries. Furthermore, the information gathered through the PoliVAN case study applications and transferability validation feedback is used to develop the necessary prerequisites before the PoliVAN can be implemented in a country.

9.1 PoliVAN transferability validation

In this section, the process and details behind the final stage in the evaluation strategy—the PoliVAN transferability validation with SSA SMEs—are discussed. This section starts with a revision of the evaluation strategy discussed earlier in this document and gives insight into the countries that participated in the validation process. Furthermore, the feedback from the SMEs and how the information was obtained is discussed.

9.1.1 Highlights from the evaluation strategy

The PoliVAN has been verified and validated through a number of processes and by a number of SMEs. The evaluation objectives (Table 1.1), up until 'transferability' have been achieved in this study. The applicability and flexibility of the PoliVAN was evidenced through the application of the PoliVAN to two case studies within the South African context. Subsequently, the updates and recommendations for the South African-specific PoliVAN were discussed. The final stage in the evaluation strategy is to investigate the transferability of the PoliVAN, in line with the aim of this study. The objective of the investigation into the transferability is to gain

insight into the possible opportunities and restrictions for other SSA countries to utilise the PoliVAN, and thus make an inference about the extent to which the PoliVAN is transferable to other country contexts.

The transferability is evaluated through a structured questionnaire and unstructured interviews with SMEs from two SSA countries, namely Mozambique and Nigeria. The participants in this process—the VAN advisers and/or representatives in these countries—were given a summary of the PoliVAN, the case studies, and the outcomes produced by the PoliVAN for the respective case studies discussed in Sections 8.3 and 8.4. The participants were asked to complete a questionnaire, whereafter an unstructured interview was conducted to gain further insight into the specific contexts of the respective countries under consideration. The background of the SMEs who participated in the SSA transferability validation process are summarised in the next subsection.

9.1.2 Sub-Saharan Africa subject matter experts

Three participants (described in Table 9.1) participated in this stage of the evaluation process. Their geographical locations are based in two countries, Mozambique and Nigeria, which provides this study with perspectives from two different VAN Operating Models and contexts.

Table 9.1: Summary of SMEs that participated in the transferability validation process

P#	OCCUPATIONAL BACKGROUND	ACADEMIC BACKGROUND	COUNTRY
P6	VAN Advisor, Ministry of Health in Mozambique; Village Reach M&E Department; 7 years of experience working for NGOs in the public health sector.	Bachelor's degree in Computer Science for Management from A Politécnica University in Mozambique; Published multiple research articles.	Mozambique
P17	Director at an African Health Advisory organisation focusing on Supply Chain Management; Project experiences with donor organisations, such as: BMFG, USAID, GAVI, and the Global Fund.	Management Practices in Health Care Delivery, Supply Chain Management; Master's in Public Health; MBA.	Nigeria
P18	Supply Chain Advisor for a supply chain consulting company in Nigeria and Botswana; working alongside the African Resource Centre to implement the VAN.	Certified with a number of Supply Chain Management programmes; BSc in Economics.	Nigeria

Participant P6 contributed to an earlier part of the evaluation process—the verification of the PoliVAN objectives. P6 is currently a VAN advisor for the Ministry of Health in Mozambique, and works alongside the VillageReach[1] organisation that has assisted countries, such

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[1]The VillageReach organisation—situated in Seattle, Washington—assists government entities in low-resource countries (i.e. SSA countries) with healthcare delivery strategies. This organisation works closely with these countries and the Bill & Melinda Gates Foundation to build sustainable and innovative supply chain systems with enhanced data availability, like that of a VAN.

as Mozambique, Nigeria, Malawi and Senegal to name a few, with the VAN concept in their respective countries. It was, therefore, insightful to engage with a VillageReach representative. Participants P17 and P18, both from Nigeria, are supply chain management experts working closely with the VAN initiative. P17 is a Director at an African Health Advisory organisation for Nigeria, whereas participant P18 is a supply chain consultant for a company focusing on both Nigeria's and Botswana's[1] pharmaceutical supply chain system. Although the SMEs were specifically asked to provide inputs from the perspective of their respective countries, their collaboration on VAN-related projects and engagement with VillageReach provided insights into the VAN-related work that this VillageReach does in other SSA countries.

The next subsection discusses the questionnaire results from the SMEs, including an interpretation of the outcomes based on evidence found from VAN implementation in SSA countries.

9.1.3   PoliVAN transferability questionnaire and results discussion

The questionnaire consisted of three parts, which are discussed in the following subsections. Each set of questions aimed to gain insight on the country's context and what is required (both from an implementation and transferability perspective) for the PoliVAN to be utilised in such a context. Details of the questionnaire, and SMEs' responses are tabulated in Appendix T. This first set of questions (discussed in Subsection 9.1.3.1) is aimed at the development of the country's VAN Operating Model with respect to the policy processes that were followed to implement their VAN, in order to gain an understanding of the country's current VAN status. The second set of questions (discussed in Subsection 9.1.3.2) is focused on whether the country would benefit from a policy analysis approach such as the PoliVAN, and if so, who would be responsible for the implementation thereof. The third set of questions (discussed in Subsection 9.1.3.3) is focused on the generic factors proposed in the PoliVAN to determine the possibility for the PoliVAN to be transferable to these countries' context.

9.1.3.1   The current VAN status in each country

The set of questions in this section aims to provide insight into the countries' VAN Operating Model—whether they have an existing operating model, how it was developed, and their policy experience with the design of the operating model. Both Mozambique and Nigeria have VAN Operating Models that were designed with guidance from the Blueprint Reference Model (BPRM). When they were asked to comment on how they found the guidance of the policy element, Nigeria's feedback highlighted the lack of policy and governance insight in the BPRM, thereby confirming a shortcoming of the BPRM which was identified in Subsections 1.1.2

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[1]Participant P18 only provided feedback based on Nigeria's context.

and 2.2.4. According to SMEs P17 and P18, the policy element of the BPRM is "*not too descriptive*" and "*...incomplete*". Participant P6 from Mozambique responded with "*N/A*" to this question, and when this feedback was discussed during an unstructured interview, P6 mentioned (similar to the response from P18) that their VAN implementation is being managed by the VillageReach organisation. This concludes that both Mozambique and Nigeria experienced the lack of policy insights from the BPRM. The final question in this part of the questionnaire asked the participants to identify whether their country has any policy processes or methods they use (specifically for the pharmaceutical sector) when new policies are being implemented or analysed. All the participants confirmed that their policy processes are also handled by VillageReach. P6 clarified this answer during the unstructured interview and referred to the Mozambique VAN publication by VillageReach (VillageReach, 2015).

There are a number of publications (VillageReach (2014, 2015, 2016)) available where the VillageReach organisation discusses the processes, implementation and lessons learnt from the VAN initiative. These publications form part of the *Final20 Policy Paper Series* available on their website. Data management, leadership and change management, and cold chain management are among a few of the publications available in the series. The policy series considers the different components of the supply chain and addresses the challenges embedded in the implementation of innovative approaches such as VAN (VillageReach, 2014). The series is called the 'policy paper series' as it highlights the importance of policymakers to continuously reassessing and addressing the challenges faced with system design changes, e.g. the VAN initiative. According to VillageReach (2014), "system design can be a significant undertaking, daunting for any policymaker."

Further investigation into the policy processes of VillageReach was done and some insights were gained from their publication about the implementation of VAN[1] in Mozambique (VillageReach, 2015). They did a comparative analysis between the current state and the planned future state of their supply chain processes[2] and highlighted the process where differences occurred (VillageReach, 2015). They have concluded that the majority of the changes in the processes are linked to the people and technology element—those responsible for executing the process and the data visibility enablers. Their policy analysis process assists in the identification key areas where policy change should be considered; however, it provides no evidence found about how the policies are planned to be analysed.

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[1]Mozambique refers to their VAN Operating Model as a Dedicated Logistics System (DLS) Operating Model.

[2]These include the demand planning, supply planning, distribution planning, and cold chain management processes as defined by the BPRM.

9.1.3.2   Implementing the PoliVAN logic model in the country

The SMEs were given a pre-read document that summarises the processes for each phase in the PoliVAN, and the outcomes produced in the two case studies. The SMEs were then asked to reflect on the ability of the PoliVAN to provide the necessary insights regarding their policy strategies in their country, and whether they would advise the VAN developers to utilise this approach to make the informed policy decisions for the VAN. Specific feedback from the respective participants are:

P6:   *"Each country have* [sic] *its own specifications. I would encourage the use of this Model on developing VAN in my country, since its starts to access what the country have* [sic] *in terms of policies for VAN and Adapt of reformulate them to VAN."*

P17:   *"Yes - it would be useful to test this out though, but it seems to be generic for our country"*

P18:   *"Yes. I believe our country and Village Reach should implement this concept. I enjoyed reading the details and outcomes in the inventory management case study."*

To implement the PoliVAN, it is required that an accountable role or team should be assigned to manage the operations and executions of the different phases and processes. In South Africa, through the case study, it became clear that the Supply Chain Technical Advisers (SCTA) will be the accountable body to manage the PoliVAN. The SSA SMEs all referred to VillageReach as the organisation that is most likely to govern the PoliVAN. Although this has only been confirmed by two countries, it appears that VillageReach may be the organisation that will govern the implementation of the PoliVAN in other SSA countries as well, especially when comparing the work of their organisation in a number of SSA countries.

The final question for this part of the questionnaire requests SMEs to provide an indication of the perceived level of effort required to execute each phase of the PoliVAN in their country's context. The detailed answers provided by the SMEs are shown in Appendix T. The reasoning for following this approach, is that the efforts required to implement the PoliVAN would be dependent on the context-specific factors[1] such as: the level of detail[2] at which a country's VAN Operating Model is designed; and the existence of policy documenting processes and a risk management framework. The perceived levels of effort assigned by the SMEs are relatively aligned for various phases (See Table T.1). However, P6 from Mozambique scored Phase 6 lower in comparison to the other countries. The choice was supported by the SME's reason given during the unstructured interview that their country already has an existing risk management and policy layout framework. However, when it was explained that other efforts such

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[1]The following factors are not exhaustive.

[2]This could potentially affect the efforts required to perform Phases 1 and 2.

as a stakeholder engagement plan and implementation plan are also required to be developed in this phase, P6 decided to change the initial answer given. The engagement with the SSA SMEs on this particular question contributed towards an understanding that the levels of effort for each phase of the PoliVAN is specific to the country's context.

9.1.3.3   The transferability of PoliVAN logic model

The final set of questions was focused on the context-specific tools provided in the PoliVAN, which requires the country to adapt the tool to their specific context and needs. In the tools section of each phase (Chapter 7), an asterisk (*) is indicated next to the tools that should be adapted according to the country's specifications. Some of the tools are generic and should be adapted to a country's *preference* (i.e. stakeholder characteristics, stakeholder analysis type, analytical dimensions and weighting factors), whereas other tools should be adapted to the country's specific *context*. The following tools were identified as context-specific during the South African case studies and are discussed in the questionnaire: the PLF-VAN-matrix; the legal hierarchy; and the stakeholder identification list. The first tool that was validated is the PLF-VAN-matrix from Phase 1. The SMEs were asked to reflect on whether their country has a similar framework (as detailed as the PLF) that illustrates the components of their pharmaceutical supply chain; if not, they were requested to indicate whether the PLF will be sufficient to guide them with the identification of the supply chain functions in their country. Participant P6 agreed that the tool is detailed and mentioned during the unstructured interview that the framework their country makes use of is similar to the PLF. The two participants from Nigeria gave mixed responses (one agreed with the PLF functions, whereas the other did not); however, their following comments appear to be aligned:

P17:   *"No. We use another, cyclic process form* [sic] *VillageReach, not as thoroughly designed as the presented PLF. This tool would be useful."*

P18:   *"Yes. We have a similar framework, which is cyclic and includes some components."*

The cyclic framework in Nigeria is based on the medicine supply chain components cycle in the *Final20 Paper Series* from VillageReach. It includes: system design; processes; data; equipment; people; funding; and political will. From the description in the policy series publications, the 'processes' refers to the logistical functions from the PLF. 'Data', 'people', 'equipment' and 'funding' refer to the management support elements (from the PLF) and the 'political will' is the enabling and policy environment from the PLF (VillageReach, 2014). Although it encompasses the PLF components at a high level, it is not sufficiently detailed to enable Phase 1 to be completed. Thus, it is recommended that Nigeria should make use

the PLF components and should adapt the functions according to their country's supply chain processes.

The next tool is focused on the legal hierarchy presented in Figure 7.5. According to P6 from Mozambique, the hierarchy provides a generic schematic of the relationship between policies and legislations, "*...because in my country all policies, rules as well SOPs depends* [sic] *on the country* [sic] *legislation and regulations.*" The participants from Nigeria had a different argument. Although they do agree that their country's policies and legislation sit within a hierarchy (this was confirmed during the unstructured interviews), their legal structure is more complicated than the one presented in the PoliVAN. The respective responses from the participants P17 and P18 are:

P18: *"We have a legal hierarchy, but it is structured differently than the one given in the case study."*

P17: *"We have a constitution with legislation (such as regulations, laws and rules similar to your hierarchy). Then there are four distinct law systems: English law, customary law, the Islamic law and the common law. The next type is the Judicial law with four case tiers."*

Although the Nigerian legal framework has a different structure, the hierarchy presented still holds value, as the emphasis should be placed on the hierarchy—the distinction between mandatory and voluntary legislations. It was evident during the unstructured interviews that both countries do have a hierarchy where some policies are easier to change than others. The third and final tool that was considered as context-specific, is the stakeholder list that allows a country to identify relevant stakeholder individuals, groups or organisations in their country context. All of the SMEs reflected well on this question and agreed that this list is sufficiently generic for their country to utilise.

9.1.4   Conclusion: PoliVAN transferability validation

In conclusion to this section, the PoliVAN underwent a validation process, through engagement with VAN SMEs from two SSA countries (Mozambique and Nigeria), using a structured questionnaire followed by unstructured interviews with each participant. The questionnaire provided to each participant covered sufficient areas of the PoliVAN to gain insight into transferability-objective and the possibility for an SSA country to utilise the PoliVAN. The following key findings from the questionnaire are highlighted:

i. The SSA country VAN representatives agree that there is a lack of descriptive policy insight and guidance within the BPRM as highlighted earlier in this study;

ii. VillageReach is responsible for the planning and implementation of the VAN initiative in many SSA countries;

iii. The policy process described by VillageReach, who manage the implementation of the VAN in many SSA countries, does not specify how the policies should be analysed;

iv. The PoliVAN outcomes from the case studies provided sufficient information, even so far that the participants from the two countries are willing to recommend the implementation of it in their country;

v. The PLF is a generic and detailed framework that will enable a country such as Nigeria, which does not currently have the detailed functions of their pharmaceutical supply chain documented, to go ahead with Phase 1 of the PoliVAN as prescribed in Chapter 7; and

vi. Even though countries have different types of laws and legislations, emphasis should be placed on the hierarchy of the documents—the mandatory and voluntary legislations. It should also be emphasised that some policies are called up into other documents which make them align with one another (important for Phase 2).

The transferability of the PoliVAN to other country contexts is by no means completely validated in this study; however, the insights gained from the engagement with SSA VAN representatives provided a reasonable indication that the PoliVAN is likely to be transferable. This has led to a recommendation for future work, namely further engagement with SMEs from VillageReach (the organisation responsible for managing the implementation of the VAN in various SSA countries) to provide more input on the transferability of the PoliVAN.

The next section takes into account the outcomes from the South African case studies and the transferability validation feedback and stipulates the required prerequisites for implementing the PoliVAN.

9.2 PoliVAN implementation prerequisite

In this section, the prerequisites for when a country plans on implementing the PoliVAN, are discussed. Although the PoliVAN has only been applied to the South African context, insights were gained from the participating SMEs to make the following suggestions on pre-implementation requirements, level of efforts to expect and country-specific prerequisites to keep in mind.

9.2.1 Managerial prerequisites before implementing the PoliVAN logic model

Before a country can embark on implementing the PoliVAN, it is suggested that a number of managerial planning details are clarified by the policy analyst(s)—allowing them to plan

accordingly. The prerequisites are discussed according to Kaizen's five W's and one H (5W1H) principle: 'why', 'what', 'when', 'where', 'who' and 'how'. The following discussion details each 'W' and 'H' and how this contributes towards the implementation of the PoliVAN.

WHY

Why does a country want to implement the PoliVAN logic model?

- The need for a country to identify relevant policies to their VAN Operating Model and the projected effect of these policies on the operationalisation of their VAN. Additionally, the need to develop informed policy decisions and strategies, in order to minimise the impact of policies on the VAN implementation and operationalisation.

WHAT

What is required from the country to implement the PoliVAN logic model?

- A developed VAN Operating Model specific to the country's needs and context.

- Having only one supply chain planning category (demand, supply, distribution planning and cold chain management) process completed is feasible; however, a more thorough application of the PoliVAN could be achieved if a comprehensive view of the entire VAN Operating Model is understood.

WHEN

When should the PoliVAN logic model be applied?

- It is recommended that the PoliVAN should be applied during the design phases of the VAN Operating Model; once the people, process and technology elements are completely designed.
- It is possible that the design of the VAN Operating Model can be continuously updated during the different design stages. The PoliVAN has proven its flexibility and can be utilised as the design updates; however, it is critical that a country does not limit the design of the VAN Operating Model based on their current policy framework.

WHERE

Where should the PoliVAN logic model be applied?

- It is suggested that the application of the PoliVAN should focus on one operational component (medicine selection, quantification and procurement, inventory management, distribution management or medicine use) at a time. This makes the analysis manageable and focused on specific policy problem areas. However, the far-reaching impact of, and interrelationships between policies should be considered during the PoliVAN application.

WHO

Who should be responsible for the management and application of the PoliVAN logic model?

- The country should clarify the accountable entity managing the PoliVAN.
- The application, and the dissemination of responsibilities should be done according to the relevant expertise for each operational component in the supply chain.
- The expertise of the various analyst(s) needs to be based on the skill requirements provided in each phase of the PoliVAN within the supply chain area under analysis.

- Each team of analysts should have a responsible body or liaison between the different supply chain areas under analysis, to consolidate the policy decisions and strategies across the supply chain functions in order to ensure policy alignment and avoid any possible contradictions.

HOW

How should be the PoliVAN logic model be applied?

- The sequential phases and steps in the PoliVAN should be followed for each application. The responsible body or analyst should have an understanding of the PoliVAN operations in each of the respective phases and steps.
- The BPRM suggests that the design of a VAN Operating Model should begin with the demand planning processes. This will similarly need to be applied to the PoliVAN, as demand planning provides the input to supply planning and so forth. Cold chain management processes are involved with the supply and distribution planning categories and should be applied according to the different categories as well to make it manageable, especially in countries where the VAN is primarily focused on vaccines.

The aforementioned prerequisites are PoliVAN-specific; meaning, any country that wants to apply the PoliVAN, should ensure that these enablers are in place, to ensure that the PoliVAN can be applied successfully. The perceived level of effort required for actors (i.e. policymakers, government officials and VAN role players) to apply the PoliVAN to their VAN Operating Model are discussed in the next section.

9.2.2 PoliVAN logic model perceived levels of effort and recommendations

During the verification process, where the specification of a logic model was compared to the PoliVAN (Table 6.5), a difference that was identified is the level of effort for the various activities in a logic model required. The perceived levels of effort required to perform each phase in the PoliVAN were considered during the application of the case studies and the SSA transferability questionnaires. The information from the two aforementioned investigations on this particular matter, formulated the following conclusion; it is not appropriate to definitively specify the levels of effort for each phase in the PoliVAN, due to the following reasons:

i. The level of analysis of the PoliVAN (i.e. it being generic and transferable across country contexts) differs from the level of analysis at which efforts are defined (i.e. this requires a specific detailed analysis to define the effort levels for each phase); and

ii. Context-specificity: As highlighted, the levels of effort required to perform each phase in the PoliVAN is specific to a country's context and can therefore not be generically defined.

The above-mentioned factors provide reasoning for not specifying the levels of effort for each phase in the PoliVAN at this stage. Investigation on the context-specific factors that affect the level of detail contribute towards the future work recommended earlier in Subsection 9.1.4.

9.2.3 Conclusion: PoliVAN implementation prerequisites

In this section, the prerequisites to implement and apply the PoliVAN was discussed, along with the expected level of effort it would take to perform each phase. The discussion in this section is applicable to any country that aims to apply the PoliVAN to their VAN Operating Model. The information in this section was gathered through the experience of the two South African case studies and insights from the SSA transferability questionnaire. The information provides a set of relative expectations on the level of resources and time required to apply the PoliVAN. The development of a VAN Operating Model takes time; for example, South Africa's VAN Operating Model has been updated a number of times over the past three years. Also, policy analysis, design and implementation are not processes that happen within a short period of time. Some policies can take up to a decade to be adopted and implemented, therefore, thorough analysis processes with sound tools and skilled resources managing these processes, are required to ensure successful policy implementation that achieves the intended outcomes (Hallsworth *et al.*, 2011).

9.3 Chapter 9: Conclusion

In this chapter, the possibility for the PoliVAN to be transferable to other country contexts is investigated, through engagement with SSA country VAN representatives from Mozambique and Nigeria. The feedback from the SMEs provided the following insights on: the current status of these two countries' VAN Operating Models; and the context-specific changes required for the PoliVAN to be transferable for these countries' contexts. Furthermore, the engagement with SMEs revealed that the planning and implementation of VANs in many SSA countries (i.e. Mozambique, Nigeria, Malawi and Senegal) are managed by the organisation VillageReach. Input from only two countries' perspectives was gathered during this transferability validation process. It is recommended that future work includes further engagement with relevant SMEs, especially VAN consultants from VillageReach, and the application of the PoliVAN to a case in an SSA country's (other than South Africa's) context, in order to prove the transferability claims.

Furthermore, the insight from this study enabled the development of PoliVAN implementation prerequisites. These prerequisites are PoliVAN-specific—processes and resources that need to be in place before a country applies a PoliVAN to their VAN Operating Model. Finally, this chapter concluded with a discussion on the relative expected levels of effort required to perform the processes in each phase of the PoliVAN.

Chapter 10

Project summary and conclusion

In this concluding chapter, a summary of all chapters is provided, with a discussion of how the chapters contributed towards achieving the objectives set out in this study and/or how it contributed towards the development of the PoliVAN. Then, a reflection on the PoliVAN as developed, verified and validated throughout this study, is given. This is followed with a reflection on the research study as a whole—the contributions that this study provides towards the research field and the relevant stakeholders in line with the VAN project. An overview of the limitations of this study and challenges that were faced during the progression of this study is subsequently discussed. Finally, recommendations for future work are provided.

10.1 Research summary

In this section, an overview of the research objectives and how they were achieved in this study is illustrated in Table 10.1, followed by a summary of each chapter.

Table 10.1: The research objectives achieved in this study

SUB-OBJECTIVES	CHAPTER / SECTION	EVALUATION OF THE OBJECTIVES ACHIEVED
Research objective 1: To provide context to this study by understanding the elements, components, and operations of a VAN Operating Model.		
RO 1.1 Investigate the Blueprint Reference Model (BPRM) to understand the different design elements.	Sections 1.1.2 and 2.1	This is achieved through a review of the BPRM pertaining to the key design elements: people, process, technology and policy. Each design element is subsequently discussed in terms of what these design requirements mean for a country's VAN Operating Model.
RO 1.2 Understand the contextualisation and outcome from developing a country-specific VAN from the BPRM: South African Model.	Sections 2.1.2 and 2.2	The key design elements from the BPRM were used to review and discuss the South African VAN Operating Model[1]. This review provided an understanding of the inputs required to design a VAN Operating Model for a country's context from the BPRM, as well as the level of detail to which a VAN can be designed. Additionally, this gave insight into the overarching aim and vision of the VAN initiative.

SUB-OBJECTIVES	CHAPTER / SECTION	EVALUATION OF THE OBJECTIVES ACHIEVED
RO 1.3 Understand the enablers that are required to successfully implement a VAN Operating Model.	Section 2.3 and Appendix C	One of the key enablers to implement a VAN initiative is the 'policy will and policy enablers' (illustrated in Figure C.1). This gave emphasis to the need for policy insight and how these policies will enable the implementation of a VAN Operating Model. The policy insight is also required, along with the other enablers, in order to plan the change management around the implementation of the VAN planning processes in a country.
Research objective 2: To identify the link between (and indirectly the effect of) pharmaceutical supply chain policies and a VAN Operating Model.		
RO 2.1 Investigate the key operations and functions of a pharmaceutical supply chain to grasp the complexity of the problem.	Sections 3.1 and 3.2	The functions of supply chain management, also referred to as logistics management, are investigated within the context of a public pharmaceutical sector. This led to the discovery of a pharmaceutical logistics framework (PLF) which details all the operational, tactical and strategic level components of what constitutes a public pharmaceutical supply chain.
RO 2.2 Identify the link between policies and the operations of a pharmaceutical supply chain.	Sections 3.1.2, 3.2.3	Various operational functions are interwoven and interrelated and are supported by managerial elements, which altogether sit within an enabling environment. The enabling environment consist of policies and other legislations, i.e. regulations, Acts, guidelines and SOPs. This provides insight into the policy element for the VAN. The policy element governs the people, process and technology elements and is considered an important enabler for the implementation and operationalisation of a VAN in a country.
RO 2.3 Identify and synthesise the similarities between the operations of a pharmaceutical supply chain and the VAN Operating Model.	Sections 3.3, 5.1 and 5.3.2	The operational components and functions from the PLF correspond to the process element of the VAN. The management support elements from the PLF correspond to the people and technology elements. The enabling environment from the PLF corresponds to the policy element of the VAN.
Research objective 3: To explore policy analysis approaches that enable decision-making strategies regarding the effect of policies on an operating model such as VAN.		
RO 3.1 Identify policy analysis methods that enable decision-making.	Sections 4.1, 4.2.1	Various policy analysis methods and models were identified. Some methods are concerned with the policy decision-making processes and the most prominent methods in literature are discussed. Various other tools were highlighted that are considered important for policy analysis.
RO 3.2 Identify methods to analyse the effect of policies on a system.	Sections 4.2.2.2, 4.2.2.3 and 4.3	The most pertinent method highlighted is the effect-implementation approach for a healthcare context by Morestin (2012). Other methods included a stakeholder analysis and sophisticated modelling.
Research objective 4: To propose a policy analysis approach that enables insight on how to identify, analyse and develop policy-specific decisions and strategies to support the BPRM with the design and implementation of a VAN Operating Model from a policy perspective.		
RO 4.1 Incorporate relevant and context-appropriate methods that identify relevant VAN-specific policies and analyse the effect these policies have on a VAN Operating model with decision-making analysis approaches and strategies.	Chapter 5	The complete design process incorporates a synthesis of the literature findings, developing design requirements, constructing the design criteria and developing the PoliVAN.

Table 10.1 continued from previous page

SUB-OBJECTIVES	CHAPTER / SECTION	EVALUATION OF THE OBJECTIVES ACHIEVED
RO 4.2 Verify the literature used and assumptions made to develop a policy analysis method.	Sections 6.2 and 6.3.	The PoliVAN underwent a through verification process, whereby the literature used to develop the PoliVAN was verified.
RO 4.3 Perform validation processes to gain insight, make recommended changes, test the applicability and develop context-specific prerequisites for future implementation.	Sections 6.3, 6.4 and 6.5. Chapters 7, 8 and 9.	The PoliVAN was validated through subject matter expert (SME) interaction and the necessary updates were made to the PoliVAN. The refined PoliVAN was applied to two case studies in the South African context where the applicability and flexibility were confirmed. To validate the context-specific prerequisites, an investigation into the transferability of the PoliVAN was undertaken with SSA VAN representatives. However, this evaluation outcome was not completely validated in this study. More on this matter is further discussed in this chapter.

[1] This refers to the original VAN Operating Model version of South Africa (2016)

This study opened in Chapter 1 with a discussion of the current real-world problem of medicine shortages in sub-Saharan African countries, and how the Visibility and Analytics (VAN) initiative aims to improve the availability of essential medicines from a supply chain perspective. In this opening chapter, a problem relating to policy, one of the VAN's design elements, is identified and described. Building on this problem statement, the aim of this study is defined as the development of a proposition or method that assists the relevant stakeholders on how to identify and develop policy-specific strategies for their country's VAN Operating Model. The research methodology included a mixed-method approach with a thorough evaluation strategy.

Chapter 2 provided context to this research study, with an overview of the VAN initiative. The guide on how to develop a VAN Operating Model for a specific country, the BPRM, and the South African VAN Operating Model were discussed. The chapter discusses the overarching objective of a VAN, and how this can be achieved through the four design elements of people, process, technology and policies. The South African VAN Operating Model was included in this chapter to identify the translation between the BPRM guidelines and how South Africa adopted this approach. It was identified that the policy element is the least-developed element, both in the BPRM and for the South African VAN Operating Model. This chapter concluded that in order to understand how country policies could affect a VAN Operating Model, it is first required to understand the system in which the VAN is to be implemented and how policies affect such a system.

Chapter 3 provided insight into the operations of a public pharmaceutical supply chain that are not known by only considering the VAN content. The link between policies relevant to the supply of medicines within the context of VAN and a pharmaceutical supply chain are subsequently identified and discussed, with the aim of gaining an understanding of the interactions between these two concepts. This chapter refrained from providing too much literature on

this matter, but rather to highlight and discuss all the the functionalities transversally. However, from the research, the information gathered still provided a deeper understanding of the functions, even though all of it were not discussed in this document. This chapter further highlights the pharmaceutical logistics framework that encompasses the operational functions of the supply chain and the managerial elements supporting the operational functions. The pharmaceutical logistics framework then illustrates how these components sit within the 'enabling environment' of policies and legislation. Chapter 3 concluded that the entire pharmaceutical supply chain and the supportive elements are not enabled by policies alone, but also other legislation such as Acts, regulations, guidelines and standard operating procedures.

Due to the non-existence of established policy analysis tools to support the problem identified in Chapter 1, different methods and tools on how to conduct a policy analysis were considered in Chapter 4. Chapter 4 identifies two types of policy analysis models: (i) the analysis *of* policies (referring to the decision-making process), as well as (ii) the analysis *for* policies—an important distinction. Furthermore, Chapter 4 identified the role of stakeholders in the policy analysis process. Throughout the discussion of the different models, the various authors of the literature presented, continuously emphasised that the policy analysis models do not necessarily have to be used 'as is', but they should be adapted to fit the nature of the problem. As evidenced by the differences between the models discussed in this chapter, policy analysis projects were interpreted from different perspectives, meaning each policy analysis tool is unique to a specific problem.

In Chapter 5, a systematic approach was used to develop a policy analysis model for a VAN, named PoliVAN. This method included: highlighting the foundational concepts from the literature provided in Chapters 2, 3 and 4; setting objectives that the PoliVAN should be able to accomplish; identifying the key design criteria from the previously mentioned chapters that are required to achieve the objectives; and selecting, adapting, and combining the various tools identified in Chapter 4 to achieve the objectives identified for the PoliVAN. The PoliVAN is considered a roadmap that includes the inputs, outputs, objectives and resources required to perform the necessary steps, which consequently details the specifications of a 'logic model' as described by its definition in that chapter.

In Chapter 6, the developed PoliVAN underwent a complete evaluation process of verification and validation. The inherent theory of the PoliVAN and the assumptions made from literature were verified with SMEs, who are academically qualified in the various topics investigated in this research study. The proposed PoliVAN was then validated by SMEs with specific knowledge of the VAN and pharmaceutical supply chains to determine whether it is relevant to the VAN and appropriate to the pharmaceutical supply chain context. The final part of this

chapter introduces the strategies for the final two validation processes: application to the case study (Chapter 8) and the PoliVAN transferability insights (Chapter 9).

Chapter 7 provides a detailed account of the refined PoliVAN—post the verification and SME validation processes and suggested improvements from Chapter 6. The PoliVAN identifies six different high-level phases, each with its own objective. In each phase, a number of steps are defined, with the appropriate tools and skills required to achieve the objective(s) in each phase. Then, the logical flow and interaction amongst the different phases are discussed. The refined PoliVAN, presented in this chapter is used for the case study validation process in Chapter 8.

In Chapter 8, the refined PoliVAN from Chapter 7 is applied to the South African VAN Operating Model through two case studies. Each case study is applied to one of two operational components from the pharmaceutical logistics framework, namely: medicine selection and inventory management. The application of the PoliVAN systematically proceeds through the six phases, providing insight into the policy problems and relevant strategies that can be followed to resolve the policy issues within the specific context of South Africa. The applicability of the PoliVAN was illustrated by both case studies. The flexibility of the PoliVAN was demonstrated with the application of the PoliVAN to two different parts of a pharmaceutical supply chain and two different planning categories (demand and supply planning) of a VAN Operating Model. The key findings from the two case studies were highlighted and the country-specific adaptions that were required to be made, were discussed. The country-specific adaptions were categorised by the preferences made by the country and the context of the country. The preference-specific adaptions from the two case studies provided the necessary insights to adjust the PoliVAN specifically to the South African context, and were highlighted at the end of this chapter. The context-specific adaptions were identified, which were subsequently used to gain insights of these adaptions within other SSA country contexts.

Chapter 9 formulates the context-specific findings from Chapter 8 into a structured questionnaire and investigates, through engagement with VAN representatives from Mozambique and Nigeria, the possibility for other SSA countries to utilise the PoliVAN. The outcomes from the transferability validation process provided insight about the need for a policy analysis method for the VAN in these countries. The transferability of the PoliVAN is investigated in this study; however, not by means of an extensive application of the PoliVAN to countries other than South Africa, but through engagements with SSA VAN representatives; the insights gained from the engagement with SSA VAN representatives provided a reasonable indication that the PoliVAN is likely to be transferable. This has led to a recommendation for future work, namely further engagement with SMEs from VillageReach (the organisation responsible

for managing the implementation of the VAN in various SSA countries) to provide more input on the transferability of the PoliVAN.

The feedback from the questionnaire and the insights gained during the two case study applications, provided insights into the perceived levels of effort required to perform the different phases in the PoliVAN. The implementation prerequisites were discussed for countries that want to apply the PoliVAN. This allows guidance to countries to plan accordingly and ensure sufficient and skilled resources are allocated to perform the number of steps in each phase of the PoliVAN.

10.2 Reflection on the PoliVAN logic model

The PoliVAN was designed through a combination of three mutually exclusive literature studies. The information gathered from each of these topics is based on evidence from previous studies (in the case of the VAN, this refers to the information provided by the developers of the BPRM and VAN initiative). The PoliVAN underwent a thorough evaluation process where SMEs confirmed the inherent theory used to develop the PoliVAN as well as confirmed it to be relevant and context-appropriate. Minor improvements were made to the PoliVAN as suggested by the SMEs during the validation process. This was valuable, because the SMEs provided insight into the context of a pharmaceutical supply chain that cannot be found in literature but only through relevant, industry- and domain-specific practical experience.

The PoliVAN underwent another validation process where the applicability and flexibility of the model was confirmed. Two case studies (from the South African VAN Operating Model) were used to test the ability of the PoliVAN model to progress through the six phases, providing the required outputs that are expected from the different phases in the PoliVAN model. The applicability of the PoliVAN was demonstrated, and the outcome of the case study provided substantial insight into:

  i. Existing policies and legislation that are relevant to the VAN Operating Model;

 ii. The effect (enabling, facilitating or hindering) that existing policies and legislation have on the VAN Operating Model;

iii. The identification of potential policy problems and formulation of policy options that could potentially address the policy problem(s) at hand;

 iv. Understanding the influence that external factors, contextual factors, and the support of relevant stakeholders might have on the policy problem solution(s); and

  v. The possible impact a potential new policy solution could have on the country's pharmaceutical supply chain system.

The insights provided through the application of the PoliVAN are similar to the objectives identified in Subsection 5.2.2. This further illustrates that the PoliVAN is able to achieve the stated objectives. The PoliVAN illustrated its flexibility in a number of ways:

   i. The PoliVAN processes were not affected by the change in South Africa's VAN Operating Model during the progression of this study;

   ii. The PoliVAN was found to be flexible as evidenced through the application to two different operational components of a pharmaceutical supply chain, namely: medicine selection and inventory management;

   iii. The PoliVAN was able to adapt the country-specific tools to the context of South Africa;

   iv. Between the two case studies, the PoliVAN was able to adapt to the different level of detail for each analysis—the inventory management component had more detailed processes at an operational level than medicine selection; and

   v. The SMEs during the case study had the ability to make preference-specific decisions in the analysis, which did not affect the processes within the PoliVAN, but which provided insight on how to specifically tailor the PoliVAN for a country such as South Africa.

Upon completion of the case studies, the SMEs confirmed that the PoliVAN is, according to their professional judgement, applicable to any SSA country that requires insight into the effect their country's policies and/or legislation might have on their VAN Operating Model. This was further validated through engagement with SSA VAN representatives. The PoliVAN phases described in Chapter 7, have an asterisk (*) next to the tools that need to be adapted to the particular country's specifications. The outcomes from the case studies provided two types of country-specific factors from these tools:

1. Preference-specific adaptions: These are the generic and best-practice tools that allow the country to fit the tools according to their needs and the type of policy under analysis. The preference of a country could potentially differ for different applications with different policy problem outcomes.

2. Context-specific adaptions: These are the tools[1] that require the country to fit the tool specifically to the context of their country.

The knowledge gained from the case studies allowed insight into the relative level of effort required to perform the different phases of the PoliVAN. This information allowed the development of implementation prerequisites to enable countries that plan on utilising the PoliVAN to plan the application timeline and resources required accordingly.

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[1] These tools include the pharmaceutical logistics framework, a country's VAN Operating planning processes and the stakeholder identification list.

One of the limitations found through the application of the PoliVAN itself, is the subjectivity of the policy impact analysis tool in Phase 5. The outcomes of the policy impacts were subjective to the scores given to each policy options by the SMEs' opinions, meaning that the SMEs could have biased the policy outcomes in their favour if it were their intention to do so. As part of a supplementary study, a Bachelor's thesis project was assigned to further the investigation into the development of a policy impact analysis tool for the PoliVAN. The aforementioned study was done under the guidance of the author of this study. This additional study has highlighted the specific shortcomings regarding the subjectivity of the current policy impact analysis tool provided in Phase 5. This additional study has proposed approached to address the shortcomings via a thorough investigation of literature, cross-examination of best-practice methods and a multi-criteria decision analysis tool that has been specifically designed for the use in Phase 5 of the PoliVAN. To provide some more insight on this work, this study's[1] abstract is included in Appendix U.

10.3 Contributions made in this study

The outcome of this study led to the unique contribution of a policy analysis logic model (PoliVAN) that assists policy analysts, health authorities, government officials, and VAN role players in a country to analyse existing policies in order to determine the potential effect they might have on a country's VAN Operating Model. This logic model subsequently proposes methods to use in identifying, analysing and developing policy-specific decisions in order to strategise the reform, adoption and implementation of policies that support the operationalisation of the VAN Operating Model, based on evidence-informed insights. The PoliVAN provides the aforementioned actors with insights on their policy and legislation landscape, and how this could potentially affect the successful implementation and operation of the VAN Operating Model they are trying to incorporate into their pharmaceutical supply chain. As highlighted earlier in this study, a country's policy and legal framework governs and enables the functioning of the operations within their pharmaceutical supply chain. The PoliVAN contributes by providing a tool with relevant insight on how to detect which policies enable, facilitate or could potentially hinder the VAN Operating Model. With this information at hand, the PoliVAN contributes by guiding the actors on how to identify the relevant policy-related problems and subsequently how to (re)formulate these policies to support the operations of the VAN within their country and legal context. Policymaking can be a daunting process; the PoliVAN assists these actors with the required, evidence-based information on policy (re)formulation to ensure that the required details and factors are considered for the policy design. The PoliVAN also contributes by providing these actors with analytical tools to evaluate how the (re)formulated

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[1]This is still an ongoing study and examinations take place in November 2019.

policy could potentially impact the pharmaceutical system through a number of factors, including the relevant stakeholders involved. The PoliVAN takes a comprehensive overview of the information and guides these actors on how to strategise the implementation of these policies. The PoliVAN provides a holistic approach, taking into account various analysis methods and policy-related factors to analyse policies for the VAN and pharmaceutical supply chain context, ensuring that a thorough analysis is achieved.

From these overarching contributions of the PoliVAN, the following supplementary contribution is made for the South African VAN Operating Model: From the case studies, it is evident that the PoliVAN is suitable for the South African context and can be specifically tailored (as discussed in Table 8.4) for further implementation in South Africa. The PoliVAN outputs produced from the case studies can be used as an initial analysis to further build on this analysis with the policy-related information that was not available in the public domain. The Supply Chain Technical Advisers (SCTA), who will most likely be the accountable body for the PoliVAN, can make use of the implementation prerequisites to plan, allocate resources and implement the PoliVAN accordingly. Furthermore, this study also contributes towards an initial insight of the PoliVAN's ability to be generic for SSA countries. The outcomes produced from the South African case studies intrigued the SSA VAN representatives to the extent that they indicated their willing to recommend the PoliVAN for their policy analysis processes when implementing the VAN. This would create the opportunity to further investigate the applicability of the PoliVAN in other SSA country contexts. This opportunity for future work is discussed further in Section 10.5.

Finally, this study also led to a number of policy analysis-related contributions and provided insight into various policy analysis methods and models. Although there are as many different approaches as authors, they are only as valuable as the purpose they are used for. This study emphasised the recommendations by Enserink *et al.* (2013) to fit the policy analysis models to the problem. In Chapter 5, a systematic approach was followed that takes into account critical factors from the research inquiry and adapts best-practice policy analysis methods to fit the context and nature of the research problem in this study. Subsequently, this study contributes toward the policy analysis landscape by illustrating how the two distinctive types of policy analysis methods (discussed in Section 4.2) can be combined to achieve the objectives of the problem at hand—within a specific context.

10.4   Limitations

The limitations mentioned here are those characteristics that influence either the design, methodology, application or interpretation of the study:

- The first limitation to this study is the time consuming aspect—the time available to study the topics required for the development of the PoliVAN. At the beginning of this study, a considerable length of time was spent on developing an understanding of the VAN, the objectives, components and different design elements. Then, another study on a pharmaceutical supply chain was conducted, and even though the industrial engineering discipline is familiar with supply chains, the pharmaceutical sector was still an unknown field, and it required time to thoroughly investigate, and understand, all the different aspects.

- The second limitation is the lack of availability of information regarding South Africa's pharmaceutical supply chain. Most of the information that exists is outdated, does not represent the current system, or is not accessible from the public domain. This limited the knowledge from a research perspective in terms of the application of the case study, and a significant portion of the case studies' work relied on the knowledge of the SMEs that was shared during the workshops.

- The limited time that SMEs' had available to participate in the case study workshops was another important limitation of the research. Due to this, the application of the PoliVAN was done at a higher level than initially intended and the scope of the case studies was constrained to the detailed analysis of one policy subproblem stream (see Figure 8.1).

- The VAN Operating Model for South Africa was updated a number of times during the progression of this study. At the time of the second case study, a more recent version of the supply planning processes was being developed. As a result of this, fewer SMEs were available to participate in the case study workshop (as the other SMEs' focus was on documenting the new version) and the remainder of the case study had to be done as a desktop exercise.

10.5 Suggested future work

In this section, the possible future work is discussed:

- For the South African PoliVAN, suggested future work includes the composition of a team of analysts that are specifically qualified for the different processes in the PoliVAN. Roles and responsibilities, including the timing of the PoliVAN implementation would need to be planned as suggested in Section 9.2.

- For SSA countries, further engagement with SSA VAN representatives would be required to gain sufficient insight into the context-specific requirements to implement a PoliVAN in these countries.

- Additionally, for SSA countries, a case study (similar to those done in this study) should be implemented, in order to draw the necessary conclusions on the context-specific adaptions required for the tools proposed by the PoliVAN.

- From the aforementioned discussion points, applying the PoliVAN to different country contexts (by means of a case study approach as done in this study), can possibly provide information that can be aggregated to derive insights into the types of policies that have an enabling and/or limiting effect on each country's VAN. This information can subsequently be used for the development of a policy typology that can be incorporated into the BPRM to further guide countries with policy decisions and strategies.

- Once a country has applied the PoliVAN to their VAN Operating Model and key stakeholders have been listed (Phase 4), stakeholder dynamic modelling could be approached to gain insight into the causal relationships between the stakeholders and their behaviour dynamic within different policy context.

- As mentioned in Section 10.2, the policy impact analysis method proposed in Phase 5 can become subjective. As part of a supplementary project to this study, an evidence-based policy impact analysis approach was developed specifically for Phase 5. This study takes on an approach that translates the subjective scoring inputs into objective outcomes. Future work that has been identified as part of this supplementary project includes the implementation of this tool in a case study setting to test its applicability and rigour to produce policy impact outcomes that are less susceptible to interpretation and manipulation.

10.6   Chapter 10: Conclusion

This chapter provided an overarching conclusion to the research study. In the beginning of this chapter, a summary of the preceding chapters was provided regarding their contribution towards the development of the PoliVAN model, and subsequently the research objectives that were achieved. This chapter also discussed the PoliVAN and how it was validated through four different evaluation stages—each stage required engagement with relevant SMEs. The PoliVAN was evaluated with six evaluation objectives: (i) the **theoretical verification** of sufficient and credible literature; (ii) the **relevance** of the PoliVAN to the VAN initiative and research inquiry; (iii) the **contextual appropriateness** of the PoliVAN for the application to a public pharmaceutical supply chain system; (iv) the **applicability** of the PoliVAN to perform the processes and provide intended outcomes; (v) the **flexibility** of the PoliVAN to adapt to different VAN Operating Models and functions of a pharmaceutical supply chain; and (vi) insights on the **transferability** of the PoliVAN to other country contexts.

This was followed by a reflection on the research study; the contribution this study made towards the VAN project and the policy analysis research field, and the challenges that were faced that became limitations to this study. Finally, possible future work was proposed with a brief discussion of how each proposed aspect of future research could improve the current PoliVAN.

References

ABDRABO, M.A. & HASSAAN, M.A. (2007). Stakeholder analysis. 86, 87, 156, 279, 280, 281

AFRICAN RESOURCE CENTRE (n.a.). URL: `https://www.africaresourcecentre.org/pages/about-us`. 17

AMENYAH, J. (2008). Interactive Look at Nigeria's Supply Chain : Nigeria Supply Chain Strategy Development Workshop. 43

ATAGUBA, J.E., DAY, C. & MCINTYRE, D. (2014). Monitoring and evaluating progress towards universal health coverage in south africa. *Public Library of Science (PLoS) Medicine Journal*, **11(9)**. 264

ATKINSON, J.A., PAGE, A., WELLS, R., MILAT, A. & WILSON, A. (2015). A modelling tool for policy analysis to support the design of efficient and effective policy responses for complex public health problems. *Implementation Science*, **10**, 26. 80, 81, 82

AVOKA ASAMANI, J., CHEBERE, M.M., BARTON, P.M., AMAH D' ALMEIDA, S., ODAME, E.A. & OPPONG, R. (2018). Forecast of Healthcare Facilities and Health Workforce Requirements for the Public Sector in Ghana, 2016-2026. *International Journal of Health Policy Management*, **7**, 1040–1052. 4

BANKS, J. (1999). Introduction to simulation. In *Proceedings of the 31st Conference on Winter Simulation: Simulation—a Bridge to the Future - Volume 1*, 7–13, ACM, New York, USA, URL: `http://doi.acm.org/10.1145/324138.324142`. 81

BARANT, L., BLACKSTOCK, K., BYG, A. & MUNOZ-ROJAS, J. (2016). Governance and policy analysis in relation to the Aberdeenshire Regional Land Use Pilot. 147, 148

BARDACH, E. (2011). Adding Value to Policy Analysis and Advice. *Journal of Comparative Policy Analysis: Research and Practice*, **13**, 562–564. 266

BARDACH, EUGENE, PATASHNIK, E.M. (2016). *A Practical Guide for Policy Analysis*. 266

Bellù, L.G. & Pansini, R.V. (2009). Quantitative Socio- Economic Policy Impact Analysis: A Methodological Introduction. Tech. rep. 79, 80, 81, 89

Berger, J., Hofmeester, N., Makhado, M., Miot, J., Moller, H., Pharasi, B., Phillips, D., Raubenheimer, T., Sallet, J.P. & Suleman, F. (2010). Medicines Procurement Reform in the Public Sector. Tech. Rep. March. 2, 21, 31, 55, 258, 259, 260, 261, 262, 263, 393

Bertram, D. (2006). Likert scales are the meaning of life. *CPSC681–Topic Report*, 1–10, URL: `http://poincare.matf.bg.ac.rs/~kristina/topic-dane-likert.pdf`. 126

Bigdeli, M., Jacobs, B., Tomson, G., Laing, R., Ghaffar, A., Dujardin, B. & Van Damme, W. (2013). Access to medicines from a health system perspective. *Health Policy and Planning*, **28**, 692–704. 1

Black, T. (1999). *Doing Quantitative Research in the Social Sciences: An Integrated Approach to Research Design, Measurement and Statistics*. SAGE Publications, ISBN: 9781446223635. 7

Borshchev, A. (2013). *The big book of simulation modeling: multimethod modeling with AnyLogic 6*. AnyLogic North America Chicago. 81

Brade, D., Lehmann, L. & Huber, R.K. (2003). *A Generalized Process for the Verification and Validation of Models and Simulation Result*. Ph.D. thesis, Faculty of computer science, University of the Bundeswehr Munich. 11, 110, 111

Bradley, B.D., Jung, T., Tandon-Verma, A., Khoury, B., Chan, T.C. & Cheng, Y.L. (2017). Operations research in global health: A scoping review with a focus on the themes of health equity and impact. 80

Bridgeman, P. & Davis, G. (2003). What use is a policy cycle? Plenty , if the aim is clear. *Australian Journal of Public Administration*, **62**, 98–102. 98, 266, 267

Brook, R.H. (1989). Practice guidelines and practicing medicine: Are they compatible? *Journal of the American Medical Association 262*, **262(21)**, 3027–31. 66

Bryan, D. & Jones, G.B. (2006). Behavioral rationality and the policy processes: Toward a new model of organizational information processing. *Handbook of public policy*. 150

Bryman, A. (2014). *Research methodology: Business and management contexts*. ISBN: 9780199076130. 8

Buse, K., Mays, N. & Walt, G. (2005). *Making Health Policy*. 73, 74

REFERENCES

CENTRE ON KNOWLEDGE TRANSLATION FOR DISABILITY AND REHABILITATION RESEARCH (????). Types of Logic Models. Tech. rep. 304, 305, 306

CERNA, L. (2013). The Nature of Policy Change and Implementation : A Review of Different Theoretical Approaches. *Organisation for Economic Co-operation and Development*, 1–31. 165

CHRISTOPHER, M. (1992). *Logistics and supply chain management*. Pitman Publishing London, URL: `http://www.icesi.edu.co/blogs/supplychain0714/files/2014/07/Martin_Christopher_Logistics_and_Supply_Chain_Management_4th_Edition___ _2011-1.pdf`. 40, 41

CLISSOLD, A., FILAR, J., MACKAY, M., QIN, S. & WARD, D. (2015). Simulating hospital patient flow for insight and improvement. *Proceedings of the 8th Australasian Workshop on Health Informatics and Knowledge Management (HIKM 2015)*, 27–30. 4

COLLINS, C., GREEN, A. & HUNTER, D. (1999). Health sector reform and the interpretation of policy context. *Health policy (Amsterdam, Netherlands)*, **47**, 69–83. 75

COLLINS, T. (2005). Health policy analysis: A simple tool for policy makers. *Public Health*, **119**, 192–196. 75

COOPER, M.C., LAMBERT, D.M. & PAGH, J.D. (1997). Supply chain management: more than a new name for logistics. *The international journal of logistics management*, **8(1)**, 1–14. 40, 41

COVENEY, J. (2010). Analyzing Public Health Policy: Three Approaches. *Health Promotion Practice*, **11**, 515–521. 67, 267

CRESWELL, J. & MILLER, D. (1997). Validity (verification) in qualitative research: Perspectives, terms, procedures, and methodologies. *Unpublished manuscript, Department of Educational Psychological Psychology, University of Nebraska-Lincoln*. 111

CROOM, S., ROMANO, P. & GIANNAKIS, M. (2000). Supply chain management: an analytical framework for critical literature review. *European Journal of Purchasing & Supply Management*, **6**, 67–83. 40

CROUCH, E. (2012). *Policy Evaluation Using Cost-Benefit Analysis : Empirical Ramifications for Two Policy Issues*. Ph.D. thesis. 80

DELEON, P. (2014). The Stages Approach to the Policy Process. In *Theories of the policy process*, 19–32. 68, 70

REFERENCES

DEPARTMENT FOR COMMUNITIES AND LOCAL GOVERNMENT: LONDON (2009). *Multi-criteria analysis : a manual*, vol. 11. 79, 277

DEPARTMENT OF ENVIRONMENTAL AFFAIRS AND TOURISM (2002). Integrated Environmental Management Information series: Screening. **7**, 18. 80

DEPARTMENT OF HEALTH (2004). Monitoring and Evaluation Framework: Comprehensive HIV and AIDS Care, Management and Treatment Plan for South Africa. 264

DEPARTMENT OF HEALTH (2017). District Health Planning and Monitoring Framework. 22, 37

DOCTEUR, E. & PARIS, V. (2009). Ensuring Efficiency in Pharmaceutical Expenditures. *Achieving Better Value for Money in Health Care*. 4

DODGSON, J.S., SPACKMAN, M., PEARMAN, A. & PHILLIPS, L.D. (2009). Multi-criteria analysis: a manual. 194, 402

DUNN, W.N. (1981). *Public Policy Analysis*. Pearson, 5th edn. 3, 4, 65, 67

DZA, M., FISHER, R. & GAPP, R. (2013). Procurement Reforms in Africa: The Strides, Challenges, and Improvement Opportunities. *Public Administration Research*, **2**. 3

EASTERN CAPE DEPARTMENT OF HEALTH (????). Standard Operating PRocedures for Primary Healthcare Facilities. 384, 388, 390

ENSERINK, B., KOPPENJAN, J.F.M. & MAYER, I.S. (2013). Chapter 2 A Policy Sciences View on Policy Analysis. *Public Policy Analysis*, 11–40. 67, 68, 70, 71, 72, 82, 98, 117, 220

FORRESTER, J.W. (1958). Industrial dynamics. a major breakthrough for decision makers. *Harvard business review*, **36(4)**, 37–66. 81

FRANCO, C. & ALFONSO-LIZARAZO, E. (2017). A structured review of quantitative models of the pharmaceutical supply chain. *Complexity*. 4

GOEL, V. & LLEWELLYN, E. (2015). Visibility & Analytics Networks (VAN) Project: Blueprint Reference Model. Tech. Rep. March. 3, 17, 18, 19, 24, 27, 32, 33, 34, 35, 94, 152, 241

GOLDER, B. & GAWLER, M. (2005). Cross-Cutting Tool Stakeholder Analysis. *Sourcebook for WWF Standards*. 82, 83, 85, 86

GRAY, A., RIDDIN, J. & JUGATHPAL, J. (2016). Health Care and Pharmacy Practice in South Africa. *The Canadian journal of hospital pharmacy*, **69**, 36–41. 253, 255

REFERENCES

Gray, A., Vawda, Y., Padarath, A. & Barron, A. (2017). South African Health Review 2017. *Health Policy and Legislation.*. 262

Griffin, P.M., Nembhard, H.B., DeFlitch, C.J., Bastian, N.D., Kang, H. & Muñoz, D.A. (2016). *Healthcare systems engineering*. John Wiley & Sons. 7

Hallsworth, M., Parker, S. & Rutter, J. (2011). Policy-making in the real world. *Political Insight*, **2**, 10–12. 211

Hanzl, S., Meschik, M. & Sammer, G. (2003). Policy Formulation and Implementation. *Portal Transport Teaching Material*, 1–75. 150

Harrison, T.P., Lee, H.L. & Neale, J.J. (2004). *The practice of supply chain management: where theory and application converge*. Springer Science and Business Media, ISBN: 978-0-387-27275-7. 20

Hasenfeld, Y. & Brock, T. (1991). Implementation of social policy revisited. *Administration & Society*, **22(4)**, 451–479. 165

Hassim, A. & Heywood, M. (2007). Budgeting for Health. *Health & Democracy: A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa*, 70–93. 50

Hassim, A., Heywood, M. & Berger, J. (2007). Developing , registering and using medicines. In *Health & Democracy*, 412–435. 254

Health (2016). South Africa Yearbook 2015/16. *South Africa Yearbook*, 243–258. 260

Hedman, L. (2016). Global approaches to addressing shortages of essential medicines in health systems. *WHO Drug Information*, **30**, 180. 2

Hofstee, E. (2006). *Constructing a good dissertation: A practical guide to finishing a Master's, MBA or PhD on schedule*. EPE, Sandton, South Africa, ISBN: 0958500711. 8

Homer, J.B. & Hirsch, G.B. (2006). System Dynamics Modeling for Public Health: Background and Opportunities. *American Journal of Public Health*, **96**, 452–458. 4

Houghton, C., Murphy, K., Shaw, D. & Casey, D. (2015). Qualitative case study data analysis: An example from practice. *Nurse researcher*, **22**. 134

Hsu, C.C. & Sandford, B.A. (2007). The delphi technique: making sense of consensus. *Practical assessment, research and evaluation*, **12(10)**, 1–8. 152

Islamy, I. (2008). Public policy analysis. 85, 160

Jaggi, S. (2003). Descriptive statistics and exploratory data analysis. *Indian Agricultural Statistics Research Institute*, **1**, 1–18. 80

Jones, T.C. & Riley, D.W. (1985). Using inventory for competitive advantage through supply chain management. *International Journal of Physical Distribution and Materials Management*, **15(5)**, 16–26. 40, 41

Kanavos, P. & Angelis, A. (2015). Using Multiple Criteria Decision Analysis (MCDA) to make coverage decisions: a methodological framework. *Journal of Pharmaceutical Policy and Practice*, **8**, O7. 4

Kennon, D. (2017). *Towards an Antifragile South African SME*. Ph.D. thesis, Stellenbosch: Stellenbosch University. 112

Kirby, N. (2017). And Now for Something Completely Different (or not?). Tech. rep. 346

Kleynhans, E., de Kock, I. & Bam, L. (2017). The Role of Policy Analysis to Support Public Medicine Availability Initiatives: The Case of VAN. In *SAIIE28 Proceedings*, October, 3371–1 − 3371–16. 2

Kleynhans, E., de Kock, I. & Bam, L. (2018). The Role of Policy Analysis to Support Data Visibility Across Public Pharmaceutical Delivery Systems: The Case of VAN. In *IAMOT 2018 Conference Proceedings*, April. 30, 31, 32, 33, 34, 244, 245

Knowlton, L.W. & Phillips, C.C. (2013). Chapter 1: Introducing Logic Models. In *The logic model guidebook: Better strategies for great results*, 2–62, SAGE Publications, 2nd edn. 302, 305, 306, 307

Kopczak, L.R. (1997). Logistics partnerships and supply chain restructuring: survey results from the us computer industry. *Production and Operations Management*, **6(3)**, 226–247. 41

Krebs, M. (2018). The South African pharmaceutical regulatory environment. 254

Kruger, J. (2016). *An investigation into the supply chain and procurement processes of a provincial department of health*. Ph.D. thesis, North-West University (South Africa), Potchefstroom Campus, URL: `https://repository.nwu.ac.za/bitstream/handle/10394/25437/Kruger_J_2016.pdf?sequence=1`. 2

Kurz, H.D. & Salvadori, N. (2000). 'Classical' roots of input-output analysis: A short account of its long prehistory. *Economic Systems Research*, **12(2)**, 153–179. 80

Kvale, S. (1989). To validate is to question. In *This chapter was presented at a Nordic Postgraduate Research Course–" The Question of Validity in Qualitative Research in the Social Sciences" at Bergby Gaard in Sweden, August 1988, and was rewritten following the discussions that the course provided.*, Studentlitteratur. 111

Larsson, A. & Ibrahim, O. (2015). Common Policy Appraisal Format: Structured Decision Evaluation of Policy Options using the Simulation Results Project acronym: SENSE4US Project full title: Data Insights for Policy Makers and Citizens. 162

Lee, H.L. & Billington, C. (1992). Managing supply chain inventory: pitfalls and opportunities. *Sloan management review*, **33(3)**, 65. 40, 41

Lee, H.L. & Ng, S.M. (1997). Introduction to the special issue on global supply chain management. *Production and Operations Management*, **6(3)**, 191–192. 40, 41

Lehmann, U. (2016). Masters in Public Health: Understanding and Analysing Health Policy. *Schooll of Publci Health University fo Western Cape*. 68, 70, 73, 74, 75, 76, 82, 83, 84, 85, 86, 155, 156, 165, 268, 269, 278, 279

Leichter, H.M. (1979). A comparative approach to policy analysis: health care policy in four nations. *American Political Science Association*, DOI: 10.2307/1962245. 75

Limpopo Department of Health (2014). Limpopo Province Primary Health Care (PHC) Standard Operating Procedures. 384, 388

Llewellyn, E. (2016). National Strategy for Improved Availability and Access : Visibility and Analytics Network VAN Briefing Materials Based on High Level Operating Model Introduction to the VAN. December. 3, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 37, 92, 188, 239, 240, 246, 247, 248, 249, 253, 376

Luyet, V., Schlaepfer, R., Parlange, M.B. & Buttler, A. (2012). A framework to implement Stakeholder participation in environmental projects. 84, 85, 87, 88

Macdonald, G. (2018). Checklist of Key Considerations for Development of Program Logic Models. Tech. rep. 305, 306, 307

MacRae, D. & Wilde, J.A. (1979). *Policy analysis for public decisions*. Brooks/Cole, ISBN: 9780878722075. 66

Maluleke, S.M. (2010). *Managing the implementation of the assessment policy in the Senior Certificate Band*. Ph.D. thesis. 66

Management Science for Health (2012). *MDS-3: managing access to medicines and health technologies*. Management Sciences for Health Arlington, VA, URL: `http://www.msh.org/resources/mds-3-managing-access-to-medicines-and-health-technologies/`. 20, 43, 44, 45, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 174, 250, 251, 260

Management Science for Health (2015). Governance in Pharmaceutical Systems. In *Leaders Who Govern*, 29:1–29:13. 59, 62

Mayers, J. (2005). Stakeholder power analysis. *Focus*, 24. 84, 85, 86, 87

Mayers, J. & Vermeulen, S. (2005). Stakeholder influence mapping. *Development*, 1–16. 86, 87, 160

Medicines Control Council (2008). Guidelines for the Registration of Medicines. 1–48. 349

Medicines Control Council (2010). Medicines Donation to South Africa. 348

Mentzer, J.T., Keebler, J.S., Nix, N.W., Smith, C.D. & Zacharia, Z.G. (2001). Defining Supply Chain Management. *Journal of Business Logistics*, **22**, 1–25. 40, 41

Merriam, S.B. (1988). *Case study research in education: A qualitative approach*. Jossey Bass. 134

Mezzanine (2017). Stock Visibility Solution Stock Visibility Solution An Overview. 31

Milstein, B. & Chapel, T. (2015). Chapter 2: Developing a Logic Model or Theory of Change. 302, 303, 304, 305, 306

Minnesota Department of Health (????). Logic Model Tip Sheet. Tech. rep., Center for Health Equity. 302, 303

Monroe, L. & Horm, D.M. (2012). Using a Logic Model to Evaluate Undergraduate Instruction in a Laboratory Preschool. *Early Education and development*, **23**, 227–241. 104, 302, 303

Morestin, F. (2012). A Framework for Analyzing Public Policies: Practical Guide. *Natioanal collaborating center for healthy policy*, **1536**, 13. 77, 78, 79, 118, 162, 273, 274, 276

Morse, J.M., Barrett, M., Mayan, M., Olson, K. & Spiers, J. (2002). Verification strategies for establishing reliability and validity in qualitative research. *International journal of qualitative methods*, **1**, 13–22. 110, 111

Mouton, J. (2001). *How to Succeed in Your Master's and Doctoral Studies: A South African Guide and Resource Book*. Van Schaik. 7, 111

Mulyaningrum, M., Kartodihardjo, H., Jaya, I.N.S. & Nugroho, B. (2013). Stakeholders analysis of policy-making process: The case of timber legality policy on private forest. *Jurnal Manajemen Hutan Tropika*, **19(2)**, 156–162. 83

Naidoo, S., Greyling, E. & Babamia, N. (2018). South African Health Products Regulatory Authority (SAHPRA): Strategic Plan for the fiscal years 2018/19 2022/23. Tech. rep. 254, 255, 347

National Department of Health (1996). National Drug Policy for South Africa. 254, 264, 347, 382

National Department of Health (2002). Pharmacy Act (No. 53 of 1974). 346

National Department of Health (2015a). Essential Drugs Programme. 46

National Department of Health (2015b). National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa. 1–10. 347, 348, 382

National Department of Health (2015c). Standard Treatment Guidelines and Essential Medicines List for South Africa: Hospital Level (Adults). Tech. rep. 348

National Department of Health (2016a). MCC Good Wholesaling and Distribution Practices. 383

National Department of Health (2016b). National Health tackles non-availability of medicine. 32

National Department of Health (2017a). Annual Perfomance Plan 2017/18 - 2019/20. Tech. rep. 345, 346

National Department of Health (2017b). District Health PLanning and Monitoring Framework. 384

National Department of Health (2017c). Regulations in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965). Tech. rep. 346, 381

National Department of Health (2017d). Standard Treatment Guidelines and Essential Medicines List for South Africa: Hospital Level (Paediatrics). Tech. rep. 348

REFERENCES

NATIONAL DEPARTMENT OF HEALTH (2017e). White paper for the National Health Insurance Policy. 188, 347, 376, 381

NATIONAL DEPARTMENT OF HEALTH (2018a). Ideal Clinic Manual Version 18. 384

NATIONAL DEPARTMENT OF HEALTH (2018b). National Guideline for the Development, Management and Use of Formularies. 179, 186, 255, 348, 354, 355, 356, 373

NATIONAL DEPARTMENT OF HEALTH (2018c). Norms and Standards Regulations Applicable to Different Categories of Health Establishments. 346, 381

NATIONAL DEPARTMENT OF HEALTH (2019). National Guideline for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa . 383, 390

NATIONAL DEPARTMENT OF TRADE AND INDUSTRY (2011). Western Cape Supply CHain Management Policy. 382, 388

NATIONAL TREASURY (2000). Guideline for Accounting Officer in accordance with PFMA. 383, 390

NATIONAL TREASURY (2003a). Municipal Finance Management Act (No. 56 of 2003). 191, 381, 390

NATIONAL TREASURY (2003b). Policy Strategy to Guide Uniformity in Procurement Reform Processes. 383

NATIONAL TREASURY (2005). Municipal Supply Chain Management Regulations). 381, 388

NATIONAL TREASURY (2017). *Public Finance Management Act (No. 1 of 1999) as ammended*. Ph.D. thesis. 191, 346, 380, 390

NATIONAL TREASURY, S.A. (2015). 2015 Public Sector Supply Chain Management Review. 83. 345

OOSTHUIZEN, L., KLEYNHANS, E. & DE KOCK, I. (2019). An impact analysis tool for the PoliVAN—understanding the impact on the pharmaceutical supply chain. 409, 410, 411

OXFORD ENGLISH DICTIONARY (2008). URL: `https://en.oxforddictionaries.com/definition/workshop`. 125

PALUMBO, D.J. (1994). *Public policy in America: Government in action*. Wadsworth Publishing Company, ISBN: 978-0155003835. 267

PARLIAMENT OF THE REPUBLIC OF SOUTH AFRICA (2005). The Constitution of the Republic of South Africa, Act 108 of 1996. 177, 178, 345, 380, 385, 387

REFERENCES

PATEL, A., NORRIS, P., GAULD, R. & RADES, T. (2009). Drug quality in South Africa: perceptions of key players involved in medicines distribution"Improving the pharmaceutical supply chain: Assessing the reality of e-quality through e- commerce application in hospital pharmacy. *International Journal of Health Care Quality Assurance*, **22**, 547–560. 257

PAUL, S., STEEDMAN, D. & SUTTON, F.X. (1989). *Building capability for policy analysis*, vol. 220. World Bank Publications. 67

PERUMAL-PILLAY, V.A. & SULEMAN, F. (2017). Selection of essential medicines for South Africa - An analysis of in-depth interviews with national essential medicines list committee members. *BMC Health Services Research*, **17**. 253, 254, 255, 256, 257

PETERS, B.G. & PIERRE, J. (2006). Handbook of Public Policy. *PUBLIC ADMINISTRATION AND PUBLIC POLICY*, **125**. 4, 79, 80, 81, 150, 165

PETRICK, I. (2008). Developing and implementing roadmaps–a reference guide. *White Paper-Pennsylvania State University*. 103

PHARASI, B. & MIOT, J. (2012). Medicines selection and procurement in south africa. *South African Health Review*, URL: `https://www.researchgate.net/publication/261436102_Medicines_Selection_and_Procurement_in_South_Africa`. 46, 256, 257

PIPKA (2014). Essays : Improving the Public Policy Cycle Model. 267

PORTNEY, K.E. (1986). *Approaching public policy analysis: An introduction to policy and program research*. Prentice Hall. 267

PRODUCTPLAN (2019). Roadmap basics. URL: `https://www.productplan.com/roadmap-basics/`. 103

QUICK, J.D., BOOHENE, N.A., RANKIN, J. & MBWASI, R.J. (2005). Medicines supply in Africa. *Bmj*, **331**, 709–710. 3

RAJA, S. & MOHAMMAD, N. (2004). Supply Chain Management for HIV/AIDS Medical Commodities. In *National HIV/AIDS Programs*. 2, 42, 43, 44, 53, 260

REED, M.S., GRAVES, A., DANDY, N., POSTHUMUS, H., HUBACEK, K., MORRIS, J., PRELL, C., QUINN, C.H. & STRINGER, L.C. (2009). Who's in and why? A typology of stakeholder analysis methods for natural resource management. *Journal of Environmental Management*, **90**, 1933–1949. 68, 85

REICH, M.R. & ROBERTS, M.J. (2011). *Pharmaceutical Reform*. 61

REFERENCES

REPUBLIC OF SOUTH AFRICA (2019). National Health Insurance Bill. 381

REPUBLIC OF SOUTH AFRICA ESSENTIAL DRUGS PROGRAMME (2018). Standard Treatment Guidelines and Essential Medicines List for South Africa: Primary Healthcare Level. Tech. rep. 348

RICHARD WILSON, B. (2002). Book Reviews: Risk-benefit analsyis. Tech. Rep. 14. 80

RICHARDSON, B.C. (1979). Limitations on the use of mathematical models in transportation policy analysis. URL: `https://deepblue.lib.umich.edu/bitstream/handle/2027.42/509/43459.0001.001.pdf?sequence=2`. 80

RIPIN, D.J., JAMIESON, D., MEYERS, A., WARTY, U., DAIN, M. & KHAMSI, C. (2014). Antiretroviral procurement and supply chain management. *Antiviral Therapy*, **19**, 79–89. 47

SCHMEER, K. (1999). Guidelines for Conducting a Stakeholder Analysis. *Health Reform Tool Series*. 83, 85

SEITER, A. (2010). *A practical approach to pharmaceutical policy*. DC: World Bank Publications, URL: `http://documents.worldbank.org/curated/en/751541468325451548/A-practical-approach-to-pharmaceutical-policy`. 60, 66

SHENKIR, W.G. & WALKER, P.L. (2007). Enterprise risk management: Tools and techniques for effective implementation. *Institute of Management Accountants*, 1–31. 166

SHUNG-KING, M. (2004). Advocacy: a strategy for change. 75, 118, 119, 130, 152, 165, 270

SIDNEY, M.S. (2006). Policy formulation: design and tools. In *Handbook of public policy analysis*, 105–114, Routledge. 150

SIVA, S., ALLAGADDA, R., PRASAD T S, D., SRIDHAR, C. & D, R. (2015). A study on drug expenditure at a community pharmacy in tirupati: An ABC analysis. **(3)**, 1–2. 261

SONG, B. & KANG, S. (2016). A Method of Assigning Weights Using a Ranking and Non-hierarchy Comparison. *Advances in Decision Sciences*, **2016**, 1–9. 369

SOUTH AFRICAN GOVERNMENT (2004). The National Health Act No 61 of 2003. *Government Gazette*, **469**, 1–94. 345, 380

SOUTH AFRICAN PHARMACY COUNCIL (2018). Competency Standards fo Pharmacists in South Africa. 349, 384

REFERENCES

STEVENS, G.C. (1989). Integrating the supply chain. *International Journal of Physical Distribution and Materials Management*, **19(8)**, 3–8. 40, 41

TAN, K.C., KANNAN, V.R. & HANDFIELD, R.B. (1998). Supply chain management: Supplier performance and firm performance. *Journal of Supply Chain Management*, **34(3)**, 2. 41

TAYLOR-POWELL, E., JONES, L. & HENERT, E. (2003). Welcome to Enhancing Program Performance with Logic Models. Tech. rep., University of Wisconsin, University of Wisconsin. 104, 305, 306

TAYOB, S. (2012). *Challenges in the management of drug supply in Public Health Care Centres in the Sedibeng District*. Ph.D. thesis. 54, 260, 261, 262

TEMA, M.A. (2014). Evaluation of the medicine procurement and supply management system in public hospitals in Lesotho Supervisor :. 20

THE SOUTH AFRICAN PHARMACY COUNCIL (2010). Good pharmacy practice in South Africa. 348, 383

TIBANE, E., NOMFUNDO, L., MALPHIA, H. & JACKY, K. (2016). Government Systems. In *South Africa Yearbook 2015/2016*, 220–242, Government Communications (GCIS). 22, 345, 380

TREASURY, N. (2004). Supply Chain Management a Guide for Accounting Officers / Authorities. 103. 349

TURNPENNY, J.R., JORDAN, A.J., BENSON, D. & RAYNER, T. (2015). The tools of policy formulation: an introduction. *The Tools of Policy Formulation*, 3–30. 150, 151

UNGERER, G.D. (2015). A competitive strategy framework for e-business start-ups. 112

USAID DELIVER PROJECT (2011). *The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities*. USAID Deliver Project, Arlington, VA. 2, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 58, 59, 61

VAN DER MERWE, D.M. (2017). The base of the pyramid: a growth framework for smme action. 112

VAN DER WESTHUIZEN, A. (2012). Documentation of medicine logistics in primary health care clinics in the Dr Kenneth Kaunda district. 190. 260

VAN LERBERGHE, W. (2008). Primary health care: now more than ever. *The world health report*, URL: `https://www.who.int/whr/2008/en/`. 1

REFERENCES

VILLAGEREACH (2014). Keeping the cold chain cold/vaccine supply chains. *Reaching the Final 20 Policy Paper Series*. 204, 206

VILLAGEREACH (2015). Enhanced Visibility, Analytics and Improvement for the Mozambique Immunization Supply Chain. Tech. rep. 18, 204

VILLAGEREACH (2016). Data for management: Its not just another report. *Reaching the Final 20 Policy Paper Series*. 204

W. K. KELLOGG FOUNDATION (2004). Logic Model Development Guide. *Logic Model Development Guide: Using logic models to bring together planning, evaluation, and action*, 27–34. 302, 303, 304, 305, 306, 307

WAGLE, U. (2000). The Policy Science of Democracy:The issue of Methodology and Citizen participation. **33**, 207–223. 81

WALKER, W.E. (2000). Policy analysis: a systematic approach to supporting policymaking in the public sector. *Journal of multi-criteria decision analysis*, **9**, 11–27. 65, 67, 68, 69, 70, 71, 97, 98, 117, 166

WALKER, W.E. & VAN DAALEN, C.E. (2013). System models for policy analysis. In *Public Policy Analysis*, 157–184, Springer. 81, 103

WALLACE, T.F. (1984). *APICS dictionary*. American Production and Inventory Control Society, ISBN: 978-1558220874. 24, 42

WALT, G. & GILSON, L. (1994). Reforming the health sector in developing countries: the central role of policy analysis. *Health policy and planning*, **9(4)**, 353–370, DOI: `https://doi.org/10.1093/heapol/9.4.353`. 4, 73, 90, 99, 269

WALT, G., SHIFFMAN, J., SCHNEIDER, H., MURRAY, S.F., BRUGHA, R. & GILSON, L. (2008). 'Doing' health policy analysis: Methodological and conceptual reflections and challenges. *Health Policy and Planning*, **23**, 308–317.

WHO AIDS MEDICINES AND DIAGNOSTICS SERVICE (AMDS) (2011). PSM (Procurement & Supply Management) Toolbox. 43

WORLD HEALTH ORGANISATION EXPERT COMMITTEE (2003). The selection and use of essential medicines: report of the who expert committee, 2002: (including the 12th model list of essential medicines). URL: `http://apps.who.int/iris/handle/10665/42620`. 46, 57

REFERENCES

WORLD HEALTH ORGANIZATION (1987). *The Rational use of drugs: report of the conference of experts, Nairobi, 25-29 November 1985*. World Health Organization. 55

WORLD HEALTH ORGANIZATION (1998). Essential Drugs Monitor. Tech. Rep. 25 & 26. 1

WORLD HEALTH ORGANIZATION (1999). Making a difference: message from the director-general. *The World health report: 1999*, URL: `http://www.who.int/whr/1999/en/`. 45

WORLD HEALTH ORGANIZATION (2001). *How to develop and implement a national drug policy*. URL: `http://apps.who.int/iris/bitstream/handle/10665/42423/924154547X.pdf;jsessionid=C9B28FAB7EFABB5FCB1E01DE8E9986DC?sequence=1`, publisher=World Health Organization. 45, 50, 60, 61, 62

WORLD HEALTH ORGANIZATION (2007). Procurement and Supply Management. 2, 43, 44

WORLD HEALTH ORGANIZATION (2010). Legislation and regulation. 60, 66

WORLD HEALTH ORGANIZATION (2016). SDH Health and Health-related Targets. *Monitoring Health for SDG*. 1, 262

WORLD HEALTH ORGANIZATION & UNICEF (1978). DECLARATION OF ALMA-ATA 1978. In *International Conference on Primary Health Care*. 1, 2

YANG, K. (2006). 23 quantitative methods for policy analysis. *Handbook of public policy analysis*, 349. 79, 80

YAZAN, B. (2015). Three approaches to case study methods in education: Yin, merriam, and stake. *The qualitative report*, **20**, 134–152. 134

YIN, R. (2013). *Case Study Research: Design and Methods*. SAGE Publications, ISBN: 9781483322247. 134, 135

ZUMA, S.M. (2016). *Framework for provision of essential medicines for the district health services*. Ph.D. thesis, University of South Africa, Pretoria, URL: `http://uir.unisa.ac.za/handle/10500/22792`. 252, 255, 258, 259, 260, 261, 262, 263, 264

Appendix A

Supply chain planning calculations

The following figures provide insight into the demand, supply, and distribution planning calculation methods—the inputs, the calculation, and the outputs.
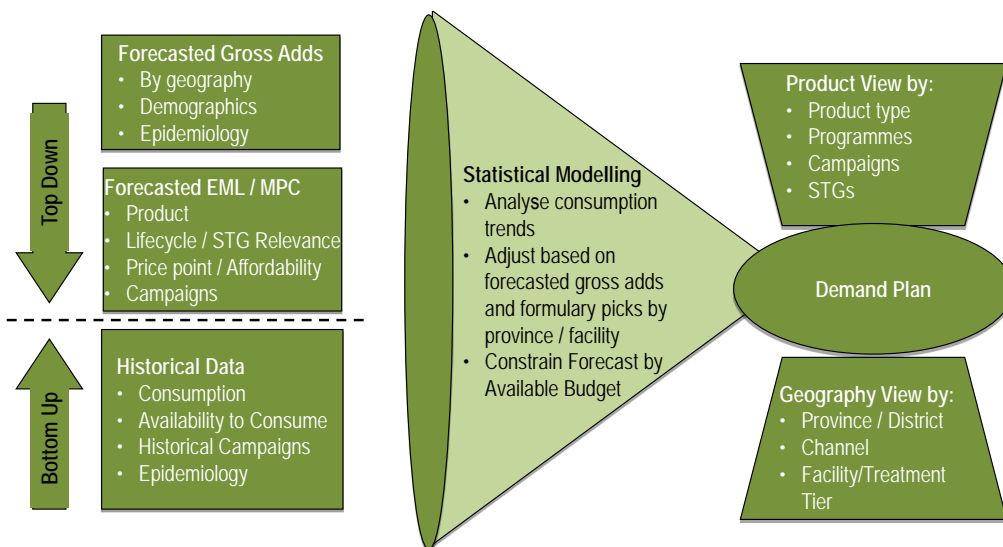
Figure A.1: Demand planning calculation (Llewellyn, 2016).
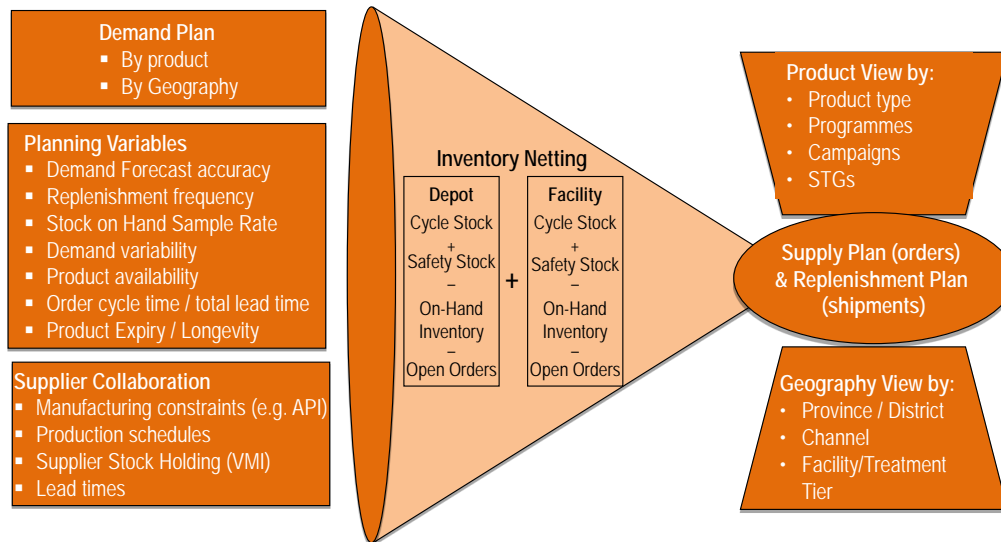
Figure A.2: Supply planning calculation (Llewellyn, 2016).
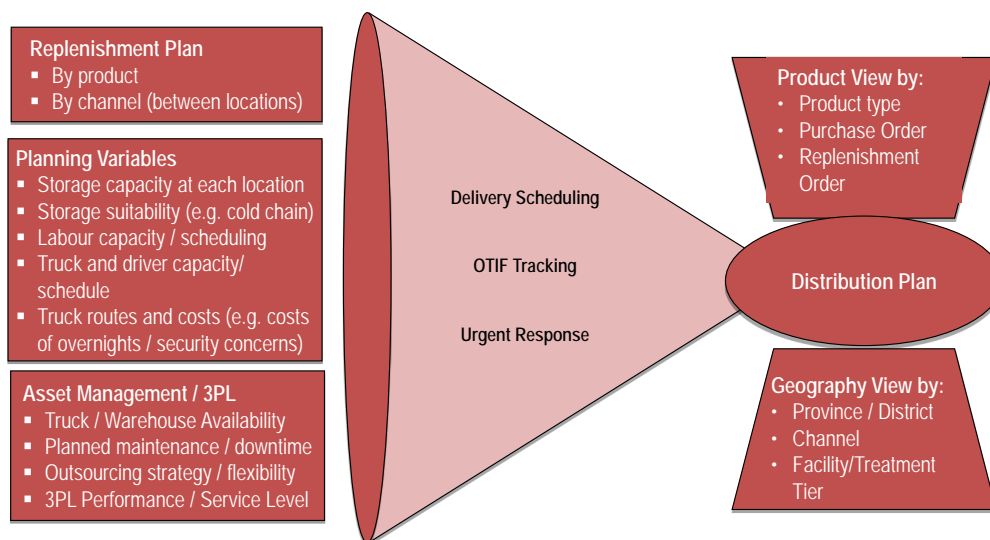
Figure A.3: Distribution planning calculation (Llewellyn, 2016).

Appendix B

Data requirements

B.1   Data requirements from the BPRM

Data elements mentioned in Table B.1 below are key to the successful implementation of a country Visibility and Analytics Network (VAN) (Goel & Llewellyn, 2015). The table helps in identifying interdependencies between data elements and VAN processes. It also defines the frequency and level of granularity at which these data elements need to be captured which helps in defining the resources (manpower and/or technology) required for performing VAN activities (Goel & Llewellyn, 2015).

Table B.1: Data requirements provided by the BPRM Goel & Llewellyn (2015).

SI No.	Data element	Planning process	Used by KPI / Sub-process	Frequency	Granularity
1	Historical consumption	DP	Statistical Forecasting	Monthly	At Storage Facility / Health Facility level
2	Forecasted Demand (unconstrained)	DP	Forecast accuracy/Forecast Bias/ Accuracy of statistical forecast/ Forecast Constrained	Monthly	By Health Facility / By SKU
3	Forecasted Demand (constrained)	DP	Forecast accuracy/Forecast Bias/ Accuracy of statistical forecast, Supply Plan	Monthly	By Health Facility / By SKU
4	% Waste	SPIM DTM	SLOB / Write Off	Monthly	By health Facility / By SKU

Table B.1 continued from previous page

SI No.	Data element	Planning process	Used by KPI / Sub-process	Frequency	Granularity
5	Epidemiological data	DP	Statistical Forecasting	Annually	At Country / National / Regional level
6	Demographics	DP	Statistical Forecasting	Annually	At Country / National / Regional level
7	Seasonality data	DP	Statistical Forecasting	Annually	At Country / National / Regional level
8	Ordered quantity	DTM	In full dispatches/Order Processing	Monthly	By Health Facility / By SKU
9	Available budget	DP SPIM	Forecast Constrained / Net Inventory Required at country level	Monthly	At Storage Facility / Health Facility level
10	Target Service Levels	SPIM	LIFR/Planning Parameters	Annually	At Storage Facility / Health Facility level
11	Target Inventory Levels	SPIM	Inventory Days of Stock (DoS)	Quarterly	At Storage Facility / Health Facility level
12	Delivery Lead Times	SPIM DTM	Planning Parameters/ Distribution Plan/ On Time Dispatches	Quarterly	Across SC, by SKU
13	Stock on Hand	SPIM DTM	Replenishment Order Planning/ Inventory Reporting and Analysis/ Inventory Days of Stock	Weekly	Across SC, by SKU
14	In Country Shipments	SPIM DTM	Supply Plan / Distribution Plan	Monthly	At CMS level
16	Inbound Delivery schedule	SPIM	Planning Parameters	Monthly/ Real Time	Across SC, by SKU
15	Supply Network (Routes)	SPIM DTM	Distribution Plan	Quarterly	Across SC
17	Order status	DTM	Order Processing / OTIF	Weekly	Across SC
18	Shipment status	DTM	Exception Management	Weekly	Across SC
19	Proof of Delivery forms (Quantity, date/time for dispatch and arrival)	DTM	On-time Dispatches; Shipping Accuracy	Weekly	At Storage Facility / Health Facility level
20	Updated contact details of Health Facilities (names, phone numbers)	DP	Day to Day Co-ordination	Quarterly	At Storage Facility / Health Facility level

Table B.1 continued from previous page

SI No.	Data element	Planning process	Used by KPI / Sub-process	Frequency	Granularity
21	Expiry dates and batch number	SPIM DTM	FEFO Compliance / SLOB / Expiry Management	Monthly	By Health Facility / By SKU
22	Vaccine Vial Monitor (VVM) status	CCM SPIM DTM	Inventory Analysis	Monthly	By Health Facility / By SKU
23	Cold Chain Equipment data (Model, Unique Identifier, Age)	CCM	Maintenance Schedule	Monthly	By Health facility
24	Preventive maintenance schedule	CCM	Preventive maintenance /budget allocation	Quarterly	By Health facility
25	Fridge Status (Up/broken)	SPIM CCM	# of facilities with Fridge breakdown & Value/Volume at Risk	Weekly	By Health facility
26	Time since breakdown	CCM	# of facilities with Fridge breakdown & Value/Volume at Risk	Weekly	By Health facility
27	Back up Health Facility	SPIM CCM	Stock Transfers / Replenishment Order Plan	Quarterly	By Health facility
28	Technicians (#, Availability, Contact)	CCM	Maintenance Schedule	Monthly	By Health facility
29	Waste reporting due to freeze/heat excursions	CCM	SLOB/ Write off	Weekly	By Volume/Value
30	Temperature Data of all cold storage equipment	CCM	Temperature monitoring during storage	Weekly	By Health Facility
31	Unmet Demand (number of patients not served due to stock out)	DP SPIM	Availability at Health Facilities	Monthly	By Health Facilities / By SKU

B.2   Data requirements for the South African VAN

Table B.2 identifies the data elements that are required for the various operational activities of the VAN for South Africa, indicating the responsible actor (level of organisation) to capture the data, what actors need to have access to the data, the frequencies at which the data are updated, and at which planning category the data is used.

Table B.2: Data requirements for the South African VAN (Kleynhans *et al.*, 2018)

Label	Data Description	Generated by	Available to	Frequency updates	Planning Category
1	Product Master Data	AMD	PMPU	6 monthly	DP & SP & DP
2	STGs and MPC	Programmes	AMD Facilities	6 monthly	DP
3	Facility Replenishment Master data: consumption rate, health trends.	Facility	AMD PMPU	Daily	DP
4	Statistical Forecasting Methodology	AMD	PMPU	Annually	DP
5	Forecast demand estimates	PMPU	AMD PMPU NDoH CFO	Monthly Monthly Annually	DP SP DP
6	Budget Allocation	NDoH CFO / NT	AMD PMPU Budget Holder	Annually Monthly Quarterly	DP & SP DP & SP DP
7	Tendering	AMD	Suppliers	Annually	SP
8	Contracting	AMD and Suppliers	PMPU	Annually	SP
9	Supplier orders	PMPU	AMD Spend Approvers	Annually Monthly	SP
10	Supplier stock availability	Suppliers	AMD	Monthly	SP
11	Storage Capacity at depots and facilities	Facilities / Depots	PMPU	Monthly	SP & DP
12	Inventory /SOH at depots	Depots	PMPU	Monthly	SP
13	Lead time, order cycle, replenishment frequencies, facility location	PMPU	AMD PMPU	Annually Monthly	SP DP
14	Third Party Logistics transport Capacity	3PL	PMPU	Monthly	SP & DP
15	Transport status	3PL	PMPU	Daily/Weekly	SP & DP
16	Missed deliveries	PMPU	Depot Manager	Daily/Weekly	DP
17	Recall of condemned / damaged stock	Facility	AMD PMPU	On delivery	SP

The information in the table was gathered by analysing the planning processes (including the calculation methods from Appendix A), and data requirements advised from the BPRM

(Section B.1). The data descriptions in this table provide a high-level perspective of the data required, however, within those elements are sub-data requirements, e.g. supplier orders (label 9)—this data element may appear simple, however, supplier orders actually contain a large amount of information i.e. the product type, the package size, the quantities needed, and the location at which the product needs to be delivered (Kleynhans *et al.*, 2018). The data required for calculating the orders are: the demanded quantities (label 5); the frequencies at which the stock at facilities and depots need to be replenished (label 3); the time it takes an order to reach the destination from the time of ordering (label 13); and the current stock available at the facilities and depots (label 10 and 12) (Kleynhans *et al.*, 2018).

B.3   Appendix B: Conclusion

As mentioned in Subsection 2.2.3, the data requirements (both from the BPRM and the South African version) clearly indicate that the data elements are dependent on one another, and that the information will only be able to successfully support the functioning of the VAN if data ownership that enforces the capturing of high-quality data is enforced (Kleynhans *et al.*, 2018). For the VAN's information system, there are not only multiple information channels, but there are different frequencies at which the data should be generated. Because there are different frequencies at which data needs to be available, policies play an important role in formalising the frequency requirements and ensuring that the responsible actor complies with these.

Appendix C

Implementation strategy for the South African VAN Operating Model

In this appendix, the implementation plan for the South African VAN Operting Model is discussed.

C.1   The implementation roadmap

The roadmap for implementation of the VAN manages resource allocation across four phases of intervention (in Figure C.1), which might have complicated interdependencies (Llewellyn, 2016). The rationale behind the categorisation of the roadmap is to simplify and clarify how resources (i.e. time, money, and effort) are allocated to each phase—enabling elements are likely to receive significant investments that will deliver benefits in the long term (Llewellyn, 2016).

C.1.1   VAN enabling elements

The first phase is the VAN enabling element which consist of once-off projects, e.g. policy enablers, information technology enablers, standard operating procedures (SOPs) for data gathering, and training and recruitment of people. These enablers are defined further in Figure C.1 (Llewellyn, 2016). It is imperative that drafted policies and political leaders are invested and engaged before the roll-out of the VAN (due to the fact that the policy element governs the other elements). The rest of the enablers are in line with the other three elements—for the system to provide end-to-end visibility, the technology capturing, analysing, and aggregating the data should be complete and functional; essential as well as temporary SOPs should be in place for transactional and data gathering processes across the demand, supply, and distribution phases; and each VAN role at the national and provincial levels needs to be allocated to the designated and competent resource, as well as the necessary training in place for resources taking ownership of new VAN role (Llewellyn, 2016).

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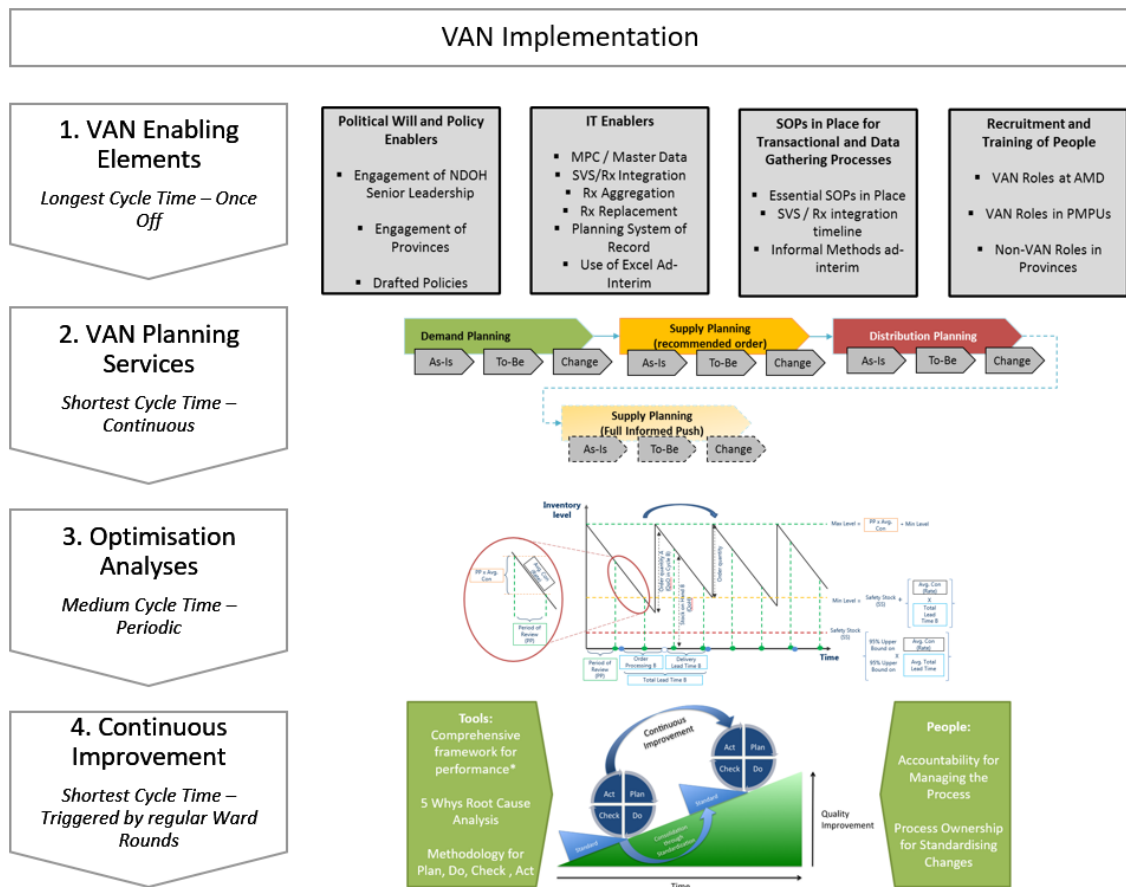
Figure C.1: The long-term roadmap for the implementation of the VAN, adapted from (Llewellyn, 2016).

The design and development of the VAN operating model requires coordinated approaches to SOP development, because SOPs are the basis for the requirements of staff competencies, policies and IT enablers.

C.1.2 VAN planning services

The second phase is the VAN planning services—the migration to the informed push model. Transitioning to an informed push approach is risky unless the people, process, technology, and policy factors are in place, so that the roll-out of the VAN services can be carefully managed with short as-is, to-be, and change cycles as illustrated in Figure C.1 (Llewellyn, 2016). In order to roll out the VAN processes, some of the other elements have requirements to be met (Llewellyn, 2016):

1. Policy

   - Policies at appropriate levels of detail that fit all contexts.

2. People / Roles

- PMPU must be sufficiently resourced and trained to handle the increased volume of work at each pocket.

- Allocation of named roles (outside the PMPU) should have taken place in line with the local organisation structure and role definitions.

- Training must have taken place to ensure staff are able to fulfil new accountabilities and responsibilities.

3. Technology / Data

- Demand planning: historical and actual data must be reliably available to populate the demand, supply and distribution plans.

- Supply planning: transition plan from facility ordering to informed push must take into account the run-out of old stock, and any STG and MPC changes that are likely to create data risks at a critical time.

- Distribution planning: products in the scope for the start of the informed push model should be those for which data is available.

C.1.3 Optimisation analysis

The third phase is the optimisation analysis phase, which builds on the basis of the VAN planning processes. The development of the VAN processes, provides generated data that is important to support the case for system optimisation (Llewellyn, 2016). The VAN model proposed some non-exhaustive key examples of system optimisation opportunities (Llewellyn, 2016):

i. Investigate constraints of minimum order quantities on direct delivery opportunity and optimise warehouses/cross-docks;

ii. Improve forecasting and reduce order volatility. Collaborate with suppliers to reduce supplier stock-holding requirements and reduce costs to NDoH. Consolidate deliveries with suppliers, and establish nominated delivery dates;

iii. Establish cross-docks or merge in transit to achieve delivery efficiencies without large unallocated inventory volume;

iv. Enhance the payment process to improve supplier cash flow; and

v. Segment products for optimal channel selection, based on volume, volatility, expiry, physical size, urgency etc. Segment supply base to identify most strategic suppliers, enhance collaboration and improve price negotiating position and service delivery expectations.

C.1.4   Continuous improvement

The fourth phase is continuous improvement which is triggered by regular ward rounds. There are currently performance dashboards that prove to be useful for identifying the issues with the current system. By use of continuous improvement, capturing the data, categorisation, and root-cause analysis will provide insight into the issues to create scalable and sustainable solutions (Llewellyn, 2016).

C.2   Appendix C: Conclusion

The implementation roadmap provides an overview of how the VAN will be initiated into the current health system; however, the first phase (enablers) should be in place in order for the VAN planning services to roll-out. Therefore, especially in the context for South Africa, emphasis is placed on the policy element before the VAN is ready for implementation.

Appendix D

Policy components

In this appendix, the components (as given by Management Science for Health (2012)) that are required for a national medicine policy is presented in Figure D.1.

Legislative and regulatory framework

- Legislation and regulations
- Drug regulatory authority
- Medicine registration and licensing
- Pharmaceutical quality assurance, including inspection and enforcement
- Pharmacovigilance
- Regulation of prescription and distribution
- Infrastructure for good governance in medicines

Choice of essential medicines

- Principles of essential medicine selection
- Selection process (market approval and selection based on national morbidity patterns)
- Selection criteria (sound and adequate evidence, cost-effectiveness)
- Use of essential medicines lists
- Traditional and herbal medicines

Supply

- Local production
- Supply system strategies and alternatives, including mix of public and private sectors
- Procurement mechanisms
- Inventory control, including prevention of theft and waste
- Distribution and storage
- Disposal of unwanted or expired medicines

Rational use of medicines

- Multidisciplinary national body to coordinate medicine use policies
- Standard treatment guidelines as the basis for selecting essential medicines and training health professionals
- Independent medicine information
- Rational medicine use training for health personnel
- Education about rational use of medicines for consumers
- Promotional activities

Affordability

- Taxes or tariffs on essential medicines
- Distribution margins and pricing

- Measures to encourage competition through generics and price information and negotiation
- Trade-related intellectual property mechanisms

Financial strategies for medicines

- Role of government in the pharmaceutical market
- Pharmaceutical financing mechanisms (public financing, user charges, health insurance, donor assistance)
- Measures to improve efficiency and cost-effectiveness

Human resources development

- Role of health professions
- Role of government in planning and overseeing training and development of human resources for the pharmaceutical sector
- Human resources management and development plan
- Education, training, and courses, including minimum requirements for each cadre of professional staff
- National and international collaborating networks
- Motivation and continuing education
- Ethical framework and code of conduct

Monitoring and evaluation

- Responsibilities and commitment
- Baseline survey of the whole country
- Indicators for monitoring
- Periodic monitoring
- Independent external evaluation every two to three years

Research

- Operational research
- Pharmaceutical development and clinical research

Technical cooperation among countries

- Information sharing
- Harmonization

Sources: Adapted from WHO 1995 and WHO 2003.

Figure D.1: Components of a national medicine policy developed by the World Health Organisation, excerpted from Management Science for Health (2012).

Appendix E

Pharmaceutical logistics framework: South African context

In this Appendix, the themes from the pharmaceutical logistics framework (PLF), described in Section 3.1 (available in Chapter 3), are discussed within the South African context.

E.1 The pharmaceutical logistics framework in the context of South Africa

Zuma (2016) performed an in-depth review of the current pharmaceutical delivery system in the public sector, with reference to the PLF. His study made use of questionnaires and interviews with qualified pharmacists across eight of the nine provinces, including nine pharmacists who operated within a medical depot setting, responsible for warehousing, procurement and distribution activities, and five pharmacists from the directorates of pharmaceutical services, responsible for the overall administration of medicine supply chain management between the depots and PHC facilities (Zuma, 2016).

From Chapter 3, a pharmaceutical supply chain is comprised of four operational functions—product selection; quantification and procurement; inventory and distribution; and product use—with core management supporting elements that are governed by an enabling environment of a policy and legal framework. The study by Zuma (2016) showed that all participating provinces agreed that the PLF is key to the provision of essential medicines in a healthcare delivery system.

There is limited literature available that describes the exact operations within South Africa's pharmaceutical supply chain system. The description provided here is therefore largely based on information from the work of Zuma (2016) referred to above, with some additional resources that represent the most recent information available.

E.1 The pharmaceutical logistics framework in the context of South Africa

E.1.1 Operational functions

Each operational function from the PLF in Figure E.1 is discussed with regards to South Africa's current processes.
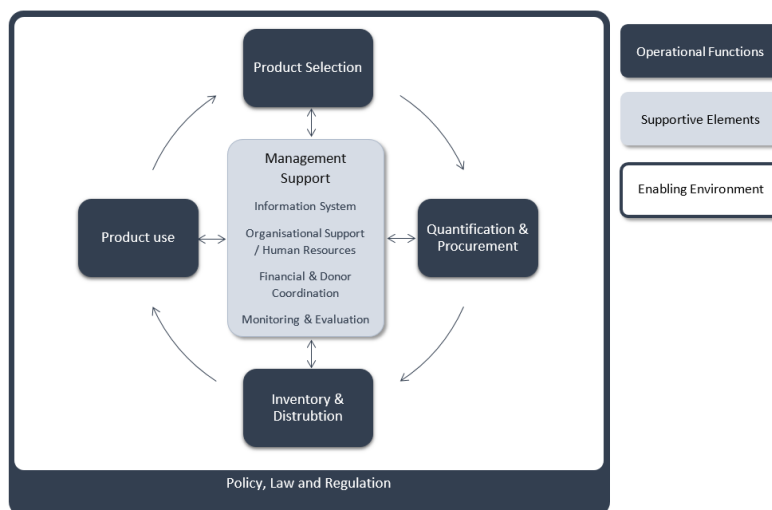
Figure E.1: Pharmaceutical logistics framework

E.1.1.1 The selection of medicines

As mentioned in Chapter 1, the South African healthcare system is a two-tier system consisting of both public and private sectors of healthcare. The public sector has three levels of care (primary healthcare, secondary hospital and tertiary/quaternary hospital) (Perumal-Pillay & Suleman, 2017). Within the National Department of Health (NDoH) is a Sector-wide Procurement Division, that is mainly responsible for selecting essential medicines; the development of standard treatment guidelines (STGs) and essential medicines lists (EMLs) for each level of the health system; the administration of health tenders; and finally, the licensing of individuals and facilities responsible for delivering pharmaceutical services (Perumal-Pillay & Suleman, 2017).

South Africa's National Department of Health (NDoH) is responsible for ensuring safe, affordable and accessible medicines. A subset of the NDoH, the Affordable Medicines Directorate (AMD), is responsible for "getting pharmaceuticals to the point of need" Llewellyn (2016). This means that the AMD is responsible for governing the operations of the pharmaceutical supply chain and ensuring medicine availability from a national level. According to the NDoH, the AMD focuses on the Essential Drugs Program[1] (EDP), contract management and the

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[1] South Africa aims to ensure the availability of safe, affordable and good quality medicines through the Essential Drugs Programme, which promotes the establishment of an Essential Medicines List (EML) and Standard Treatment Guidelines (STGs) for PHC and hospital level (adults, paediatrics, tertiary and quaternary)Gray *et al.* (2016).

E.1 The pharmaceutical logistics framework in the context of South Africa

licensing of pharmacists and pharmacies. The EDP is promoted through the National Drug Policy, which was adopted in 1996 National Department of Health (1996).

Medicines need to be registered to be available on the EML. Registration is one of the criteria that is required for medicines to be considered for the EML—the other criterion includes evidence-based criteria as determined by the World Health Organisation Guidelines (Perumal-Pillay & Suleman, 2017). The most important structure involved in this system of control in South Africa is the Medicines Control Council (MCC) (Hassim *et al.*, 2007). Recent amendments to the Medicines Act brought about the replacement of the Medicines Control Council, a regulatory body that sat under the NDoH, with the newly incorporated South African Health Regulatory Products Authority (SAHPRA) (Krebs, 2018). SAHPRA is the Regulatory Authority of South Africa, which is responsible for the regulation of health products intended for human and animal use, the licensing of manufacturers, wholesalers and distributors of medicines, medical devices, radiation emitting devices, and the conduct of clinical trials (Naidoo *et al.*, 2018). Being an independent organ of state, SAHPRA will levy fees in respect of applications for licensing and the registration of medicines. It is anticipated that such fees will be utilised to appoint skilled and experienced persons to assist the Authority in fulfilling its objects and functions. Fortunately for the pharmaceutical industry, SAHPRA has advised that in the coming months, they will focus on enhancing and streamlining the evaluation and assessment process in respect of medicines—the registration of which previously averaged around four to six years for originator medicines and approximately three to four years in respect to generic medicines (Krebs, 2018).

SAHPRA has 5 programmes to support its functions, namely:

- Programme 1: Administration

- Programme 2: Authorisation Management

- Programme 3: Inspectorate and Regulatory Compliance

- Programme 4: Medicines Evaluations and Registration

- Programme 5: Medical Devices Diagnostics and Radiation Control

Whilst SAHPRA has established target timelines internally for the evaluation medicines, the registration process has resulted in these timelines not being met on a continuous basis, with a significant backlog in the processing of applications for medicine registration (Naidoo *et al.*, 2018). According to Naidoo *et al.* (2018), "delays could have an impact on the availability of medicines in the country with potentially adverse consequences for public health as well as an impact on the pharmaceutical industry" (Naidoo *et al.*, 2018). The time taken for the evaluation of medicines vary depending on the workload, but should be approximately 12 months for generic medicines. With the current backlog in the system, the evaluation and

E.1 The pharmaceutical logistics framework in the context of South Africa

approval may, however, take significantly longer (Naidoo *et al.*, 2018). SAHPRA still receives a substantial number of paper-based submissions, which results in large volumes of document that need to be filed and stored. Due to the large number of paper-based applications and the reasonable time in which these applications need to be processes, a project wass initiated by SAHPRA in order to improve the current processes by implementing an electronic document system (EDMS) (Naidoo *et al.*, 2018).

An Essential Drugs Programme (EDP) was established in accordance with the National Drug Policy of 1996, which had the aim "to ensure an adequate and reliable supply of safe, cost-effective medicines of acceptable quality to all citizens of South Africa and the rational use of medicines by prescribers, dispensers and consumers" (Gray *et al.*, 2016). South Africa is one of the countries that has effectively adopted and developed a national essential medicines list (EML), based on the World Health Organisation (WHO) guidelines (Perumal-Pillay & Suleman, 2017). The EDP facilitates the development of standard treatment guidelines (STGs) and EML for different levels of care (PHC and hospital level for adults, paediatrics, tertiary and quaternary hospitals). There are currently just over 1200 items on the consolidated national EML (including different strengths and pack sizes). An Expanded Programme on Immunization (EPI) offers a comprehensive range of vaccines, free to all public sectordependent patients (Gray *et al.*, 2016).

All provinces utilise the national EML, whereby a National Essential Medicines List Committee (NEMLC) and provincial-, district- and facility-based Pharmaceutical Therapeutic Committees (PTCs) are facilitating the selection of medicines (Zuma, 2016). The provincial PTCs (PPTCs) have the autonomy to select medicines for their provincial EML (based on the national EML) funded by their provincial budgets. The selection process is based on guidelines ((National Department of Health, 2018b)) that stipulate how to select a particular drug to be used in the pharmaceutical system. A description of the process for the selection of medicines in South Africa is not easily available in the public domain. According to Perumal-Pillay & Suleman (2017), "little is known about the NEMLC processes for medicine selection and how these have changed over time. There also seems to be a lack of published information on suggestions to improve the South African EML policy implementation as it evolves over the years, which could benefit other low and middle income countries." Perumal-Pillay & Suleman (2017) performed an in-depth analysis on the selection processes for essential medicines in South Africa, and concluded that the selection in terms of the addition and removal of medicines on the EML revolves around a decision flow system and stipulated criteria for medicine selection (Perumal-Pillay & Suleman, 2017). Figure E.2 presents the decision flow model of the decision-making process for the STG/EML review and medicine selection process.

E.1 The pharmaceutical logistics framework in the context of South Africa
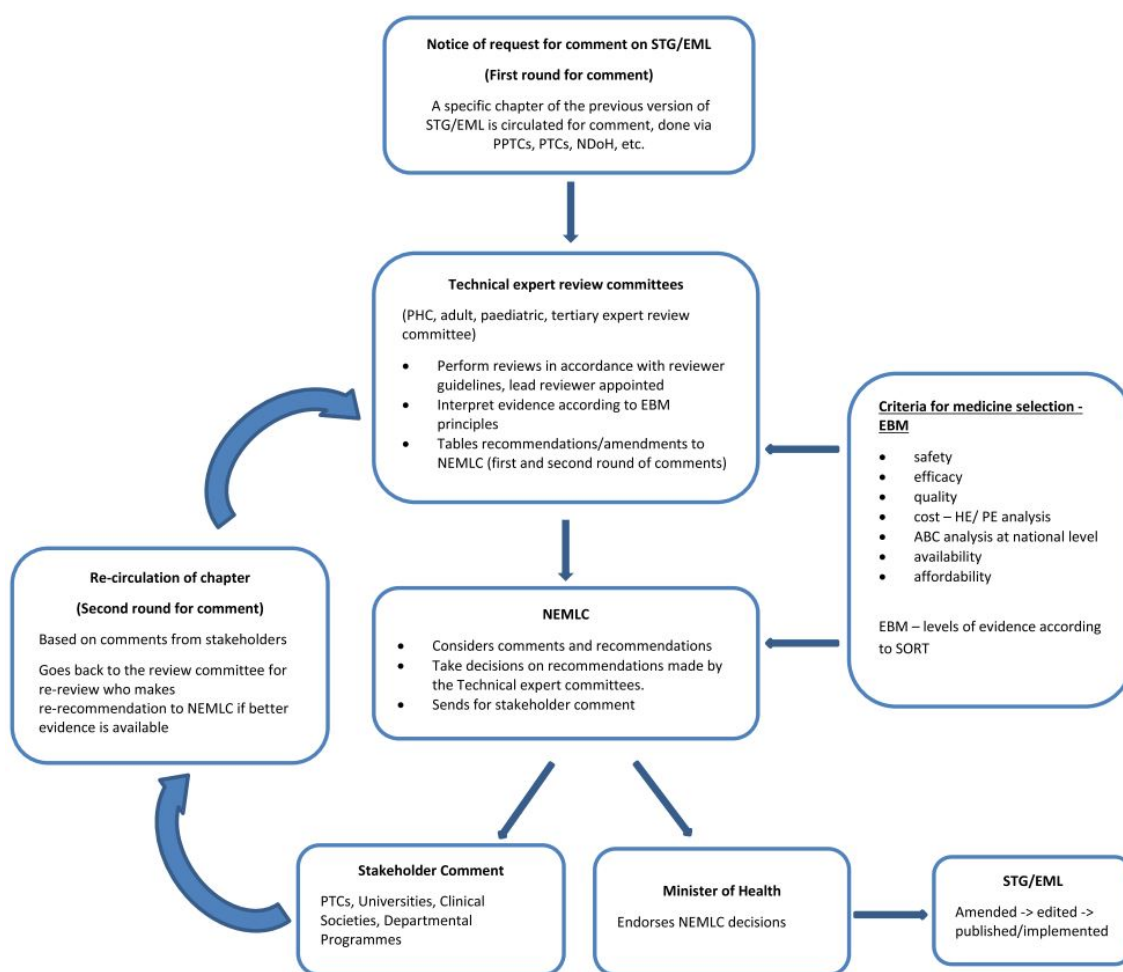
Figure E.2: Decision flow model for medicine selection in South Africa (Perumal-Pillay & Suleman, 2017).

In April 2018, the NDoH released the National Guideline for the Development, Management and Use of Formularies. This guideline outlines the concept of a formulary and providing guidance for the minimum content thereof; provides standardised terminology for development, management and use of formularies; describes; the principles of a standardized hierarchy of formulary development from the EML for all levels of care; and allocates roles and responsibilities for the development, management and use of formularies.

The decisions of the NEMLC guide the procurement of medicines in the public sector and form the basis for initiating medicines tender processes. In relation to programmes funded through conditional grants (notably the ARV programme), these decisions are binding at provincial level Pharasi & Miot (2012). There is a problem with regards to the alignment between the selection and procurement processes—according to Perumal-Pillay & Suleman (2017), the NEMLC often select medicine based on efficacy and cost without taking into consideration whether the product is widely available for procurement. Hence, stock-outs

continue to occur at facility level. The process to check whether the selected medicine for procurement is on tender is not formulated in an actual policy, but within SOPs communicated informally rather than being available on a centralised repository (Perumal-Pillay & Suleman, 2017). The provincial PTCs also have a degree of autonomy, as their provincial Member of the Executive Council (MEC) or Head of Department enables them to make selections of medicines funded from provincial budgets (Pharasi & Miot, 2012). Decision making regarding the selection of health products may, therefore, vary from province to province, which results in inequitable access to medicines and other health-related products (Pharasi & Miot, 2012).

The monitoring and evaluation (M&E) component of an EML policy is vital for the successful functioning of an EDP (Perumal-Pillay & Suleman, 2017). The M&E aspect provides information on how the policy and documents are being received and accepted by those who need to implement it. According to a study done by Perumal-Pillay & Suleman (2017), this component is severely lacking in South Africa's STG/EML programme. The study highlighted challenges and shortfalls affecting the STG/EML implementation, monitoring and evaluation processes. The most prominent challenges and shortfalls are listed as follows (Perumal-Pillay & Suleman, 2017):

i. Communication processes between the organisational structures (national to provincial and departmental), as well as the dissemination of information along these lines;

ii. The lack of health economic expertise in the country;

iii. Poor outcomes monitoring and evaluation of STG/EML decisions and rational use of medicines by patients;

iv. Blurred lines of roles and responsibilities between committees (PTCs, provincial PTCs, NEMLC); and

v. The alignment of processes (medicines selection with procurement) in the STG/EML process.

Next, a discussion of how the selected medicines are procured in South Africa.

E.1.1.2 Procurement of essential medicines

South Africa uses a closed system for drug procurement in the public sector. A central national body oversees the procurement process with active involvement from the provinces. Provinces are responsible for quantifying their drug requirements based on the EML and any additional drugs they have prioritised. Once the tenders are awarded, provinces are informed of the preferred suppliers and provinces then purchase their medicines directly from these suppliers (Patel *et al.*, 2009).

E.1 The pharmaceutical logistics framework in the context of South Africa

One of the challenges with the requisition of the correct amount of products, is the lack of communication between the depots and the suppliers, before and during contact. Another challenge is that the pharmaceutical services at PHC facilities and hospitals have not taken ownership of the quantification process, and shift the blame towards the depots—a majority of the pharmacies within hospitals and PHC facilities place orders every two weeks at the depots, and order according to their consumption. The actual consumption data is not always accurate, because if an item is out of stock, facilities use another pack size or strength, which then skews the usage of the product, leading to inaccurate consumption data (Berger *et al.*, 2010).

The bulk of the medicines in the public sector are procured through national tenders. The tenders are managed by the AMD (in collaboration with the National Treasury), the contract manager for all contracts awarded (Berger *et al.*, 2010). Zuma (2016) states that there is no single province that is solely dependant on national contracts. In some cases, when suppliers fail to deliver services, provinces use buy-outs to ensure continuous stock, leading to the NDoH paying the difference for buying-out (Berger *et al.*, 2010). A quotation system[1] is used for procuring drugs that are not on contract (Zuma, 2016). According to policy, buy-outs may not exceed 10% of the budget (Berger *et al.*, 2010).

Some provinces highlighted problems as to why suppliers fail to deliver the contracted service. Some of the reasons are: due to a failure in the National Treasury's electronic system (tender delays lasted between six and twelve months); allegations that the tender allocation is not transparent; and a lack of ownership (Berger *et al.*, 2010). When a supplier fails to deliver the services that are set out in its contracts, penalties are applied to the specific supplier; however, in South Africa's current system, penalties are not implemented and provincial depots resort to cancelling the orders (Berger *et al.*, 2010).

Opposing views regarding where the responsibility for monitoring supplier performance lies, causes this phenomenon. The provinces believe that it is the National Treasury's responsibility to monitor supplier performances and take action against them; however, the National Treasury states that their role is to facilitate the arrangement and administration of tenders, and that the NDoH must manage the contracts (Berger *et al.*, 2010).

Even though medicines are usually procured through contracts, the prices quoted for the different hospitals and facilities varied amongst the different provinces. There is a disparity in the price of a product between different provinces from the same supplier, as well as between two different suppliers from the same tender, which can be a result of manufacturers billing provinces differently from the contractual price, or provinces purchasing from suppliers that are not tendered (Berger *et al.*, 2010).

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[1]A quotation system is where quotes are requested from suppliers that have not been pre-qualified as a contracted supplier (Berger *et al.*, 2010).

E.1.1.3   Inventory and distribution management of essential medicines

There is no clear uniform representation of the pharmaceutical distribution network in South Africa; however, Figure E.3, is a representation of how the participants described the distribution network.
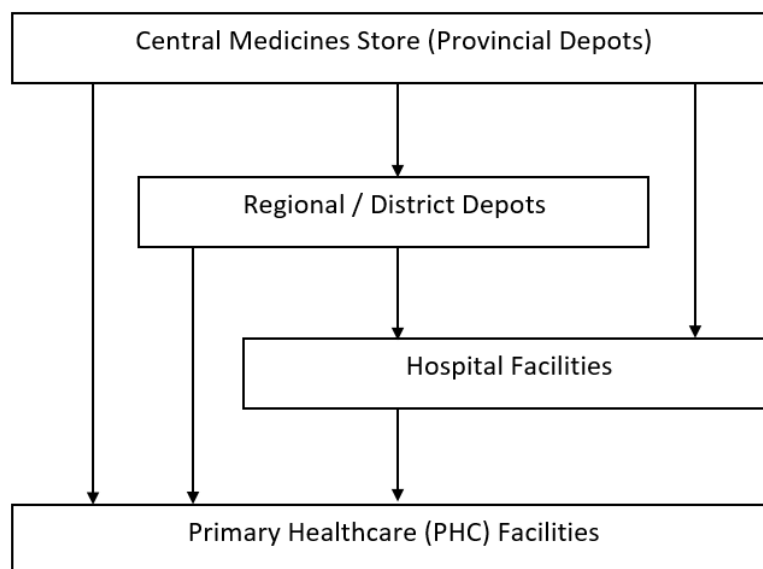
Figure E.3: Illustration of the current public pharmaceutical distribution network in South Africa, adapted from Zuma (2016).

According to an in-depth review performed by a health ministerial task team, there are currently too many medicine depots across South Africa. Every province has at least one provincial depot (with the Eastern Cape and Western Cape having two each), with additional depots for specialised patient-ready packs, antiretrovirals (ARVs), or chronic medicine dispensing. In some provinces, additional regional sub-depots serve as a transit point between the provincial depot and PHC facilities. Too many depots can become an expensive intermediary in a pharmaceutical supply chain (Berger *et al.*, 2010).

Zuma (2016) indicated that there are various distribution methods that are employed in the provinces in South Africa. Most of the provinces use outsourced services between the district depots and facilities—only one province uses in-sourced transportation. In the Free State, the contractor is paid based on the weight of consignment, meaning that deliveries do not take place unless the accumulation of stock is at the right weight for dispatch (Berger *et al.*, 2010). Only two provinces directly distribute medicines from the depots to the PHC facilities, whereas the rest of the provinces distribute to the hospitals and district depots, who in turn distribute to the catchment facilities (Zuma, 2016). The distribution of medicines between multiple points before it reaches the PHC facilities, has an impact on the turnaround

E.1 The pharmaceutical logistics framework in the context of South Africa

times, which influences the shelf-life of the medicines, creates opportunity for stock to get lost in transit, and makes tracking the expiry date of the medicines even harder (Zuma, 2016).

In 2010, only one provincial depot was licensed in terms of the Medicine and Related Substances Act, 1965[1]. Non-compliance with this Act is due to the lack of standardised SOPs, security issues, inadequate storage space, the lack of pharmacy personnel, and the lack of temperature control (for cold chain management) (Berger *et al.*, 2010). These factors are all outlined in the Good Warehousing Practice guidelines that are substantiated by the Medicine and Related Substances Act. SOPs describe in detail how these guidelines should be executed. SOPs for inventory management are important in ensuring the availability of medicines. SOPs assist in the process of ordering stock, stock rotation, and maintaining adequate levels of stock. Good Pharmacy Practice stipulates that all institutions must have SOPs available and implemented; however, there is no uniform set of SOPs used across South Africa. In the case where SOPs are available, the SOPs with regards to the inventory and ordering processes differ between provinces and districts (Berger *et al.*, 2010; Van der Westhuizen, 2012).

Provinces across South Africa each handle orders differently—a majority require approval from a hospital or district pharmacist before the depots can process and issue the ordered medicines, due to nurses in the clinics not being able to handle the orders as an additional function. Requiring approval from pharmacists, however, increases the stock replenishment turnaround time and in some regions pharmacists are not always available (Zuma, 2016).

For the majority of the PHC facilities, stock management systems are paper-based and done manually, by means of stock cards or bin cards. The use of an integrated information system is discussed in more detail in Subsection E.1.2. As mentioned in Section 3.1, an inventory management system is interconnected with storage capacity and replenishment orders. Ordering systems are also based upon minimum and maximum inventory levels, to avoid over- or under-stocking Raja & Mohammad (2004). Orders can only be accurate if accurate inventory levels are used for the quantification of order sizes (Management Science for Health, 2012).

According to a study done by Tayob (2012), PHCs use different storage and inventory management policies, e.g. first-in-first-out (FIFO) and first-expire-first-out (FEFO)—the lack of a standardised method that is consistently applied, prevents the monitoring of the expiry date of each product. The ordering of medicines is done at the facility level, where in different facilities, different healthcare workers order the medicines; in some cases the pharmacy assistant orders the medicines; in the absence of a pharmacy assistant the sister in charge orders the

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[1]The Medicines and Related Substances Act, 1965 (Act 101 of 1965), provides for the registration of medicines and other medicinal products to ensure their safety, quality and efficacy. The Act also provides for transparency in the pricing of medicines (Health, 2016).

medicines, in some clinics the nurse in charge orders the medicines; and, in a very small number of cases, the financial manager orders the medicines (Tayob, 2012).

E.1.1.4   The rational use of medicines

There are different approaches across the provinces for the promotion of rational use of medicines. Some provinces use the ABC Analysis[1] method to determine whether irrational use of medicine has occurred, whereas other provinces conduct training sessions, held by either the PTCs or district pharmacists, to attempt to prevent irrational use from occurring (Zuma, 2016). All participants in the Zuma (2016) study reported that there is limited capacity building for the rational use of medicine.

E.1.2   Management support

From Figure 3.2, the management support functions consists of human resource management, information system, financial coordination, and monitoring and evaluation. Zuma (2016) found that the pharmacists had different perspectives on the management of pharmaceutical services in terms of human resource management, reporting lines, information systems, and financial management. None of the provinces researched by Zuma (2016) indicated the availability of a uniform (standardised across all provinces) legal framework for the provision of medicines at PHC level, covering the four operational functions of selection, procurement, distribution and rational use.

Organisational and human resource management

Tenders are arranged nationally by the NDoH's AMD in collaboration with the NT, with three responsible functions (Berger *et al.*, 2010): (i) selection of medicines for EML and rational use; (ii) facilitating and coordinating the procurement and distribution of medicines; and (iii) licensing of pharmacy premises and issuing dispensing licenses. The staffing or non-availability of adequate resources within the AMD has placed a constraint on the operational activities of the AMD—from the three sections within the AMD with 19 available posts, only 5 were filled in 2010 (Berger *et al.*, 2010). The structure of the head of pharmaceutical services (HOPS) among the provinces and the extent to which they oversee pharmaceutical functions at medicine depots is not standardised (Berger *et al.*, 2010)—the reporting lines between district pharmacists and district managers are also blurred and non-standardised (Zuma, 2016). The HOPS has the responsibility of all pharmaceutical services and staff management in the

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[1] "It is a method of classifying items or activities according to their relative importance. It is also known as 'separating the vital few from the trivial many' because for any group of things that contribute to a common effect, a relatively few contributors account for a majority of effects. "The analysis of this phenomenon is known as Pareto analysis (Siva *et al.*, 2015).

respective provinces, and has the ability to manage each activity in the medicine supply chain; however, the NDoH can hold the HOPS accountable for any medicine shortages (Berger *et al.*, 2010).

Not only is there no uniform management system across the provinces, there is also a lack of sufficient pharmacists—in most provinces, the district and facility pharmacist posts are only partially filled (Zuma, 2016). Due to the scarcity of registered pharmacists and pharmacist assistants in the public sector, nurses are empowered to manage medicine supply at PHC facilities (Tayob, 2012).

South Africa is the country with the highest number of skilled healthcare workers in the sub-Saharan Africa region, with a density of more or less 60 per 10 000 population. Unfortunately, this figure is relatively low in comparison to the wealthier regions of America, Europe and the Eastern Mediterranean. Their densities range from 160–244 skilled healthcare professionals (per 10 000 population) (World Health Organization, 2016). The shortage of pharmacy personnel in South Africa is well known (Berger *et al.*, 2010). There is a lack of comprehensive data on pharmaceutical personnel, which is a significant gap in the human resource policies for the health sector, and therefore results in failed budget plans for training, deployment, and human resource development in the health sector (Berger *et al.*, 2010).

Information system

Medicine availability in public-sector facilities has been highlighted at National Health Council meetings, and technological systems, such as the Stock Visibility System (SVS) and the roll-out of the RxSolution software in all provinces, are in process (Berger *et al.*, 2010). The SVS has been implemented in more than 3 000 clinics countrywide by (Gray *et al.*, 2017). This is the first time that a uniform stock and consumption management system has been implemented in all public sector hospitals and facilities. However, as explained in Section 2.2.3, the pharmaceutical supply chain system functions on various information systems across the provinces.

For the management of tenders, the NDoH has a Contract Management System that administers tender item specification and tender life cycles, which interfaces with MEDSAS, a system used by the depots to manage the storage and distribution of products. The National Treasury uses another system to administer tender processes, called Rfx. The Western Cape Government uses Sourcelink to administer the provincial tender processes; however, there is no information on what systems other provincial governments use for their tender processes. These three systems (MEDSAS, Rfx, and Sourcelink) run on different platforms and are owned by different entities (Berger *et al.*, 2010).

E.1 The pharmaceutical logistics framework in the context of South Africa

For the ordering of products, only a few hospital facilities uses the Remote Demander Module to order against the depots, and the depots use EDI as an ordering system against the suppliers—both these systems interface with MEDSAS (Berger *et al.*, 2010). Although there are a few technology systems used to conduct some management and ordering, the information landscape is fragmented, making visibility across the supply chain cumbersome. Information for the use of decision-making is not readily available, making it difficult for the NDoH to obtain an informative view on the pharmaceutical supply chain (Berger *et al.*, 2010).

Financial coordination

The primary sources of funds include government financing (i.e. taxes), health insurance schemes, and donor financing. The National Treasury allocates funds to the Government department through two funding mechanisms—equitable shares[1] and conditional grants[2]. Provincial and local governments are responsible and accountable for their allocated funds and how they are spent on the provision of essential medicines. Policies indirectly influence the provincial and local government spending (Berger *et al.*, 2010). Problems with provinces having to decide the division of the funds are the following (Berger *et al.*, 2010):

i. The provincial budget allocation in terms of funds available to procure medicine is not defined, making financial planning difficult;

ii. The medicine selection process is not linked to the budget calculation. Changes in STGs and EMLs does not result in amendments being made to the budget; and

iii. The financial information system regarding pharmaceutical expenditure is poor, making it difficult to monitor actual expenditure.

Currently, provincial budgets are managed differently: they are either handled as a centralised budget whereby facilities can receive medicines without having to prove financial resources; or facilities have to prove budget availability with each order placed, which in some cases leads to the withholding of medicine supply, leading to stock-outs (Zuma, 2016).

Monitoring and evaluation

The monitoring and evaluation (M&E) component of the supporting elements links to each of the operational functions. The aim is to monitor and evaluate the processes and activities within the pharmaceutical supply chain. There is a lack of available M&E frameworks in the

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[1]Equitable division of funds takes into account the functions assigned to each sphere and the capacity of each government sphere (Berger *et al.*, 2010).

[2]Conditional grants are funds allocated by the national government, conditional to certain services, for example: human settlement development. HIV/AIDS services are funded through conditional grants, while other health services are funded through equitable shares (Berger *et al.*, 2010)

public domain on monitoring and evaluation frameworks for the components of a pharmaceutical supply chain; however, the country has a number of disease-specific or programme M&E frameworks (Ataguba *et al.*, 2014). for example, the most comprehensive framework available is the Monitoring and Evaluation Framework for Comprehensive HIV and AIDS Care, Management and Treatment Programme for South Africa (Department of Health, 2004),

Concluding Section E.1.2 and as mentioned in Section 3.1, the management support functions are those that support and impact the operational functions. Each of these supporting elements is linked to the four operational functions (selection, procurement, distribution, and rational use), and is enabled by a legal framework consisting of legislations, policies, guidelines, and SOPs. The next function from the PLF is discussed in the light of the current existing legal framework for the South African pharmaceutical health system.

E.1.3   Policy, law and legal framework

All the provinces form the Zuma (2016) study had a common understanding of the legislations under which the medicine supply services is governed—all participants indicated that the National Drug Policy[1] and the Medicines and Related Substances Act are some of the key legislative frameworks. Other legislative frameworks mentioned are those governed by the Medicines and Related Substances Act, the Good Warehousing Practices and Good Distribution Practices (Zuma, 2016).

According to the National Drug Policy, "a full evaluation of the National Drug Policy will take place every three years" (National Department of Health, 1996). A majority of the participants from the Zuma (2016) research also agreed that the National Drug Policy has never been reviewed in the light of primary healthcare. Similar to the components from Table 3.3, South Africa's national drug policy consists of the following components (National Department of Health, 1996): (i) drug selection; (ii) traditional medicines; (iii) drug pricing; (iv) procurement and distribution; (v) rational use of drugs; (vi) human resource development; (vii) research and development; (viii) technical cooperation; (ix) monitoring and evaluation; and (x) legislation and regulations.

E.2   Appendix E: Conclusion

From Section E.1, it is clear that South Africa's pharmaceutical supply chain runs differently across the various provinces, indicating that either some provinces do not follow the legislative frameworks, or there is a lack of standardised policies, laws and regulations among the

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[1]The national drug policy for South Africa aims is to ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa and the rational use of drugs by prescribers, dispensers and consumers (National Department of Health, 1996).

provinces. By taking into account the PLF in Figure E.1, policies and legislations—the enabling environment of a pharmaceutical supply chain. A pharmaceutical supply chain cannot function without appropriate laws, regulations and policies to guide the government on how to enforce the operational activities of the pharmaceutical supply chain.

Appendix F

Other approaches to the rational model

Various authors have provided their take on the rational model. The steps from the rational policy analysis models may vary among the authors; however, there are underlying similarities. Bardach (2011) proposed a practical framework for policy analysis, referred to as the 'eightfold path'. The eight steps are the following (Bardach, Eugene, Patashnik, 2016):

1. Define the problem: The problem is an important part of the analysis, it gives reason for doing an analysis and provides a sense of direction;

2. Assemble evidence: Assembling evidence of the problem within the real-world setting;

3. Construct alternatives: This refers to alternative courses of action (policy options) to solve the problem defined in the first step;

4. Select criteria: This step identifies criteria to be used to assess the policy alternatives, to determine the potential outcome (impact) of each policy option;

5. Project outcomes: This is an evaluation/analysis approach to determine the outcomes based on the criteria selected from the previous step;

6. Confront trade-offs: In some cases policy alternatives produce better outcomes from a different criterion selected, therefore, a trade-off method needs to be utilised, i.e. criterion weighting factor;

7. Decide: Selecting the best policy alternative based on the projected outcomes; and

8. Tell your story: Convey the policy options, analysis method, and policy choice to important stakeholders.

Another approach to the rational model is the Australian policy cycle approach by Bridgeman & Davis (2003). The cycle breaks down the policy process into discrete activities, following

in a sequential and cyclic fashion (Bridgeman & Davis, 2003; Coveney, 2010). The cyclic approach encourages the development and improvement of policies over time with the benefit of iterative inputs (Pipka, 2014). The steps of the Australian policy cycle are listed and described (Pipka, 2014):

1. Identify issues: Issues that emerges through some mechanism;

2. Policy analysis: Research and analysis of problem in order to establish sufficient information regarding a decision about a policy;

3. Policy instruments: Identification of legislative instruments regarding the problem, i.e. legislations and regulation;

4. Consultation: Gathering expertise and information to inform policy development;

5. Coordination: Financial, cabinet, and parliamentary mechanisms of the government;

6. Decision: A decision or acceptance is made by a ministry or authoritative body;

7. Implementation: Once policy is approved, it needs to be implemented; and

8. Evaluation: The policy implementation process should be measured, monitored and evaluated.

Portney (1986) defines public policy "not as a product of government action but as a political process", and proposes the following five stages for policy analysis: (1) Problem formation; (2) Policy formulation; (3) Policy adoption; (4) Policy implementation; and (5) Policy evaluation. Palumbo (1994), with the seven steps from his policy analysis model:

1. Agenda setting: Defining the nature of the problem;

2. Policy definition: Defining the policy targets;

3. Policy design: Conducting a decision analysis of policy alternatives;

4. Policy legitimation: Opinions, surveys, stakeholder engagement, etc.;

5. Implementation: A formative evaluation;

6. Impact: A summative evaluation; and

7. Termination: A political feasibility evaluation.

F.1   Appendix F: Conclusion

The steps from the rational policy analysis models may vary among the authors, however, there are underlying similarities. Figure 4.2 (in Chapter 4), illustrates how the steps within the different models are categorised into the four building blocks (agenda-setting, policy formulation, policy implementation, and policy evaluation) of policy analysis.

Appendix G

Additional information regarding the policy analysis triangle

For the sake of brevity, the following sections include additional information regarding some of the health policy analysis triangle factors.

G.1 Actor behavioural characteristics

These behavioural characteristics are based upon an actor's judgement on whether they will lose or gain from the process, or whether policies are aligned with or against the values and beliefs (Lehmann, 2016). Lehmann (2016) categorises types of interests in the following categories:

i. Self-interest: The interests of those that have a stake in the outcomes of the policy;

ii. Group interest: The interest in labour or a business;

iii. Political interest: Political parties or personal political gain or loss; and

iv. Public interest: A concern for the public good.

G.2 Actor power factors

According to Lehmann (2016), "what actors are able to do within a policy process is also shaped by their power relative to other actors." The power of an actor can be sourced from a few factors—actors usually draw from a range of factors, rather than one (Lehmann, 2016):

i. Personal factors—i.e. skills, knowledge, personality (charisma, and approach to others), reputation, and etc.

ii. Organisational factors—i.e. occupational position within an organisation, reputation, organisation norms.

iii. Policy process—i.e. formal role or position within the policy process.

iv. Contextual—i.e. political status or societal status.

G.3   Micro contextual factors

Micro-level context refers to the more immediate and local factors that may impact or influence a policy or the implementation of a policy (Lehmann, 2016). (Lehmann, 2016) may include some questions:

- **Organisational capacity**

    - Are the right people in the right place with the right skill?

    - Does the system allow the actors to use their skills effectively?

    - Have appropriate 'task networks' been established?

    - Is the organisational structure appropriate for the implementation?

    - How does the public sector environment enable or disable the organisational functioning?

- **Organisational context and culture**

    - How do shared ideas, values, traditions and etc., determine how employees behave?

    - What managerial practices exist?

    - What influences are there from various actors in the organisation?

- **Previous policies and experiences**

    - What experiences are there with prior policies?

- **Social contexts surrounding the organisation**

    - What social networks, social values, and socio-political influences impact the organisation?

G.4   Appendix G: Conclusion

In this appendix, additional information about the policy analysis triangle (introduced by Walt & Gilson (1994)) is discussed.

Appendix H

Policy definition and formulation checklist

The following figures are extracted from the health policy analysis course module by Shung-King (2004), that provides a checklist for: (i) implementation strategies to include to reduce the likelihood of poor implementation (Figure H.1); (ii) key factors to consider when defining a policy problem (Figure H.2); and (iii) key information required when drafting a policy document (Figure H.3).

<u>Checklist: Minimizing the likelihood of poor implementation</u>

Implementation issues to consider at the policy formulation stage:

General
☑ Policy (including implementation guidelines) should be clearly articulated
☑ Clear, realistic timeframes should be in place
☑ Policy should be based on valid evidence/scientific facts

Role-players
☑ All relevant role-players should be consulted
☑ Their position and influence with regard to this policy should be ascertained
☑ Their role in implementation should be clearly defined

Support systems/ resources
☑ Political support at all levels for the policy option selected
☑ Implications considered and support systems in place for implementation e.g. human resources, financial resources, drug support, transport etc.
☑ Training of staff considered and organized
☑ Monitoring and evaluation built in

Figure H.1: Implementation strategies to reduce the likelihood of poor policy implementation

Checklist: Problem definition

☑ How and why did the problem get on the agenda?

☑ Is the causal structure of the problem understood?

☑ What are the relevant health related/ scientific facts?

☑ What is the current practice with regard to this problem? (provincial, national, international levels)

☑ Are there experiences /lessons from elsewhere that must be considered?

☑ Who are the key role-players?
(within the department, other departments, non-governmental organizations, private institutions, interest groups, citizen groups, labor groups)
❑ What role does each play?
❑ How will they be affected?
❑ How are they likely to respond?
❑ Are there important conflicts between role-players?
❑ Who will be involved in the policy formulation?
❑ At what stage?
❑ How will they be involved?

☑ What are the values and aspirations relevant to the problem?
❑ Who holds these values?
❑ Is there a conflict of values?
❑ Which values are in conflict?
❑ How important is the conflict?

☑ What are the financial and resource issues and implications?

☑ What are the:
❑ administrative
❑ legal
❑ social
❑ political
issues that need to be considered?

☑ Are there existing policies that have a bearing on the policy being developed?
❑ What are they?
❑ How do they affect the policy being developed?

☑ Is further research needed?
❑ What are the research questions?
❑ Who will conduct it?
❑ How long will it take?
❑ Are there resources available?

Figure H.2: Factors to consider when defining the policy problem

Checklist: Drafting a policy document

Your policy document should include the following:

Introductory sections

☑ Title

☑ Date

☑ Authors

☑ Acknowledgements

☑ Terms of reference

☑ Forward by minister/ relevant official

☑ Requests for comments (if policy in draft stage)

☑ Executive summary

☑ Definitions of terms

Background information

☑ Context/ current situation

☑ Policy development process

☑ Policy options considered, rationale for selecting this option, evidence base

Body/ crux of policy

☑ Mission statement

☑ Purpose

☑ Aims and objectives

☑ Target group

Implementation guidelines

☑ How the policy will be implemented?

☑ Timeframes

☑ Resources required for implementation

☑ Responsible people and roles

☑ Training component

☑ Monitoring and evaluation

Other issues to consider

☑ Spelling, clear layout, easy reading language

Figure H.3: Key information required when drafting a policy document

Appendix I

Effect-implementation analysis model

For the sake of brevity, a detailed discussion from the effect-implementation model (identified in Subsection 4.2.2.2 in Chapter 4) is provided here.

I.1   Description of the analytical dimensions

Here is a more detailed description of each analytical dimension discussed in Subsection 4.2.2.2.

Effectiveness: This dimension aims to analyse the policy in its effectiveness to achieve its objective. Some difficulty with this dimension is that it is difficult to pinpoint the cause and effect of the policy, if there are many policies that may focus on the same targeted problem. Another element to analyse is the influence of implementation context on the effectiveness—the same policy being implemented in two different contexts may not have the same effects (Morestin, 2012).

Unintended effects: These are all the outcomes produced by implementing the policy (under study), but are unrelated to the objective of the specific policy. Unintended effects can be either positive or negative, and can be produced in areas such as an environment, political, and social context (Morestin, 2012).

Equity: The objective of this dimension is to identify whether the policy being analysed might have a different effect on different groups (i.e. age, gender, socio-economic status and religion). It is important to take this dimension into consideration, because policies might improve health issues, but result in deepening inequalities in a country (Morestin, 2012).

Cost: The first type of cost that comes to light is cost incurred by the government; however policies can also generate cost gains (cost for other actors). These factors can strongly influence the way stakeholders react to a given policy (Morestin, 2012).

Feasibility: The feasibility dimension is about analysing the technical components that make up a policy, and consists of a series of elements. On a practical level, the dimension refers to the availability of resources, i.e. materials, people, and technology. The dimension can also refer to whether the policy conforms with existing legislations, i.e. Acts, regulations and guidelines—especially for this element the distribution of roles and responsibilities among the national, regional and local level must be considered. Another element that contributes to this dimension is pilot programmes, where feasibility is proven by pre-existing experience (Morestin, 2012).

Acceptability: The acceptability of a public policy refers to how stakeholders judge the policy. In addition, the judgement of the policy by stakeholders includes external factors, besides the other five dimensions—these factors are concerned with the stakeholder's values, beliefs, power and interests towards a particular policy. A policy that does not gather support from the relevant stakeholder, has a greater risk of not being adopted or implemented. Therefore, the acceptability of the policy by the stakeholders should be analysed (further discussed in Section 4.3) (Morestin, 2012).

I.2 Summary List—analytical dimensions for analysing public policies

In practice, it is not typical to document all the elements associated with each analytical dimension. The following list can assist with determining the impact policies might have on the system—by answering the questions in the summarised list. Inversely, this list does not claim to be exhaustive (Morestin, 2012), and questions that are considered to be important to the analysis can be added. The list is a complete extract from the study by Morestin (2012):

Effectiveness

- What are the effects of the public policy under study (positive, neutral, negative) on the targeted health problem?

- How effective is this policy in terms of its intermediate effects?

- Is the intervention logic of this policy plausible?

- How does the implementation context influence this policy's effectiveness?

- How much time is needed before effects can be observed? Do the effects persist over time?

Unintended effects

- Does the policy under study produce unintended effects, whether positive or negative?

- How can the negative unintended effects be mitigated?

Equity

- What are the effects (intended or unintended) of the policy under study on different groups?

- Does this policy create, reinforce or correct social inequalities in health?

Cost

- What are the financial costs and gains for the government? For other actors (industry, community organisations, consumers, taxpayers, etc.)?

- How are the costs distributed over time?

- To what extent are the costs apparent?

- How do the costs of the policy under study compare with those of other potential policies, including that of inaction? What is the cost-effectiveness of the policy under study for the government, for society?

Feasibility

- Are the required human, material, and technological resources available?

- Does the policy being studied fall under the legal jurisdiction of the authority who wishes to adopt it? Is it in conformity with existing legislation?

- Is this policy a follow-up to a pilot programme?

- Can this policy be administered by pre-existing mechanisms?

- Is the authority promoting this policy also the one that will implement it?

- If not, how many different actors are involved in implementing this policy? Are they effectively guided by the policy's promoters? Do they cooperate well?

- Do the opponents of this policy have the ability to interfere with its adoption, its implementation?

Acceptability

- Which actors are or would be affected by the public policy under consideration?

- Is the problem targeted by this policy considered a social issue that requires intervention? What are stakeholders reactions to the idea of intervening to address this problem?

- How do stakeholders think the issue should be addressed?

- What do stakeholders think of the proposed policy? Of its effectiveness, its unintended effects, its equitability, its cost, and its feasibility? Of the degree of coercion it involves?

- What do stakeholders think of the conditions surrounding adoption and implementation of this policy?

- Can the policy's acceptability evolve during the period in which it is being implemented?

I.3 Data collection methods

Table I.1: Data collection methods by Morestin (2012).

DATA COLLECTION METHODS	DESCRIPTION	TIME REQUIRED	SPECIFIC COMPETENCIES	ROBUSTNESS	CONTEXTUAL RELEVANCE
Group brainstorming	Attempt to answer the questions in the summary list.	A few hours to a few days	No	2 (Informal knowledge, but the confluence of several sources enriches reflection)	Yes
Consultation with experts	Use the summary list as an interview guide or as a grid to fill out	A few days	No	3 (Expert knowledge, but only one source)	Depends on whether the expert understands the context well.
Deliberative process	Bring together relevant stakeholders and stimulate discussion among participants.	A few weeks	Facilitation analysis / synthesis of a significant amount of data.	4 (Several types of expertise, interaction between several perspectives)	Yes
Literature review	The questions in the summary list are answered by referring to published data.	A few months	Documentary search / synthesis of a significant amount of data	5 (Numerous sources, credibility of scientific publications, methodical process)	Yes, if the data are drawn from the applicable context
Methods for synthesising knowledge	An approach that combines a literature review and the organization of deliberative processes.	A few months	Documentary search / synthesis of a significant amount of data	5 (Numerous sources, credibility of scientific publications, methodical process)	Yes, due to deliberative processes.

Table I.1 continued from previous page

DATA COLLECTION METHODS	DESCRIPTION	TIME REQUIRED	SPECIFIC COMPETENCIES	ROBUSTNESS	CONTEXTUAL RELEVANCE
Individual reflection	Attempt to answer the questions in the summary list (see Appendix)	A few hours	No	1 (Informal knowledge, a single source)	Yes

I.4 Multi-criteria decision analysis tool

Multi-criteria analysis (MCDA) is an example of a technique that can be used to identify a preferred option or to distinguish between acceptable and unacceptable possibilities (Department for Communities and Local Government: London, 2009). A decision is made (or a preferred option is chosen) by analysing an array of results for multiple dimensions that vary in nature. The MCDA is a matrix with options in each row, and a performance dimension(s) in the column. Each option is individually assessed, the expected consequences of each option is assigned with a score—dimensions are often measured in in different units (numbers, a degree or extent to, binary, etc.) (Department for Communities and Local Government: London, 2009). The score can be converted to a scale of preference, e.g. between 0 and 100. Numerical weights can be assigned to the dimensions to give the relative importance of a dimension in the decision-making process (Department for Communities and Local Government: London, 2009).

I.5 Appendix I: Conclusion

In this appendix the analytical dimensions from the effect-implementation analysis model (introduced in Subsection 4.2.2.2) is discussed in detail. A list of questions is provided to assist with the decision of which analytical dimensions to include in the analysis. Finally, a brief discussion of the multi-criteria analysis tool is discussed.

Appendix J

Stakeholder Analysis models

For the sake of brevity, the following sections provide detailed discussion on the stakeholder analysis methods identified in Section 4.3 (Chapter 4).

J.1 Stakeholder power and position map

The stakeholder map is an effective tool to illustrate (visually) the position of a stakeholder according to two characteristics. Lehmann (2016) uses the following two characteristics in his example: power and the level of support of a stakeholder. Similar to all stakeholder analysis methods, the key stakeholders (individuals, groups, or organisations) need to be identified. Using the table in Figure J.1, answer the following questions (Lehmann, 2016):

Form 1. Stakeholder analysis part 1				
Actor	Interests, values & concerns		Forms and level of power to influence implementation	
	What are the actor's interests and values of relevance to this policy?	What were the actor's hopes or concerns in relation to this policy?	What forms of power could the actor mobilise in this policy story?	What power limits did the actor face in this policy story?

Figure J.1: Stakeholder tabular that is used to define their characteristics (Lehmann, 2016).

   i. What are the actors interests and values relating to the policy issue?

  ii. How is the actor likely to see the impact of the policy action?

 iii. Is the actor likely to support or oppose the policy action?

  iv. What power resources does the actor have?

v. What capacity does the actor have to mobilise resources?

The analyst should gather information regarding the stakeholders and complete the form in Figure J.1. Next, select two characteristics (in this case power and interest) and position the stakeholders on the map (Figure J.2) based on the information provided in Figure J.1. This allows the analyst to judge the level of power the stakeholders are likely to have around the policy issues ('very high to very low'); as well as whether the stakeholder would see the impact of the policy on them as strongly positive, strongly negative or somewhere in between (Lehmann, 2016), indicating whether a stakeholder should be involved in the decision-making process, or excluded from the process.

FORM 2: ACTOR POWER & POSITION MAP

Instruction: Locate your actors on this map of support and opposition for implementation, taking account of their power level

	high support	<< <<	not mobilised/neutral	>> >>	high opposition
	Enthusiastic	Helpful Compliant	Hesitant/Indifferent	Uncooperative Opposed	Hostile
Power of actor					
Very High v v					
Medium					
v v **Very Low**					

Figure J.2: Stakeholder power and position map (Lehmann, 2016).

J.2   Quantifying-evaluation tool

This SHA method of Abdrabo & Hassaan (2007) is conducted through the following steps, which are briefly mentioned and then described in more detail:

1. Develop a checklist of all the stakeholders that are relative to the project or policy reform;

2. Identify each stakeholder's interest and their attitude towards the selected policy reform or project;

3. Estimate the level of power and influence towards the project or policy reform, based upon human, financial, and political resources; and

4. Evaluate the degree and need for stakeholder involvement.

Figure J.3 illustrates a table that can be used to complete the different steps. The table and the scale to which the criteria are evaluated are illustrated. According to the authors, the

threshold limits in the scale are not set values, and are a guideline on how the involvement of stakeholders and their influence on the project or policy reform can be analysed, meaning that the threshold limits can be slightly modified according to the analyst's desire (Abdrabo & Hassaan, 2007).

Stakeholder	Criteria of evaluation							Decisions	
	Interests	Attitude	Power			Influence	Total	The need for involvement	Extent of involvement
			H	F	P				

Scale

Attitude	3	Highly supportive	2	Moderately supportive	1	Neutral	-2	Moderately negative	-3	Highly negative
Power H	5	Very strong	4	Strong	3	Average	2	Weak	1	Very weak
F	5	Very strong	4	Strong	3	Average	2	Weak	1	Very weak
P	5	Very strong	4	Strong	3	Average	2	Weak	1	Very weak

The need for involvement (If total) > 10 Should be involved   < 10 Could be disregarded

The extent of involvement (If total) < 20 To be informed   20 – 30 To be consulted   > 30 In decision making process

Figure J.3: Table illustration with stakeholder evaluation scale, (Abdrabo & Hassaan, 2007).

The first step is quite simple—the list of stakeholders refers to those that have a vested interest in the decision or policy that has been promoted (Abdrabo & Hassaan, 2007). The list should also contain actors that might not have anything at stake; however, they have the power to influence the decisions. The next step is the identification of the stakeholder's interest, where the analyst should list the stakeholder's possible motives and concerns on the issue that is being addressed (Abdrabo & Hassaan, 2007). The attitude column refers to the potential reaction of the stakeholder towards a decision. The estimation can be scored according to the values on the scale provided. The attitude value is also an indication of the stakeholder's 'acceptability' towards a policy decision, which links to the effect-implementation method in section 4.2.2.2.

A stakeholder's power refers the quantity of resources the stakeholder has available in terms of Human (H), Financial (F), and Political (P) resources, and their ability to mobilise them (Abdrabo & Hassaan, 2007). The stakeholder's influence on a decision is determined by the sum of the three power levels. And the 'Total' of each stakeholder is the product of the value of the attitude and the value of the influence (i.e. 'Attitude' x 'Influence' = 'Total') (Abdrabo & Hassaan, 2007).

The total value is used to determine whether or not to involve a stakeholder in the decision-making process. If the total is less than 10, then the stakeholder or stakeholder group can be disregarded. However, if the total is equal or more than 10, then the stakeholder should

be involved in the policy reform process. The extent of the stakeholder's involvement is also determined by how far above the threshold value of 10, the stakeholder's total value is.

The extent of involvement is divided into three groups: (1) where the stakeholder's total value is between 10 and 20—the group should only be informed of the decisions that are made; (2) where the stakeholder's total value is between 20 and 30—the group should be consulted; and (3) where the stakeholder's total is higher than 30—the group should be involved in the decision-making process (Abdrabo & Hassaan, 2007). The results from the extent of involvement can be incorporated into the policy development, policy change and policy implementation strategies.

J.3 Appendix J: Conclusion

In this appendix, a brief discussion of a stakeholder power and position map is provided. This is followed by a detailed discussion of the quantifiable stakeholder analysis tool.

Appendix K

Comparison between various research products

Table K.1 summarises the definition and specifications of different research 'product' outputs. The table is used to identify the fitting product in this research study. A logic model was considered the best fit for the PoliVAN and this research study.

Table K.1: Identification and definition of different research products

FRAMEWORK	ROADMAP
• A broad overview, outline, or skeleton of interlinked items (i.e. a system, concept or text) which supports a particular approach to a specific objective (BusinessDictionary, 2019). • A conceptual framework is a network, or "a plane," of interlinked concepts that together provide a comprehensive understanding of a phenomenon or phenomena. The concepts that constitute a conceptual framework support one another, articulate their respective phenomena, and establish a framework-specific philosophy (Jabareen, 2009).	• A plan or strategy intended to achieve a particular goal (ProductPlan, 2019). • A roadmap is a strategic plan that defines a goal or desired outcome, and includes the major steps or milestones needed to reach it (Petrick, 1997). • A key characteristic of a roadmap is a high-level plan, defining the overarching strategic objective, and capturing the major steps (ProductPlan, 2019.
MODEL	**LOGIC MODEL**
• A theoretical model gives an abstract description of a given system (Achinstein, 1965). • A model is not the real world, but merely a human construct to help better understand the real world systems. In general, all models have an information input, an information processor, and an output of expected results (Starting Point, 2019). • Usually mathematical / statistical or conceptual models (Starting Point, 2019).	• A logic model presents a picture of how your effort or initiative is supposed to work. It explains why your strategy is a good solution to the problem at hand. Effective logic models make an explicit, often visual, statement of the activities that will bring about change and the results you expect to see for the community and its people (Taylor-Powell, 2008). • Other names include: roadmap (Taylor-Powell, 2008). • A logic model includes the following components: Purpose, context, inputs, activities, outputs, effects (Taylor-Powell, 2008).
TOOLKIT	**BLUEPRINT**
• A set of tools designed to be used together or for a particular purpose (Beaven, 2019). • A fixed set of procedures, guidelines, criteria, etc., established to ensure a desired or required result or prevent oversights (Beaven, 2019).	• The term "blueprint" is derived from the domain of architecture, which means "detailed plan of action" (Adkoli, 2012). • A Blueprint is a map or specification for a type of program, which ensures that all the aspects of a specific technical domain are covered (Community Toolbox, 2018).
STRATEGY	**TYPOLOGY**
• A strategy is the process you use to approach a problem. It is a way of describing *how* you are going to get things done. It is less specific than an action plan (Community Toolbox, 2018).	• A typology is the selection of a certain number of combinations of groups of variables. The selection may be more or less explicit, more or less valid, and more or less based on the data afforded by empirical research (Capecchi, 1968).

Appendix L

Subject matter expert master table

Table L.1 in this appendix summarises all the subject matter experts from this study into a consolidated table. This table provides the following information about each participant in this case study: their occupational and academic background to showcase their credibility; the country they reside in; and whether they are familiar with the VAN initiative. Then the SMEs' participation in the various evaluation processes are indicated to illustrate the different evaluation processes that have been covered, as well as where the different SMEs provided their expertise.

Table L.1: The master table of SMEs that participated in the evaluation process in this study

| | PARTICIPANT INFORMATION | | | | EVALUATION PARTICIPATION | | | | | | |
| | | | | | VERIFICATION | | | VALIDATION | | | |
P#	OCCUPATIONAL BACKGROUND	ACADEMIC BACKGROUND	COUNTRY	FAMILIAR WITH VAN	Pharmaceu-tical supply chain	Policy analysis	PoliVAN Objectives	SME Workshop	Workshop case study	Desktop case study	SSA Transferability
P1	Health supply chain programme officer at Bill and Melinda Gates Foundation.	Bachelor of Arts, Business Administration and Operation Management; MSc in Supply Chain and Operations Management.	Nigeria	Yes	X						
P2	Senior pharmaceutical supply chain consultant; 9+ years of experience as supply chain consultant in pharmaceutical industry.	B.S. in Supply chain Management; MSc in Public Health; Certified Supply Chain Professional (CSCP).	United States of America	Yes	X						
P3	Public and Private Sector Supply Chain; Private Sector Pharmaceutical Distribution; Public Sector Technical Advisor - Medicine Supply Chain.	BSc (Pharm); MBA	South Africa	Yes	X		X			X	
P4	Medical doctor by training; 10 years Deputy Director at Children Research Institute working on policies; Associate Professor at UCT (Health Policy and Systems Division)	MB ChB Medicine; PhD Social Policy	South Africa	No		X					
P5	Public Health Specialist; Senior lecturer and researcher at Stellenbosch University, Division of Public Health and Health Systems	Masters in Public Health Medicine; MBA	South Africa	No		X					
P6	VAN Advisor, Ministry of Health in Mozambique; Village Reach M&E Department; 7 years of experience working for NGOs in the public health sector.	Bachelor's degree in Computer Science for Management from A Politécnica University in Mozambique; Published multiple research articles.	Mozambique	Yes			X				x

	PARTICIPANT INFORMATION				EVALUATION PARTICIPATION						
					VERIFICATION			VALIDATION			
P#	OCCUPATIONAL BACKGROUND	ACADEMIC BACKGROUND	COUNTRY	FAMILIAR WITH VAN	Pharmaceu-tical supply chain	Policy analysis	PoliVAN Objectives	SME Workshop	Workshop case study	Desktop case study	SSA Transferability
P7	Health economist, Deputy Director within Affordable Medicines Directorate. Technical lead on many of the VAN initiatives and technology led supply chain reforms; Managing Executive: Health & Social Innovation at Mezzanine.	BA degree in Psychology, English; BA(Hons) in English Literature; MSc. In International Health Policy; Health economist; Multiple published articles.	South Africa	Yes			X				
P8	Cluster Manager: Governance, Monitoring and Evaluation at Systems for Improved Access to Pharmaceuticals and Services, Management Sciences for Health; Technical advisor for NDoH.	Diploma in Pharmacy; Master of Public Administration (M.P.A),	South Africa	Yes				X	X		
P9	Pharmacy Technical Assistance Manager: rational medicine use; Pharmacist; Member of South African Pharmacy Council.	BSc (Pharm)	South Africa	Yes				X	X		
P10	Public health consultant; National Health Service (NHS) Service Development, Governance, and Project Management; Managing Director at leading consulting companies in health advisory.	BSc Political Science and Law	South Africa	Yes				X	X	X	
P11	Senior business analyst at Imperial Logistics; Management Systems, Risk Management, Monitoring and Evaluation; Technical advisor at NDoH.	BSc (Hons) Microbiology	South Africa	Yes				X			
P12	Manager at PwC (health advisory); Technical advisor for NDoH; Hospital operations manager.	BSc (Pharm); Post-graduate diploma in Health Economics	South Africa	Yes				X			

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P#	OCCUPATIONAL BACKGROUND	ACADEMIC BACKGROUND	COUNTRY	FAMILIAR WITH VAN	Pharmaceu-tical supply chain	Policy analysis	PoliVAN Objectives	SME Workshop	Workshop case study	Desktop case study	SSA Transferability
	PARTICIPANT INFORMATION				EVALUATION PARTICIPATION						
					VERIFICATION			VALIDATION			
P13	VAN Programme Manager for NDoH; Supply Chain Operations Manager for Helthcare; Supply Chain Development Lead at African Resource Centre (ARC)	MEng Aeronautical Engineering; Masters in Supply Chain Management	South Africa	Yes					X	X	
P14	Clinical pharmacist for 6+ years; Technical advisor for NDoH; Health Policy Specialist for NDoH.	BSc (Pharm)	South Africa	Yes					X		
P15	USAID Supply Chain Consultant for NDoH; 20 years' experience in supply chain management; Business process re-engineering	BEng (Industrial Engineering); MBA	South Africa	Yes						X	
P17	Director at an African Health Advisory organisation focusing on Supply Chain Management; Project experiences with donor organisations, such as: BMFG, USAID, GAVI, and the Global Fund.	Management Practices 0in Health Care Delivery, Supply Chain Management; Master's in Public Health; MBA	Nigeria	Yes							X
P18	Supply chain Advisor for a supply chain consulting company in Nigeria and Botswana;	Certified with a number of Supply Chain Management programs; BSc in Economics.	Nigeria	Yes							x

Appendix M

Verification process questionnaires

POLICY ANALYSIS LOGIC MODEL FOR A VAN OPERATING MODEL

By

Emma Kleynhans

(PUBLIC) PHARMACEUTICAL SUPPLY CHAIN CONTENT VERIFICATION

DISSERTATION TITLE:

The Development of a Policy Analysis Logic Model to Support Public Medicine Availability Initiatives in the Context of VAN

QUESTIONNAIRE

The following questions aim to verify the literature used to develop the PoliVAN logic model. As mentioned, three mutually exclusive literature topics were considered to be able to develop the PoliVAN logic model: (i) the Visibility and Analytics Network (VAN) concept; (ii) public pharmaceutical supply chains and the link to policy; and (iii) policy analysis methods and models. The following questions are relevant to the operations of a pharmaceutical supply chain.

1. The Pharmaceutical logistics framework (PLF)

Please indicate which of the identified activities make up the operational component depicted in the pharmaceutical logistics framework (Figure 1). Also, indicate and give additional activities that are important that is not been provided in the lists below:

Medicine Selection

- ☐ Registration
- ☐ Essential medicines list (EML)
- ☐ Standard treatment guidelines (STG)
- ☐ Donor requirements
- ☐ Other: _____
- ☐ Other: _____
- ☐ Other: _____

Medicine use

- ☐ Diagnosis / follow-up
- ☐ Prescribe
- ☐ Dispense
- ☐ Use and adherence
- ☐ Other: _____
- ☐ Other: _____
- ☐ Other: _____

Quantification and procurement

- ☐ Quantification and forecasting
- ☐ Procurement method
- ☐ Funds and budgeting
- ☐ Supplier selection and monitor
- ☐ Contracting
- ☐ Order status and monitoring
- ☐ Product inspection (receive and check of medicines)
- ☐ Payment
- ☐ Other: _____
- ☐ Other: _____
- ☐ Other: _____

Inventory and distribution management

- ☐ Port clearing
- ☐ Product inspection (CMS)
- ☐ Inventory control
- ☐ Storage
- ☐ Requisition / ordering and allocation of suppliers
- ☐ Delivery methods
- ☐ Other: _____
- ☐ Other: _____
- ☐ Other: _____

Management support elements

Information system

- ☐ Pharmaceutical management information system
- ☐ Indicator-based monitoring
- ☐ Integrated network
- ☐ Other: _____
- ☐ Other: _____
- ☐ Other: _____

Organisation and HR management

- ☐ Personnel management
- ☐ Education and training
- ☐ Accountability
- ☐ Reporting structures
- ☐ Other: _____
- ☐ Other: _____
- ☐ Other: _____

Financial and donor coordination

- ☐ Financing and budgeting strategies
- ☐ Analyse and control of expenditures
- ☐ Donor financing
- ☐ Other: _____
- ☐ Other: _____
- ☐ Other: _____

Monitoring and evaluation

- ☐ Programme planning and implementation, monitoring and evaluation.
- ☐ Other: _____
- ☐ Other: _____
- ☐ Other: _____

Policy, law and legal framework (Governance)

Policy is considered to describe a broad framework of goals and objectives followed by public institutions to address a particular (set of) problem(s). These goals and objectives are translated into actions stipulated in rules, guidelines, or procedures in a policy, that will address the needs of the beneciaries. The contents of a policy are supported and enforced by country-specific laws and regulations. The figure below highlights the different levels of legislation. Policies are supported by the mandatory legislations (i.e. Acts and regulations), whilst voluntary legislations (i.e. guidelines, rules and standard operating procedures (SOPs)) stipulate how the aims and objectives should be executed.

Do you agree that the legal hierarchy depicted below provides a good generic representation of the relationship between the different levels of legislation?

    Yes

    No

If no, explain:

_____
_____
_____
_____
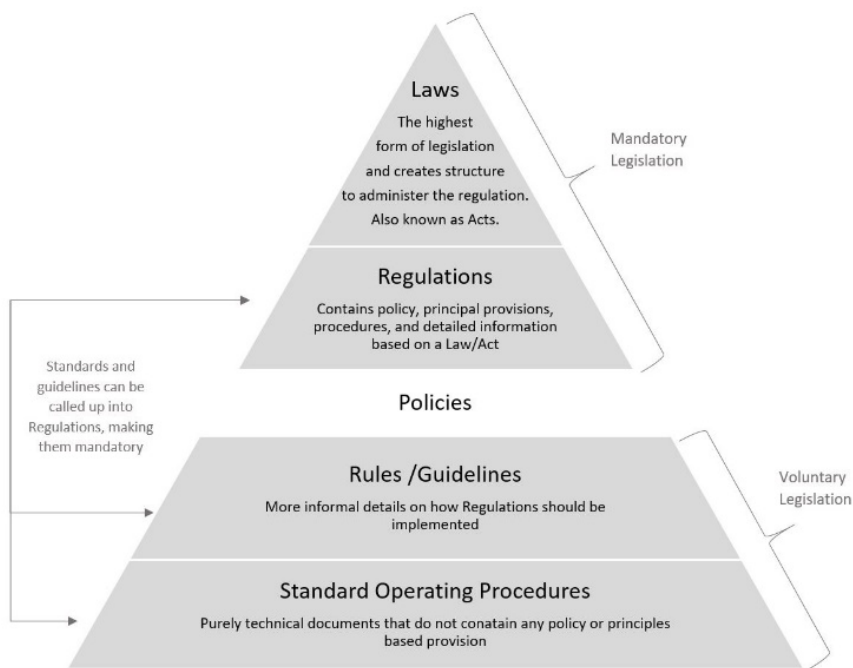
Governing practices

Governing bodies (i.e. statutory bodies, governing boards and advisory councils) at the different levels of the health system (national, regional and local) are key in strengthening the governance at all steps of the pharmaceutical system (Management Science for Health, 2015). Five governing practices have been identified that can help strengthen the performance of pharmaceutical systems, and subsequently reduce the possibility of medicine stock-outs. Please indicate the importance of each of these practices in governing the pharmaceutical supply chain [very unimportant (VU) to very important (VI)]. In the case of additional practices not mentioned, please add them.

	VU	U	N	I	VI	Comment
Accountability						
Stakeholder engagement						
Setting strategic direction						
Stewarding resources						

Continuously improving governance					

2. Key role players in a public pharmaceutical system

The following individual, groups and organisations (with examples) are identified as the key role players in a public pharmaceutical system. They are those that could potenitally affect/influence a policy, implement and/or execute a policy:

- **International influencers** – World Health Organisation (WHO), United Nations (UN), etc.
- **NGO (non-government organisation)** – funding agencies, donor organisations, health programmes, etc.
- **Government** – Ministry of Health, Ministry of Finance, and other relevant departments.
- **Ministerial appointed committee** – task teams appointed by the Government to analyse and investigate healthcare sector or pharmaceutical-related issued.
- **Public sector healthcare workers** – primary healthcare facilities, hospitals, central medicines stores, etc.
- **Private sector entities** – distributors, wholesalers, clinics, pharmacies, hospitals, etc.
- **Third party services** – transport services, non-government owned information system services, suppliers, etc.
- **Beneficiaries** – patients
- **Media** – Newspapers, television news, radio, social media, etc.
- **Societies** – politicians, councils, academia, etc.

Do you agree that the identified role players above includes all the possible stakeholders (individuals, groups or organisations) that play a role in the pharmaceutical supply chain?

Yes

No

If No, please explain and provide your corrections:
_____
_____
_____
_____
_____

3. Analysing pharmaceutical supply chain-related policies

Please indicate whether you agree/disagree with the following statements:
A pharmaceutical supply chain is governed by multiple policies and legislations that are intended for different operational functions and different levels of the health system.

Agree

Disagree

If disagree, please explain:
_____
_____
_____
_____

Identifying and analysing various policies—that govern a country's pharmaceutical supply chain—can become long and tedious as multiple policies and legislations exist for a pharmaceurical supply chain.

Therefore, categorising supply chain operations into major functions (as illustrated in Figure 1), and analysing policies according to each funtion repsectively can be more efficient.

Agree

Disagree

If disagree, please explain:

_____
_____
_____
_____

This PLF structure (Figure 1) is considered the same for any level of a healthcare system; however, the processes within each function might vary between countries in accordance with country specific policies, laws and regulations. Do you agree that the operational functions in Question 1 is generic in such manner that a country can use the functions to identify the operations of their public pharmaceuitcal supply chain, and subsequently to identify the relevant policies of those operations?

Agree

Disagree

If disagree, please explain:

_____
_____
_____
_____

POLICY ANALYSIS LOGIC MODEL FOR A VAN OPERATING MODEL

By

Emma Kleynhans

POLICY ANALYSIS METHODS AND MODELS CONTENT VERIFICATION BOOKLET

DISSERTATION TITLE:

The Development of a Policy Analysis Logic Model to Support Public Medicine Availability Initiatives in the Context of VAN

QUESTIONNAIRE

The following questions aim to verify the literature used to develop the PoliVAN logic model. As mentioned, three mutually exclusive literature topics were considered to be able to develop the PoliVAN logic model: (i) the Visibility and Analytics Network (VAN) concept; (ii) public pharmaceutical supply chains and the link to policy; and (iii) policy analysis methods and models. The following questions are relevant to policy analysis methods and models.

1. Policy analysis as a decision-making tool
Policy analysis is able to support decision-making strategies through the following measures (to name a few): analysing public policies retrospectively or prospectively; assessing future implications of current (or new) policies on a new (or current) system; and determining if already existing policies need to be modified, or terminated. **In the light of the problem statement (as well as the aim of this study), to what extent do you agree that policy analysis is a good tool / method to approach this study?** Strongly disagree   Disagree   Neutral   Agree   Strongly agree   Comments: _____ _____ _____ _____

2. Selecting an appropriate policy analysis approach	
Enserink et al. (2013) argues that policy analysis and the process of policy-making are isomorphic mirror images of one another. The overarching decision-making process for the analysis of policies is built on the four building blocks: agenda setting, policy formulation, implementation and evaluation (Lehmann, 2016). Each of the four building blocks is associated with a complex set of decisions and processes that are required for a policy to be put into effect (Lehmann, 2016). Various authors have provided their own take on the policy analysis decision-making process; the following five are the most prominent models identified in literature: (i) rational model; (ii) political game; (iii) advocacy coalition; (iv) garbage can; and (v) institutional process. A summary of these five models is available in Appendix A.	
Two different (conflicting) views for the choice of policy analysis approach is given below:	
Enserink et al. (2013) suggest that the analysts' understanding of policy analysis should not be one-dimensional, because policy analysis constantly "faces boundary tensions and dilemmas, where conflicting demands on policy analysis and methods, the analyst, the outcomes and the process needs to be balanced"	Walker (2000) argues that the analyst should use the simplest model possible, because the analyst will have to explain the policy analysis methodology and results to the policy-maker, who is generally not familiar with complex analysis models— "the simpler the model the easier it will be to explain and the better the chance that the policy-maker will understand the analysis".
For this study, the rational model was chosen as the decision-making model for the PoliVAN, due to the already complex nature of a pharmaceutical supply chain. To what extent do you agree with the choice of decision-making strategy? In case of a disagreement, please provide your reason in the comment section. Strongly disagree Disagree Neutral Agree Strongly agree	

Comments:

_____
_____
_____
_____

3. Policy, law and legal framework hierarchy

Legislations and regulations provide a legal basis for the policy and make it enforceable (Management Science for Health, 2012). Countries have different policies and legislations based on their context; however, the basic relationship between health legislation remains constant. In literature, there is no comprehensive illustration of the relationship between different legislations and how policies fit within this hierarchy. The figure below illustrates the relationship between the various levels of legislation (interpreted from multiple literature sources).
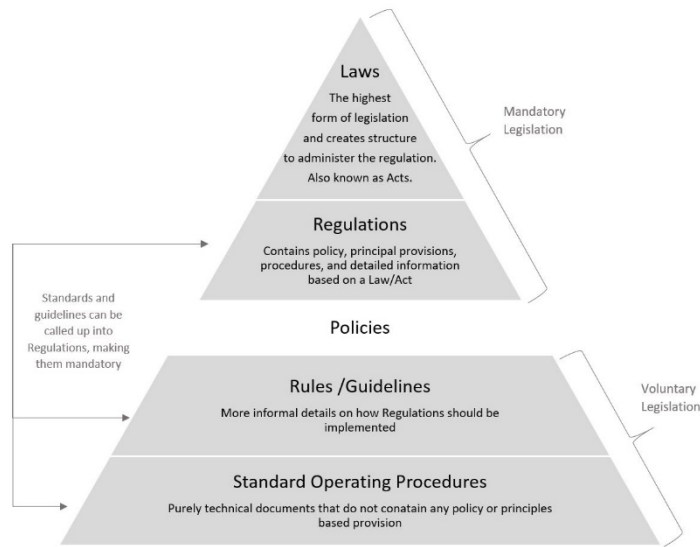
To what extent do you agree that this diagram illustrates the relationshop between policies and legislation. In case of disagreement, please provide a more suitable hierarchy of the relationship between policy and legislations in the comment section.

Strongly disagree   Disagree   Neutral   Agree   Strongly agree

Comments:

_____
_____
_____
_____

4. Policy formulation

Policy formulation is the development of effective and acceptable courses of action for addressing what has been placed on the policy agenda (been identified as a problem). Policy formulation requires both policy design and policy tools (Peters & Pierre, 2006). Policy design is considered a process preceded by multiple policy choices, the design of new policy alternatives, and selecting the best policy for adoption. There is no universally accepted method for policy formulation, due to country-specific and problem-specific contexts. Based on multiple sources, policy formulation follows the following process: (i) problem analysis (agenda-setting); (ii) specation of problem objectives; (iii) policy option development; and (iv) policy design.

Shung-King (2004) developed a policy formulation checklist (available in Appendix B) that allows policy analysts to check that all the necessary factors are considered when formulating policies, and setting up policy documents. In this study, the components of the policy formulation checklist by Shung-King (2004) is used and adapted to fit the context of the VAN project, which is then incorporated into the PoliVAN.

Does the checklist by Shung-King (2004) provide all the necessary components that need to be considered when formulating/reformulating policies?

Yes   No

 If no, explain: _____
_____
_____
_____

5. Stakeholder analysis

Actors form the core element of the policy analysis triangle framework (the four key factors of a health policy: process, content, context and actors). Therefore, it is important to understand who the actors and stakeholders are in the system—what drives them, what their role is in the policy process, as well as how they will influence policy decisions. The terms `actor' and `stakeholder' are used interchangeably (Lehmann, 2016). Stakeholders that are influenced by a certain decision or action usually respond to the decision, as they are those with the power to influence the policy result (Mulyaningrum et al., 2013). A stakeholder analysis (SHA) approach provides a means of understanding how stakeholders may affect policy change. A SHA is a process of systematically gathering and analysing qualitative information to determine whose interests should be taken into account when developing and/or implementing a policy or programme (Schmeer, 1999). A SHA gathers knowledge about actors and stakeholders, about their beliefs, behaviour, interest and the intentions they bear on the decision-making and implementation processes of policies (Schmeer, 1999).

A stakeholder analysis is a commonly used approach in policy analysis

Yes   No

To what extent do you agree that a stakeholder analysis is able to provide sufficient information on how to manage the development and implementation of a policy, within the policy analysis process?

Strongly disagree   Disagree   Neutral   Agree   Strongly agree

Comments:
_____
_____
_____
_____

6. Policy impact analysis

There are multiple tools and methods available for the analysis of a policy, based on its potential impact. One such method, is a multi-criteria decision analysis—an impact evaluation method that measures policies against predefined dimensions in order to project the potential impact policies could have on a system. This approach is best used for policy options with multiple and often conflicting objectives that stakeholder groups and/or decision-makers value differently. Dimensions may be selected based on the context of the policy and the purpose of the analysis.

A basic depiction of a multi-criteria decision analysis table is shown on the next page. This technique enables the analyst to create an overview of the alternative policy options/solutions with respect to the criteria (dimensions relevant to the policy scope) – with subjective judgements about the relative importance of the evaluation criteria (weight factor) in the particular decision-making context – and to identify, by scoring the policies accordingly, the best possible options.

Decision Factors	Dimensions	D_1	D_2	D_3	…	D_n	Weighted Total Score
	Weight	w_1	w_2	w_3	…	w_n	
	Direction	$d1$	$d2$	$d3$	…	dn	
Policy consideration 1		score 1	score 2	score 3	…	score n	= SUMPRODUCT(Weight, score)
Policy consideration 2							
Policy consideration 3							
…							
Policy consideration n							

To what extent do you agree that a multi-criteria decision analysis (policy impact analysis) approach is a good evaluation tool that enables policy analysts to identify the impact of policy choices on a complex system, such as a pharmaceutical supply chain?

Strongly disagree   Disagree   Neutral   Agree   Strongly agree

In the case of a disagreement, please explain:

_____
_____
_____
_____

When it comes to policies being adopted, many stakeholders (some powerful) have an influence on whether the policies get implemented or not. With regards to the analytical dimensions to analyse and score the policy options, do you agree that the stakeholders' opinion (e.g. their acceptance or disregard towards a policy option) should be considered as a dimension in the multi-criteria decision analysis?

Yes   No

If no, explain: _____
_____
_____
_____

7. Policy implementation

Passing policies for adoption does not guarantee success if policies are not well implemented (Cerna, 2013). Hasenfeld & Brock (1991) said implementation should involve processes that make decisions and actions to put policies into action. In Appendix B, Shung-King (2004) identified some elements that should be considered for an implementation plan. By taking into account those elements, and additional elements identified through literature:

To what extent do you agree that the following aspects should be included in an implementation plan [very unimportant (VU) to very important (VI)]:
Please, if unimportant, provide a reason in the comment section. Also, please add aspects of an implementation plan that should be considered that is not mentioned.

	VU	U	N	I	VI	Comment
Policy design (draft) plan						
Stakeholder engagement plan						
Risk assesment (contingency plan)						
Monitoring and evaluation plan						

POLICY ANALYSIS LOGIC MODEL FOR A VAN OPERATING MODEL

By

Emma Kleynhans

VERIFICATION OF THE OBJECTIVES

DISSERTATION TITLE:

The Development of a Policy Analysis Logic Model to Support Public Medicine Availability Initiatives in the Context of VAN

QUESTIONNAIRE

The following questions aim to verify the objectives set out for the PoliVAN—those that the PoliVAN aims to achieve.

1. PoliVAN objectives

It is evident that policies are not the only governing element situated in the enabling environment, but that other legislation, e.g. regulations and guidelines, also govern the operations of a pharmaceutical supply chain. This indicates that multiple legislative instruments will need to be taken into account to comprehensively analyse the impact of policies (and other relevant legislation) on a pharmaceutical supply chain (relevant to the scope of the VAN model). Furthermore, the policy analysis approach should ideally be transferable to other SSA countries that have, or plan to adopt and implement the VAN concept. Hence, a policy analysis approach, designed to support an operational model such as VAN from a number of perspectives, should aim to address the following objectives:

☐ **Objective 1:** To identify and take into account multiple policy and legislative instruments that are relevant to the scope of the VAN Operating Model for the specific country;

☐ **Objective 2:** To identify types of (or specific) policies and legislations that enable the implementation and operationalisation of the VAN Operating Model, as well as to identify those that do not support the country-specific VAN Operating Model;

☐ **Objective 3:** To propose a method that makes use of policy analysis processes to determine the impact policy options might have on the VAN Operating Model or the health system;

☐ **Objective 4:** To take into account the influential factors, i.e. external/contextual factors, stakeholder engagement strategies, and decision-making strategies; and

☐ **Objective 5:** To provide policy analysis insight into possible policy decision and strategies for governance authorities to develop and/or make informed policy decisions, to successfully implement the VAN Operating Model.

Do you agree that the abovementioned objectives encompasses all the necessary elements in order for the PoliVAN to achieve the aim of this study?

Yes

No

If no, please indicate which objectives are relevant and add/change/edit the objectives that you believe should be considered. Also include an objective if, in your opinion, it has been left out and needs to be considered.

Objective__:_____
_____
_____

Objective__:_____
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Objective__:_____
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Objective__:_____
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_____

Objective__:_____
_____
_____

Appendix N

Logic model literature review

In this appendix, additional literature on logic models is presented. It provides an introduction on how logic models are defined in order to strengthen and support the choice of 'product' chosen for the PoliVAN. The appendix starts with an introduction and definition of logic model and further elaborates on three different types of logic models. The reason behind utilising logic models and their advantages are then subsequently discussed. This appendix ends with a detailed identification and discussion of logic model components. This information is used for the verification of the PoliVAN logic model in Chapter 6.

N.1   What is a logic model?

Logic models are a visual method of presenting an idea, project, programme or initiative. Basically, a logic model is a systematic and visual way to present an understanding of the relationships among resources that should be utilised to operate a programme; the activities that should be executed; and the changes and/ or results the programme hope to achieve (Monroe & Horm, 2012; W. K. Kellogg Foundation, 2004). Similarly, Knowlton & Phillips (2013) describes logic models as a way to describe an understanding of the relationships (or connections) among elements necessary to operate a programme. A logic model can be viewed as a roadmap or blueprint for how a programme or initiative will roll out in order to reach the intended outcomes and overall goals (Minnesota Department of Health). Some other names include (Milstein & Chapel, 2015):

- Road map, conceptual map, or pathways map;

- Mental model; or

- Blueprint for change.

Like a road map, a logic model shows the route travelled (or steps taken) to reach a certain destination (Milstein & Chapel, 2015; W. K. Kellogg Foundation, 2004). A detailed logic

model should indicate precisely how each activity will lead to desired changes. Alternatively, a broader plan sketches out the chosen routes and how far the activities will go. This road map aspect of a logic model reveals the relationship among different elements, and the order of the activities (Milstein & Chapel, 2015). According to Monroe & Horm (2012), logic models vary in their structure and purpose, making them particularly useful because they can be created and modified to accommodate any programme." Standard features of a logic model include inputs, activities, outputs, and outcomes; however, some resources include components, i.e. purpose, conditions, context and assumptions. Further details regarding the component are discussed in Section N.2. Figure N.1 provides a structural overview of a typical logic model.
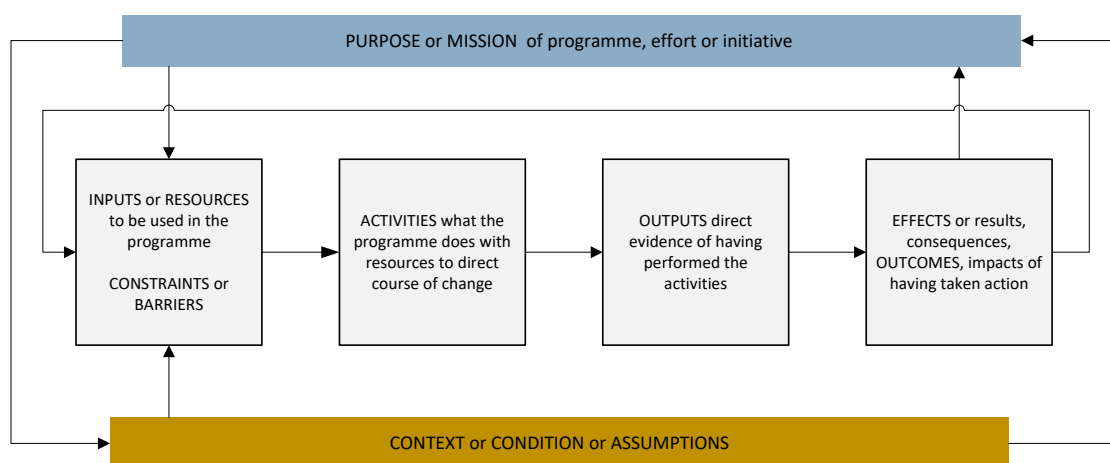
Figure N.1: Structural overview of a logic model, adapted from Milstein & Chapel (2015); Minnesota Department of Health; W. K. Kellogg Foundation (2004).

Inputs: Resources dedicated to or used by the programme or initiative. Inputs can also act as constraints on the programme that should be factored in (Minnesota Department of Health).

Activities: Activities include strategies, techniques, and interventions that direct actions. In some cases, activities are referred to as approaches (Minnesota Department of Health).

Outputs: The direct products of the activities (Minnesota Department of Health).

Outcomes: The benefits or changes for stakeholders in your programme. These are usually identified by setting out objectives for a programme. Outcomes may also include performance targets which are numerical targets (Minnesota Department of Health).

Assumptions: Assumptions are the underlying beliefs about how the programme will work.

External factors: These are conditions in the environment in which the programme exists. Some factors cannot be controlled, and could potentially influence the programme's success (Minnesota Department of Health).

Logic models are not always linear in construction Centre on Knowledge Translation for Disability and Rehabilitation Research, in practice, most logic models are more complex and fall into one of three categories identified by W. K. Kellogg Foundation (2004): the theory approach model; outcome approach model; activities approach model; or a blend of these types. The following provides a discussion of the different logic model types.

Theory approach logic model: According to Centre on Knowledge Translation for Disability and Rehabilitation Research, "this model is based upon the theoretical premises upon which a project was designed and provides a theory-based rationale for the exploration, problems, issues, needs to be pursued by the project, and how the project intends to produce "solutions" connecting project results with proven strategies."

Outcomes approach logic model: This model emphasises the relationship between the planned activities and expected outcomes. An activity or a set group of activities will produce a set of outcomes or an outcome, respectively (Centre on Knowledge Translation for Disability and Rehabilitation Research).

Activities approach logic model: Activities are carefully planned and describe the scope of work. They are often placed with time indicators that triggers the beginning or end of the activity (Centre on Knowledge Translation for Disability and Rehabilitation Research).

Typically, it is not unusual for a programme or initiative to use all three types of logic models for different purposes (W. K. Kellogg Foundation, 2004)—no one logic model fits all need. According to Centre on Knowledge Translation for Disability and Rehabilitation Research, "logic models should assist projects in describing, planning, implementing, monitoring, and/or appraising a project in the most practical manner." There is no exact blueprint when it comes to identifying and constructing a logic model. Each programme, project or initiative will address a logic model development with different aims and approaches (Centre on Knowledge Translation for Disability and Rehabilitation Research). The flexibility of the logic modelling process allows for a variety of approaches to be described within the context of a project's scope (Centre on Knowledge Translation for Disability and Rehabilitation Research).

Using a logic model helps organise and systematise the planning, management, and evaluation functions of a project or programme (W. K. Kellogg Foundation, 2004). Logic models have multiple benefit Milstein & Chapel (2015): (i) logic models integrate planning, implementation, and evaluation; (ii) logic models integrate planning, implementation, and evaluation; and (iii) logic models enhance accountability by keeping stakeholders focused on outcomes.

N.2 Key components of a logic model

Details regarding the different components of a logic model are presented in the following sub-sections. The information gathered her is used to verify the PoliVAN logic model in Chapter 6. The information presented is gathered from multiple different authors and sources that have provided sufficient literature output regarding logic models.

Inputs

- Human Resources: knowledge, skills and expertise (Centre on Knowledge Translation for Disability and Rehabilitation Research; Knowlton & Phillips, 2013; Macdonald, 2018; Milstein & Chapel, 2015; W. K. Kellogg Foundation, 2004).

- Fiscal resources: funds, donations, grants and guidelines (Centre on Knowledge Translation for Disability and Rehabilitation Research; Macdonald, 2018; Milstein & Chapel, 2015; W. K. Kellogg Foundation, 2004).

- Technology and material equipment (Knowlton & Phillips, 2013; Taylor-Powell *et al.*, 2003).

- Involvement and/or collaboration (Macdonald, 2018; Milstein & Chapel, 2015; Taylor-Powell *et al.*, 2003).

Activities

- Processes (Knowlton & Phillips, 2013; Macdonald, 2018; Milstein & Chapel, 2015; W. K. Kellogg Foundation, 2004).

- Conduct workshop and training (Taylor-Powell *et al.*, 2003).

- Techniques and tools (W. K. Kellogg Foundation, 2004).

- Interventions (Macdonald, 2018).

- Programmes (Macdonald, 2018; Milstein & Chapel, 2015).

Outputs

- Tangible artefacts from the activities: information and products / goods (Centre on Knowledge Translation for Disability and Rehabilitation Research; Knowlton & Phillips, 2013; Macdonald, 2018).

- Service delivered: educational programming or training delivered (Centre on Knowledge Translation for Disability and Rehabilitation Research; Macdonald, 2018; W. K. Kellogg Foundation, 2004).

Outcomes

- Expected benefits and/or changes (Centre on Knowledge Translation for Disability and Rehabilitation Research; Macdonald, 2018; W. K. Kellogg Foundation, 2004).

- Objectives that are achieved (Knowlton & Phillips, 2013; Macdonald, 2018; Milstein & Chapel, 2015).

- The results of the logic model that benefits the system or adheres to the situation (Centre on Knowledge Translation for Disability and Rehabilitation Research).

- Environmental and/or organisational outcome: how organisational systems or policy structures will be affected (Centre on Knowledge Translation for Disability and Rehabilitation Research).

Assumptions or conditions

- In narrative form—not part of the illustration (Macdonald, 2018).

- Limitations or barriers (Macdonald, 2018).

- Level of effort that is required (Milstein & Chapel, 2015; Taylor-Powell *et al.*, 2003).

- The things we assume to be in place to implement or execute the activities of the logic model (Knowlton & Phillips, 2013; Taylor-Powell *et al.*, 2003).

Context and external factors

- In narrative form—not part of the illustration (Macdonald, 2018).

- Contextual factors: geographic, demographic, economic, political (Macdonald, 2018).

Development and illustration

- Has underlying logic and objective, purpose and/or a need for change (Centre on Knowledge Translation for Disability and Rehabilitation Research; Knowlton & Phillips, 2013; Macdonald, 2018; Milstein & Chapel, 2015; W. K. Kellogg Foundation, 2004).

- Has a clear situation that is the foundation of the logic model—clear priorities that determines the desired outcomes (Taylor-Powell *et al.*, 2003; W. K. Kellogg Foundation, 2004).

- Evidence-based and relevant information is presented and used for the stakeholder to understand the logic (Macdonald, 2018).

- The "boxes" and "arrows" depict the underlying logic (Knowlton & Phillips, 2013; Macdonald, 2018; W. K. Kellogg Foundation, 2004).

- The components are clearly illustrated (Macdonald, 2018).

- Easy, straightforward language is used (Macdonald, 2018).

- The narrative of the logic model is explained: what is included in each component; the importance of each component; the rationale of the logic paths; does the logic model indicate contributions towards the outcomes; and specify timeframe for each outcome (Knowlton & Phillips, 2013; Macdonald, 2018; W. K. Kellogg Foundation, 2004).

N.3   Appendix N: Conclusion

This appendix concludes the introduction and details of a logic model. It is clear that many authors have delft into this topic to provide sufficient information on the design, construction and use of a logic model. Sufficient information is gathered in order to thoroughly verify the PoliVAN logic model in Chapter 6.

Appendix O

Validation workshop: Activity workbook

POLICY ANALYSIS LOGIC MODEL FOR VAN

VALIDATION WORKSHOP

ACTIVITY WORKBOOK

THESIS TITLE:

The Role of Policy Analysis to Support Medicine Availability Initiatives: The case of VAN

Participant name*: _____

Email address*: _____

Occupation: _____

Background: _____

*The participant's personal information will not appear in the thesis document of this study, but is required for reference purposes.

CONTENTS

1. INTRODUCTION

This document is an action workbook that allows the participants to engage by taking notes and to follow progression of this validation workshop. This document includes a questionnaire for the validation of the PoliVAN logic model, and appendixes to which some of the questions in the questionnaire refers. The following lines allow the participants to make notes while the student presents her work.

Notes:

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2. QUESTIONNAIRE

PARTICIPANT'S INSIGHT / KNOWLEDGE			PARTICIPANT'S RESPONSE				COMMENTS
The following questions are based on the literature overview provided			Please indicate your answer with 'X'				COMMENTS
	i.	Are you familiar with the VAN?	Yes		No		
	ii.	Are you currently working on a project regarding the VAN? Explain.	Yes		No		
	iii.	Are you familiar with the operations of a pharmaceutical supply chain?	Yes		No		
	iv.	Are you currently working in a public pharmaceutical system? Explain.	Yes		No		
	v.	Are you familiar with policy analysis models?	Yes		No		
	vi.	Are you currently directly involved with country legislations and/or the analysis thereof? Explain.	Yes		No		

The following questions aim to validate the overall and sectional parts of the proposed PoliVAN logic model. Please indicate the level to which you agree with the statement provided in each section. Also, comment in the case of a disagreement or with a possible suggestion. Included in this document are appendixes to which some questions refer to for additional attention.

VALIDATION QUESTIONS			PARTICIPANT'S RESPONSE					COMMENT (Please comment in the case of disagreement)
			Strongly agree (4)	Agree (3)	Neutral (2)	Disagree (1)	Strongly disagree (0)	
OVERARCHING PROPOSED POLICY ANALYSIS (PA) MODEL – Appendix A								
	1.	The literature used to develop the PoliVAN logic model is sufficient?						
	2.	The objective of the PoliVAN logic model fits the aim of this study?						
	3.	The six phases in the PoliVAN logic model aim to achieve the overall objective of the study?						
	4.	The layout makes the process of the PoliVAN logic model easy to understand and follow?						
	5.	It is necessary to illustrate the inputs and outputs of the PoliVAN logic model						
	6.	It is necessary to illustrate the tools and skills requirement for the PoliVAN logic model?						
	7.	The routes explained provide a clear understanding of the logical flow of the PoliVAN logic model						
	8.	The proposed PoliVAN logic model covers sufficient areas to analyse policies for a VAN Operating Model?						
	9.	The proposed PoliVAN model can be used for other developing country contexts?						

VALIDATION QUESTIONS			Strongly agree (4)	Agree (3)	Neutral (2)	Disagree (1)	Strongly disagree (0)	COMMENT (Please comment in the case of disagreement)
STEP 1: INVESTIGATE POLICY LANDSCAPE – Appendix B								
	10.	Narrowing the search scope is a useful approach to gather relevant policy and legislations? (B.1)						
	11.	The PLF components cover the most pertinent operations of a public pharmaceutical supply chain? (B.2)						
	12.	The PLF-VAN-matrix is a useful tool to identify the part of a pharmaceutical supply chain a country's VAN is focused on? (B.3)						
	13.	The tools identified for Phase 1 is able to achieve the objective of this phase? (B.1)						
	14.	The legislation hierarchy provided is correct? (B.4)						
	Additional comments:							
STEP 2: SORT EXISTING POLICIES – Appendix C								
	15.	To identify (dis)enabling policies on a VAN Operating Model, fits the study's objective? (C.1)						
	16.	The method proposed to identify VAN criteria is useful? (C.2)						
	17.	The assessment matrix proposed to assess policy content is a valuable tool? (C.3)						
	18.	The indicators proposed will provide insight into those policies (dis)enabling a VAN? (C.3)						
	Additional comments:							
STEP 3: POLICY FORMULATION – Appendix D								
	19.	Policy option formulation is a useful method to propose policy design and policy changes? (D.1)						
	20.	The policy formulation checklist for the VAN provides the necessary information to design policies for a VAN? (D.2)						
	21.	Phase 3 requires a group of experts, with knowledge about pharmaceutical supply chain policies and the country's VAN?						
	Additional comments:							
STEP 4: STAKEHOLDER ANALYSIS – Appendix E								
	22.	A stakeholder analysis is considered a necessary analysis as part of the overall analysis of policies? (E.1)						

VALIDATION QUESTIONS			Strongly agree (4)	Agree (3)	Neutral (2)	Disagree (1)	Strongly disagree (0)	COMMENT (Please comment in the case of disagreement)
	23.	All possible stakeholder individuals, groups or organisations and stakeholder characteristics are identified? (E.2)						
	24.	The tool(s) selected to analyse relevant stakeholders are useful and will be able to provide sufficient information on how to manage stakeholders? (E.3)						
	25.	It is useful to know which stakeholders to involve in a policy design, adoption and implementation process (E.3)						
	Additional comments:							
STEP 5: POLICY IMPACT ANALYSIS – Appendix F								
	26.	Policy impact analysis is considered necessary for the objectives of the PoliVAN logic model? (F.1)						
	27.	The analytical dimensions are sufficient to determine the potential impact of a policy decision?						
	28.	The scorecard approach is a useful way to score policy options to identify the best possible option? (F.3)						
	29.	The policy impact analysis tool should make use of weighted dimensions (considering some dimension more important than others)?						
	30.	If none of the policy options has a desired score, they should be reformulated (iterative process)?						
	Additional comments:							
STEP 6: POLICY STRATEGY AND PLAN OF ACTION								
	31.	After performing Phases 1-5 from the PoliVAN model, it is possible that valuable insight about VAN policies are available?						
	32.	This phase should include a policy design plan (for best policy decision)?						
	33.	This phase should include a policy implementation plan?						
	34.	This phase should include a policy contingency plan based on possible unintended consequences?						
	35.	The roles of Government authorities, VAN personnel, and relevant stakeholders are required?						
	36.	What other plans need to be included?						

APPENDIX A

A.1   OVERARCHING PROPOSED POLICY ANALYSIS (PPA) MODEL

The objective: The PoliVAN logic model aims to identify types of policies relevant to a country's VAN Operating Model that could potentially affect the success of the VAN. Subsequently, the PoliVAN logic model aims to develop a proposition that will enable both health system authorities and VAN personnel to develop policy-specific strategies to support the objectives of the VAN.
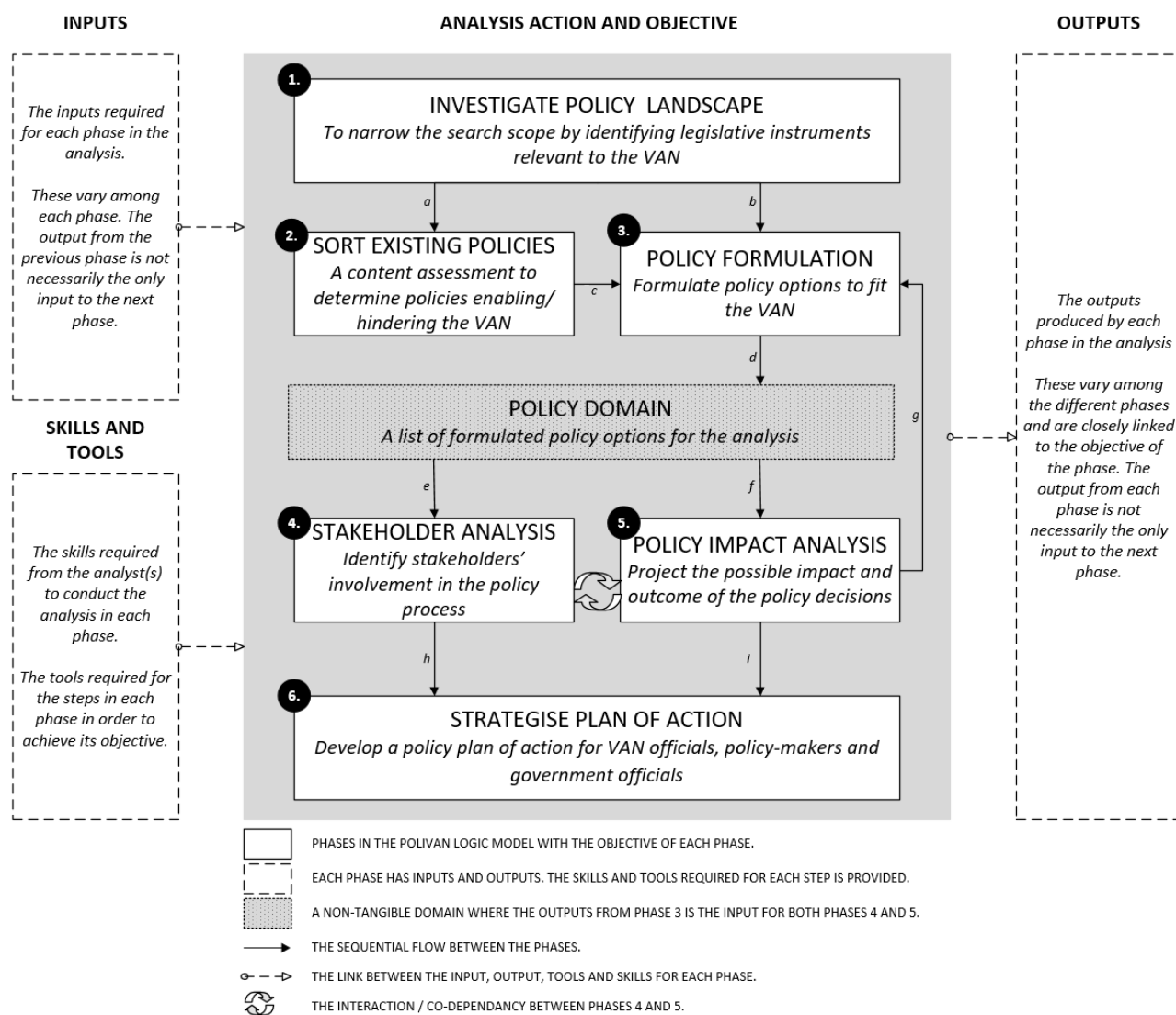
Figure 1: High-level PoliVAN logic model

Routes:

a) Existing country policies and legislations that are relevant to the VAN model

b) Gaps, where policies/legislations for a specific part of the pharmaceutical supply chain does not exist.

c) Legislations that require change/reform—those not fully enabling the VAN.

d) The formulated/or reformulated policy decisions (from Phase 3) as input to the analysis phase (Phases 4 and 5).

e) The policy options from Phase 3 is used as an input for the stakeholder analysis

f) The policy options from Phase 3 is used as an input for the impact analysis.

g) The outcome from Phase 5 will indicate whether policy options require reformulation.

h), **i)** The outcome from Phases 4 and 5 are used to develop a policy plan of action.

APPENDIX B

B.1   PHASE 1: INVESTIGATE POLICY LANDSCAPE
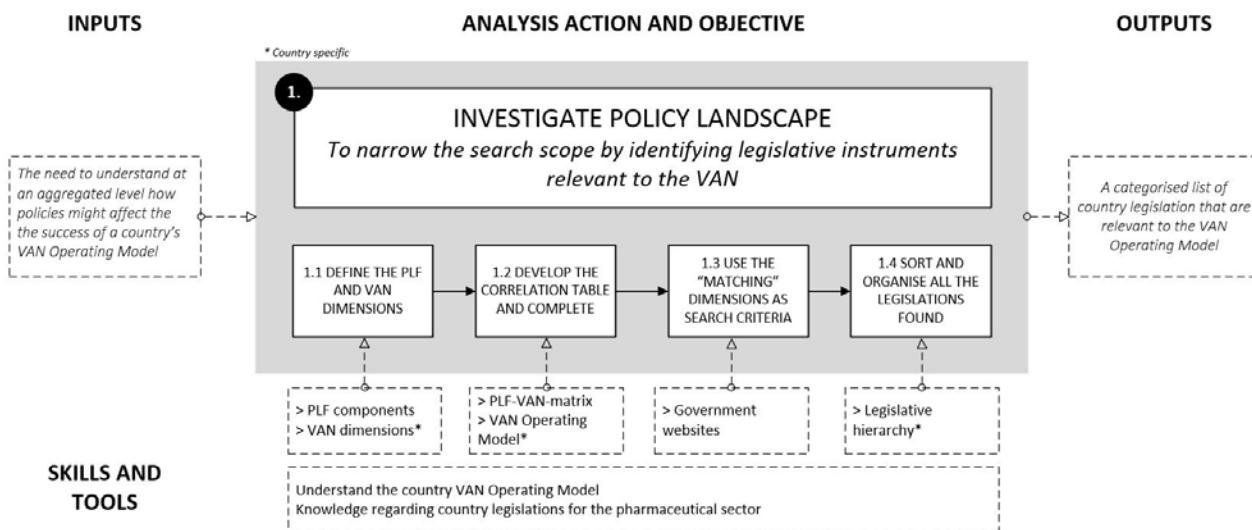
Figure 3: Detailed version of proposed Phase 1

B.2   PHARMACEUTICAL LOGISTICS FRAMEWORK (PLF) COMPONENTS
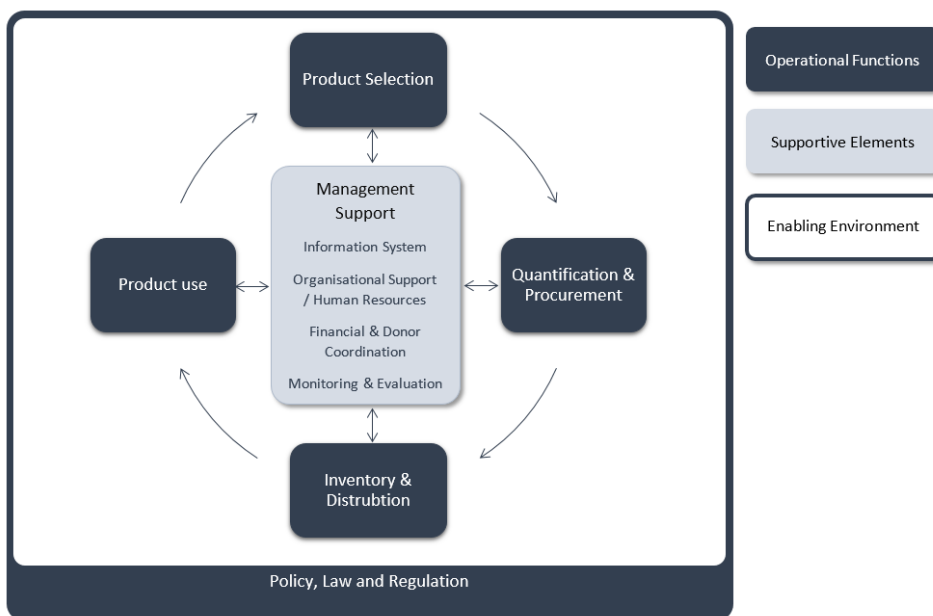
Figure 2: Pharmaceutical Logistics Framework (PLF). Source: Management Sciences for Health (2012). MDS-3: managing access to medicines and health technologies. Management Sciences for Health Arlington, VA

OPERATIONAL FUNCTIONS	
Medicine Selection	**Medicine USe**
☐ Registration	☐ Diagnosis and follow-up
☐ Essential medicines list	☐ Prescribing
☐ Standard treatment guidelines	☐ Dispensing
☐ Donor requirements	☐ Product use and adherence

Inventory and Distribution Management	Quantification and Procurement
☐ Receipt and inspection (national warehouse/CMS) ☐ Inventory control ☐ Storage ☐ Requisition (ordering) and allocation of suppliers ☐ Removal of expired medicine ☐ Delivery methods	☐ Quantification and forecasting ☐ Funds and budgeting ☐ Procurement method ☐ Supplier selection and monitoring ☐ Contracting ☐ Order status and monitoring ☐ Product inspection (receive / check order) ☐ Payments

MANAGEMENT SUPPORT ELEMENTS

Information Systems	Organisation and Human Resource Management
☐ Pharmaceutical management information system ☐ Indicator-based monitoring system ☐ Integrated network	☐ Personnel management ☐ Education and training ☐ Accountability ☐ Reporting structures

Financial and Donor Coordination	Monitoring and Evaluation
☐ Financing and budget strategies ☐ Analyse and control expenditures ☐ Donor financing	☐ Programme planning, implementation, monitoring and evaluation

B.3   PLF-VAN-MATRIX TOOL

Pharmaceutical Logistics Framework	VAN Planning processes			
Operational Components	DEMAND PLANNING	SUPPLY PLANNING	DISTRIBUTION PLANNING	COLD CHAIN MANAGEMENT
Product Selection				
Market approval/Registration				
Therapeutic formularies	X			
STGs/EML select and update	X			
Donation	X			X
Quantification and Procurement				
Quantification and Forecasting	X			
Procurement method		X		
Funds and budgeting	X			
Supplier selection and monitor		X	X	
Contracting		X		X
Order monitor				
Product inspection (depots/facilities)				
Payments				
Inventory Management				
Port clearing				
Product inspection (CMS)				
Inventory control		X		X

Figure 4: A tool that identifies parts of a pharmaceutical supply chain that a VAN Operating Model focuses on.

B.4 LEGISLATIVE HIERARCHY
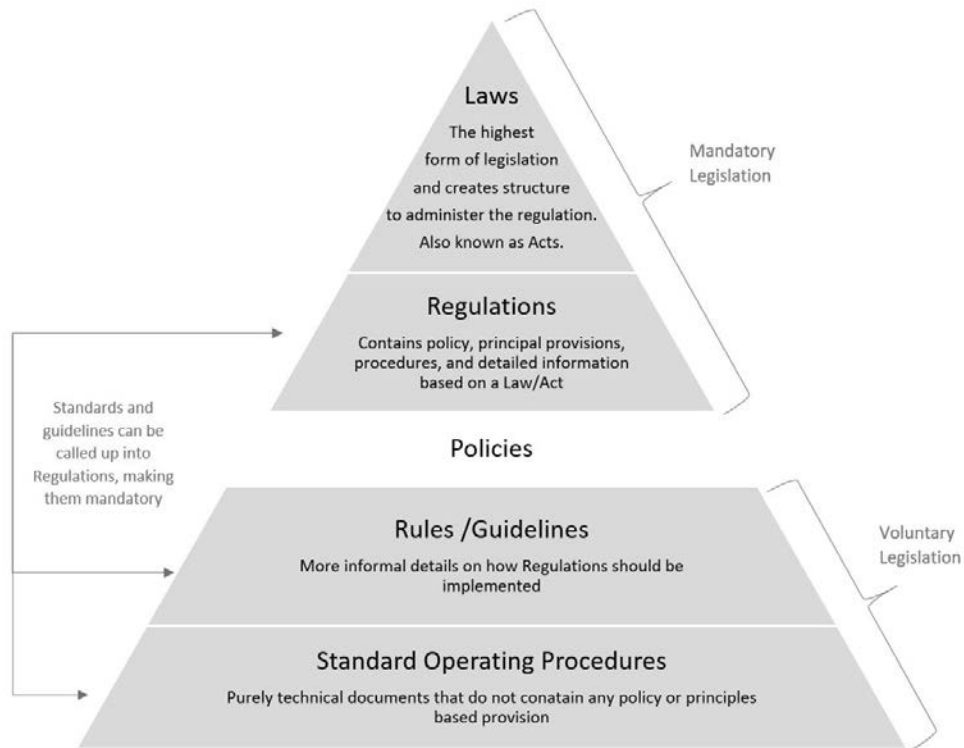
Figure 5: Illustration of the hierarchy in which legislations are categorised.

APPENDIX C

C.1 PHASE 2: SORT EXISTING POLICIES
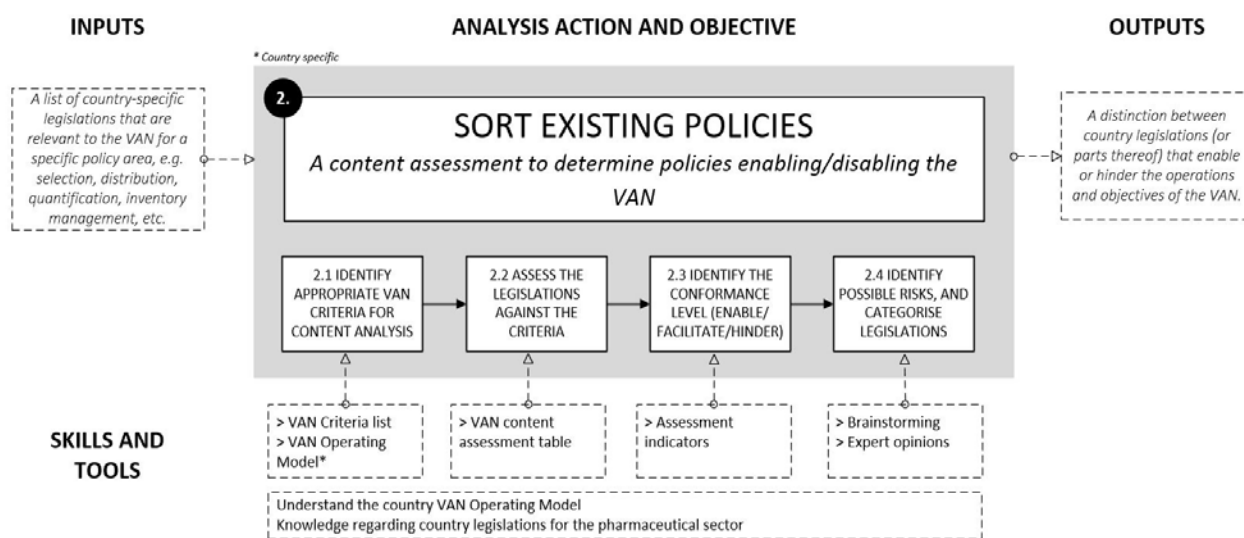
Figure 6: Sorting existing policies into groups--those enabling, facilitating or hindering.

C.2 VAN CRITERIA LIST GUIDELINE

The following table is a guide for the development of a VAN criteria list for a country's VAN (based of the Blueprint Reference Model). The content in each list may vary among the different countries. In the case where a list does not already exist for the country, the headings can be used as a guide to develop such a list.

Process ID	Process name	Process description	Frequency	Locations (scale of granularity	Responsibility	Customer
ID for the activities in the planning process maps, e.g. DM1.1 for the first sub process in Demand planning	The name of the process/sub-process indicated by the process ID	A description of the activity	The frequency at which the process is updated or performed, for example: - Annual - Monthly - Weekly - Daily	This refers to the scale of the application (national, regional, local)	This is the role that is responsible and/or accountable for the process	This is the role that needs to be informed and or/ consulted with regards to the activity

The following table is an example from the Blueprint Reference model:

Process ID	Process name	Process description	Frequency	Locations (scale of granularity	Responsibility	Customer
DP 1.1.1	Review previous performance	Compare data received from healthcare experts/facility representatives with historical trends and market intelligence data (make changes if required)	Monthly	Regional level	Supply chain analyst	Supply chain analyst/ country demand planner
DP 1.1.2	Update Expected demand data	Healthcare experts/facility representatives need to update expected demand data in a system or excel-based tool	Monthly	Regional/local level	Healthcare experts/facility representatives	Supply chain analysts
DP 1.1.3	Non receipt of expected data and consider historical data	In case of trend data not updated by health facilities, escalate to MoH and consider historical demand for statistical forecasting	Monthly	Regional level	Supply chain analysts	MoH
…	…	…	…	…	…	…

9

C.3 POLICY CONTENT ASSESSMENT TABLE AND INDICATORS

Figure 7: A policy content assessment matrix to identify policies enabling, facilitating or hindering the VAN.

Figure 8: The indicators used to assess the policy content against the VAN criteria

APPENDIX D

D.1   PHASE 3: POLICY FORMULATION

Figure 9: Formulating/reformulating policy options of policies that either do not exist for part of the VAN or hinders the VAN and requires reform.

3.1 PROBLEM ANALYSIS:

To formulate policy options, the problem needs to be understood—this can be based off the previous analysis in Phase 2.

- Why is the problem on the agenda?
- What area of the PLF is the policy under development focused on?
- What is the current practice of the problem? (national, regional, local levels)
- What is the complexity of the problem?

D.2   VAN POLICY OPTION DEVELOPMENT CHECKLIST

There are no exact methods on how to formulate policies, however, the policy formulation steps indicate that the analyst should identify policy objectives. In literature, a checklist[1] is used to understand what is required by the policy. The checklist is used and adapted to fit the context of a VAN.

Please add additional information if you feel it is required:

✓	VAN CHECKLIST
	Planning processes
	The process planning category in which the policy is formulated (demand, supply, etc.)
	The level and frequency at which the process needs to be performed
	The affect the process activity has on the rest of the supply chain
	VAN KPI's are met
	Roles and Responsibilities
	The process activity correlates with process owner
	The roles include their accountabilities and responsibilities

---

[1] King, M.S. (2004). *Advocacy: a Strategy for change*. School of public health, University of the Western Cape.

✓	VAN CHECKLIST
	The skills required to perform each role
	The roles should fit with the existing organisational structure of the country
	The reporting lines (whether to inform or consult) among the VAN and existing roles
	The level (national, regional, or local) of the organisational structure the role operates at.
	Contingency plans for skills development plan, i.e. training, education, incentives, KPI's
	Information system
	The data requirement for the process activity
	The type of software to be used
	Transparency (those requiring access and visibility over the data)
	Data capture/generating accountability
	The KPI's specific data elements need to provide

APPENDIX E

E.1   PHASE 4: STAKEHOLDER ANALYSIS
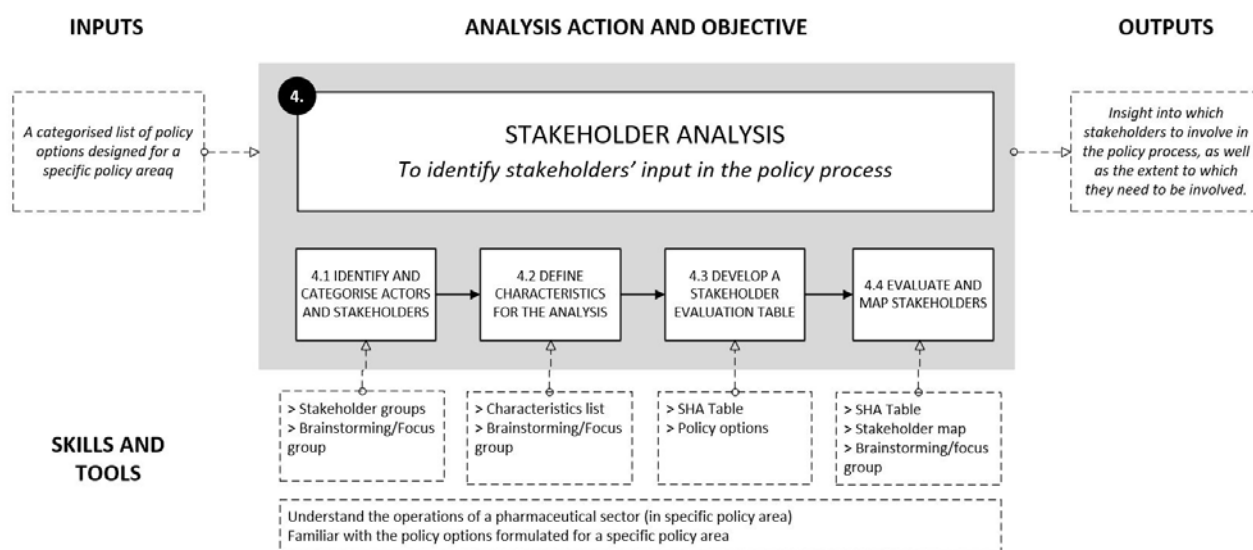
Figure 10: The steps to conduct a stakeholder analysis

E.2   STAKEHOLDER GROUPS AND CHARACTERISTICS

Please add additional groups or characteristics if you think there are others:

INDIVIDUALS, GROUPS, ORGANISATION	EXAMPLE OF POSSIBLE STAKEHOLDERS
Government	Ministry of Health, Ministry of Finance, Departments, etc.
Health sector level	National, regional, local levels of the healthcare sector
NGO (Non-governmental organisations)	Funding Agencies, donor organisations, health programmes, etc.
Media	Newspapers, news, social media, etc.
Consumers	Patients
VAN-specific	Process planners, supply chain analysts, budget holders, facility representative, liaisons, etc.
Private	Transport services, IS services, suppliers, etc.

CHARACTERISTICS	DESCRIPTION
Position and organization	Position the stakeholder has and the organization that he/she works for.
Knowledge of policy	The level of accurate knowledge the stakeholder has regarding the policy under analysis.
Level of support	Support refers to the level of degree a stakeholder is affected by a policy decision, and how he would respond to it (positively or negatively).
Interest	The interest the stakeholder has in the policy, regardless of whether he/she is affected by the policy or not.
Resources	Resources can be of many types—human, financial, technological, political, and other. The analysts should consider the stakeholder's access to all of these resources.
Power	Power refers to the ability of the stakeholder to affect the implementation of the health reform policy due to the strength or force the stakeholder possesses.

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Leadership	Leadership is specifically defined here as the willingness and ability to initiate, convoke, or lead an action for or against the health reform policy.
Attitude	A stakeholder's attitude is determined by the level of interest he/she has in a policy area combined with how they are impacted by the policy (positively or negatively.

E.3   STAKEHOLDER ANALYSIS TOOL

STAKEHOLDERS (Relevant to the policy analysis area)	CHARACTERISTICS					
	C1	C2	C3	...	...	Cn
Stakeholder 1						
Stakeholder 2						
Stakeholder 3						
⋮						
⋮						
Stakeholder n						

Figure 11: An example of a table to identify stakeholders and list (and describe) their characteristics

POLICY CLASSIFICATION		EVALUATION CRITERIA						DECISION STRATEGY	
Policy Typology	Stakeholders	Attitude (A)	Resources			Influence (I)	Total	Need for Involvement	Extent of Involvement
			H	F	P				
Policy area under analysis	S1	Impact-interest score	Human Resource	Financial Resource	Political Resource	= H + F + P	= A * I		
	S2								
	S3								
	...								
	Sn								

MEASURING SCALE FOR EVALUATION CRITERIA

ATTITUDE (IMPACT-INTERST SCORE)

4 — Highly supportive
2
0 — Neutral / no support
-2
-4 — Highly oppose

POWER SCORE

5 – Make own decision for organisation
4
3 – Make a decision with several persons
2
1 – Cannot make decisions

DECISION SCORE

Need for involvement: | Total >= 15 | Involve

Extent of involvement: | Total < 15 | Disregard

| Total >= 45 | Decision-making

| Total **30** - 45 | Consult

| Total **15** - 30 | Inform

Figure 12: An example of the stakeholder analysis table and measuring scale.

APPENDIX F

F.1   PHASE 5: POLICY IMPACT ANALYSIS
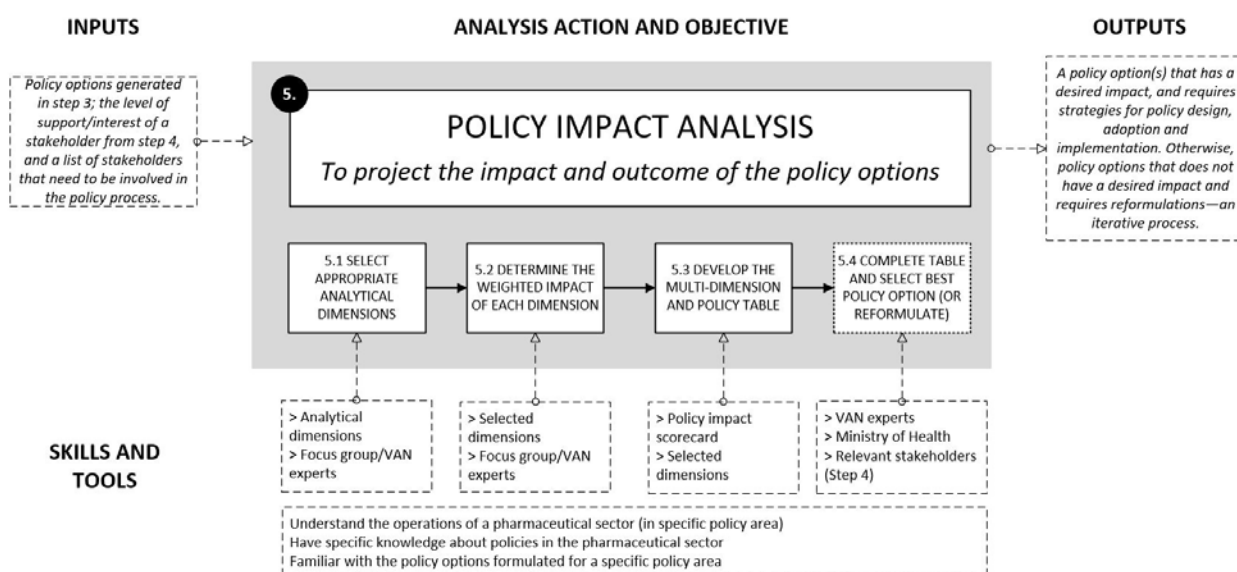
Figure 13: The steps to analyse the impact the policy options from Phase 3 might have on the health system

F.2   ANALYTICAL DIMENSIONS

POLICY IMPACT ANALYTICAL DIMENSIONS		
CATEGORY	DIMENSIONS	DESCRIPTION
EFFECT	Relevance	Does it support or oppose the content and objectives of the VAN? To what extend is the policy appropriate for the objectives of the VAN?
	Unintended effects	What is the probability of unforeseen consequences of this policy?
	Contextual factors	These are factors relating to macro (i.e. social, environmental and political) and micro (i.e. health outcomes and organisational structure) contexts.
IMPLEMENTATION	Feasibility	The feasibility of a policy in terms of technical and operational factors. How feasible is the policy option for the country's infrastructure?
	Cost	The availability of funds for the adoption, implementation, and execution of the policy.
	Acceptability	The input gathered from relevant stakeholders on whether they support or oppose the policy option.
	Legal coherence	Do other governing legislative instruments support the policy? How well does policies within the same landscape (i.e. health) support the policy option? Does it require a mandatory legislation to extensively change?
ADDITIONAL?		

F.3 POLICY IMPACT SCORECARD

Decision Factors	Dimensions	D_1	D_2	D_3	…	D_n	Weighted Total Score
	Weight	w_1	w_2	w_3	…	w_n	
Policy consideration 1		score 1	score 2	score 3	…	score n	= SUMPRODUCT(Weight, score)
Policy consideration 2							
Policy consideration 3							
…							
Policy consideration n							

Figure 14: An example of how policy options can be assessed in a simple table.

Appendix P

Updated demand plan for the South African VAN

The latest draft version of the demand plan is updated in September 2018. In the following sections, the updated information is provided, especially focusing on the key planning principles, input for the demand planning, roles, and responsibilities, and demand plan customers. The information in this Appendix is taken directly from the new and updated demand plan.

P.1 Key principles

Here is a summary of the key demand-planning principles:

- Demand planning is performed to estimate the quantities of medicine needed to fulfil forecasted patient needs.

- The demand planning process is a monthly repeatable process that should forecast the demand for the next 24-36 months in monthly time buckets.

- Demand planning activities occur throughout the financial year and take place on a monthly, quarterly, and annual basis.

- Data accuracy is critical for effective demand planning and data collection should be done as close to the patient as possible.

- A statistical baseline forecast should be generated by using the best fit algorithms that could be automatically selected with tools such as Forecast Pro.

- A statistical baseline forecast should be enriched with insights to the potential future demand from various sources such as epidemiological data, historical data and enrichment demand drivers.

- National and provincial personnel play a key role in the demand planning process.

- Key performance indicators (KPIs), segmentation rules and the hierarchy setup are defined by NDoH. These are reviewed annually, and are standardised across all Provinces.

- Demand planning outputs inform budgeting and finance activities as well as several critical supply chain activities including supply planning, distribution planning, procurement and contract oversight.

- Given the criticality of demand planning as an 'upstream' activity that informs many aspects of supply chain operations, senior officials at national and provincial level must monitor the forecast accuracy and its impact on supply chain performance.

- A key output of demand planning is an unconstrained demand plan—'one number' that reflects true requirements for patients receiving medicine from health establishments in the public sector, as well as health establishments providing healthcare services on behalf of the public sector. All other forecasts in the organisation should be aligned to the official demand plan.

- All demand plans should be cashed up i.e. converting a volume number into a monetary value (rand) and reviewed by Finance.

- Constraints such as available budget, supplier capacity, and other outside factors unrelated to patient requirements are applied to the unconstrained demand plan to yield a constrained demand plan, which reflects the actual quantities of medicines that NDoH and provinces will attempt to supply.

- A Provincial Demand Review Committee will be established in each province and chaired by the HOPS. Members should be appointed by the Ministry of Health.

- The Demand Review Committee must approve the both Unconstrained and Constrained Demand Plans, which are then signed by the HOPS.

P.2 Inputs into the demand plan

The statistical baseline forecast is enriched with inputs that are critical to driving the forecast accuracy. Three sources of input are identified and categorised:

- **Epidemiological data sources including, but not limited to:**

    - District Health Information System (DHIS)
    - Tier.net [1]
    - ETR.net [2]

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[1] This is an online web domain site.
[2] This is an online web domain site.

- **Historical inputs including, but not limited to:**

  - Historical orders/issues/consumption data from multiple warehouse management systems (WMS) and (ESMS) which should include at least two years of history.
  - Trends from medicine-related campaigns conducted during the previous period.
  - 'Out of stocks' experienced during the previous period.
  - Any forced constraints e.g. budget or supplier capacity during the previous period.

- **Enrichment demand drivers (known changes):**

  - Campaign information for the upcoming period of the forecast.
  - Changes to number and location of facilities.
  - Demographics data typically provided from Statistics SA.
  - Epidemiological data.
  - Input from national programmes such as the Expanded Programme on Immunisation (EPI), and other programme teams.
  - Inputs from the National Health Laboratory Services (NHLS).
  - Changes to EML, STG or contracts.
  - Inputs from Pharmaceutical and Therapeutics Committees (PTC).

P.3   Planning processes

Here, the process map (Figure P.1) for the new and updated demand planning process is provided.

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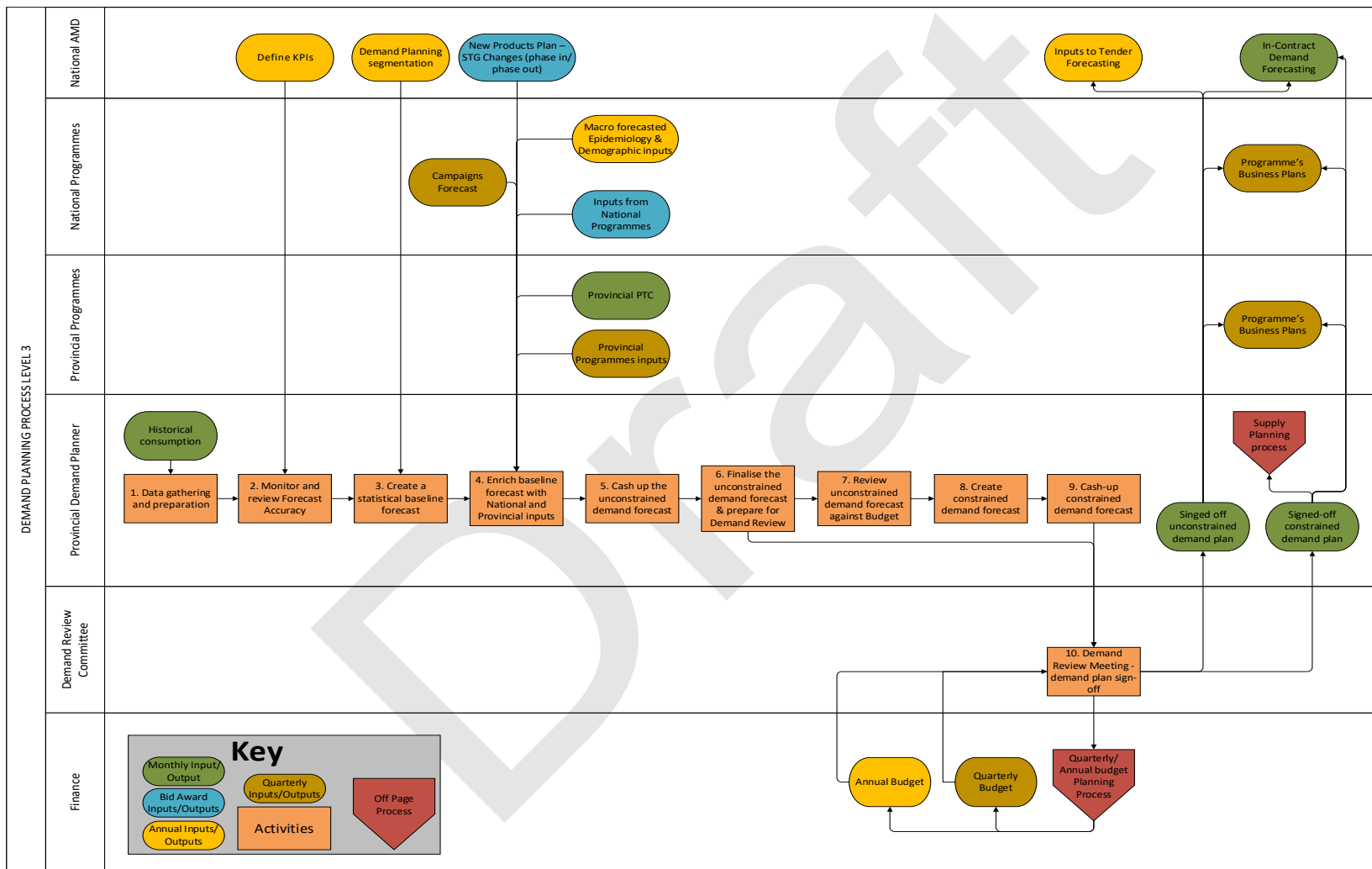
Figure P.1: Updated demand planning process map for the South African VAN Operating Model

P.3 Planning processes

Next, the demand planning processes in Figure P.1 are explained in Table P.1 (the following table is directly taken from the new demand plan document):

Table P.1: Updated demand planning processes for the South African VAN Operating Model

#	Process Step	Role	Description	Output	System and tools
1	Data gathering and preparation	Provincial Demand Planner	Set up a hierarchical perspective from which to base the forecast, e.g. top down: provincial ➜ warehouse ➜ contract ➜ item ➜ health establishment. The forecasting hierarchy should be set by NDOH. Historical consumption data is received from the demanders as per the agreed schedule and is then reviewed and cleansed against the master data lists – (Currently the MPC, which will be replaced by the MHPL.) Where data is available, information relating to unmet demand must be incorporated, for example prescription data versus dispensing data. Link to costs, VEN, ABC analysis, ATC to enable ease of forecasting and financial cashing up. This task takes place on a monthly basis around fourth day of the month. Clear assumptions regarding the data must be captured and maintained.	Cleansed data	ESMS MS Excel
2	Monitor and review forecasting accuracy	Provincial Demand Planner	This step applies continuous improvement processes to demand planning. Monitoring of the defined KPIs (outlined in Section 13) takes place on a monthly basis. The aim is to establish the root cause for poor forecast performance and identify opportunities for improvement.	KPI performance review and root cause analysis and improvement plans	Forecast Pro[3] MS Excel
3	Create a statistical baseline forecast	Provincial Demand Planner	The statistical baseline forecast is created using a forecast tool (Forecast Pro) that will automatically select the correct algorithm for the relevant data set. The statistical forecast should use the appropriate segmentation[4] as an input per annual guidance provided by AMD. AMD is responsible for determining the principles for segmentation on an annual basis,	Statistical Baseline Forecast **(Unconstrained)**	Forecast Pro

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[3] Forecasting tool used by NDOH to support demand planning activities
[4] Supply chain segmentation during demand planning involves applying variable degrees of precision to forecasting consumption of more critical (VEN), more expensive, higher volume, or more volatile medicines that have the potential to more adversely impact financial and patient outcomes.

Table P.1 continued from previous page

#	Process Step	Role	Description	Output	System and tools
4	Enrich baseline forecast with national and provincial inputs	Provincial Demand Planner	Demand enrichment drivers are reviewed on a monthly, quarterly, annual basis or as required to enrich the statistical baseline forecast and ensure it considers appropriate inputs. • Review changes to the EML and all Provincial formularies - **Quarterly** • Create and incorporate any data relating to campaigns that may cause changes in demand - **Quarterly** or as need arises. • The Provincial Supply Chain Team (PMPU) will receive input from Provincial Pharmaceutical and Therapeutics Committee (PPTC) including provincial programmes that may influence the demand - **Quarterly** • The Provincial Supply Chain Team will also review notifications regarding health establishments in the province to include any that have opened or closed, or changed status – **Quarterly** • Input of macro forecasted epidemiology and populations statistics is received from national programmes, Statistics SA and National Health Laboratory Services (NHLS) - **Annually** Sufficient lead-time is required to ensure that the supply chain can react to amendments in adequate time to avoid stock shortages.	Enriched Baseline Forecast **(Unconstrained)**	Forecast Pro
5	Cash up the demand forecast	Provincial Demand Planner	The unconstrained demand forecast (quantity) is then converted to a cashed up (rand) forecast – **Monthly**	**Unconstrained** Cashed Up Demand Forecast	Forecast Pro MPC/MHPL
6	Finalise the unconstrained demand forecast and prepare for Demand Review	Provincial Demand Planner	The demand forecast is finalised and the documents for the monthly demand review meeting are prepared.	**Unconstrained** Demand Forecast Demand Review presentation	Forecast Pro MS PowerPoint
7[5]	Review unconstrained demand forecast vs. Budget	Provincial Demand Planner	The purpose is to review the unconstrained demand forecast against available budget and identify any constraints.	Constraints identified	Forecast Pro

---

[5] The process for identifying and applying budget constraints are under review. When completed, this document will be updated. Provincial Finance and the PPTC should be involved in this process step.

Table P.1 continued from previous page

#	Process Step	Role	Description	Output	System and tools
8[6]	Create a constrained demand forecast	Provincial Demand Planner	A constrained demand forecast is created, incorporating any identified budget constraints.	**Constrained** Demand Forecast	Forecast Pro MS Excel
9[7]	Cash up the constrained demand forecast	Provincial Demand Planner	The constrained demand forecast is converted into a cashed up (rand) forecast	**Constrained** Cashed Up Demand Forecast	Forecast Pro MS Excel
10	Meeting of Demand Review Committee and Demand Plan sign-off	Demand Review Committee	The Demand Review meeting takes place in the second week of the month. The purpose of the Demand Review Meeting is to: • Establish root causes of poor forecasting performance, • Review and agree on the unconstrained demand forecast, • Apply judgement to the demand forecast, • Identify any gaps or opportunities and potential over- or under-forecasting, • Compare against the annual budget and agree to budget constraints, • Identify options to close gaps, exploit opportunities and recommend adjustments to the forecast[8], and • Identify any concerns for escalation to provincial stakeholders or AMD. The signed-off Unconstrained Demand Plan is submitted to AMD and becomes a critical input to the Tender Forecasting process in preparation for the upcoming tender/s. The Unconstrained and Constrained Demand Plans are submitted to the Contract Management Unit (CMU) for the monthly In-Contract Demand Forecasting and supplier engagements. The signed-off Constrained Demand Plan is provided to Provincial Supply Planning and Provincial Finance. The Unconstrained and Constrained Demand Plans are also given through to the Provincial and National Programmes' business plans	Signed off **Unconstrained** Demand Plan Signed off **Constrained** Demand Plan	MS Excel

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[6] The process for identifying and applying budget constraints is under review. When completed, this document will be updated. Provincial Finance and the PPTC should be involved in this process step.
[7] ibid
[8] Gaps between the Unconstrained and Constrained Demand Plans should be solved for by national and provincial personnel identifying opportunities to reduce costs in supply chain operations, medicine procurement, and apply other cost reduction levers to help "close the gap". Provincial Finance and the PPTC to play a vital role in this process step.

P.4 Stakeholder roles and responsibility

As mentioned shared responsibility and collaboration between NDoH and the Provinces will result in a consistently developed demand plan without compromising unique provincial insights. Roles and responsibilities of specific stakeholders are shown in Table P.2.

Table P.2: Stakeholder roles and responsibilities

Stakeholder	Role and responsibilities
The National Department of Health (NDOH)	Responsible for the definition of demand planning KPIs, the segmentation rules, the hierarchy setup, national enrichment information and the review and consolidation of the provincial forecasts.
National Demand Planning Lead	Responsible for overseeing the National Demand Planning Team and for providing the required National inputs to the Provincial Demand Planning team.
National Demand Planner	Responsible for aggregating the provincial demand plans for input into In-Contract Demand Forecasting and Tender Forecasting.
National Enrichment Input Providers	Responsible for providing enrichment inputs into the statistical baseline forecast – including EDP, NEMLC, EPI, NHLS, other programme teams, campaign teams and Statistics SA.
Provincial Demand Review Committee	Responsible for approving and making recommendations on the Final Unconstrained Demand Forecast and Constrained Demand Plan. Demand Review Committee composition may vary based on provincial size but it is recommended to include the following representatives: • Head of Pharmaceutical Services for the Province (HOPS) (Chairperson) • Provincial Demand Planning Lead • Provincial Finance Representative • Provincial Warehouse Representative (e.g. Manager or Responsible Pharmacist) • District Pharmacist(s) (the number of District Pharmacists on the committee will vary based on the size of the Province but should be sufficient to represent District perspectives) • A representative from the procurement subcommittee of the PPTC (quarterly)
Provincial Budget Holders	Responsible for the budget and applying constraints to the unconstrained demand plan shown in Step 8 of the Demand Planning Process.
Provincial Demand Planner	Responsible for generating the provincial demand plan as described in the demand planning process Table O.1.
Provincial Enrichment Input Providers	Responsible for providing enrichment inputs into the statistical baseline forecast – including EPI, other programme teams, and campaign teams.

P.5   Key Customers

Demand planning process customers are described in Table P.3.

Table P.3: Key customers of the demand planning process

	Customer	Roles
National	Bid Specification Committee (BSC)	They will use the Unconstrained Demand Plan for the relevant tender cycle. The Tender Forecast is presented at the Bid Specification Meeting to determine national quantities of the relevant products required for each tender.
National	Contract Management Unit (CMU)	They will use the both the Unconstrained and Constrained Demand Plans to inform cost reduction strategies and manage supplier performance. During the contract period, CMU compares the latest Demand Plans against the amount included in a specific contract to identify gaps. In addition, CMU assists supplier planning by informing suppliers of expected national demand for the next quarter and the remainder of the contract period
Provincial	Provincial Senior Management	They will compare the Unconstrained Demand Plan to Constrained Demand Plan and make operational and financial trade-offs to close the gap between the two.
Provincial	Provincial Budget Holders	They will compare the Unconstrained Demand forecast against available budgets and identify any potential financial constraints. The resultant Constrained Demand Plan will be published taking the budget constraints into account. The budget holder will use the Constrained Demand Plan to generate the budget update for the remainder of the financial year. The budget holder would also use the Constrained Demand Plan for future year financial planning.
Provincial	Supply Planner	Supply Planners will use the Constrained Demand Plan as one of their primary inputs for adjusting safety stocks and for replenishment planning. They will inform executives whether they will be able to meet medicine demand based on supplier and other constraints.

P.6   Appendix N: Conclusion

In this appendix, the details of the updated demand planning processes for the South African VAN Operating Model are discussed. The details in this appendix are used for the medicine selection case study in Chapter 8 and Appendix R.

Appendix Q

Updated supply plan for the South African VAN

A previous version of the supply plan is updated in July 2018[1]. In the following sections, the updated information (from the original version in Chapter 2) is provided, especially focusing on the key planning processes, the order and replenishment processes, the inventory management tool and algorithm, and key enablers to roll-out the supply plan. The information in this Appendix is taken directly from the updated supply plan. Only the necessary information relevant to the case study is provided.

Q.1 Supply plan process map

Figure Q.1 illustrates the updated supply planning process map for the South African VAN Operating Model. Figure Q.2 illustrates the data flow across the different information system tools; an overview of the product flow; the responsibilities of the different roles across the organisational levels; and those who need to have visibility.

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[1]The 2019 version is still a work in progress and is not ready to be utilised for the illustrative case study.
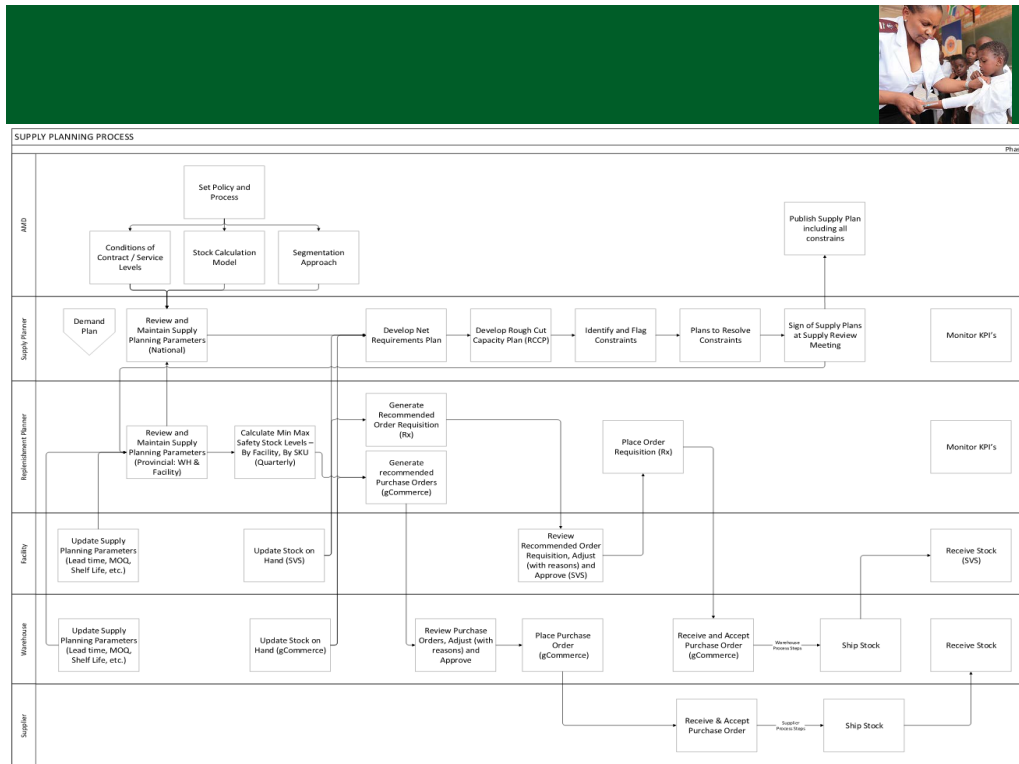
Figure Q.1: The updated supply planning process map for the South African VAN
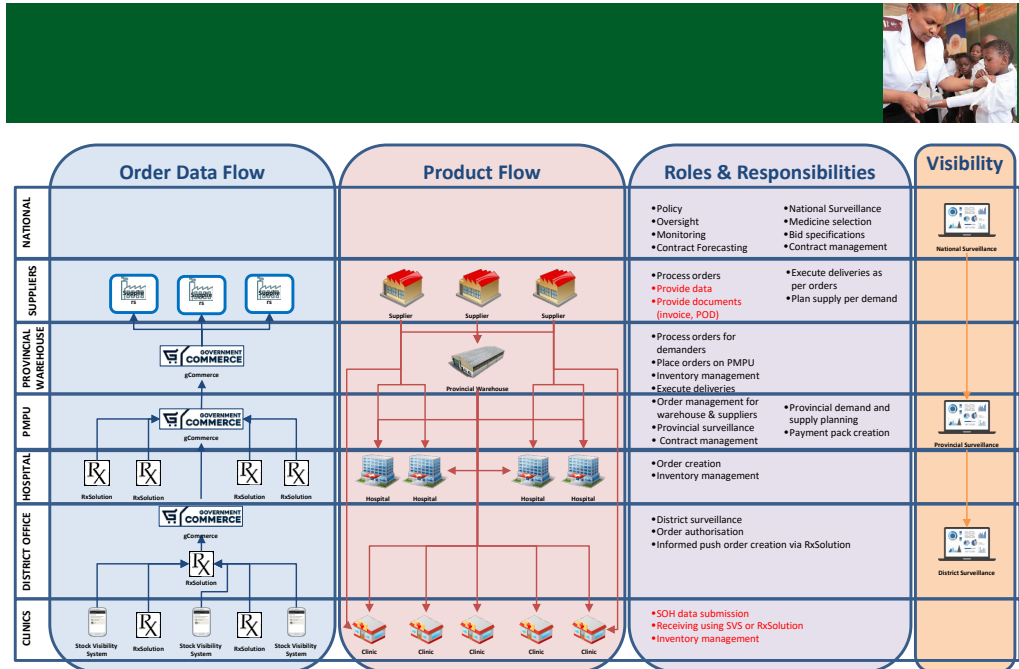
Figure Q.2: The integration of the information systems, the product flow, and the responsibilities across the different organisational levels

Q.2 The supply and replenishment planning

Figure Q.3 illustrates the different ordering and delivery processes between the PMPU, suppliers, warehouses and facilities.
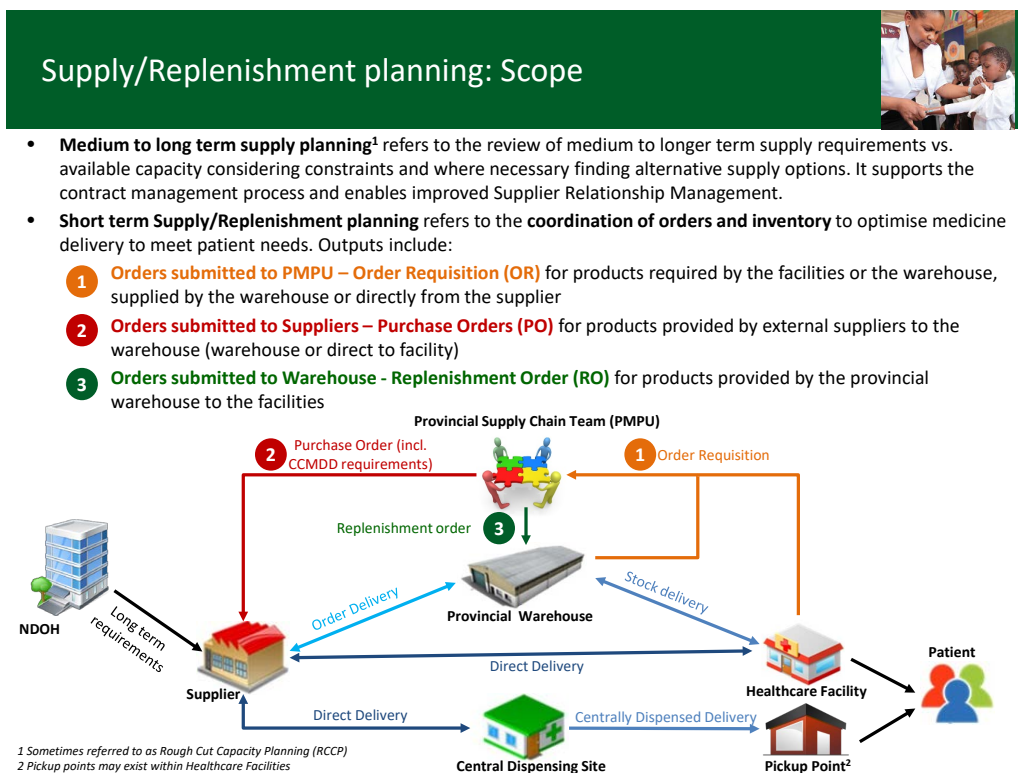
Figure Q.3: The different ordering and delivery methods

Figure Q.4 discusses the two replenishment models. The different supply chain processes are illustrated in Figure 2.1. The updated supply plan will initially focus on the informed push model and will in the future focus on the informed method for some processes. Figure Q.5 details the replenishment processes for the informed push model.
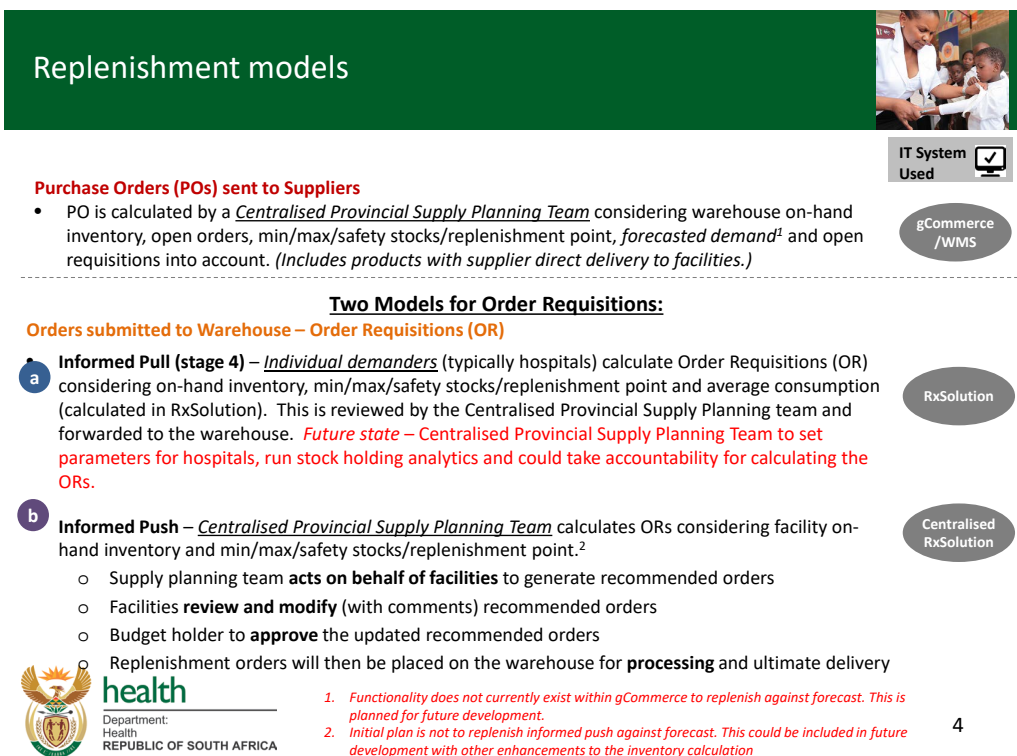
Figure Q.4: An overview of the two replenishment models considered for supply planning Stage 3 and Stage 4 from the supply chain stages in Figure 2.1
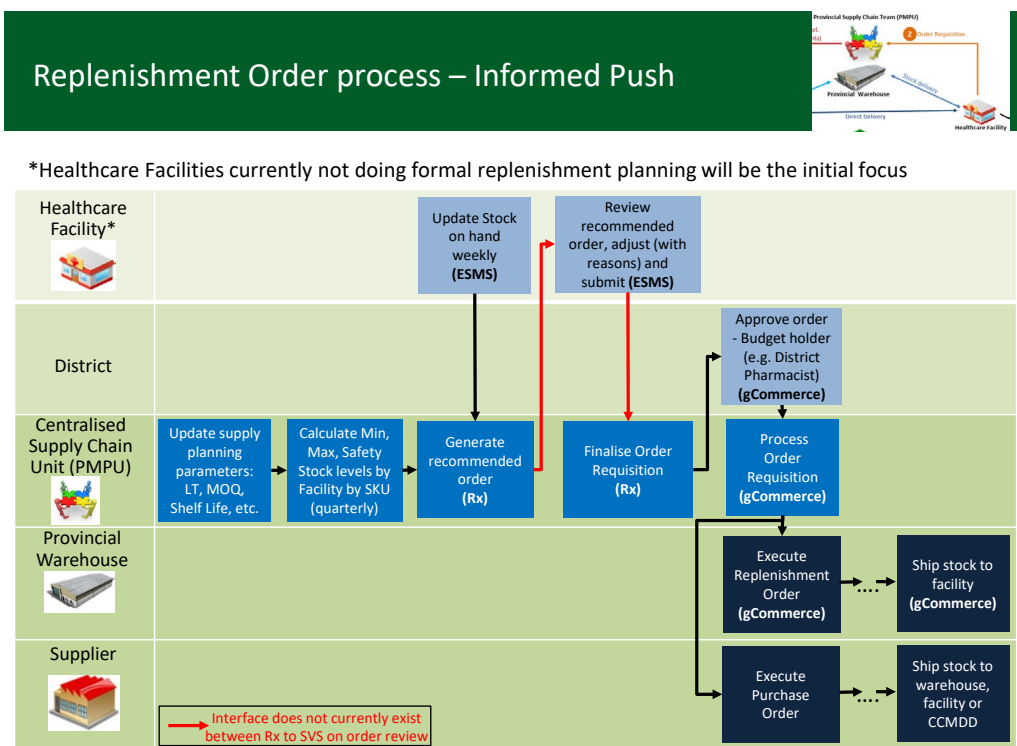
Figure Q.5: Process map for the informed push replenishment order process

Q.3   Inventory calculation: RxSolution

Figure Q.6 presents the internal mathematics of the RxSolution software. Figure Q.7 presents the stock calculations used as inputs into the RxSolution algorithm. These inputs should be calculated by facility per stock keeping unit (SKU).
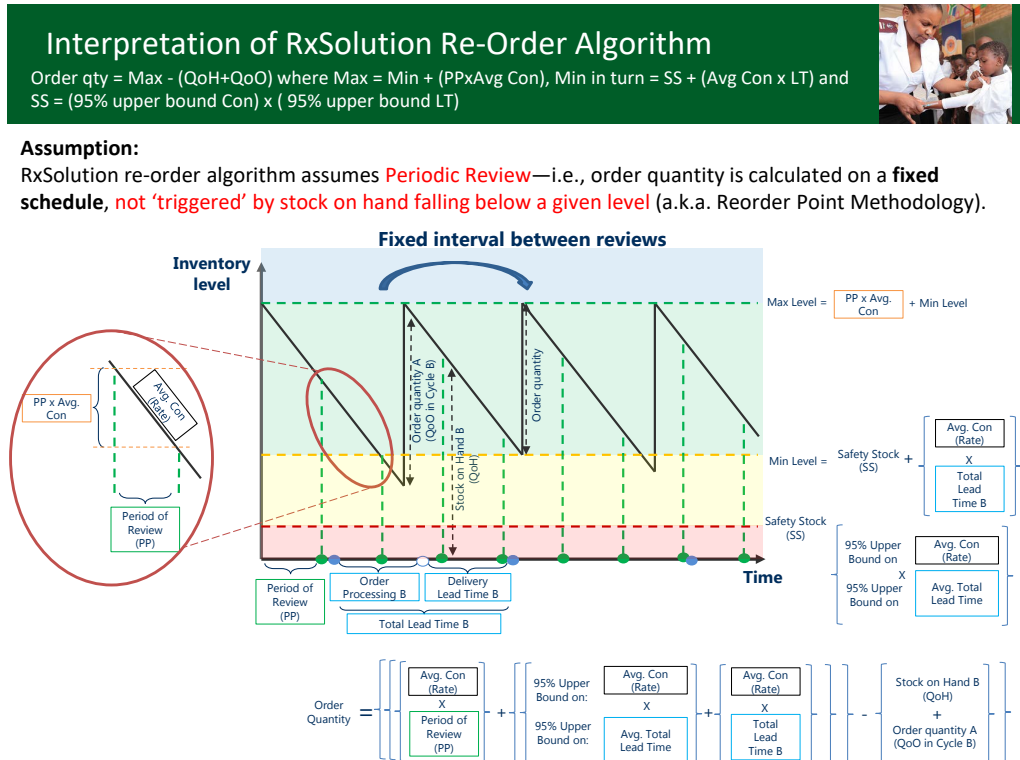
Figure Q.6: Details of the inventory algorithm within the RxSolution software

Stock calculation - basics

Safety stock = Average consumption x Average lead time.

Minimum = Safety Stock + (Average consumption * Average lead time)

Maximum = Minimum + (Procurement Period * Average consumption)

Order Quantity = Maximum - (On hand Inventory + Open Orders)

Notes:
- For Safety stock - where the Confidence Interval is reliable use **CI** instead of average
- For Min - where the average has been used, the safety stock is multiplied by a **factor of 1.5** to account for variations in consumption and lead time.
- The lead time is the agreed delivery period according to the tender document, and the lag time is the actual performance of the supplier. It is best to use the lag time and, if the sample is sufficiently strong, the CI. Failing this, the default that is used is the lead time
- The lag time is calculated as the difference between the date of the purchase order and the date when the product was actually received.
- Procurement period – 4 different settings (A-D). The values for these four settings will be determined by the institution's procurement strategies, patient dynamics, and tender specifications. Default procurement periods to be determined in consultation with the institutional pharmacy and therapeutics committee and the relevant procurement agency.
- Shipper pack info sources - The tender document; Consultation with the supplier; Observation of the size of the shipper packs dispatched to you
- If the shipper pack is greater than 1, then this value is rounded up to the nearest multiple of the shipper pack.
- Several further details are included in the RxSolution manual - **ANNEX 5. AUTOMATED STOCK REORDER CALCULATION**

Figure Q.7: Stock calculations used for the RxSolution algorithm

Q.4   Key enablers and performance indicators

Figure Q.8 identifies the enablers required to roll-out the supply plan. These are identified after a baseline assessment was made on the current system. Figure Q.9 provides the key performance indicators (KPIs) that should cover the critical processes of the supply plan.

Figure Q.8: Key enablers in required to roll-out the supply plan

Figure Q.9: Critical key performance indicators for the supply plan processes

Q.5   Conclusion: Appendix Q

In this appendix, the details of the previously updated supply plan for the South African VAN Operating Model are discussed. The details in this appendix are used for the inventory management case study in Chapter 8 and Appendix S.

Appendix R

Case study 1: medicine selection

In this appendix, the practical application of the case study is provided with sufficient details on how the case study was performed. Some key findings from the application of this case study are available in Section 8.3. The sequence of this appendix follows the six phases of the PoliVAN logic model, which is discussed in detail in Chapter 7. The sixth phase is where the outcome from the previous five phases are analysed to determine the best policy decisions and strategies. Due to the scope of the case study workshop, the sixth phase is not done as proposed by the PoliVAN logic model; however, recommendations are provided based on the outcomes presented during this case study. The detailed version of the case study is provided in this appendix, whereas the interpretation of the process is provided in Chapter 8.

R.1 The medicine selection policy landscape

In this section the first phase of the PoliVAN logic model is applied to the medicines operational function. The updated demand plan from the South African VAN Operating Model (Appendix P) is used to identify the medicine selection operational functions of a pharmaceutical supply chain that are relevant to the VAN, and subsequently identify the relevant policies and legislations governing those processes.

R.1.1 Identifying the key medicine selection functions

The PLF-VAN-matrix tool is presented Table R.1 to illustrate the link between South Africa's VAN Operating Model and pharmaceutical supply chain system, based on the pharmaceutical logistics framework (PLF) components. From the table, it is clear that the medicine selection functions are all documented in the demand plan (version 2) of South Africa's VAN Operating Model. The VAN Operating Model, respective of the medicine selection functions, are concerned with the 'therapeutic formularies' and 'STGs/EML selection and substitution'. The demand planning processes in the VAN document does not explicitly focus on market approval

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or the registration of medicines; however, the SMEs during the case study suggested that this function should be included in the analysis.

Table R.1: PLF-VAN-matrix for the medicine selection functions

PHARMACEUTICAL LOGISTICS FRAMEWORK	VAN PLANNING PROCESSES		
OPERATIONAL COMPONENTS	DEMAND PLAN [1]	SUPPLY PLAN [2]	DISTRIBUTION PLAN [3]
Medicine selection			
Market approval/Registration	X		
Therapeutic formularies	X		
STGs/EML selection and substitution	X		
MANAGEMENT SUPPORT ELEMENTS	DEMAND PLAN [1]	SUPPLY PLAN [2]	DISTRIBUTION PLAN [3]
Information System			
Pharmaceutical management information system	X		
Indicator-based monitoring	X		
Integrated network	X		
Organisation and HR management			
Personnel management	X		
Education and training			
Accountability	X		
Reporting and organisational structures	X		
Financial and donor coordination			
Financing and budgeting strategies			
Analyse and control expenditures	X		
Donor financing			
Monitoring and evaluation			
Programme planning and implementation	X		
Monitoring and evaluation (key performance indicators.)			
[1] Demand plan version 2, September 2018. [2] Supply plan version 2, July 2018/2019. The latest version is currently being updated. [3] Distribution planning version 1, October 2016.			

These functions, including those of the management support elements, subsequently highlight the governing policies and legislations which need to be identified. The policies and legislation that are identified are discussed in the next subsection.

R.1.2 Categorising the relevant medicine selection policies and legislation

The following list of policies and legislation are those that are available in the public domain involving the functions within the medicine selection component of the pharmaceutical logistics framework. Most of the policies and legislation are retrieved from the National Department of Health (NDoH) and National Treasury websites. The title and description of each document is briefly discussed according to the legislation hierarchy, along with a description of its main objective.

R.1.2.1 Laws

Constitution of the Republic of South Africa, 1996

As stated by Tibane *et al.* (2016): "The Constitution is the supreme law of the land. No other law or government action can supersede the provisions of the Constitution."

In terms of Section 27(1)(a) of the Constitution, "everyone has the right to have access to health care services, including reproductive health care" and that (3) "no one may be refused emergency medical treatment". In terms of Section 28(1)(c), "every child has the right to basic nutrition, shelter, basic health care services and social services" (Parliament of the Republic of South Africa, 2005).

Section 40 of the Constitution sets the rules for how government works. There are three spheres of government in South Africa: National government; Provincial government; and Local government. The spheres of government are autonomous, and the Constitution says that the spheres of government are "distinctive, inter-related and inter-dependent". At the same time they all operate according to the Constitution and laws and policies made by national Parliament (Parliament of the Republic of South Africa, 2005).

In terms of Section 217 of the Constitution, according to the National Treasury (2015), "when government contracts for goods and services it must do so in a way which is fair, equitable, transparent, competitive and cost-effective."

R.1.2.2 Acts

National Health Act 61 of 2003

"To provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services; and to provide for matters connected therewith" (South African Government, 2004). The aim of the Act is to ensure that everyone has access to equal health services by building a national health system that governs both the public- and private health services. Since the implementation of the Health Act, a National Health system is legislated by the Act: The public and private sector is incorporated and the establishment of a District Health System (DHS) for the implementation of primary healthcare (PHC) in South Africa (South African Government, 2004).

Medicines and Related Substances Act 72 of 2008 and Act 14 of 2015

As stated in the annual performance plan for 2017-2019, the Act "provides for the registration of medicines and other medicinal products to ensure their safety, quality and efficacy, and also provides for transparency in the pricing of medicines" (National Department of Health, 2017a).

The Amendment Act 72 of 2008, must be read together with a further Amendment Act, being the Medicines and Related Substances Amendment Act 14 of 2015. Both Amendment Acts come into force simultaneously and give effect to numerous amendments to the Medicines Act. The most significant amendment to the Act is the change in the regulatory authority, from the Medicines Control Council (MCC) to the South African Health Products Regulatory Authority (SAHPRA) (Kirby, 2017).

Pharmacy Act 53 of 1974

As stated in the Act, the Act aims to "provide for the establishment of the South African Pharmacy Council and for its objects and general powers; to extend the control of the council to the public sector; and to provide for pharmacy education and training, requirements for registration, and practice of pharmacy, the ownership of pharmacies and the investigative and disciplinary powers of the council; and to provide for matters connected therewith" (National Department of Health (2002) and National Department of Health (2017a)).

Public Finance Management Act 1 of 1999

"To regulate financial management in the national government and provincial governments to ensure that all revenue, expenditure, assets and liabilities of those governments are managed efficiently and effectively to provide for the responsibilities of persons entrusted with financial management in those governments and to provide for matters connected therewith" (National Treasury, 2017).

R.1.2.3   Regulations

Norms and Standards Regulations Applicable to Different Categories of Health Establishments in terms of section 90(1A) of the National Health Act 61 of 2003

"These Regulations apply to all health establishments to the extent indicated in these Regulations." "The purpose of these Regulations is to promote and protect the health and safety of users and health care personnel" (National Department of Health, 2018c).

General regulations in terms of section 35 of the Medicines and Related Substances Act 101 of 1965

"The Minister of Health, in consultation with the Authority, intends in terms of section 35 of the Medicines and Related Substances Act 101 of 1965, to make the Regulations in the Schedule". "The Regulations are intended to give effect to the Medicines and Related Substances Amendment Act 72 of 2008, and the Medicines and Related Substances Amendment Act 14 of 2015, once the said Acts are brought into operation" (National Department of Health, 2017c).

R.1.2.4   Policies

National Drug Policy

The National Drug Policy, adopted in 1996, serves the healthcare needs of South Africa in the following ways (National Department of Health, 1996): (i) it offers a description of the approach by which pharmaceutical services in the country will be managed; (ii) it offers guidance to stakeholders, health care providers, suppliers of goods and services, and governmental and non-governmental agencies of ways in which they can contribute to achieving the policy's main aim; (iii) it follows a clear and logical system for reducing inefficiency and waste and improving efficiency and effectiveness through the development of an adequate pharmaceutical infrastructure; and (iv) it facilitates the design, production and implementation of appropriate programmes for human resource development in health care (National Department of Health, 1996).

As stated by Naidoo *et al.* (2018): "health objectives of the National Drug Policy are to ensure the availability and accessibility of essential drugs to all citizens, to ensure the safety, efficacy and quality of drugs, to promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information and to promote the concept of individual responsibility for health, preventive care and informed decision making".

National Health Insurance Policy (White paper)

As stated in the white paper published by National Department of Health (2017e): this policy "lays the foundation for moving South Africa towards universal health coverage (UHC) through the implementation of National Health Insurance (NHI) and establishment of a unified health system. The move towards Universal Health Coverage (UHC) through implementation of NHI is derived from the following: The Reconstruction and Development Programme (RDP); the Constitutional mandate based on the Section 27 of the Constitution; the 1997 White Paper for the Transformation of the Health System; and Vision 2030 of the National Development Plan Vision 2030".

National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa

As provided in the policy document by National Department of Health (2015b): "the purpose of the National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa is to provide standards for the establishment of a non-statutory, multidisciplinary, advisory committee, to be called the Pharmaceutical and Therapeutics Committee (PTC) in all provinces, districts and institutions in South Africa."

"The PTC shall be committed to the governance of an effective medicines management system to provide equitable and reliable access to medicines and quality care while making the best use of available resources" (National Department of Health, 2015b).

R.1.2.5 Rules and guidelines

Standard Treatment Guidelines

The standard treatment guidelines (STGs) serve as a "standard for practice" (National Department of Health, 2017d), but do not replace sound clinical judgement. There are three different STGs: the STG for primary healthcare (PHC) level (Republic of South Africa Essential Drugs Programme, 2018); the STG for the adult hospital level (National Department of Health, 2015c); and the STG for the paediatric hospital level (National Department of Health, 2017d). Each treatment guideline in these STGs and Essential Medicines List (EML) has been designed as a progression in care from the current Primary Health Care (PHC) STGs and EML.

Rules relating to Good Pharmacy Practice

Rules relating to good pharmacy practice in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974. The South African Pharmacy Council (SAPC) has developed the Good Pharmacy Practice (GPP) standards. According to The South African Pharmacy Council (2010), "the aim of the GPP standards is to ensure that all practising pharmacists and other health care professionals provide a service of high quality for the public and private sector alike. Council therefore encourages every health care professional providing medicine to the public, to embrace the document and sup- port its implementation."

National Guideline for the Development, Management and Use of Formularies (Draft)

A provided in the guideline, the "purpose of this guideline is to define the concept of a formulary in the context of the provision of health care services in health establishments in the public sector and provide guidance in the development, management and use of such formularies at all levels of care. It aims to emphasize *[sic]* the importance of formularies as the basis for the procurement and management of medicine in health establishments to support medicine availability and rational use thereof" National Department of Health (2018b).

Medicine Donation to South Africa

These guidelines are still from the MCC, and has not been updated accordance with the new Regulatory Authority, SAHPRA. These guidelines by the Medicines Control Council (2010) aim to "improve the quality of donations, not to hinder them. They are intended to serve as

a base for national guidelines, to be reviewed, adapted and implemented by the government and organizations *[sic]* dealing with drug donations".

Guidelines for the Registration of Medicines

The guideline describes the information required for the registration of medicines and for an application to amend a registered medicine. The information submitted will be evaluated in terms of the provisions of the Medicines and Related Substances Control Act (Medicines Control Council, 2008).

R.1.2.6   Standard operating procedures

Competency Standards for Pharmacists in South Africa in terms of Section 33(o) of the Pharmacy Act 53 of 1974

The competency standards is a "tool to help the professionals assess their own learning needs. Gaps in knowledge, skills, attitudes and values are identified by comparing personal knowledge, skills, attitudes and values with those required by the competency standards. Competency standards have also been structured to assist with identifying areas, within current or future practice, that may require modification and/or improvement in knowledge, skills, attitudes and values" (South African Pharmacy Council, 2018).

After the previous competency standards published in 2006, the competency standards have been revised and developed to "encompass the changes and developments in all sectors of pharmacy and practice, including new technologies, work processes, changes in legislation and international trends, primarily to ensure public safety" (South African Pharmacy Council, 2018).

R.1.2.7   Other relevant documents

General and special conditions of contract

As stated in Clause 2.1 in the general conditions of contracts: "[T]hese general conditions are applicable to all bids, contracts and orders including bids for functional and professional services, sales, hiring, letting and the granting or acquiring of rights, but excluding immovable property, unless otherwise indicated in the bidding documents" (Treasury, 2004), and where applicable, the special conditions of contract are also provided throughout the different clauses to cover the specific supplies, services or works (Treasury, 2004).

R.2   Sorting the medicine selection policies

The policies and legislations identified in the previous section are used to assess the effect on the VAN Operating Model, specifically focussing on the demand planning category. This section

constitute Phase 2 of the PoliVAN logic model. The following subsections progressively sets out the VAN criteria for the analysis, assesses the enabling an/or hindering effect of existing policy and legislation, as well as identify possible policy problems. For the remainder of this appendix and the sake of brevity, the term 'policy' will be used to refer to both policies and legislations.

R.2.1 Demand Planning VAN criteria assessment

From the demand planning process map and operational processes in Appendix P, the only process from the demand planning document that is directly focused on the selection of medicines, is Process Step 4—"enrichment baseline forecast with national and provincial inputs". Within this step are five substeps which is listed in Table R.2. This table was generated by using the generic VAN process table proposed in the PoliVAN logic model (Figure 7.3), which includes the identification of the process, the frequency of occurrences, the relevant stakeholders and the technology tools and software to be utilised.

Table R.2: Demand planning process steps to identify VAN criteria

ID	Process name/ Process description	Frequency	Locations (scale of granularity)	Responsibility	Customer	Software/Tool
4.	Enrichment baseline forecast with national and provincial inputs					
4.1	Review changes to EML and all Provincial formularies.	Quarterly	National and provincial	Triggered by AMD, and feedback provided by national programmes, PMPUs	AMD Demand Manager	(as-is tools) EML spreadsheet, EML clinical guide, STG books, MPC/MHPL.
4.2	Create and incorporate any data relating to campaigns that may cause changes in demand.	Quarterly	National	National programmes, EDP, EDI	Provincial Demand Planner	Forecast Pro
4.3	Receive input from Provincial Pharmaceutical and Therapeutics Committee (PPTC) including provincial programmes that may influence the demand.	Quarterly	National	PPTCs, Provincial programmes, EDP, EPI	PMPU	Forecast Pro
4.4	Review notifications regarding health establishments in the province to include any that have opened or closed, or changed status	Quarterly	Provincial	PMPU	Provincial Demand Planner	Not identified
4.5	Receive input of macro forecasted epidemiology and populations statistics from national programmes, Statistics SA and National Health Laboratory Services (NHLS)	Annually	Provincial	StatsSA, NHLS, National programmes	Provincial Supply Chain Team (PMPU)	Statistics SA, the rest not identified

As shown in Table R.2, the processes focuses on the quarterly review changes to the (national) Essential Medicines List (EML) and provincial formularies. It is the responsibility of the Affordable Medicines Directorate (AMD) to determine the cycle plans for the updates of the national EML. Once a new product or regimen needs to be included or removed[1] from the national EML, the demand planning manager (role within the AMD) interrogates the

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[1]The selection will include input from national programmes on the unexpected trends, health outcomes, epidemiology, etc.

formularies and the impact that the addition or removal of a product might have on the supply chain (the rest of the demand and supply plan). The Provincial Medicine Procurement Units (PMPUs) then needs to check the effect of these changes on the supply chain, and feed this information back to the AMD demand manager (the customer in this subprocess).

The AMD is the governing body for the VAN processes at a national level and is the link between the NEMLC responsible for the selection of medicines, and the rest of the VAN planning roles (such as the PMPUs). The AMD needs to plan for and set up procurement mechanisms to enable procurement by provinces of the medicines that are required for the patients' need (which are determined by the responsible bodies, namely the NEMLC and the PTCs). These procurement mechanisms should respond to the changes made to the EML/STGs. Continuous engagement from the national and provincial programmes is required for the inputs such as the health outcomes from the medicines specific to their therapeutic area. Their inputs will determine whether the current medicines are effective, and their suggestions may include proposing that changes be made to the EML and STGs.

Once medicines are added or removed from the EML/STGs, it is the responsibility of the AMD to disseminate the changes down to the provincial level, where the provincial demand planner and the PMPU for demand planning need to take the necessary action to prepare the rest of the procurement activities for the change in the supply chain. Not only the information regarding the medicine type should be disseminated to the relevant stakeholder, but also the forecasted quantities of medicines to be added. This allows the provincial demand planning team to check current stock availability of medicines at different depots and facilities to 'time' the phase in/out of the medicines that is both beneficial to the budget and the patients' need. The provinces (the gatekeepers) should have the authority to make products available on the provincial formularies (based on the time required to phase a product in/out) depending on the available stock sitting within the province.

The changes to the EML/STGs should inform the budget to assess whether there are funds available to procure the medicines that are added, or redirect the budget toward other needs when a product is removed. The provincial demand planner is responsible for engaging with the budget holder in order to check availability. The available funds need to be visible to the AMD as well. Having access to available funds will allow the AMD to take the necessary action to review the current contracts and inform the provincial level of what can be procured within the transactional system. For the above-mentioned processes, sufficient lead time is required between the medicine approval and procurement for the province to be able to adapt their medicine stock. The VAN requires a 'stage' (a deliberate pause) after medicines are approved for the EML, and before the addition or removal of medicines on the formularies.

The details of the VAN processes and discussion amongst the SMES shaped the VAN criteria[1] It is deemed likely that more criteria would have been generated if time had permitted for a longer and more detailed discussion. Table R.3 provided, is the VAN content assessment table with the VAN criteria and the policies identified in the previous section. The assessment indicators are used to illustrate the enabling, facilitating or hindering effect of the policies and legislations on the VAN criteria. The indicators are given after a meticulous look through the various policy documents. Inputs from the SMEs during the workshop were given when some policy documents were unclear.

The next subsection focuses on the discussion regarding the enabling, facilitating and hindering policies and legislations.

R.2.2   Enabling and hindering medicine selection policy identification

The indicators used for the assessment are available in Section 7.3. The constitution is left out from the content assessment due to its high-level governance with limited detail on the processes of medicine selection. However, it does provide the necessary information of the health-related laws to understand the context within South Africa. The rest of the policies were analysed in Table R.3 and are categorised according to the assessment indicators.

Those that are ambiguous and/or have no effect on the VAN criteria: Pharmacy Act 53 of 1974; General regulations in terms of section 35 of the Medicines and Related Substances Act 101 of 1965; and MCC Guidelines for Medicine Donation to South Africa.

Those enabling the VAN criteria: National Health Act 61 of 2003; Medicines and Related Substances Act 72 of 2008 and Act 14 of 2015; Public Finance Management Act 1 of 1999; Norms and Standards Regulations Applicable to Different Categories of Health Establishments in terms of Section 90(1A) of the National Health Act 61 of 2003; National Drug Policy; National Health Insurance Policy (White paper); Rules relating to Good Pharmacy Practice; MCC Guidelines for the Registration of Medicines; and Competency Standards for Pharmacists in South Africa in terms of Section 33(o) of the Pharmacy Act 53 of 1974.

Those facilitating the VAN criteria: National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa; Standard Treatment Guidelines (PHC Level, Adult Hospital Level, and Paediatric Hospital Level).

Those hindering the VAN criteria: National Guideline for the Development, Management and Use of Formularies (Draft); and General and special conditions of contract.

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[1]This is what the VAN intends to do. Therefore, the aim is to find a more granular level purpose (the purpose in terms of this subprocess in relation to the VAN).

Table R.3: Policy content assessment against VAN criteria for medicine selection

		General and Special conditions of Contract	Competency Standards for Pharmacists in South Africa	Guidelines for the Registration of Medicines	Medicine Donations to South Africa	National Guideline for Development, Management and Use of Formularies	Rules Relating to Good Pharmacy Practice	Standard Treatment Guidelines (PHC level)	Standard Treatment Guidelines (Adult hospital level)	Standard Treatment Guidelines (Paediatric hospital level)	National Policy for the Establishment and Functioning of PTCs	National Health Insurance Policy	National Drug Policy	General Regulations of the Medicines and Related Substances Act	Norms and Standards Regulations to different categories of Health Establishments.	Public Finance Management Act	Pharmacy Act	Medicines and Related Substances Act	National Health Act
E	**Enabling the VAN operationalisation:** The policies and legislation support the VAN Operating Model and no reform is required.																		
F	**Facilitating the VAN operationalisation** he policies and legislation support the VAN Operating Model; however, there are spects that require reform.																		
—	**Hindering the VAN operationalisation:** The policies and legislation do not support the VAN Operating Model and the implementation of the VAN could have consequences.																		
?	**Ambiguous:** The impact of the policies and legislation on the VAN Operating Model cannot be determined because it depends on too many factors.																		
0	**No impact/effect on the VAN Operationalisation:** The policies and legislation has either no relationship or too much of an indirect relationship with the VAN Operating Model.																		
1	AMD responsible to set up procurement mechanisms to enable the functions of procurement (based on the STGS updates)	0	0	0	?	E	0	0	0	0	0	E	0	0	E	0	0	0	E
2	National and provincial programmes need to evaluate health outcomes and define beneficiary segments to determine the medicines required for the EML and STGs by the therapeutic area of their programme	0	E	E	0	E	E	E	E	E	E	E	E	0	E	0	0	E	E
3	AMD is responsible to review contract to inform which products are allowed to be procure in the transactional (contracting) system	F	0	?	0	E	0	—	F	F	0	E	?	0	0	0	0	0	0
4	The list of product to be added/removed should inform the provinces (gatekeepers). The province should have the authority to "turn on" a product for procurement.	0	?	0	0	—	0	F	F	F	F	0	0	0	E	0	0	?	E
5	The dissemination of the changes in the EML and STGs should not only be the product, but also the forecasting quantities of each product to update demand and procurement plan and check stock holdings	0	E	0	0	F	E	?	?	?	?	E	?	0	0	0	0	0	0
6	Review the budget to check the availability of funds and whether product are able to be procured (if added) and whether the budget can be utilised for other products (if removed)	0	E	0	0	?	E	0	0	0	E	E	E	0	0	E	0	?	E
7	Sufficient lead time is required for the provinces to be able to adapt their medicine stock according to the updated EML. The VAN requires a 'stage' (deliberate pause) after medicines are added/removed to/from the EML and before the provinces are able to make procurement arrangements.	F	0	0	0	—	0	F	?	?	0	0	0	0	0	0	0	0	0

It was interesting to find that all of the Acts identified from the policies and legislations either have no effect, an enabling effect, or are ambiguous. During a discussion with the SMEs, it was concluded that it is probably the result of the level within the legislation hierarchy an Act is situated, because Acts do not necessarily provide details on the 'who's' and the 'how's', but they do give effect to regulations and guidelines that provide more guidance at an increased level of detail. For example the National Guideline for the Development, Management and Use of Formularies (National Department of Health, 2018b). There are two methods of insights that can be generated from the content assessment matrix, and subsequently determine how the policy problems are identified:

i. The grouping of policies and legislation based on their enabling and/or hindering effect; or

ii. The identification of VAN criteria not completely supported or enabled by policies and legislation.

Type (i) has already been done—the grouping of the policies and legislation based on their enabling/hindering effect. Type (ii) is considered the best option to determine possible policy problems, due to the little number of policies hindering or facilitating the VAN criteria. The hindering category are the policies that prohibit the operationalisation of the VAN criteria, whereas the facilitating policies require attention with the detail specified in the document.

The next step in Phase 2 is to determine the alignment among the policies identified. The level of alignment between the policies and legislations (Table R.4) is identified by assigning the relevant indicator[1] (as discussed in Section 7.3). The table is one-sided and not a mirror populated matrix. Thus, the table should be analysed from left to right. The ambiguous and no-effect policies were removed from this analysis, as they are not relevant to further analysis in this case study. The details of this table are revisited during Phase 6 of the case study.

The next subsection discusses the criteria that are impacted by the hindering policies and legislation and subsequently the policy problems are identified.

R.2.3 Medicine selection policy problem analysis

From the VAN criteria (the third criterion), contractual commitments need to be reviewed in order to identify whether the selected medicines can be procured in the system. Contracts in South Africa usually comprise a two- to three-year agreement and the Essential Medicines List (EML) and Standard Treatment Guidelines (STGs) (PHC- and hospital level) are each reviewed at different times. This constrains the ability to align the procurement of products with the selection of medicines. The VAN requires the relevant provincial authority to to

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[1] 'S' for strong alignment, 'A' for alignment. 'L' for little alignment, and 'N' for no alignment.

Table R.4: The case study alignment matrix illustrating the relationship between the policies and legislation

		National Health Act	Medicines and Related Substances Act	Public Finance Management Act	Norms and Standards Regulations to different categories of Health Establishments.	Rules relating to Good Pharmacy Practice	National guideline for the development, management and use of formularies	National Drug Policy	National Health Insurance policy	National Policy for the Establishment and Functioning of PTCs	Competency Standards for pharmacists in South	STG and EML for Primary Healthcare and	General and special conditions of contract
S	**Strong Alignment** The two policies are synergistic as their objectives, targets, or the influence on the pharmaceutical supply chain are perfectly aligned.												
A	**Alignment** The objectives, targets, or the influence on the pharmaceutical supply chain of the two policies under consideration are moderately aligned.												
L/N	**Little to No Alignment** The objectives, targets, or the influence on the pharmaceutical supply chain of the two policies under consideration are not aligned or are only marginally aligned.												
National Health Act			L	A	A	L	A	S	N	S	N	N	N
Medicines and Related Substances Act		L		L	L	L	L	S	A	A	N	S	N
Public Finance Management Act		L	N		N	N	N	N	N	N	N	N	S
Norms and Standards Regulations to different categories of Health Establishments.		S	L	N		A	L	L	N	L	A	A	L
Rules relating to Good Pharmacy Practice		N	A	A	A		N	A	N	N	S	L	N
National guideline for the development, management and use of formularies		N	A	N	N	S		S	N	S	L	S	N
National Drug Policy		L	S	L	L	A	S		N	L	A	S	A
National Health Insurance policy		A	A	A	L	N	N	L		N	N	S	S
National Policy for the Establishment and Functioning of PTCs		A	A	N	N	N	S	S	N		N	S	N
Competency Standards for pharmacists in South Africa		N	N	N	A	A	A	L	N	L		N	N
STG and EML for Primary Healthcare and Hospital Level		N	N	N	N	N	A	S	N	S	N		N
General and special conditions of contract		N	N	S	N	N	N	N	N	N	N	N	

start procuring a product—within a reasonable time—once the supply chain is ready for the changes that need to happen (the fourth criterion). Within the formulary guideline (National Department of Health, 2018b), it states that medicines should be immediately available for the public once they have been approved by the National Essential Medicines List Committee (NEMLC). This does not allow the provinces to adapt the supply chain to ensure that the medicines approved by NEMLC can be readily available.

The seventh criterion (which can operate in conjunction with the fourth criterion) requires that sufficient lead time is made available for the pharmaceutical supply chain to adjust the current stock holding (phasing in/out of products) when a new product is added or removed from the EML. This criterion is also strongly affected by the formulary guidelines (National Department of Health, 2018b). Additionally, if a supplier does not adhere to contract terms, strict penalties are issued against them, but when the buyer (in this case the government) needs to buy out or terminate the contract due to the removal of medicines from the EML, no

consequences are applied to the government within the contract—thus the general conditions of contract are one-sided. The above discussion provides insight into the possible problems identified with the VAN criteria and policy documents. The next subsection highlights and discusses the policy problems.

R.3   Policy formulation for medicine selection

In this section the problems highlighted from the VAN criteria discussion Phase 2 is used to formulate policy options in the attempt to support the implementation of the VAN Operating Model from a policy perspective. This sections starts with the identification of the policy problems and selecting a problem that will be further addressed in this case study. The reason for selecting one policy problem is to stay within the limits of the scope by only illustrating the application of the PoliVAN logic model. Then, the problem is further discussed and with the use of brainstorming techniques, various policy options are generated, which is subsequently used as the inputs for Phases 4 and 5.

R.3.1   Medicine selection policy problem identification

During the workshop a high-level problem was identified, which was subsequently categorised in to three manageable sub-problems. The high-level policy problem is highlighted; **there are currently no prescriptive details within policy or legislation that provide for the link between the selection of medicines and the procurement of medicines**. This problem formulated during the discussion about the VAN criteria that are affected. The following three subproblems were identified to divide the problem into manageable parts:

- **Policy subproblem 1:** *The phase in/out of medicines added to the national EML and the link to procurement.* There is no legislation concerned with the phasing in and out of medicine in the procurement system. Technically, once a change in EML is approved by the NEMLC, the medicines should be available immediately (National Department of Health, 2018b). There is currently no policy or legislation that provides for a deliberate pause within the procurement system in order for the medicine to be made available for prescribing, and subsequently available to the patients. The demand planning guideline (the new demand plan as discussed in Section 8.2.1 and Appendix P) and the formulary guideline (National Department of Health, 2018b), both alluded at high-level to the fact that the supply chain requires time to adapt; however, this text is not sufficiently prescriptive to be enforced. For enforcement to be feasible, the provincial level requires authority to determine 'when' the products are allowed to be 'switched on' in the formulary for procurement, which will be determined by the amount of stock left within the provinces to be used or phased out.

- **Policy subproblem 2:** *The alignment between the selection processes and the contracting processes—linking the timing of these processes.* The review and selection of medicines occurs periodically, but contracts are agreed for two to three years. This lack of temporal alignment typically results in buy-outs, and the suppliers are often disadvantaged by this outcome. In order to appropriately procure medicines and ensure they are available for a sufficient period, the AMD that is responsible for setting up procurement methods and disseminating the changes in EML and STGs, needs to know where they are in the contracting calendar.

- **Policy subroblem 3:** *Unfair contractual agreements between the government and the suppliers.* The general conditions of contracts tend to be one-sided—imposing penalties for poor performing suppliers but not for poor performing demanders (the NDoH, in this case). When there is a change in regimen[1], and changes are made to the EML, suppliers are not compensated for the changes in price and the manufacturers benefit. This require renegotiation of contract terms. The general conditions of contracts should be analysed to determine whether they provide sufficient protection for suppliers, backed by policy and governmental processes that allow for negotiation on price.

For the remainder of the case study, only one policy problem was selected to continue the analysis. The SMEs suggested that policy problem two would be a good choice, as possible policy solutions were already identified and discussed during the process of identifying problems. The next subsection focuses on the formulation of policy options to support policy problem number two.

R.3.2 Formulated medicine selection policy options and design

During this phase of the case study workshop, three policy options were identified to solve the problem about the alignment (time frame) between medicine selection and contracting. These options aim to contribute towards overarching integration processes between the selection, planning and procurement functions in the pharmaceutical supply chain for the VAN Operating Model. By means of a brainstorming session and SME engagement conversations, the four policy problems were identified and formulated with the use of the 'VAN policy objective and formulation checklist' (Available in Chapter 6, page 153). Each policy option and its objective is discussed below.

Policy option 1: To view contracts by therapeutic area

The option is to change contracting clustering to contracting of medicines by therapeutic categories, such as HIV, TB, antibiotics, cardiovascular, etc. The analytics of total cost of

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[1]A prescribed course of medicine for a medical treatment.

treatment will be simplified by contracting in this way, as would the facilitation of changing regimens (because all treatments within a regimen would be contracted to the same cadence). The analytics produced from the implementation of this policy could potentially inform the selection of medicines because review committees would be able to focus on one specific disorder at a time, bringing together both cost and clinical information. Currently bid specification and review meetings are focussed on a range of therapeutic groups at one time, because the tender-clustering of products, demands that products from several different therapeutic classes are re-contracted at the same time. This will provide a level of analysis that is currently unavailable which could inform decision-making for both AMD and the Programmes by providing visibility by therapeutic programme, and subsequently approve the alignment (timeframe) between the selection of medicines informed by changes to regimens and the speed with which those medicines can be contracted. This will have a secondary (but important) effect on reducing the number of medicines that have to be contracted off-contract, with a corresponding decrease in costs and an increase in transparency and accountability for off-contract procurement.

Policy option 2: To enable strategic collaboration with potential suppliers of strategic products

The option is to change the extent of strategic collaboration with suppliers. Strategic sourcing is an organised and collaborative approach, which takes advantage of the size and nature of government spending to obtain th/e best possible service and value from selected suppliers. This policy option aims to adopt a product segmentation approach (the Kraljic Matrix) to identify 'strategic or 'critical products, where there would be benefits to the supply chain of including 'collaboration elements in the 'Special Conditions of Contract for that segment of products. Meaning, special conditions of contract will be set based on the type of segment in which products are categorised.

When focusing on the 'strategic products, this could potentially improve supplier relationship with the prospect of suppliers allowing us to see automatically the amount of finished goods (inventory) the supplier has, contributing towards end-to-end visibility objective of the VAN, and subsequently, the analytics for demand- and supply plan.

The use of the Kraljic approach provides a practical tool for determining the type of procurement strategy for specific products/services. The Kraljic Matrix (also known as a purchase portfolio matrix) groups products based on two dimensions: (1) profit impact and (2) supply risk. The policy under consideration aims to enable greater supplier collaboration pre and post contract for products that fall into the critical and strategic segments. The general recommendation for supplier management in the 'strategic quadrant (high profit impact and high supply risk) is to maintain a strategic partnership in order to counterbalance the supply risk.

Policy option 3: Therapeutic reference pricing—a different contracting approach

This policy proposes a different form of contracting method than the current reference pricing system in used. This is when a reference price for a group of medicines (suggested for a specific therapeutic area) is contracted by supplier, rather than contracting for a single medicine at a specific price. Research have indicated that reference pricing is a cost-effective procurement method within a pharmaceutical supply chain. This policy will provide a clear link between the selection of medicines and the contracting processes.

Policy option 4: Procurement card ("Government Credit Card")

This policy aims to implement the use of procurement card that takes away the laborious process of different transactions in order to pay for medicines. This will replace the workload done for every single transaction that requires a heavy-duty authorisation process, which may result in several invoices every month, quarter of annual cycle for the same medicine, albeit in slightly different quantities. In light of the strategic segmentation approach above (The Kraljic Matrix) there may be products where the procurement cost is low, and where the risks of highly delegated procurement authority are correspondingly low, but the transaction frequency is high. In such cases, a policy modification may be desirable to reduce the number of authorisation steps required to process an order and a procurement card mechanism may be appropriate. This approach would effectively delegate authority to the card holder for all authorisations in the chain, for a specific group of medicines, and within a pre-set budget cap.

The procurement card will impose strict forms of limitations concerning the spending amount and those who have the authority to use it and approve the payments. The authority will most likely sit at a provincial level, because each province has their own budget. In result, this will speed up the authorisation process, and improve the ordering and payment processes to facilitate the availability of medicine. In terms of the VAN, this may simplify complete visibility on the budget holder spending and provides data on the spending within each province. This will also provide data visibility in terms of financial reports, because the process to get financial reports from the BAS system is non-optimal.

The details of each policy provided in Table R.5. The information in this table will be used to further identify relevant stakeholder and analyse its impact on the pharmaceutical system. This table will also provide the detailed information to design the final policy for implementation so that it is in line with the VAN objectives and specifications. The next section uses the policy options formulated in this section to identify relevant stakeholders and analyse their possible reactions to the policy options described.

Table R.5: Details regarding the four policy options for the medicine selection case study

A VAN POLICY OBJECTIVE AND FORMULATION CHECKLIST		POLICY OPTION 1 — To view contracts by therapeutic area, e.g. HIV, TB, Cardiovascular	POLICY OPTION 2 — To enable strategic collaboration with potential suppliers of strategic products.	POLICY OPTION 3 — Therapeutic reference pricing—a different contract approach.	POLICY OPTION 4 — Procurement card ("government credit card").
The policy option aims to support either of the VAN objectives:	End-to-end visibility: data aggregation from multiple sources bringing end-to-end visibility across health commodities and programs, and ultimately the entire value chain.	Will provide a level of analysis that is currently unavailable which could inform decision-making for both AMD and the Programmes by providing visibility by therapeutic programme.	This could potentially improve supplier relationship with the prospect of suppliers allowing us to see automatically the amount of finished goods (inventory) the supplier has	Provides a clear link between the selection of medicines for a STG and the contracing processes.	Complete visibility of budget holder of spend on medicines within each province.
	Analysis and insight: analytical processes to create operational plans, and optimise the system.	Will provide a level of analysis that is currently unavailable which could inform decision-making for both AMD and the Programmes by providing visibility by therapeutic programme.	This could potentially improve supplier relationship with the prospect of suppliers allowing us to see automatically the amount of finished goods (inventory) the supplier has	Provides a clear link between the selection of medicines for a STG and the contracing processes.	Complete visibility of budget holder of spend on medicines within each province.
	Continuous improvement: standardised problem resolution processes, conditional actions, and SOPs used to solve challenges and implement ongoing improvements.	Will provide a level of analysis that is currently unavailable which could inform decision-making for both AMD and the Programmes by providing visibility by therapeutic programme.	This could potentially improve supplier relationship with the prospect of suppliers allowing us to see automatically the amount of finished goods (inventory) the supplier has	Provides a clear link between the selection of medicines for a STG and the contracing processes.	Complete visibility of budget holder of spend on medicines within each province.
Operational functions (process element):	Scope of intended activities.	Contracting processes will be revised. Selection of medicine processes may need to be revised. Supplier management processes will be revised (looking at procurement by therapeutic class and not just by medicine). Possible changes to KPIs for suppliers, selection and contracting, because another dimensions is added to the measurements.	The type of contracting and contracting processes need to be revised. Supplier management and monitoring processes may need to be revised.	Revision of reference prices for appropriate medications into therapeutic groups. Implementation of revised contracting methods based on the therapeutic reference pricing.	Delegations of authority in terms of the PFMA and other legislation to be reviewed and revised. Consultation with Treasury at National and Provincial Level. Consultation with CFO (national andprovincial) Consultation with banks Revision of ordering and payment processes Implementation and training. Banks also need to be included into this process.
	How it fits into the planning process category (demand-, supply-, distribution planning)	This process will inform both supply and demand planning	Will inform both the demand and supply planning	Will inform both supply and demand planning.	Will inform both supply and demand planning.
	The link to the rest of the supply chain.	Will impact selection, contracting, contract management and potentially the rational use of medicine, because if you are monitoring the medicines and the contracts differently, then it **might** change how medicines are used.	Impact on the selection of medicines, contracting and contract management processes, supply selection an monitoring processes,	Impact on the selection, contracting and contract management processes.	Impact on the ordering and payment processes at provincial and possibly district Level.
	Level of frequency of intended activities.	Three timelines: process revision (which is a once-off process); alignment of contract cycle through the procurement process (as one does the contracting) once every three years; and the analysis of the and monitor the contracts once a month.	N/A	Annually	Initial policy changed and implementation (once off) Frequency of Ordering and payment processes using the "procurement card" - to be determined in policy

A VAN POLICY OBJECTIVE AND FORMULATION CHECKLIST		POLICY OPTION 1	POLICY OPTION 2	POLICY OPTION 3	POLICY OPTION 4
		To view contracts by therapeutic area, e.g. HIV, TB, Cardiovascular	To enable strategic collaboration with potential suppliers of strategic products.	Therapeutic reference pricing—a different contract approach.	Procurement card ("government credit card").
Organisational structure (people element):	Process owner of intended activities (VAN role).	Contract Management Unit (CMU), as well as the national demand- and supply planners.	N/A	EDP and Contract Management Unit.	PMPU Financial Manager
	Stakeholder roles and responsibilities.	AMD - draft policy; AMD - revise processes; NHC - approve policy; Contract management unit - implement new processes; Ssppliers to consult; and provincial demand- and supply planners tie consult.	AMD - draft policy AMD - revise processes NHC - approve policy Contract Management Unit - implement new processes EDPD - implement new processes Suppliers - consult	AMD - draft policy AMD - revise processes NHC - approve policy Contract Management Unit - implement new processes EDP - implement new processes Pricing Committee - consult Suppliers - consult	Treasury - approve policy requirements, NHC - approve policy, AMD - develop policy, Provinces - input into and approve delegations and Treasury
	Location granularity	National level (transversal contracting)	National level	National level	To be discussed through policy development process - national, provincial, district or facility?
	The link to existing country roles (non-VAN roles)	Contracting and contract management unit which is direclty invloved in planning; Essential Drugs Programme; and national Programmes (TB, HIV, EPI etc)	Contracting personnel Contract management personnel Essential Drugs Programme National Programmes (TB, HIV, EPI etc) Supppliers	Selection, contracting and contract management teams	Ordering and payment clerks roles. Possibly district and facility pharmacists responsible for ordering; however recommended order are provided by PMPUs.
	Reporting lines among the different roles and levels	The AMD reports to National programmes and contracting and contract management teams on the change in EML/STGs, which informs the products to be procured per therapeutic class. The national programmes provide input on the products to procure as part of the medicine selection process. Once the demand plan is approved, signed off demand plan is reported back to the national programmes and AMD which informs the CMU.	The AMD and Contract management unit	N/A	N/A
Information system (technology element):	Data requirement for intended activity	EML / STGs, because those would provide the products selected within each therapeutic groups. If available (dependand on the ePrescribing tool), prescription data by diagnosis of therapeutic area to inform further selection and contracting processes.	EML / STGs Master Healt Product List Suupliers information (stock visibility) 0	STGs / EML and reference Pricing	Budget allocations and availability. Informed push orders. Clear, approved and signed delegations of authority of identified personnel. If this apporach is only allowed in cases of emergency, then informed push won't apply.

A VAN POLICY OBJECTIVE AND FORMULATION CHECKLIST		POLICY OPTION 1 To view contracts by therapeutic area, e.g. HIV, TB, Cardiovascular	POLICY OPTION 2 To enable strategic collaboration with potential suppliers of strategic products.	POLICY OPTION 3 Therapeutic reference pricing—a different contract approach.	POLICY OPTION 4 Procurement card ("government credit card").
	Software/tool to be implemented/used	Master Data Project (master data of products, such as generic names). Access required to the warehosue management system (procurement /contracting and warehouse modules). ePrescribing (when available). EML Clinical App - have STGs and EML on it.	Master Data ; WMS (procurement /contracting and warehouse modules); ePrescribing (when available); EML Clinical App - have STGs and EML	Master Data WMS (Procurement module) and EML Clinical App	Basic Accounting System (BAS) and WMS (procurement and warehouse modules).
	Interoperability	The vision is that all the data systems and tools are interoprable.	All	All	Between BAS and WMS, linked to each other
	Data transparency	Available at National level for the AMD and the rest of the process owners.	Improved visibility to stock on hand and full treatment costs for a regimen by therapeutic area, because tendering / contracting timelines are aligned	N/A	Budget information currently only available to budget holders. Would need visibility from the person who orders / pays.
Monitoring and evaluation:	Strategic outcomes	Improve the allignement of contracting processes (to the therapeutic areas) for the selection of medicines.	To drive cost efficiency through strategic collaboration with suppliers on the strategic products	To drive cost efficiency through innovative reference pricing structures. To align selection and contracting.	Improve the ordering and payment processes to facilitate the availability of medicine.
	Continuous improvement plans	Monitoring the use of reporting, how the analysis is actually used by the EDP, contract management unit and national programmes. This will provide an indicator of how useful contracting by theraoeutic contracts are.	The use of the Kraljic model demands continuous monitoring and updating to continue its effectiveness. Monitoting the changes in market conditions, such as new suppliers entering the market and the availability of new products or substitute products, which will change the classification, and the resulting procurement strategy, of products.	Monitor the ultimate cost of medicines to inform the reference pricing.	Rigid monitoring of ordering and spend made by credit card to inform continuous improvement and compliance.
	Key performance indicators (KPIs)	Improved health outcomes; improved availability of medicines; and more imporved alignment between the timeing of the selection of medicines and contracting.	Improved visibility on the availability of strategic products at suppliers. Improved suppliers partnership. Cost effectiveness of medicine against the supply risk. Supplier and buyer complinace	Cost of medicine by therapeutic group.	Compliance with PFMA and authority of delegation Order to payment time and delivery, do you get medicines more quickly?
Human resource development:	Education, training and/or skill development	Training required on the implementation of new processes and the training required for the analysis of new data groupings (by therapeutic area). No new staff is required.	Training required on the implementation of new processes training required for analysis and use of Kraljic matrix. No new staff required	Training required for existing staff managing selection, contracting and contract management. Possible training of Pricing Committee.	Training required for existing staff at all levels impacted.
	Workforce capacity (hire, deploy, retain, motivate, etc.)	Motivate existing workforce.	Motivate - existing workforce	Motivate - existing workforce	Motivate - existing workforce
Financial and donor coordination:	Financial sources/requirements	Initial funding required for development of IT data analysis capability through existing systems. Training and implementation resources required.	Initial funding required for development of Kraljix Matrix capability. Training and implementation resources required	Initial funding required for development of reference pricing capability. Training and implementation resources required.	Funding required for upfront development of policy and processes. Ongoing funding for provincial budgets
	Budget allocation and update	N/A	N/A	N/A	Possible revision of level of budget allocation.
	Disbursement (release of funds)	N/A	N/A	N/A	Possible revision on the release of funds for procurement.

R.3 Policy formulation for medicine selection

R.4   Stakeholder analysis for the policy options

In this section, a stakeholder analysis for each policy option is conducted. The evaluation tables are populated for each policy option with the inputs from the workshop SMEs. The information in the table is used to provide three types of analysis outputs to make informed decisions regarding the stakeholders.

R.4.1   Stakeholder evaluation table for medicine selection

For the stakeholder analysis (SHA) the relevant stakeholders were identified through a brainstorming technique. Evaluation scores (see Figure 7.13) are used to evaluate the stakeholders. As suggested by the SMEs, all of the characteristics were used in this analysis. The five SMEs from the case study workshop were asked to score each of the stakeholders based on their relevant experience within the policy field, where they work with relevant stakeholders on a regular basis. The average was taken from the participant's score; however, when there was an outlier, e.g. if four SMEs' answers ranged between '3' and '5', but the other SME's score is '1', then this score is disregarded. Figures R.1 to R.4 illustrate the stakeholders identified, the scores given by the SMEs, and the analysis outcomes produced by the data.

For each policy options there are three types of analysis done: (i) to determine the extent of stakeholder involvement; (ii) to determine the ability of an opposing stakeholder to influence the decisions; and (iii) to determine the ratio of power between the internal and external stakeholders. The details of each analysis type for this case study are discussed in the next subsection.

R.4.2   Stakeholder analysis outcome methods

Here the three analysis types from the stakeholder evaluation tables are discussed. The interpretation of the evaluation table is only discussed in Phase 6 and is focused on the chosen policy option for the VAN.

Power-attitude map

For the first analysis type, each policy option and the stakeholder's characteristics towards the policy option are plotted on a power-attitude-map (which is shown below the table for each policy option). The attitude[1] takes into account a stakeholder's knowledge about the policy option, the interest the stakeholder might have towards the policy option (regardless of whether they are impacted by the policy), and the stakeholder's level of support (positive or negative, which is determined by how the stakeholder is impacted).

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[1]The attitude is calculated as the combined sum between the knowledge and interest of a stakeholder, multiplied by their level of support (positive or negative).

STAKEHOLDER ANALYSIS	POLICY OPTION 1: To view contracts by therapeutic area										
Stakeholders	Position	Knowledge	Interest	Support	Attitude	Financial Resources	Political Resources	Human Resources	Total Resources	Power	Opinion leaders
Affordable Medicines Directiorate (AMD)	Internal	2,9	3,7	1	6,6	2,2	0	3	5,2	2,9	Yes
Banks	External	1,0	1,3	1	2,3	0,0	0,6	0,3	0,9	0,0	No
Clinical societies and patient advocacy groups	External	3,7	3,3	1	7	0,9	2,2	0,7	3,8	0,7	No
Department of Trade and Industry (DTI)	External	4,6	3,7	1	8,3	2,1	2,3	2,2	6,6	0,0	No
Expert Review Committee	Internal	5,0	2,6	1	7,6	1,1	2,8	2,7	6,6	1,6	Yes
Head of Pharmaceutical Services (HOPS)	Internal	3,7	2,1	1	5,8	2,6	3,0	2,2	7,8	2,4	Yes
Health establishments (and service delivery platform, i.e. school healthcare services)	Internal	1,3	2,0	1	3,3	1,4	2,3	2,4	6,1	0,6	No
Health Technology Assessment (HTA) committee	Internal	4,0	3,3	1	7,3	1,7	2,8	2,7	7,2	1,5	Yes
National Aids Councils	Internal	3,7	3,3	1	7	0,1	0,1	0,2	0,4	0,0	No
National Essential Medicines List Committee (NEMLC)	Internal	5,0	3,3	1	8,3	1,2	2,6	2,4	6,2	2,7	Yes
National Health Council (NHC)	Internal	3,3	2,2	1	5,5	2,7	0,6	1,1	4,4	2,6	Yes
National Programmes	Internal	4,6	4,0	1	8,6	1,0	1,4	2,4	4,8	2,2	Yes
National Treasury	External	1,9	1,3	1	3,2	3,0	2,7	2,8	8,5	2,8	Yes
Patients	External	2,3	3,3	1	5,6	0,1	0,2	0,2	0,5	0,3	No
Pharmaceutical Therapeutic Committee (PTC)	Internal	4,0	3,2	1	7,2	2,6	2,6	3,0	8,2	0,8	Yes
Pricing committee (NHI document and the other MACs)	Internal	1,0	3,3	1	4,3	1,9	2,2	3,0	7,1	0,9	Yes
Private medical schemes	External	2,9	1,0	1	3,9	0,6	0,4	0,3	1,3	1,2	Yes
Provincial Budget holders (chief financial officer)	Internal	1,6	1,6	1	3,2	2,4	2,7	1,9	7,0	1,2	Yes
Provincial Medicine Procurement Unit (PMPU)	Internal	2,4	3,9	1	6,3	2,5	2,6	2,1	7,2	1,6	No
Provincial Pharmaceutical Therapeutic Committees (PPTCs)	Internal	4,0	3,2	1	7,2	2,7	2,2	2,7	7,6	0,9	Yes
South African Health Regulatory Authority (SAHPRA)	Internal	2,3	1,5	1	3,8	1,4	0,9	0,7	3,0	0,9	No
Suppliers	External	3,3	4,0	-1	-7,3	2,2	2,8	2,0	7,0	2,5	No
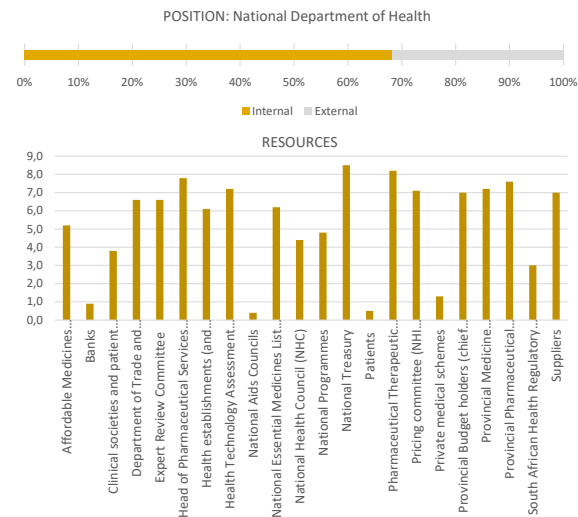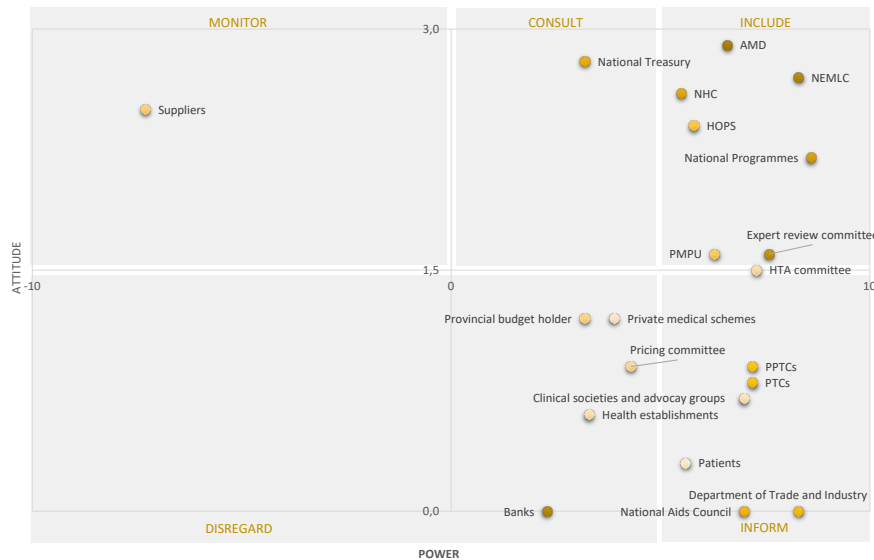
Figure R.1: Stakeholder analysis for policy option 1

STAKEHOLDER ANALYSIS	POLICY OPTION 2: To enable strategic collaboration with potential suppliers of strategic products									
Stakeholders	Position	Knowledge	Interest	Support	Attitude	Financial Resources	Political Resources	Human Resources	Total Resources	Power	Opinion leaders
Affordable Medicines Directiorate (AMD)	Internal	4,1	2,9	1	7	2,2	0	3	5,2	2,9	Yes
Banks	External	1,0	0,0	1	1	0,0	0,6	0,3	0,9	0,0	No
Clinical societies and patient advocacy groups	External	2,2	0,4	1	2,6	0,9	2,2	0,7	3,8	0,7	No
Department of Trade and Industry (DTI)	External	2,2	2,1	-1	-4,3	2,1	2,3	2,2	6,6	0,0	No
Expert Review Committee	Internal	3,9	2,8	1	6,7	1,1	2,8	2,7	6,6	1,6	Yes
Head of Pharmaceutical Services (HOPS)	Internal	4,1	3,0	1	7,1	2,6	3,0	2,2	7,8	2,4	Yes
Health establishments (and service delivery platform, i.e. school healthcare services)	Internal	3,6	0,4	1	4	1,4	2,3	2,4	6,1	0,6	No
Health Technology Assessment (HTA) committee	Internal	2,1	0,1	1	2,2	1,7	2,8	2,7	7,2	1,5	Yes
National Aids Councils	Internal	1,0	2,2	1	3,2	0,1	0,1	0,2	0,4	0,0	No
National Essential Medicines List Committee (NEMLC)	Internal	4,3	2,7	1	7	1,2	2,6	2,4	6,2	2,7	Yes
National Health Council (NHC)	Internal	3,6	2,7	1	6,3	2,7	0,6	1,1	4,4	2,6	Yes
National Programmes	Internal	0,9	2,6	1	3,5	1,0	1,4	2,4	4,8	2,2	Yes
National Treasury	External	2,0	2,8	1	4,8	3,0	2,7	2,8	8,5	2,8	Yes
Patients	External	1,0	0,2	1	1,2	0,1	0,2	0,2	0,5	0,3	No
Pharmaceutical Therapeutic Committee (PTC)	Internal	2,1	2,9	1	5	2,6	2,6	3,0	8,2	0,8	Yes
Pricing committee (NHI document and the other MACs)	Internal	1,8	2,4	1	4,2	1,9	2,2	3,0	7,1	0,9	Yes
Private medical schemes	External	0,8	0,3	1	1,1	0,6	0,4	0,3	1,3	1,2	Yes
Provincial Budget holders (chief financial officer)	Internal	4,6	1,0	1	5,6	2,4	2,7	1,9	7,0	1,2	Yes
Provincial Medicine Procurement Unit (PMPU)	Internal	3,0	2,9	1	5,9	2,5	2,6	2,1	7,2	1,6	No
Provincial Pharmaceutical Therapeutic Committees (PPTCs)	Internal	4,0	2,9	1	6,9	2,7	2,2	2,7	7,6	0,9	Yes
South African Health Regulatory Authority (SAHPRA)	Internal	0,8	1,9	1	2,7	1,4	0,9	0,7	3,0	0,9	No
Suppliers	External	2,9	1,1	1	4	2,2	2,8	2,0	7,0	2,5	No
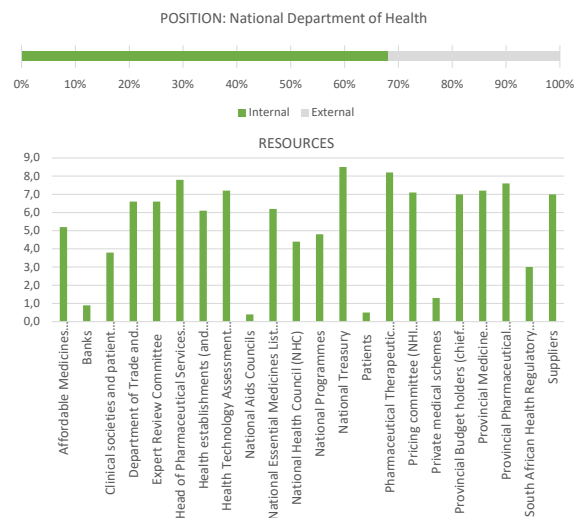
Figure R.2: Stakeholder analysis for policy option 2

STAKEHOLDER ANALYSIS	POLICY OPTION 3: Therapeutic reference pricing - a different contracting approach										
Stakeholders	Position	Knowledge	Interest	Support	Attitude	Financial Resources	Political Resources	Human Resources	Total Resources	Power	Opinion leaders
Affordable Medicines Directiorate (AMD)	Internal	4,0	4,2	1	8,2	2,2	0	3	5,2	2,9	Yes
Banks	External	1,0	0,0	1	1	0,0	0,6	0,3	0,9	0,0	No
Clinical societies and patient advocacy groups	External	1,4	1,9	1	3,3	0,9	2,2	0,7	3,8	0,7	No
Department of Trade and Industry (DTI)	External	2,6	3,6	1	6,2	2,1	2,3	2,2	6,6	0,0	No
Expert Review Committee	Internal	2,8	4,3	1	7,1	1,1	2,8	2,7	6,6	1,6	Yes
Head of Pharmaceutical Services (HOPS)	Internal	2,7	3,2	1	5,9	2,6	3,0	2,2	7,8	2,4	Yes
Health establishments (and service delivery platform, i.e. school healthcare services)	Internal	2,9	4,3	1	7,2	1,4	2,3	2,4	6,1	0,6	No
Health Technology Assessment (HTA) committee	Internal	4,2	3,3	1	7,5	1,7	2,8	2,7	7,2	1,5	Yes
National Aids Councils	Internal	1,0	1,1	1	2,1	0,1	0,1	0,2	0,4	0,0	No
National Essential Medicines List Committee (NEMLC)	Internal	3,8	4,5	1	8,3	1,2	2,6	2,4	6,2	2,7	Yes
National Health Council (NHC)	Internal	2,6	4,0	1	6,6	2,7	0,6	1,1	4,4	2,6	Yes
National Programmes	Internal	2,4	3,9	1	6,3	1,0	1,4	2,4	4,8	2,2	Yes
National Treasury	External	4,2	3,9	1	8,1	3,0	2,7	2,8	8,5	2,8	Yes
Patients	External	1,2	1,9	1	3,1	0,1	0,2	0,2	0,5	0,3	No
Pharmaceutical Therapeutic Committee (PTC)	Internal	3,2	4,1	1	7,3	2,6	2,6	3,0	8,2	0,8	Yes
Pricing committee (NHI document and the other MACs)	Internal	4,1	3,0	1	7,1	1,9	2,2	3,0	7,1	0,9	Yes
Private medical schemes	External	2,9	4,4	1	7,3	0,6	0,4	0,3	1,3	1,2	Yes
Provincial Budget holders (chief financial officer)	Internal	2,3	3,2	1	5,5	2,4	2,7	1,9	7,0	1,2	Yes
Provincial Medicine Procurement Unit (PMPU)	Internal	2,1	4,0	1	6,1	2,5	2,6	2,1	7,2	1,6	No
Provincial Pharmaceutical Therapeutic Committees (PPTCs)	Internal	3,3	3,5	1	6,8	2,7	2,2	2,7	7,6	0,9	Yes
South African Health Regulatory Authority (SAHPRA)	Internal	1,9	2,1	1	4	1,4	0,9	0,7	3,0	0,9	No
Suppliers	External	2,6	4,1	1	6,7	2,2	2,8	2,0	7,0	2,5	No
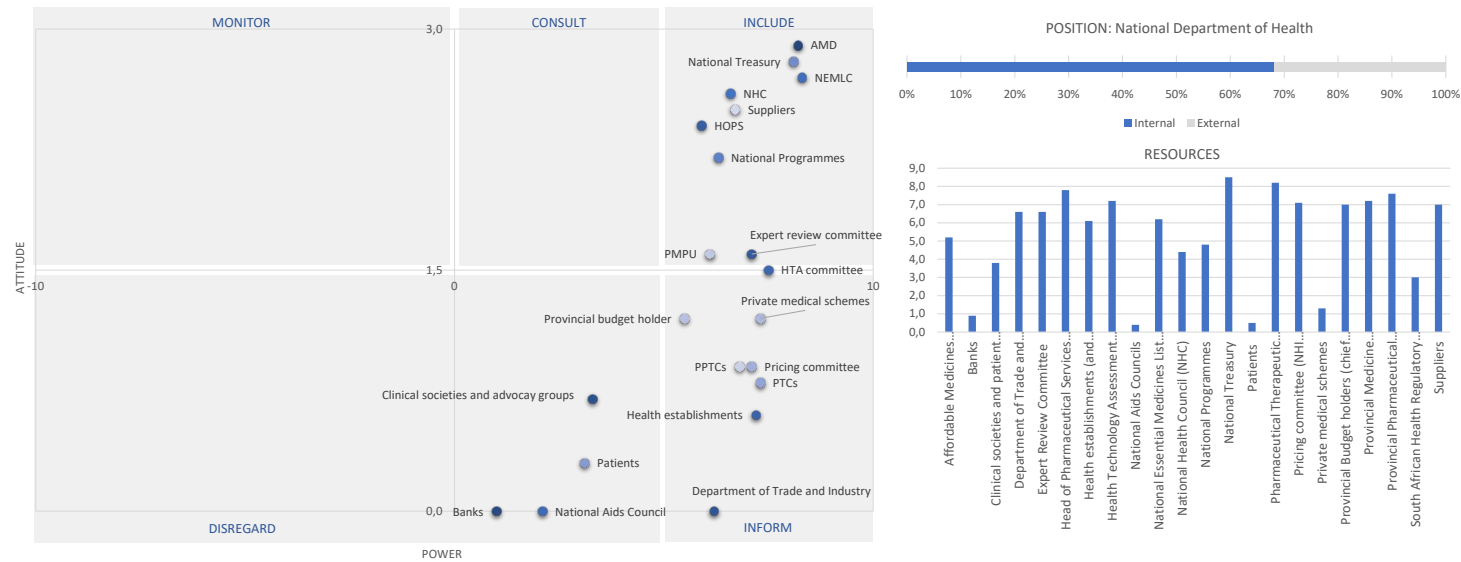
Figure R.3: Stakeholder analysis for policy option 3

STAKEHOLDER ANALYSIS	POLICY OPTION 4: Procurement card (``Government Credit Card")									
Stakeholders	Position	Knowledge	Interest	Support	Attitude	Financial Resources	Political Resources	Human Resources	Total Resources	Power	Opinion leaders
Affordable Medicines Directiorate (AMD)	Internal	3,9	3,9	1	7,8	2,2	0	3	5,2	2,9	Yes
Banks	External	0,1	0,9	1	1	0,0	0,6	0,3	0,9	0,0	No
Clinical societies and patient advocacy groups	External	0,1	0,9	1	1	0,9	2,2	0,7	3,8	0,7	No
Department of Trade and Industry (DTI)	External	4,4	1,2	1	5,6	2,1	2,3	2,2	6,6	0,0	No
Expert Review Committee	Internal	1,2	4,1	1	5,3	1,1	2,8	2,7	6,6	1,6	Yes
Head of Pharmaceutical Services (HOPS)	Internal	4,7	3,4	1	8,1	2,6	3,0	2,2	7,8	2,4	Yes
Health establishments (and service delivery platform, i.e. school healthcare services)	Internal	1,8	1,1	1	2,9	1,4	2,3	2,4	6,1	0,6	No
Health Technology Assessment (HTA) committee	Internal	1,2	2,0	1	3,2	1,7	2,8	2,7	7,2	1,5	Yes
National Aids Councils	Internal	1,0	1,2	1	2,2	0,1	0,1	0,2	0,4	0,0	No
National Essential Medicines List Committee (NEMLC)	Internal	2,1	3,7	1	5,8	1,2	2,6	2,4	6,2	2,7	Yes
National Health Council (NHC)	Internal	3,9	4,8	1	8,7	2,7	0,6	1,1	4,4	2,6	Yes
National Programmes	Internal	3,6	4,6	1	8,2	1,0	1,4	2,4	4,8	2,2	Yes
National Treasury	External	4,1	3,1	-1	-7,2	3,0	2,7	2,8	8,5	2,8	Yes
Patients	External	0,1	0,8	1	0,9	0,1	0,2	0,2	0,5	0,3	No
Pharmaceutical Therapeutic Committee (PTC)	Internal	3,6	3,9	1	7,5	2,6	2,6	3,0	8,2	0,8	Yes
Pricing committee (NHI document and the other MACs)	Internal	2,1	1,9	1	4	1,9	2,2	3,0	7,1	0,9	Yes
Private medical schemes	External	0,6	1,1	1	1,7	0,6	0,4	0,3	1,3	1,2	Yes
Provincial Budget holders (chief financial officer)	Internal	4,6	3,0	1	7,6	2,4	2,7	1,9	7,0	1,2	Yes
Provincial Medicine Procurement Unit (PMPU)	Internal	3,5	3,6	1	7,1	2,5	2,6	2,1	7,2	1,6	No
Provincial Pharmaceutical Therapeutic Committees (PPTCs)	Internal	4,6	2,2	1	6,8	2,7	2,2	2,7	7,6	0,9	Yes
South African Health Regulatory Authority (SAHPRA)	Internal	1,3	1,1	1	2,4	1,4	0,9	0,7	3,0	0,9	No
Suppliers	External	3,1	3,8	1	6,9	2,2	2,8	2,0	7,0	2,5	No
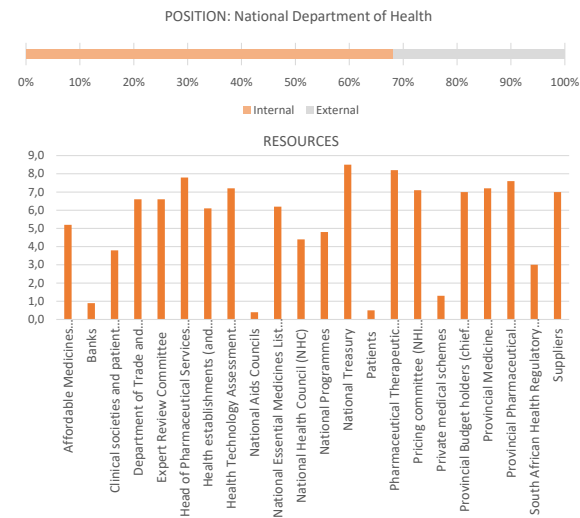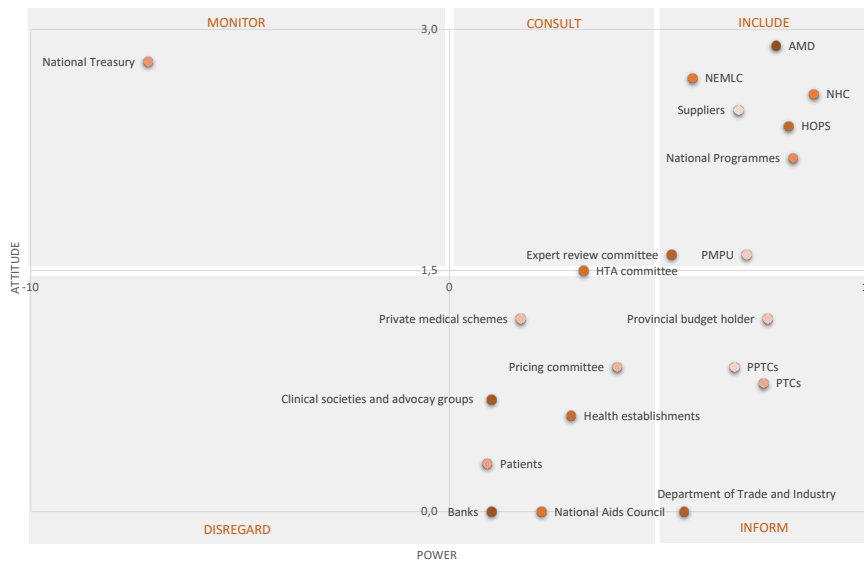
Figure R.4: Stakeholder analysis for policy option 4

The power characteristic is the level of power that a stakeholder has to influence the policy option. The power-attitude map was used to categorise the stakeholders according to their suggested degree of involvement in the policy process: include, inform, consult or disregard.

Stakeholder influence and access to resources

For the second analysis, the degree of a stakeholders' access to resources (financial, political or human) is provided in a bar diagram. The outcome of the power-attitude map was investigated and when an outlier was identified—stakeholders not supportive of the policy option—their access to resources were investigated to determine the influence they could potentially have. This information is then utilised to decide whether the SMEs wanted to change a stakeholder's involvement status. The resources could also be combined with the 'opinion leader' attribute, which are complimenting characteristics. Their level of access to resources and their ability to persuade the political or human resources could provide useful insight to manage these stakeholders.

It was also noticed when populating the stakeholder evaluation tables, that the 'resources' attribute for each stakeholder is be constant across the different policies. This is because the degree to which these stakeholders have access to resources are independent of the policy being addressed. Similar can be said for the 'power' attribute.

Stakeholder position analysis

For this analysis the percentage of internal vs. external stakeholders are given. The third analysis will most likely be the same for all policy options considered in the analysis, because the stakeholders' position is a constant characteristic. The type of position for the analysis should be identified. In this case study, the position within the National Department of Health was used to identify which department would be responsible for the policy implementation.

The interpretation of the results from the evaluation tables are further discussed in Section R.6, where the best policy option decision is made and the policy strategies are discussed. The next section discusses the fifth phase in the PoliVAN logic model, the policy impact analysis. The interaction between Phase 4 and Phase 5 is also discussed in the next section.

R.5   Policy impact analysis for the policy options

In this section, the application of the policy impact analysis tool is illustrated and discussed. This section starts with the selection and breakdown of the analytical dimensions, then the policy impact analysis tool is set up and populated with inputs from the SMEs that formed part of the workshop. Finally, an interpretation of the analysis done with the selection of the best policy option to address the policy problem identified during Phase 2 of the case study.

R.5.1 Selecting appropriate analytical dimensions and weightings for the medicine selection case

The policy impact analysis is constructed by making use of the analytical dimensions as provided by Table 7.8. The SMEs from the case study workshop suggested that all of the analytical dimensions should be included for this specific case study. The dimensions are further broken down into sub- and sub-subdimensions as describes by their description in Table 7.8 (see the analytical dimensions used in this study in Figure R.5).

As mentioned during the development of the PoliVAN model, the decision to include or remove dimensions from the analysis is completely up to the analysts responsible for applying the PoliVAN to their specific VAN case study, but it is recommended that careful thought is given to the inclusion and removal of analytical dimensions.

Given that each country has a different context and objective with regards to the VAN Operating Model, it is recommended that the weighting factors be included whenever the PoliVAN logic model is applied. There are many sources available that propose sophisticated methods on how to carefully select and assign the weighting factors in order to avoid subjectivity (e.g. Song & Kang (2016) propose three different methods: (i) the normal weighted sum method; (ii) an analytical hierarchy process method that assigns weights according to the dimension's hierarchical level; and (iii) the technique for order preference by similarity to the ideal solution).

In this case study, The weighting factor for each dimension was assigned during the workshop. The 'criticality' and 'feasibility' dimensions were given the highest weighting preference of 30% and 25% respectively. The reason for this was because the policy options are designed to enable the link between medicine selection and the procurement functions. The third-highest weighting preference of 15% was given to the 'acceptability' dimension. The reason for this was because the policy option sits within the legislation of three departments: the NDoH, National Treasury and the Department of Trade and Industry. Thus, numerous different stakeholders are involved. The rest of the dimensions were given either 5% or 10% preference.

R.5.2 Policy impact analysis table and discussion

The analytical dimensions are given a range metrics and scores to evaluate the different policy options based on the possible impact it could have on the pharmaceutical supply chain system. These metrics are developed from the scoring table (Table 7.9) in Chapter 7.

The evaluation table for the policy impact analysis is presented Table R.6. The scoring method used are also given in the table with the direction of preference already being incorporated. The total score is calculated by the total sum of all the scores given and the
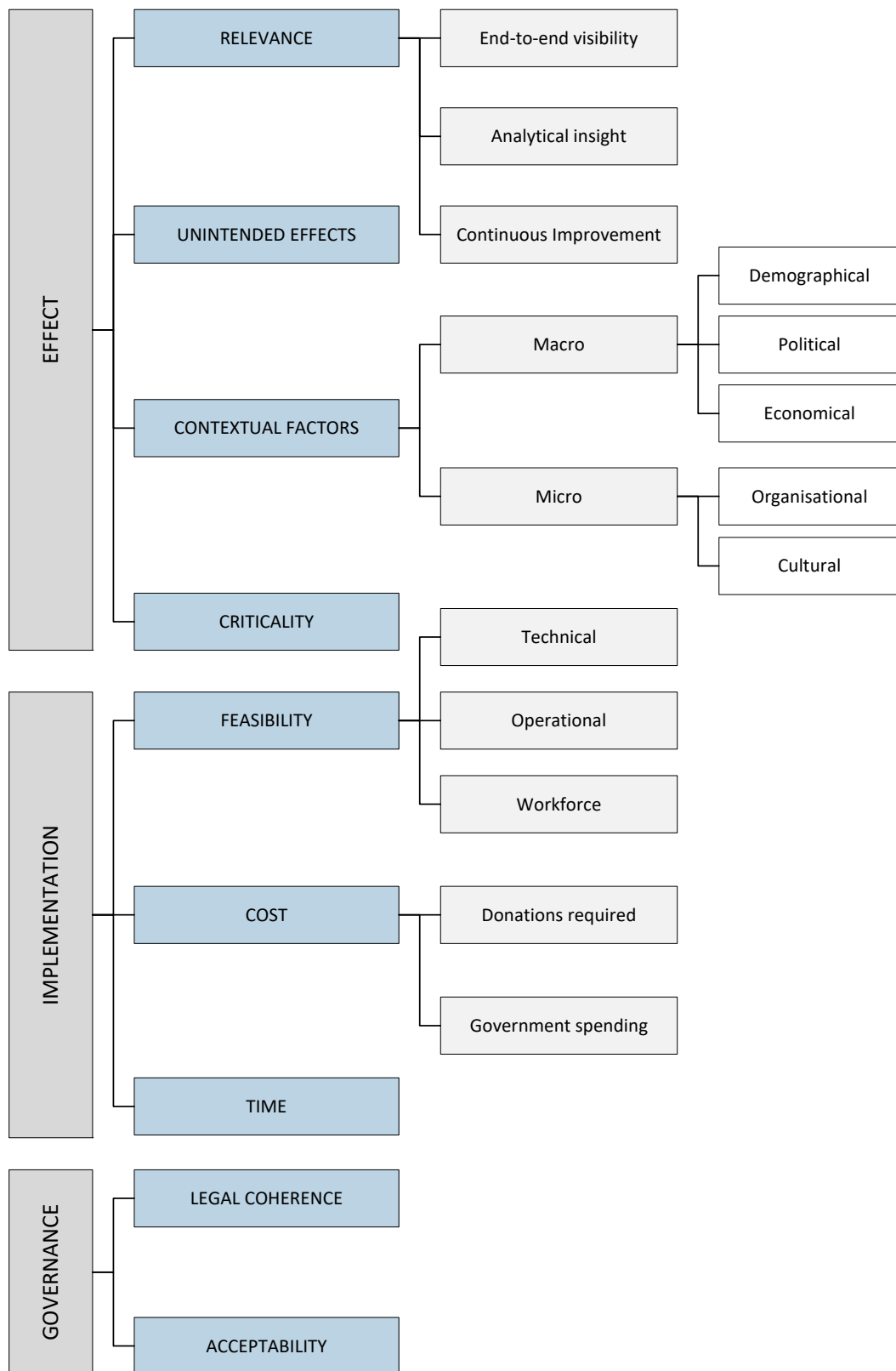
Figure R.5: Analytical dimensions constructed for this case study

maximum available total score is 70. The total weighted score is calculated by the sum of the weighted averages. The data in the table was populated with inputs from the SMEs during the workshop and the 'acceptability' dimension was scored after the completion the stakeholder analysis. The acceptability is scored according to the percentage of stakeholder in support of the policy option. The support percentage for policy options 1 to 4 are: 96%, 96%, 100% and 96% respectively. This means that each policy option is scored a '5' on the metric scale.

As seen on the evaluation table, policy option 1 has the best overall weighted outcome among the four policy options—the option with the least impact on the pharmaceutical supply chain. Using the information from Table R.6, the following conclusions are drawn (this is also a description of how the analysis can be understood):

- The policy option is relevant to two of the three main objectives of the VAN, which provides a level of analysis to inform decision-making for both the AMD and programmes by providing visibility by therapeutic programme.

- The probability of the policy option to produce unintended effects is very low.

- The probability for contextual factors to influence the success of the policy option is very low.

- The criticality of the policy option is high as this will impact the selection, contracting, and potentially the rational use of medicines[1].

- For the technical feasibility, the policy option is dependent on the ePrescribing tool which is currently in development. Access is required to the warehouse management system for procurement and contracting. The vision is that all the systems should be interoperable, but these systems are at the moment working in isolation. For the operational feasibility, the majority of the operations remain the same, therapeutic classes have already been established; however, slight operational changes might need to occur within the contracting of medicines. For the workforce feasibility, this policy only requires initial training, but no additional workforce is required.

- From the alignment matrix done in Phase 2, there are no hindering possibilities from a policy or legislation perspective; however, a prescriptive policy should be considered.

The outputs and insight produced by the preceding phases are use to develop policy decision plans and strategies. The strategies identified in this case study are discussed in the next section.

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[1]Monitoring medicines and the contracts differently might change how medicines are used.

Table R.6: Policy impact analysis evaluation table for the medicine selection case study

Categories	EFFECT									
Weight	5%			5%	5%					30%
Dimensions	RELEVANCE			UNINTENDED EFFECTS	CONTEXTUAL FACTORS					CRITICALITY
					Macro			Micro		
	End-to-end visibility	Analytical insight	Continuous improvement		Demographical	Political	Economical	Organisational	Cultural	
Policy Option 1	5	2	5	5	3	3	3	2	3	4
Policy Option 2	5	4	0	5	3	1	2	1	3	4
Policy Option 3	1	1	3	5	3	2	2	2	3	2
Policy Option 4	2	2	5	4	3	2	1	2	2	2
Scoring Metrics	5 - Highly relevant 4 - Relevant 3 - Moderately relevant 2 - Slightly relevant 1 - Little/no relevance			5 - 0% → 20% 4 - 20% → 30 % 3 - 30% → 50% 2 - 50% → 70% 1 - 70% → 80%	3 - Low impact 2 - Moderate impact 1 - High impact					0 - Very high affect 1 - High affect 2 - Moderate affect 3 - Slight affect 4 - Little affect 5 - No affect

Categories	IMPLEMENTATION					GOVERNANCE			TOTAL SCORE	TOTAL WEIGHTED SCORE
Weight	20%			10%		5%	15%	5%		
Dimensions	FEASIBILITY			COST		TIME	Acceptability	Legal Coherence		
	Technical	Operational	Workforce	Donations required	Government spending					
Policy Option 1	2	3	2	3	3	3	5	5	61	53,10
Policy Option 2	3	2	2	1	2	2	5	3	48	45,90
Policy Option 3	2	2	3	3	2	3	5	2	46	41,40
Policy Option 4	3	3	2	3	3	4	5	5	53	46,35
Scoring Metrics	3 - Feasible 2 - Moderately feasibly 1 - Slightly feasible 0 - Not feasible			3 - Low/no input required 2 - Moderate input required 1 - Big input required		5 - Weeks 4 - Months 3 - A year 2 - A few years 1 - Multiple years	5 - 80% → 100% 4 - 70% → 80% 3 - 50% → 70% 2 - 30% → 50% 1 - 20% → 30%	5 - No effort 4 - Low effort 3 - Moderate effort 2 - High effort 1 - very high effort		

R.5 Policy impact analysis for the policy options

R.6   Medicine selection policy decision and recommendations

The final phase of the PoliVAN logic model is where the outputs and analysis outcomes from the preceding phases are used to make informed policy decisions and strategies. The policy option that is considered the best approach for the policy problem is to change contracting clustering to contracting of medicines by therapeutic categories, such as HIV, TB, antibiotics and cardiovascular (Policy option 1). The details of this policy option are available in Table R.5. Although the term 'policy' has been used throughout this entire analysis, legislations, such as regulations, guidelines and SOPs were also be taken into consideration during this analysis.

The first thing to determine is the level at which the policy should be designed. For example, a recommendation would be to make it a policy statement, where it stipulates within specific guidelines such as the formulary guidelines (National Department of Health (2018b)) the development and management of formularies according to therapeutic area. However, the policy should be supported through mandatory legislations, such as the Medicines and Related Substances Act 72 of 2008 and Act 14 of 2015 that govern the management of the medicines or a regulation from the Department of Trade and Industry regarding contracts or contract terms. The alignment matrix from Phase 2 is useful to identify the degree of alignment between other policies or legislation. Figure R.6 illustrates the correlation matrix for the formulary guidelines in detail, with a discussion that follows.

- The guideline **aligns** with the Medicines and Related Substances Act concerning the procurement and supply of medicines.

- The guideline **strongly aligns** with the rule relating to good pharmacy practice, which stipulates the minimum standards for the selection of pharmaceuticals by institutional pharmacies (Rule 2.4.1).

- The guideline **strongly aligns** with the National Drug Policy, as this policy promotes the establishment of PTCs (Section 7.5).

- The guideline **strongly aligns** with the National policy for the Establishment and Functioning of Pharmaceutical Therapeutics Committees in South Africa, based on Section 10 and 12.

- The guideline **strongly aligns** with the Essential Medicines List and Standard Treatment Guidelines for PHC level. The Formulary is a list of medicines that is approved for use in the healthcare system by authorised prescribers and dispensers, and it is used to determine the medicines to be selected for the EML and STGs.

If Policy option 1 is design as a policy statement and the details are stipulated within the formulary guidelines, then the policies and/or legislation which are aligned and strongly aligned

Figure R.6: Analytical dimensions constructed for this case study

should be monitored to ensure that the newly formulated policy is well structured within the legal hierarchy and existing policies. To completely design the policy is beyond the scope of this study; however, the details in the policy formulation table can be used as the initial design step (Step 3.4 in Phase 3) and can further be updated and refined by incorporating the insights from the stakeholder- and policy impact analysis.

One of the key design plans proposed in this phase is a stakeholder management and engagement plan. To include a stakeholder management plan in the policy design, the stakeholder evaluation table needs to be analysed to develop a strategy of how to engage with the stakeholders during the final decisions, adoption and implementation of the policy option. As discussed, three types of analyses can be done. The first type is to identify which stakeholders to involve in the policy process. In Section 7.6, the stakeholder map is defined as a visual approach to map stakeholders according to their characteristics. Some stakeholder maps can either use complimentary or competing characteristics. The power-attitude map (which are competing characteristics) is generally used in practice to identify which stakeholders to involve

or disregard from the policy process. The attitude is calculated by combining the knowledge and interest score, and multiplying it by the support. The power characteristic is a score given according to the stakeholders ability to affect the implementation of the policy.

Figure R.7 illustrates the stakeholder map for policy option 1. The map is also divided by the different involvement categories and it is clear which stakeholder to involve or disregard.
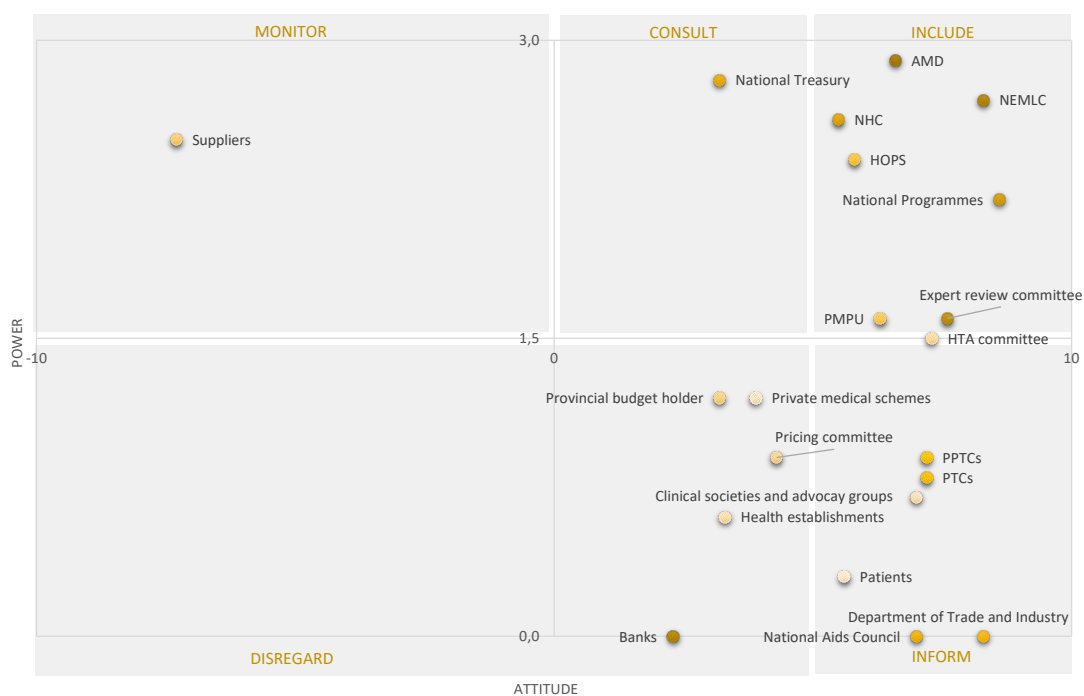
Figure R.7: Power-attitude stakeholder map for policy option 1

The map provides a clear distinction between the stakeholders to keep informed in the policy process, and those to disregard from the policy process. From the way in which the stakeholders are grouped, and taking into account who they are and their relevance to the policy option, it is clear that the policy map provided relatively accurate outputs; however, some minor changes can be recommended based on the 'resources' attribute. Which makes use of the second type of analysis

From the schematic, only the National Treasury needs to be consulted during the policy process. The difference between the consulting a stakeholder and including the stakeholder, is that stakeholders are consulted to gather their opinions (because they have high power), but their opinions are not necessarily taken into account because of their attitude score, which includes the 'knowledge'[1] attribute. However, it is clear the National Treasury has access to many resources (meaning, that they have the capacity and ability to access financial, political

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[1] The level of knowledge that a stakeholder has with regards to a specific policy option.

and human/workforce resources), therefore it is recommended that the National Treasury should be included in the decision-making process.

The Health Technology Assessment (HTA) committee (a borderlin case on the horizontal axis), which is a committee established by the National Health Insurance (NHI) policy, responsible for reviewing the "range of health interventions and technology using the best available evidence on cost-effectiveness, allocative, productive and technical efficiency and HTA. It will consist of a panel of multi-disciplinary experts to recommend prioritisation, selection, distribution, management and introduction of interventions for health promotion, disease prevention, diagnosis, treatment and rehabilitation" (National Department of Health, 2017e). Because the VAN is intended to be implemented in the context of the NHI policy (Llewellyn, 2016), and they have a high score with access to resources; it is recommended that the HTA committee should rather be included in the decision-making process.

Another change that is recommended, is to move the patients from the 'keep informed list' to the 'disregarded list', because although they are interested and impacted (positively) by the policy option, they do not have access to many resources as in the cases of the National Treasury or HTA committee. However, the same cannot be said for the National Aids Council. Although their access to resources is also relatively low, they do have far more interest in the contracting of medicines by therapeutic area, than the patients.

The third type of analysis is to determine the balance between the internal and external stakeholders' power characteristics. This analysis is done to determine whether the National Department of Health potentially has the power to manage the policy process. The internal and external characteristics were focused on the stakeholders role within the government. From the evaluation table in Figure R.1, it is clear that almost 70% of the stakeholders are internal and work within the provision of the National Department of Health. Thus, it is advised that the National Department of takes ownership of the policy process. Phase 6 of the PoliVAN logic model also suggest that other strategy plans, such as an implementation plan and risk management plan need to be included into the policy strategy process; however, due to the fact that the case study is done to illustrate the application of the PoliVAN logic model, the development of such a plan is deemed beyond the scope of the case study. This concludes Phase 6, and ultimately the application of the PoliVAN logic model to the selection of medicine function.

R.7 Appendix R: Conclusion

In this appendix, the application of the PoliVAN model proceeded systematically through the six phases, where detailed accounts of the different analyses within each phase of the PoliVAN model are presented.Each phase in the logic model produced the expected outputs stipulated

for each phase. Altogether, the insights and the accumulation of information gathered were sufficient to make the necessary policy decisions and strategies. Although, the scope[1] was limited for illustrative purposes, the insights provided by the outcomes were sufficient to make a thorough policy decision. During the process of the application, some key findings in terms of the applicability of the PoliVAN logic model were identified. These findings are discussed in Section 8.5.

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[1]An attempt was made to strike a balance between demonstrating the applicability and the flexibility of the PoliVAN as comprehensively and thoroughly as possible whilst constraining the case study to a feasible scope

Appendix S

Case study 2: inventory management

In this appendix, the practical application of the desktop review case study is provided with sufficient details on how the case study was performed. Some key findings from the application of this case study are available in Section 8.4. The sequence of this appendix follows the first five phases of the PoliVAN logic model, which is discussed in detail in Chapter 7. The sixth phase is where the outcome from the previous five phases are analysed to determine the best policy decisions and strategies. Due to the scope of the case study workshop, the sixth phase is not done as proposed by the PoliVAN logic model; however, recommendations are provided based on the outcomes. The detailed version of the case study is provided in this appendix, whereas the outcomes and interpretation of the outcomes are provided in Chapter 8.

S.1 The inventory management policy landscape

In this section the first phase of the PoliVAN logic model is applied to the inventory management operational function. The updated supply plan from the South African VAN Operating Model (Appendix Q) is used to identify the inventory management operational functions of a pharmaceutical supply chain that are relevant to the VAN, and subsequently identify the relevant policies and legislations governing those processes.

S.1.1 Identifying the key inventory management functions

The PLF-VAN-matrix tool is presented Table S.1 to illustrate the link between South Africa's VAN Operating Model and pharmaceutical supply chain system, based on the pharmaceutical logistics framework (PLF) components. From the table, it is clear that the inventory functions are all documented in the supply plan (the 2018 version) of South Africa's VAN Operating Model. The inventory management operational functions that South Africa's VAN is concerned with is 'inventory control', 'supplier requisition and allocation', 'requisition / ordering', and 'managing expired stocks'. Although storage is a critical part of inventory management, the supply plan does not explicitly focus on this function, but rather the distribution plan of the

South African VAN. These functions, including those of the management support elements subsequently highlight the governing policies and legislations which need to be identified. The policies and legislation that are identified are discussed in the next subsection.

Table S.1: The inventory management section from the PLF-VAN-matrix

PHARMACEUTICAL LOGISTICS FRAMEWORK	VAN PLANNING PROCESSES		
OPERATIONAL COMPONENTS	DEMAND PLAN [1]	SUPPLY PLAN [2]	DISTRIBUTION PLAN [3]
Inventory management			
Product inspection (CMS)			
Inventory control		X	
Storage			
Supplier requisition allocation		X	
Requisition/ordering		X	
Expired medicine management		X	
MANAGEMENT SUPPORT ELEMENTS	DEMAND PLAN [1]	SUPPLY PLAN [2]	DISTRIBUTION PLAN [3]
Information System			
Pharmaceutical management information system		X	
Indicator-based monitoring		X	
Integrated network		X	
Organisation and HR management			
Personnel management		X	
Education and training		X	
Accountability		X	
Reporting and organisational structures		X	
Financial and donor coordination			
Financing and budgeting strategies			
Analyse and control expenditures		X	
Donor financing			
Monitoring and evaluation			
Programme planning and implementation			
Monitoring and evaluation (key performance indicators.)		X	
[1] Demand plan version 2, September 2018. [2] Supply plan version 2, July 2018/2019. The latest version is currently being updated. [3] Distribution planning version 1, October 2016.			

S.1.2 Categorising relevant inventory management policies and legislation

The following list of policies and legislation are those involving the functions within the inventory management component of the pharmaceutical logistics framework. These are only the documents that are available in the public domain, although there could be other policies and legislations available. The majority of the policies and legislation are retrieved from the National Department of Health (NDoH) and National Treasury websites. The list below has also been validated by SMEs (P3 and P10 from the SME table in Appendix L). Throughout the following subsections, each document is identified according to the legislation hierarchy, along with a brief description–for the sake of diligence–of its main objective.

S.1.2.1 Laws

Constitution of the Republic of South Africa, 1996

As stated by Tibane *et al.* (2016): "The Constitution is the supreme law of the land. No other law or government action can supersede the provisions of the Constitution."

In terms of Section 27(1)(a) of the Constitution, "everyone has the right to have access to health care services, including reproductive health care" and that (3) "no one may be refused emergency medical treatment". In terms of Section 28(1)(c), "every child has the right to basic nutrition, shelter, basic health care services and social services" (Parliament of the Republic of South Africa, 2005).

Section 40 of the Constitution sets the rules for how government works. There are three spheres of government in South Africa: National government; Provincial government; and Local government. The spheres of government are autonomous, and the Constitution says that the spheres of government are "distinctive, inter-related and inter-dependent" (Parliament of the Republic of South Africa, 2005). Section 104 (1) The legislative authority of a province is vested in its provincial legislature; however, according to Section 146, "National legislation that applies uniformly with regard to the country as a whole prevails over provincial legislation" (Parliament of the Republic of South Africa, 2005).

S.1.2.2 Acts

National Health Act 61 of 2003

"To provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services; and to provide for matters connected therewith" (South African Government, 2004).

Public Finance Management Act 1 of 1999 (PFMA)

"To regulate financial management in the national government and provincial governments to ensure that all revenue, expenditure, assets and liabilities of those governments are managed efficiently and effectively to provide for the responsibilities of persons entrusted with financial management in those governments and to provide for matters connected therewith" (National Treasury, 2017).

Municipal Finance Management Act 56 of 2003 (MFMA)

"To secure sound and sustainable management of the financial affairs of municipalities and other institutions in the local sphere of government; to establish treasury norms and standards

for the local sphere of government; and to provide for matters connected therewith" (National Treasury, 2003a).

Medicines and Related Substances Act 72 of 2008 and Act 14 of 2015

The Amendment Act 72 of 2008, must be read together with a further Amendment Act, being the Medicines and Related Substances Amendment Act 14 of 2015. Both Amendment Acts come into force simultaneously and give effect to numerous amendments to the Medicines Act.

National Health Insurance Policy (Bill) 2019

The purpose of this Act is to "establish and maintain a National Health Insurance Fund in the Republic funded through mandatory prepayment that aims to achieve sustainable and affordable universal access to quality health care services" (Republic of South Africa, 2019).

S.1.2.3   Regulations

Norms and Standards Regulations Applicable to Different Categories of Health Establishments in terms of section 90(1A) of the National Health Act 61 of 2003

"These Regulations apply to all health establishments to the extent indicated in these Regulations." "The purpose of these Regulations is to promote and protect the health and safety of users and health care personnel" (National Department of Health, 2018c).

General regulations in terms of section 35 of the Medicines and Related Substances Act 101 of 1965

"The Minister of Health, in consultation with the Authority, intends in terms of section 35 of the Medicines and Related Substances Act 101 of 1965, to make the Regulations in the Schedule". "The Regulations are intended to give effect to the Medicines and Related Substances Amendment Act 72 of 2008, and the Medicines and Related Substances Amendment Act 14 of 2015, once the said Acts are brought into operation" (National Department of Health, 2017c).

Supply Chain Management Policies in terms of MFMA

Regulations set out by the Minister of Finance to establish supply chain management policies in terms of the Municipal Finance Management Act (National Treasury, 2005).

S.1.2.4   Policies

National Health Insurance Policy (White paper) 2017

As stated in the white paper published by National Department of Health (2017e): this policy "lays the foundation for moving South Africa towards universal health coverage (UHC) through

the implementation of National Health Insurance (NHI) and establishment of a unified health system. The move towards Universal Health Coverage (UHC) through implementation of NHI is derived from the following: The Reconstruction and Development Programme (RDP); the Constitutional mandate based on the Section 27 of the Constitution; the 1997 White Paper for the Transformation of the Health System; and Vision 2030 of the National Development Plan Vision 2030."

National Drug Policy

The National Drug Policy, adopted in 1996, serves the healthcare needs of South Africa in the following ways (National Department of Health, 1996): (i) it offers a description of the approach by which pharmaceutical services in the country will be managed; (ii) it offers guidance to stakeholders, health care providers, suppliers of goods and services, and governmental and non-governmental agencies of ways in which they can contribute to achieving the policy's main aim; (iii) it follows a clear and logical system for reducing inefficiency and waste and improving efficiency and effectiveness through the development of an adequate pharmaceutical infrastructure; and (iv) it facilitates the design, production and implementation of appropriate programmes for human resource development in health care (National Department of Health, 1996).

National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa (2015)

As provided in the policy document by National Department of Health (2015b): "the purpose of the National Policy for the Establishment and Functioning of Pharmaceutical and Therapeutics Committees in South Africa is to provide standards for the establishment of a non-statutory, multidisciplinary, advisory committee, to be called the Pharmaceutical and Therapeutics Committee (PTC) in all provinces, districts and institutions in South Africa." "The PTC shall be committed to the governance of an effective medicines management system to provide equitable and reliable access to medicines and quality care while making the best use of available resources" (National Department of Health, 2015b).

Supply Chain Management Policy (Western Cape)

The aim of this policy is to provide a supply chain framework to ensure sound, sustainable and accountable management within the City of Cape Town. This policy also aim to ensure uniformity in the supply chain management systems between different organisational level, in all spheres (National Department of Trade and Industry, 2011).

Policy Strategy to Guide Uniformity in Procurement Reform Processes

This policy strategy aims to promote uniformity in the all spheres of government, interpreting the governments preferential procurement legislation and policies. This policy is also "introducing parameters for the promulgation of a regulatory framework in terms of the PFMA and MFMA to ensure compliance to minimum norms and standards" (National Treasury, 2003b).

S.1.2.5 Rules and guidelines

MCC Good Warehousing Practices

The aim of this guideline is to provide guidance for the distribution of pharmaceutical products, which applies to both products for human and for veterinary use as per Act 101 National Department of Health (2016a).

Rules relating to Good Pharmacy Practice

Rules relating to good pharmacy practice in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974. The South African Pharmacy Council (SAPC) has developed the Good Pharmacy Practice (GPP) standards. According to The South African Pharmacy Council (2010), "the aim of the GPP standards is to ensure that all practising pharmacists and other health care professionals provide a service of high quality for the public and private sector alike. Council therefore encourages every health care professional providing medicine to the public, to embrace the document and support its implementation."

National Guideline for the Establishment and Functioning of PTCs (2019)

The aim of this document is provide guidelines and management tools for the use by Pharmaceutical Therapeutic Committees (PTCs) to "promoting an outcomes-based approach for good governance and rational selection and medicine use in the functioning of these bodies". The guidelines further aim to standardise the functions, roles, responsibilities and objectives for all PTCs (National Department of Health, 2019).

Guideline for Accounting Officer in accordance with PFMA

This Guide intents to facilitate a general understanding of the changes to supply chain management practices. It is a guideline to assist accounting officers in the implementation of supply chain management functions in their institution (National Treasury, 2000).

S.1.2.6   Standard operating procedures

Competency Standards for Pharmacists in South Africa in terms of Section 33(o) of the Pharmacy Act 53 of 1974

The competency standards is a "tool to help the professionals assess their own learning needs. Gaps in knowledge, skills, attitudes and values are identified by comparing personal knowledge, skills, attitudes and values with those required by the competency standards. Competency standards have also been structured to assist with identifying areas, within current or future practice, that may require modification and/or improvement in knowledge, skills, attitudes and values" (South African Pharmacy Council, 2018).

District Health Planning and Monitoring Framework

"These guidelines recognise that District Planning, Budgeting, and Monitoring is a single objective and it therefore strives to streamline the process. The revised District Planning and monitoring system is an effort to improve both efficiency and effectiveness of the process, thereby promoting better service delivery of District Health Services and improve health outcomes in South Africa through a direct focus on planning and monitoring for implementation" (National Department of Health, 2017b).

Primary Healthcare Standard Operating Procedures (Eastern Cape)

This document is a toolkit that contains Standard Operating Procedures (SOPs) applicable to pharmaceutical services in the Eastern Cape Province. These SOPs are in line with the National Core Standards, Ideal Clinic standards and Good Pharmacy Practice (Eastern Cape Department of Health).

Primary Healthcare Standard Operating Procedures (Limpopo)

This document contains Standard Operating Procedures (SOPs) applicable to pharmaceutical services in the Limpopo. These SOPs are in line with the National Core Standards, Ideal Clinic standards and Good Pharmacy Practice (Limpopo Department of Health, 2014).

Ideal Clinic Manual Version 18 (2018)

This manual is a reference document which guides the managers to determine the status of Ideal Clinic dashboard elements in a facility. The manual is a useful tool for managers at sub-district, district, provincial and national level to ensure progressive discipline of those reporting to them (National Department of Health, 2018a).

S.2   Sorting the inventory management policies

The policies and legislations identified in the previous section are used to assess the effect on the VAN Operating Model, specifically focussing on the demand planning category. This section constitute Phase 2 of the PoliVAN logic model. The following subsections progressively sets out the VAN criteria for the analysis, assesses the enabling an/or hindering effect of existing policy and legislation, as well as identify possible policy problems. For the remainder of this appendix and the sake of brevity, the term 'policy' will be used to refer to both policies and legislations.

S.2.1   Supply planning VAN criteria assessment

From the updated supply planning document (Appendix Q), a list of key VAN criteria is identified. These criteria should be met by the system in order for the VAN to function as desired (from an inventory management perspective). A full-day workshop with subject-matter experts (P13 and P15 from the SME Table in Appendix L) was undergone to identify the key VAN criteria. P13 is part of the VAN design project and P15 is currently focused on the development of inventory management policies for the VAN.

Table S.2 provided, is the VAN content assessment table with the VAN criteria and the policies and legislations identified in the previous section. Due to the amount of processes within the inventory management function, categorising the criteria into a number of themes made the analysis more manageable. The assessment indicators are used to illustrate the enabling, facilitating or hindering effect of the policies and legislations on the VAN criteria. The indicators are given after a meticulous look through the various policy documents. Input from SME, P3, was given during this stage when some policy documents were unclear.

The next subsection focuses on the discussion regarding the enabling, facilitating and hindering policies and legislations.

S.2.2   Enabling and hindering policy identification

The South African constitution is not used in the assessment table, as the laws stipulated in the document are high-level and does not directly affect the inventory management operations. However, it does provide the necessary context in order to understand the other policies and legislations. For example, according to the constitution, no patient may be refused healthcare treatment (Parliament of the Republic of South Africa, 2005). In the event of a stock-out, where the budget has already been exceeded, the system should still procure medicine to provide for the patients in need.

Another important law in the South African constitution, is the establishment of provincial governments (each with their own head of department and treasury), which are autonomous

Table S.2: The VAN assessment matrix for inventory management

Legend

Code	Description
E	**Enabling the VAN operationalisation:** The policies and legislation support the VAN Operating Model and no reform is required.
F	**Facilitating the VAN operationalisation** he policies and legislation support the VAN Operating Model; however, there are spects that require reform.
—	**Hindering the VAN operationalisation:** The policies and legislation do not support the VAN Operating Model and the implementation of the VAN could have consequences.
?	**Ambiguous:** The impact of the policies and legislation on the VAN Operating Model cannot be determined because it depends on too many factors.
0	**No impact/effect on the VAN Operationalisation:** The policies and legislation has either no relationship or too much of an indirect relationship with the VAN Operating Model.

Column key (policies/legislation)

1. Ideal Clinic Manual Version 18 (2018)
2. Primary Healthcare Standard Operating Procedures (Limpopo)
3. Primary Healthcare Standard Operating Procedures (Eastern Cape)
4. District Health Planning and Monitoring Framework
5. Competency Standards for Pharmacists in South Africa (2018)
6. Guideline for Accounting Officer in accordance with PFMA
7. National Guideline for the Establishment and Functioning of PTCs
8. Rules Relating to Good Pharmacy Practice
9. MCC Good Warehousing Practices
10. Policy Strategy to Guide Uniformity in Procurement Reform
11. Supply Chain Management Policy (Western Cape)
12. National policy for the establishment and functioning of PTCs
13. National Drug Policy 1996
14. National Health Insurance Policy Bill 2019
15. National Health Insurance Policy (White Paper) 2017
16. Supply Chain Management Regulation in terms of MFMA
17. General Regulations in terms of Section 35 of the Medicines Act
18. Norms and Standards Regulation applicable to Health
19. Medicines and Related Substances Act 72 of 2008 and Act 14 of
20. Municipal Finance Management Act 56 of 2003 (MFMA)
21. Public Finance Management Act 1 of 1999 (PFMA)
22. National Health Act 61 of 2003

Stock capturing and data availability

#	Requirement	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
1	A centralised PMPU should have accessible master data such as product and location data. These include on-hand inventory, open orders, min/max levels, safety stock, lead time, storage capacity per facility and forecast demand per facility or hospital in the respective Province.	E	F	F	?	0	0	0	F	—	?	F	0	?	F	F	F	0	F	E	0	0	?
2	Stock count and data capturing should be done electronically in order to fulfil the informed push approach.	E	F	—	0	E	0	E	?	E	0	0	0	0	?	0	0	0	0	E	0	0	0
3	Facilities and Warehouses should update make their data visible and update quarterly.	E	?	?	E	E	0	E	0	F	0	0	0	0	0	0	0	0	0	0	0	0	?
4	AMD is responsible for managing and governing the data.	0	0	0	0	?	0	E	0	0	E	0	0	0	F	0	0	0	0	0	0	0	E
5	Demand planning forecasting data should be made available by Demand planning PMPU	0	0	0	0	?	0	F	0	0	0	0	0	0	0	E	0	0	0	0	0	0	0

Software tools and information systems

#	Requirement	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
6	All PMPUs should place orders to suppliers and manage budget spending through gCommerce.	—	0	0	0	0	0	?	0	F	0	0	0	E	0	—	?	E	0	0	—	—	0
7	All PMPUs should calculate recommended orders with RxSolution.	0	—	—	0	E	0	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	SVS is used to communicate recommended order and approve recommended.	0	—	—	0	0	0	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	A simple inventory calculation model is used to calculate min/max and safety stock levels in a facility.	E	F	F	0	E	0	0	0	0	0	0	0	E	0	0	F	0	E	0	0	0	0

Inventory calculations

#	Requirement	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
10	The instance of the algorithm should be based on best practices inventory policies. Use lead time, order quantities, shelf life data to calculate min, max, and safety stock per facility by SKU.	F	0	E	0	0	0	0	0	?	0	F	0	E	0	?	0	0	E	0	0	0	0
11	The RxSolution should make use of demand driven material requisition planning (DDMRP) practices to fully support informed push.	?	0	0	0	0	0	0	0	0	0	—	0	0	0	0	0	0	0	0	0	0	0
12	The update inventory calculation model should be used by provinces (PMPU owns the tool and use quarterly).	—	?	0	F	0	0	0	0	0	0	0	0	E	0	0	0	0	F	0	0	0	0
13	Replenishment should be calculated and make use of the VEN and ABC practices. The PTCs are responsible for classifying the VEN categories and PMPU is responsible for calculating ABC.	0	0	0	0	0	0	—	0	0	0	0	0	0	0	0	0	0	0	E	0	0	0

Order requisition and approval

#	Requirement	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
14	PMPU sends order recommendation. Facilities should approve recommended order or make adjustments to orders through SVS.	E	—	—	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	Replenishments should be executed by Suppliers and warehouses.	E	0	0	0	0	0	0	0	E	0	E	0	0	0	E	0	0	0	0	0	0	0
16	The VAN should supply according to forecasted provided by the demand plan.	0	—	—	0	0	0	0	0	0	0	0	0	0	E	0	0	0	0	0	0	0	0

Budget allocation and approval

#	Requirement	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
17	Budget holder is responsible for approving the recommended orders (District level) through gCommerce.	E	0	0	F	0	E	0	F	0	F	?	?	0	E	F	E	0	0	0	—	?	E
18	The inventory targets per province should link to provincial budgets and be monitored by budget spender and approver	?	0	0	?	0	0	0	0	0	0	E	0	E	?	0	F	0	0	0	0	?	0
19	The budget demand plan operations should inform supply planning on the rationing of budget per provinces and SKU. The budget should be disseminated to budget holder role, which need to be at a provincial level according to demand planning guideline.	?	0	0	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	?	0	?	0

Supply chain inventory key performance indicators (KPIs)

#	Requirement	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
20	KPIs should cover all critical processes within supply planning processes, i.e. inventory stock on hand (%); slow moving or obsolete stock (%); order placement to suppliers (%); budget adherence (%); replenishment process cycle times and medicine returns.	F	F	F	0	0	0	F	0	0	0	0	0	0	0	0	F	0	0	0	0	0	?
21	On-time and in-full (OTIF) should be the ultimate metric for supply planning team.	E	E	E	0	0	0	E	0	0	0	0	0	0	E	0	0	E	E	0	E	E	E

Training and education

#	Requirement	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
22	Training and retention op specialised skills in the workforce should be undertaken to implement a PMPU at provincial level.	?	0	0	0	E	0	E	E	0	0	0	0	E	0	E	F	0	0	0	0	0	E

(Parliament of the Republic of South Africa, 2005). For the VAN to be integrated and operate as intended, this is probably one of the biggest obstacle regarding policy-making. Every province has the authority to pass and enforce legislation, as long as it is enabled by national legislation (Parliament of the Republic of South Africa, 2005). Therefore, this law in the constitution should be kept in mind when making policy decisions.

The rest of the policies and legislation are analysed in Table S.2 and categorised according to the assessment indicators. Due to the number of VAN criteria, some policies might enable a group of VAN criteria, but hinder other criteria. The following categories are made based on the policies and legislations that specifically require reform or change (meaning they impose a risk on the operation of the VAN).

Ambiguous or no-effect: The South African Constitution and National Policy for Establishing and Functioning of PTCs 2015.

Enabling effect: Medicines and Related Substances Act 72 of 2008 and Act 14 of 2015; National Health Act 61 of 2003; General Regulations in terms of Section 35 of the Medicines Act; National Drug Policy 1996; Guideline for Accounting Officer in accordance with PFMA; and Competency Standards for Pharmacists in South Africa (2018).

Facilitating effect: Norms and Standards Regulation applicable to Health Establishments; Supply Chain Management Regulation in terms of MFMA; National Health Insurance Policy Bill 2019; Policy Strategy to Guide Uniformity in Procurement Reform Processes; Rules Relating to Good Pharmacy Practice; and District Health Planning and Monitoring Framework.

Hindering effect: Public Finance Management Act 1 of 1999; Municipal Finance Management Act 56 of 2003; National Health Insurance Policy (White Paper) 2017; Supply Chain Management Policy (Western Cape); MCC Good Warehousing Practices; National Guideline for the Establishment and Functioning of PTCs 2019; Primary Healthcare Standard Operating Procedures (Eastern Cape); Primary Healthcare Standard Operating Procedures (Limpopo); and Ideal Clinic Manual Version 18 (2018).

In the case study for the selection of medicines, two types of categorisation were identified for identifying the policy problem: (i) the grouping of policies and legislation based on their enabling and/or hindering effect; or (ii) the identification of VAN criteria not completely supported or enabled by policies and legislation. Due to the number of hindering policies and legislation, the second categorisation type was used.

The hindering policies[1] are the most concerning effect; however, the policies categorised as facilitating also requires attention. The hindering category are the policies that prohibit the

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[1]For the sake of brevity, the term 'policies' will further refer to policies and legislations.

operationalisation of the VAN criteria, whereas the facilitating policies require attention with the detail specified in the document. From the hindering category, it is clear that a majority of the policies are at an operational level—standard operating procedures (SOPs) and guidelines. The MFMA and PFMA, which are concern with the financial and budgeting operations, are the only two Acts that have hindering effects on the VAN Operating Model for South Africa.

The next step in Phase 2 is to determine the alignment among the policies identified. The level of alignment between the policies and legislations (Table S.3) is identified by assigning the relevant indicator[1] (as discussed in Section 7.3). The table is one-sided and not a mirror populated matrix. Thus, the table should be analysed from left to right. The ambiguous and no-effect policies were removed from this analysis, as they are not relevant to further analysis in this case study. The details of this table are revisited during Phase 6 of the case study.

The next subsection discusses the hindering and facilitating effects and subsequently identifies the policy problem that will be used for the remainder of the PoliVAN analysis.

S.2.3 Inventory management policy problem analysis

There are a number of criteria which the policies had a hindering effect on. The first concern is the inventory calculations—the data that should be available to calculate the stock accordingly. This is also linked to the RxSolution[2] being implemented across South Africa. Currently, the calculations specified in the 2018 Ideal Clinic Manual is different than what is required by the RxSolution and proposed by the supply plan document of the VAN Operating Model. In the MCC Good Warehousing Practices guideline, unclear specifications of inventory calculations are provided. Although the Supply Chain Management Framework Regulations has been developed to create uniformity across provinces (National Treasury, 2005), there are still different SOPs implemented across different provinces, utilising different stock management software (Eastern Cape Department of Health; Limpopo Department of Health, 2014; National Department of Trade and Industry, 2011).

Another problem identified with the stock calculation, is the use of stock cards at facilities. The SOPs provided to manage inventory promotes the capturing of stock levels using the stock cards (Eastern Cape Department of Health; Limpopo Department of Health, 2014). The current SOPs[3] require two teams to perform this task and a recount is required if the stock counts are different. Then, the data needs to be entered on a electronic platform (if available) and sent to district hospitals. This is not in line with the end-to-en visibility objective and electronic data capturing specifications of the VAN. The electronic stock capturing

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[1]'S' for strong alignment, 'A' for alignment. 'L' for little alignment, and 'N' for no alignment.

[2]In Chapter 2, the two stock management systems proposed by the VAN is identified.

[3]The SOPs are referred to the available documents in the public domain from the Eastern Cape and Limpopo provinces.

Table S.3: The case study alignment matrix illustrating the relationship between the policies and legislation for inventory management

Legend:

Code	Meaning
S	**Strong Alignment** — The two policies are synergistic as their objectives, targets, or the influence on the pharmaceutical supply chain are perfectly aligned.
A	**Alignment** — The objectives, targets, or the influence on the pharmaceutical supply chain of the two policies under consideration are moderately aligned.
L/N	**Little to No Alignment** — The objectives, targets, or the influence on the pharmaceutical supply chain of the two policies under consideration are not aligned or are only marginally aligned.

Column key (C1–C22):
C1 = Ideal Clinic Manual Version 18 (2018);
C2 = Primary Healthcare Standard Operating Procedures (Limpopo);
C3 = Primary Healthcare Standard Operating Procedures (Eastern Cape);
C4 = District Health Planning and Monitoring Framework;
C5 = Competency Standards for Pharmacists in South Africa (2018);
C6 = Guideline for Accounting Officer in accordance with PFMA;
C7 = National Guideline for the Establishment and Functioning of PTCs;
C8 = Rules Relating to Good Pharmacy Practice;
C9 = MCC Good Warehousing Practices;
C10 = Policy Strategy to Guide Uniformity in Procurement Reform;
C11 = Supply Chain Management Policy (Western Cape);
C12 = National policy for the establishment and functioning of PTCs 2015;
C13 = National Drug Policy 1996;
C14 = National Health Insurance Policy Bill 2019;
C15 = National Health Insurance Policy (White Paper) 2017;
C16 = Supply Chain Management Regulation in terms of MFMA;
C17 = General Regulations in terms of Section 35 of the Medicines Act;
C18 = Norms and Standards Regulation applicable to Health;
C19 = Medicines and Related Substances Act 72 of 2008 and Act 14 of 2015;
C20 = Municipal Finance Management Act 56 of 2003 (MFMA);
C21 = Public Finance Management Act 1 of 1999 (PFMA);
C22 = National Health Act 61 of 2003

Policy	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	C18	C19	C20	C21	C22
Ideal Clinic Manual Version 18 (2018)		A	A	N	L	N	L	L	N	L	N	L	N	N	N	N	N	N	N	N	N	L
Primary Healthcare Standard Operating Procedures (Limpopo)	A		N	A	A	N	N	S	L	N	N	N	S	N	N	N	A	N	S	N	S	L
Primary Healthcare Standard Operating Procedures (Eastern Cape)	A	N		N	L	N	A	S	N	N	N	A	A	N	N	N	N	L	A	N	L	L
District Health Planning and Monitoring Framework	S	L	L		S	N	L	A	N	N	N	L	A	N	N	A	L	L	L	L	S	L
Competency Standards for Pharmacists in South Africa (2018)	A	N	N	L		N	L	S	L	A	A	L	S	S	S	A	L	N	L	N	N	N
Guideline for Accounting Officer in accordance with PFMA	N	N	N	N	N		N	N	N	N	L	N	N	N	N	L	N	N	N	S	S	N
National Guideline for the Establishment and Functioning of PTCs 2019	L	N	N	N	L	N		A	N	N	N	S	S	A	A	N	N	L	A	N	N	A
Rules Relating to Good Pharmacy Practice	L	N	N	N	S	N	N		N	N	N	N	A	N	N	N	A	A	A	N	N	A
MCC Good Warehousing Practices	N	N	N	N	A	L	N	S		N	L	N	S	N	N	L	S	N	S	N	N	A
Policy Strategy to Guide Uniformity in Procurement Reform Processes	N	N	N	N	N	L	N	N	L		A	N	N	N	N	A	N	N	N	S	S	N
Supply Chain Management Policy (Western Cape)	N	N	N	N	N	L	N	N	N	L		N	N	N	N	S	N	N	N	S	A	N
National policy for the establishment and functioning of PTCs 2015	N	N	N	N	L	N	S	L	N	N	N		S	A	A	N	A	L	S	L	A	S
National Drug Policy 1996	L	N	N	L	L	N	A	S	S	N	N	S		N	N	N	L	N	S	N	A	A
National Health Insurance Policy Bill 2019	A	N	N	S	A	A	A	L	L	L	L	N	L		A	S	A	A	A	A	S	S
National Health Insurance Policy (White Paper) 2017	A	L	L	S	L	S	S	L	L	N	N	S	A	S		N	A	A	A	A	S	S
Supply Chain Management Regulation in terms of MFMA	N	N	N	N	N	L	N	N	N	A	A	N	N	N	N		N	N	N	S	S	N
General Regulations in terms of Section 35 of the Medicines Act	L	L	L	L	S	N	L	S	A	N	N	L	S	N	N	N		L	S	N	N	A
Norms and Standards Regulation applicable to Health Establishments	A	L	L	S	A	N	N	A	A	N	N	N	N	A	N	N	N		S	N	N	A
Medicines and Related Substances Act 72 of 2008 and Act 14 of 2015	A	A	A	L	A	N	S	A	L	N	S	S	N	N	N	A	L	L		N	N	S
Municipal Finance Management Act 56 of 2003 (MFMA)	N	N	N	A	N	S	N	N	A	A	N	N	L	L	S	S	S	N	N		S	N
Public Finance Management Act 1 of 1999 (PFMA)	N	N	N	N	N	S	N	N	N	A	A	N	N	S	S	A	N	N	N	S		N
National Health Act 61 of 2003	A	L	L	S	A	N	A	L	L	N	N	A	S	A	A	N	A	S	A	N	N	

system proposed is the Stock Visibility Solution (SVS) system. Pilot tests are currently being implemented in South Africa; however, the use of such system has only been stipulated in the 2017 National Health Insurance (NHI) policy. The implementation has not been disseminated to guideline or SOP level.

Another problem is the replenishment of medicines according to the VEN[1] and ABC[2] practices. The VAN utilises these two approaches to determine the optimal procurement method and distribution strategy for each medicine. The VAN requires clinical practitioners to determine the VEN classification and supply chain experts (the highly skilled experts within the PMPUs) to determine the ABC classification; however, the 2019 PTC guideline allows members of PTCs to manage the ABC classification, which is impractical from a logistics stand-point for the VAN Operating Model.

The VAN Operating Model is key to analytical insights and continuous improvement. A problem identified with a number of policies is the lack of key performance indicators (KPIs) identified to monitor stock levels. In some primary healthcare (PHC) SOP policies, little to none KPIs are documented (Eastern Cape Department of Health). The MCC wholesale and distribution guidelines provide SOPs on high-level KPIs such as: service level agreements, receipt of stocks and stock control. However, these guidelines and SOPs do not provide the detailed KPIs proposed by the VAN in order to have the data visibility, and informed push system. The new 2019 PTC guideline promotes the use of the National Surveillance Centre[3] that aims to report stock availability information to the relevant healthcare and supply chain professional; however, not all the recommended VAN KPIs for inventory management and stock control are available within the dashboard.

In the VAN supply plan document, it is detailed that the PMPU should recommend order to the PHC facilities, and then the facilities should respond to the recommendations (via SVS) on whether they approve or suggest an adjustment. Once a order is approved, it is the responsibility of the PMPU to place orders at either the suppliers or the warehouse (depending on the procurement strategy) through gCommerce[4]. However, the recommended orders should also be approved by the budget holder (a role created within the VAN). The MFMA and PFMA are the two act that stipulate the financial and accounting laws and regulations in South Africa. These acts highlight the role of an accounting officer. Each department (provincial and local) should have an accounting officer which is responsible for the management of the budgets in accordance with the national revenue fund (National Treasury, 2003a, 2017). The accounting officer may also delegate its authority to other roles, within the regulations of the accounting officer (National Treasury, 2000). There is currently no policy that enables the budget holder role in the VAN to take the form of the accounting officer, specifically for medicine procurement.

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[1]These are medicines being classified as either 'vital', 'essential' or 'non-essential'.

[2]These are procurement strategies based on the 80/20 segmentation principle. For example, 20% of medicines account for 80% of the budget.

[3]A medicine availability dashboard that reports data collected by the SVS, RxSolution systems, warehouse management system and respective systems used in provinces (National Department of Health, 2019).

[4]This is a warehouse management system utilised by some provinces in South Africa

The policy should also provide guidance on the relationship between the the provincial and local level.

It should be noted that these are not necessarily the only problems that exist, but are those that can be identified from the available policy documents used in this case study. The discussion of the problems are also summarised and discussed at high-level, as a discussion regarding the evidently hindering policies can become lengthy. The next section focuses on the identification of the policy problems and the (re)formulation of policies and legislations in order to address the problems identified.

S.3 Policy formulation for inventory management

In this section the problems highlighted from the VAN criteria discussion Phase 2 is used to formulate policy options in the attempt to support the implementation of the VAN Operating Model from a policy perspective. This sections starts with the identification of the policy problems and selecting a problem that will be further addressed in this case study. The reason for selecting one policy problem is to stay within the limits of the scope by only illustrating the application of the PoliVAN logic model. Then, the problem is further discussed and with the use of brainstorming techniques, and ad hoc inputs from SMEs various policy options are generated, which is subsequently used as the inputs for Phases 4 and 5.

S.3.1 Inventory management policy problem identification

During the workshop with SMEs, P13 and P15, a number of policy problems were identified and policy options and solutions were informally suggested. From the previous discussion, the number of policy problems could be categorised into the following problem categories:

- **Policy subproblem 1:** *Inventory calculation and stock integration system.* Currently, the RxSolution being proposed by the VAN has a different inventory calculation method set than the demand-driven supply chain method required for the VAN. The RxSolution is also not utilised by all of the provinces in South Africa. This is due to the automatism given to each province (stipulated in the Constitution). Policies are required to standardise these processes and enable demand-driven inventory management. Regardless of the RxSolution, the stock calculation stipulated in SOPs (to calculat the min/max levels and lead time) are different for provinces. The capturing processes for the stock are also done manually (with SOPs supporting this), which i not aligned with the VAN objectives.

- **Policy subproblem 2:** *Replenishment according to VEN and ABC.* The replenishment of stock should be done according to the classification of VEN and ABC practices. The

PTC should take on the roles of determining the VEN classification, whilst the PMPUs and or AMD should be responsible to set out policies and procedures for the classification of ABC.

- **Policy subroblem 3:** *Best-practice KPIs for stock monitoring across the supply chain.* Standardised stock management KPIs should be implemented across the entire pharmaceutical system at all levels. An integrated network system should be able to capture the relevant data and make it available in the form of best-practices KPIs for relevant supply chain experts in the PMPUs and AMD.

- **Policy subroblem 4:** *Integration of the VAN budget holder role with current South African finance roles.* There are currently three different financing models being utilised across South Africa for the procurement of medicines. With the new National Health Insurance Bill being implemented, a new financing structure will be utilised and standardised approaches should be considered. There is also no prescriptive documentation of the current role that will be addressed to the VAN budget holder.

For the remainder of the case study, only one policy problem was selected to continue the analysis, which is policy problem 1. The choice was based on the policy problem that was emphasised the most during the workshop with SMEs, P13 and P15. The information gathered by the workshop also provided the necessary information required to develop policy options and populate the policy formulation checklist table in Phase 3. Because the remainder of the case study is a desktop review study, having sufficient information from the workshop helped with further analysis in this case study. The next subsection focuses on the formulation of policy options to support policy problem number one.

S.3.2 Formulated inventory management policy options and design

After the workshop, the policy problems were analysed and through literature review of best practices methods and understanding the South African context, policy solutions were formulated to the selected policy problem for the analysis. SMEs P3 and P10 were contacted during this stage to provide their input to populate the policy formulation checklist. When policies were formulated, it was noticed that the policy options were complimenting each other, rather than having different solution types. It was concluded that the objective for the policy problem identified was clear in what the policy requirements were. Therefore, it was not necessary to formulated different policy options, but rather formulate policies that enable the requirements of the VAN within the legal limits. The details of the adjustments made to the stakeholder analysis and policy impact analysis are discussed within the respective sections.

Once the policies were formulated, one SME from the workshop, P15, were asked to validate the formulated policies and provide additional inputs. The policies are briefly discussed. The details of the policies are formulated with the policy checklist, see Table S.4.

Policy option 1: National policy for provincial demand-driven inventory management

This policy aims to implement demand-driven material requirement planning (DDMRP) practices in the inventory management and order calculation processes. It would be the responsibility of the Affordable Medicines Directorate (AMD) to stipulate within a national policy the algorithm that will be used for order calculations. The algorithm will be disseminated down to provincial level, where the PMPUs will be responsible to plug-in province specific data per location and per SKU. The system, RxSolution will be used across all provinces, meaning that some province will have to implement change management process to transition to the RxSolution system. Accountability and responsibilities of calculating the recommended orders will need to change. The quality and type of data required per province to plug-in the algorithm will need to be managed.

Policy option 2: Standardised stock management SOPs for all Health Establishments

It was identified after analysing the current SOPs in place for stock management at facility level. The first problem is that the SOPs across provinces differ and the SOPs required by the VAN are not stipulated or available within a policy or legislation. This policy aims to implement standardised SOPs across all provinces that are linked to bo ideal clinic manual and supply chain prescripts in a province. Change management processes are required for educating and training facility staff to have the necessary competence to perform these tasks. Accountability measures and incentives will need to be implemented to ensure accurate and quality stock management processes are executed.

Policy option 3: National policy for the transition to an electronic stock management system

Stock capturing and management are currently done manually in South African health facilities, by means of stock cards. The problem with this that inaccurate data are captured, and sometimes are not being done, because it is considered high effort (Berger *et al.*, 2010). The current SOPs require the staff two count stock in two teams in order to validate the correct number of stock on hand. Then, the the quantities needs to be entered into a computer system or sent to the district hospital. The time to collect the data and accuracy of the data has been a problem in South Africa. This policy aims to transition to an electronic stock capturing system that provides real-time and accurate data to PMPUs on the current stock on hand, by facility and per SKU. Similar in this policy, change manage processes need to be

implemented to transition to new methods of stock capturing and overwriting current policies enabling stock cards.

The information in Table S.4 will be used to further identify relevant stakeholder and analyse its impact on the pharmaceutical system. This table will also provide the detailed information to design the final policies for implementation so that it is in line with the VAN objectives and specifications. The next section uses the policies formulated in this section to identify relevant stakeholders and analyse their possible reactions to the policies described.

S.4 Stakeholder analysis for inventory management policy options

In this section, a stakeholder analysis for each policy is conducted. The evaluation tables are populated for each policy option with the inputs from the workshop SMEs. The information in the tables is used to provide three types of analysis outputs to make informed decisions regarding the stakeholders.

S.4.1 Stakeholder evaluation table for medicine selection

For the stakeholder analysis (SHA) the relevant stakeholders were identified through the discussions during the workshop. Additionally, an investigation of previous policies that identifies relevant stakeholders for similar processes were done. The stakeholder list in Table 7.4 was utilised to ensure that all possible stakeholders are identified. Different stakeholders for the policies were identified for each policy, as these were not competing policies, but rather complementing policies that will govern at different levels in the health system.

The evaluation scores (see Figure 7.13) were used to evaluate the stakeholders for each policy. Similar to the medicine selection case study, all of the characteristics were used in this analysis. The stakeholders were scored with inputs from two SMEs P3 and P10, based on their relevant experience within the inventory management landscape. Figures S.1 to S.3 illustrate the stakeholders identified, the scores given by the SMEs, and the analysis outcomes produced by the data.

For each policy there are three types of analysis that is done in this case study: (i) to determine the extent of stakeholder involvement; (ii) to determine the ability of an opposing stakeholder to influence the decisions; and (iii) to determine the ratio of power between the internal and external stakeholders. Please see Subsection R.4.2 for a detailed account of each process. The interpretation of these processes are discussed in Section S.6. The next section discusses the policy impact analysis processes and execution of the policies formulated in Phase 3.

S.4 Stakeholder analysis for inventory management policy options

Table S.4: Details regarding the three policy options for the inventory management case study

	A VAN POLICY OBJECTIVE AND FORMULATION CHECKLIST	POLICY OPTION 1 National policy for provincial demand-driven inventory management	POLICY OPTION 2 Standardised stock management SOPs for Health Establishments	POLICY OPTION 3 National policy for the transition to electronic stock management system
The policy option aims to support either of the VAN objectives:	End-to-end visibility: data aggregation from multiple sources bringing end-to-end visibility across health commodities and programs, and ultimately the entire value chain.	PMPUs are enabled with on-hand data to recommded th right order for facility. AMD has visibility of all provinces using the sam instance of RxSolution.	A standardised approach to taking stock, ensuring that the type and quality of data is similar across the pharmacrutical supply chain and country.	Electronic stock capturing system will provide real-time, and accurate stock level data.
	Analysis and insight: analytical processes to create operational plans, and optimise the system.	Demand-driven inventory principle. Requires real-time and accurate data. Supply chain experts responsible for managing the calculations.	These SOPs will require facility representatives to capture stock levels and calculate the min, max and safety stoock levels for the respective PMPUs.	Facillity healthworkers will not be required to beform any analytical processes, but to make use of computers or electronic system to capture the data.
	Continuous improvement: standardised problem resolution processes, conditional actions, and SOPs used to solve challenges and implement ongoing improvements.	All provinces will use a standardised algorithm with province-specific data. Complimenting policies for SOPs and standardised processes should be made.	All facilities and provinces will use standardised approaches to capture stock levels.	The integration between SVS and RxSolution is required. When stock is captured, KPIs according to Global Fund and WHO guidelines should be implemented to monitor and manage the quality of the data.
Operational functions (process element):	Scope of intended activities.	Master data per facility, per SKU would be required. Additionally, accurate lead time and forecasted demand should be ready. The warehouse system should set up processes to facilitate the new inventory management processes.	The facilities will capture the data of stock electronically through SVS. They will use the data to calculate the min, max and safety stock levels and send this data to a provincial level.	SOPs should be in place. The data captured iis utlised by the PMPU to make recommended orders to the facility. The facility may approve the order, or make adjustments based on external campaigns or programmes they are aware of.
	How it fits into the planning process category (demand-, supply-, distribution planning)	Requires forecasted demand from demand planning, is managed by the supply planning PMPUs and inform distribution planning on replenishment details.	This is part of the supply planning processes.	This is embedded into the supply planning processes and is strongly linked with the technology and dat visibility element of the South African VAN.
	The link to the rest of the supply chain	The maximum allowable lead time (inout data required by PMPU) per supplier is stipulated in tender documents and suppler contracts. Accurate and timely updates of forecasted demand is required. The inventory management calculation informs suppliers and warehouses of replenishment and distribution plans.	Data provides input for the order calculation per facility .	It provides the real-time on hand stock availabiltiy for PMPUs to calculate recommmended order, as well as provide the visibility at national level for stock availability management.
	Level of frequency of intended activities	Once off process implement the RxSolution instance across all provinces and in facilities. Continuous process of updating master table and monitoring the system outputs.	The implementation of SOPs is a once off process with training and education. Monitoring these procedures will need to be done either monthly or quarterly.	Stock capturing, continuous, as new orders are delvired. Stock count monthly or bi-weekly. PMPU should aggregate the data monthly.
Organisational structure (people element):	Process owner of intended activities (VAN role)	AMD at a national level. PMPU (supply planning) at provincial level and facility managers at local level.	District manager responsible for monitoring the SOPS at the facilities.	Facility representative is process owner of stock capturing. The government is responsible for implementing the IT system and tools at all the facilities and ensure the operability of these systems.
	Stakeholder roles and responsibilities	AMD should be responsible for establishing the RxSolution algorithm and manage the agregated data. Provincial PMPUs are responsible for master data in respective provinces. Facilities should ensure that accurate and quality master data are aggregted at provincial level	Facility representatives responsible for stock capturing. District manager responsible for monitoring the facilities. PMPU responsible for follow-up on data manage sata at a provincial level.	Healthworkers at facility are responsible for stock take. District manager is responsible for continuous evaluation of these processes. PMPUs should evluate the data quality and check on the captured versus actual data.
	Location granularity	Provincial and facility level	Facility level	Facility level
	The link to existing country roles (non-VAN roles)	N/A	Facility representatives should communicate with district manager which communicates with PMPU.	Facility representatives should communicate with district manager which communicates with PMPU.
	Reporting lines among the different roles and levels	Facility should provide accurate on-hand data for PMPUs, PMPUs aggregate data to national level.	Continuous communication between health facility manager and staff members. Bi-weekly / monthly communication between PMPUs and district heslth managers.	Continuous communication between health facility manager and staff members. Bi-weekly / monthly communication between PMPUs and district heslth managers.

S.4 Stakeholder analysis for inventory management policy options

Table S.4 continued from previous page

A VAN POLICY OBJECTIVE AND FORMULATION CHECKLIST		POLICY OPTION 1 National policy for provincial demand-driven inventory management	POLICY OPTION 2 Standardised stock management SOPs for Health Establishments	POLICY OPTION 3 National policy for the transition to electronic stock management system
Information system (technology element):	Data requirement for intended activity	Lead times (supplier to warehouse; supplier to facility, warehouse to facility); average consumption; demand forecast; stock levels (min, max, safety stock), product master data (expiry date, shelf life); minimum order quantity; shipper pack sizes per SKU, supplier reliability; consumption rate per SKU; re-order	Stock levels, i.e. minimum and maximum levels, safety stock level, stock on hand. Best-practices methods should by identified on what data is required and how to calculate these values.	To capture the stock, the essential medicines list and standard treatment guidelines are required.
	Software/tool to be implemented/used	RxSolution	Stock Visibility Solution (SVS) for order - on hand data capturing and stock taking. Inventory calculation module/tool for stock level calculation.	Infrastructure of IT tools and software should be in place, including data network reach where required.
	Interoperability	All provinces should make use of RxSolution; however, only one instances can run at a time, thus every province will make use of the same algorthm.	Standardised SOPs should be incorporated into the other SOPs of the healthworks' daily clinical practices.	SVS has been implemented across 3000+ facilities in South Africa. Not interoperable with RxSolution.
	Data transparency	AMD has insight on the inventory data of all provinces. Provinces have insigth on inventory levels at facility level.	Accurate stock taking procedures will ensure quality data that will be available toe PMPUs.	SVS stock capturing data will provide PMPU with real-time on-hand data visibility.
Monitoring and evaluation:	Strategical outcomes	Improve the allignement of stock calculation processes and data sharing for inventory management.	Improve standardisation of stock capturing and stock management across all visibilities, in order for PMPUs to havev similar insights with data that are aligned. With what the VAN requires	To remove the use of stock-cards and manual stock capturing ethods with electronic and real-time stock capturing methods.
	Continuous improvement plans	Monitoring the use of stock calculations and how the analysis is actually used by the PMPU. Continuously monitor the accuracy and the data to determine wheter the facility are providing quality data.	Monitoring the adherence of SOPs with KPIs. Occasionally review the competency of health workers at facility level who manages these processes. Evaluation protocols should be implemented in the policy document.	Continuous software updates and training should be implemented. SOPs in stock capturing methods should include electronic methods and overwrite the manual processes currently in place. Implement plans to integrate the SVS data with RxSolution.
	Key performance indicators (KPIs)	Forecast error, lead time accuracy, accurate stock levels indicated (spot checks); data visibility; real-time insight.	Data availability, data similarity, on-time and accurate data, quality data.	Data accuracy, stock availability, % stock on-hand, network range and operability, real-time (timely data).
Human resource development:	Education, training and/or skill development	Facility representatives will have to undergo training on how to calcuate accurate min, max, safety stock level, using the inventory calculation model proposed in the VAN.	Training of specialised skills at facilitiy level to manage SVS tool and do stock level calculations.	Initially training and education on managing the systems and tools is required. The continuous monitoring and evaluation is required when software updates or updates on the tools are being implemented.
	Workforce capacity (hire, deploy, retain, motivate, etc.)	Establish PMPU at provincial level to make the supply chain calculations. Relief facility representatives from their role of determining order quantities, and ensure they focus more on stkc capturing accuracy.	Not applicable, unless current resources show incompetence at managing the stock calcuation model and executiong the provide SOPs.	Not applicable, unless current resources show incompetence at managing the SVS tool and provide accurate stock taking data.
Financial and donor coordination:	Financial sources/requirements	Implementation of RxSolution. Would require a technical team to install the system at all facilities. Training is required. Technology hardware infrastructure is required and data nerwork (internet) is required.	N/A	Implementation of hardware and software of SVS at all facilities. This would require a technical team to make these installations. Training of facility workforce. Network coverage and availability.
	Budget allocation and update	The forecastedd budget should be made availble to PMPUs or Budget holder should communicate available funds to determine if there is sufficient budget to place recommended orders.	N/A	Once off installation with ontinuous data network availability is required.
	Disbursement (release of funds)	The timing of funds being available will impact the order capacity.	N/A	N/A

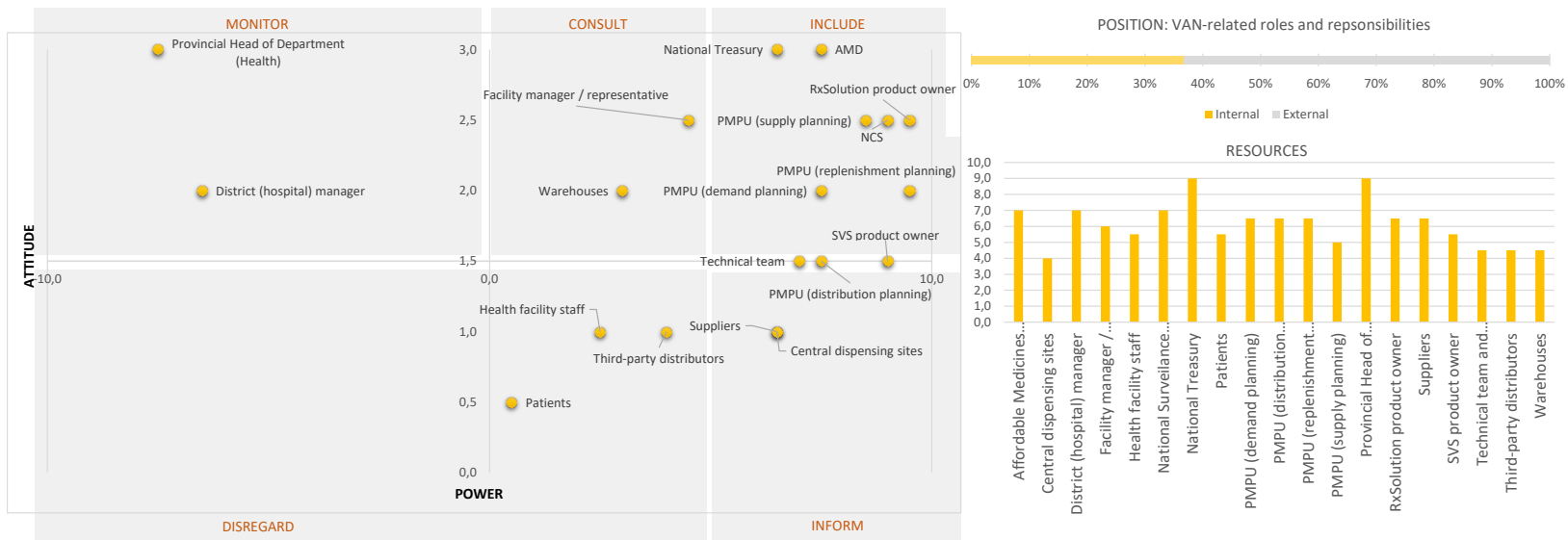| STAKEHOLDER ANALYSIS	POLICY 1: National policy for provincial demand-driven inventory management									
Stakeholders	Position	Knowledge	Interest	Support	Attitude	Financial Resources	Political Resources	Human Resources	Total Resources	Power	Opinion leaders
Affordable Medicines Directorate (AMD)	Internal	3,5	4,0	1,0	7,5	2,0	2,0	3,0	7,0	3,0	Yes
Central dispensing sites	External	3,0	3,5	1,0	6,5	1,0	1,0	2,0	4,0	1,0	No
District (hospital) manager	External	3,5	3,0	-1,0	-6,5	2,0	3,0	2,0	7,0	2,0	No
Facility manager / representative	External	1,5	3,0	1,0	4,5	1,0	3,0	2,0	6,0	2,5	Yes
Health facility staff	External	1,0	1,5	1,0	2,5	0,0	3,0	2,5	5,5	1,0	Yes
National Surveilance Center (NSC)	External	5,0	4,0	1,0	9,0	3,0	2,0	2,0	7,0	2,5	Yes
National Treasury	External	3,5	3,0	1,0	6,5	3,0	3,0	3,0	9,0	3,0	Yes
Patients	External	0,5	0,0	1,0	0,5	2,5	2,0	1,0	5,5	0,5	No
PMPU (demand planning)	Internal	3,5	4,0	1,0	7,5	2,0	2,5	2,0	6,5	2,0	Yes
PMPU (distribution planning)	Internal	3,0	4,5	1,0	7,5	2,0	2,5	2,0	6,5	1,5	Yes
PMPU (replenishment planning)	Internal	5,0	4,5	1,0	9,5	2,5	2,0	2,0	6,5	2,0	Yes
PMPU (supply planning)	Internal	4,5	4,0	1,0	8,5	2,0	1,5	1,5	5,0	2,5	Yes
Provincial Head of Department (Health)	External	3,5	4,0	-1,0	-7,5	3,0	3,0	3,0	9,0	3,0	Yes
RxSolution product owner	Internal	5,0	4,5	1,0	9,5	3,0	1,5	2,0	6,5	2,5	No
Suppliers	External	3,5	3,0	1,0	6,5	2,5	2,0	2,0	6,5	1,0	No
SVS product owner	Internal	5,0	4,0	1,0	9,0	2,5	1,0	2,0	5,5	1,5	No
Technical team and network providers	External	4,0	3,0	1,0	7,0	2,0	1,5	1,0	4,5	1,5	No
Third-party distributors	External	2,0	2,0	1,0	4,0	2,0	1,5	1,0	4,5	1,0	No
Warehouses	External	3,0	0,0	1,0	3,0	1,0	1,5	2,0	4,5	2,0	Yes

Figure S.1: Stakeholder analysis for policy 1

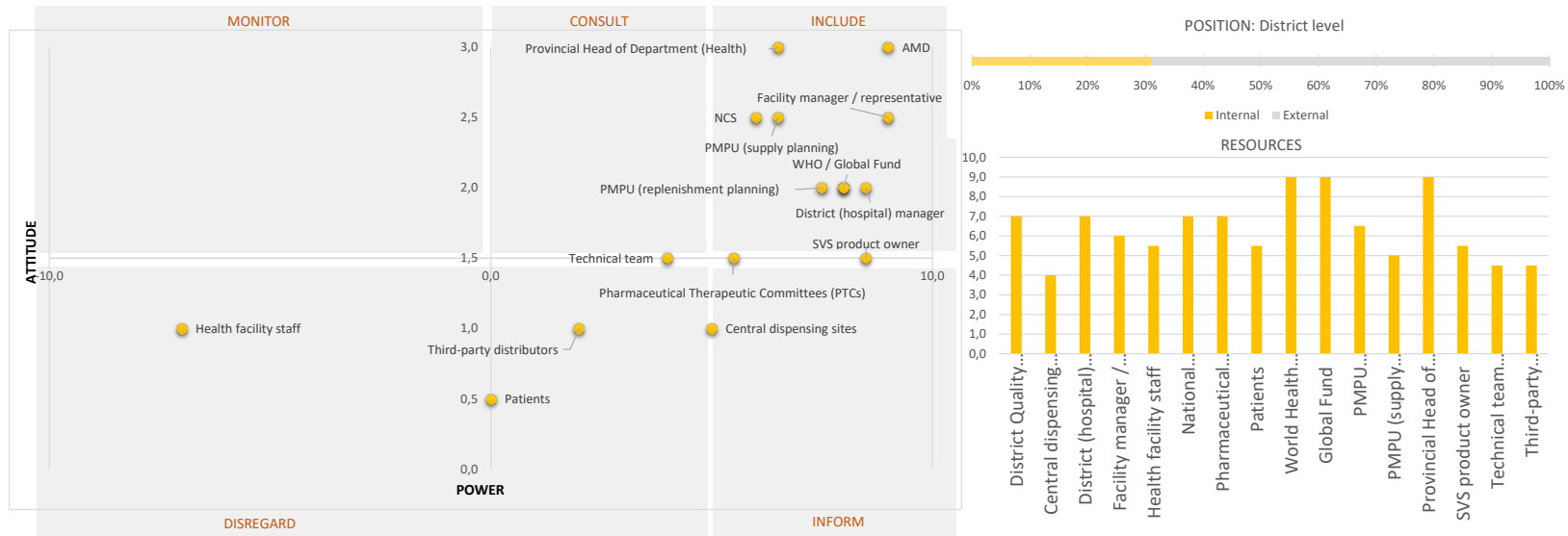| STAKEHOLDER ANALYSIS	POLICY 2: Standardised stock management SOPs for all Health Establishments									
Stakeholders	Position	Knowledge	Interest	Support	Attitude	Financial Resources	Political Resources	Human Resources	Total Resources	Power	Opinion leaders
District Quality Manager	Internal	5,0	4,0	1,0	9,0	2,0	2,0	3,0	7,0	3,0	Yes
Central dispensing sites	External	2,5	2,5	1,0	5,0	1,0	1,0	2,0	4,0	1,0	No
District (hospital) manager	Internal	4,5	4,0	1,0	8,5	2,0	3,0	2,0	7,0	2,0	No
Facility manager / representative	Internal	5,0	4,0	1,0	9,0	1,0	3,0	2,0	6,0	2,5	Yes
Health facility staff	Internal	3,5	3,5	-1,0	-7,0	0,0	3,0	2,5	5,5	1,0	Yes
National Surveilance Center (NSC)	External	2,0	4,0	1,0	6,0	3,0	2,0	2,0	7,0	2,5	Yes
Pharmaceutical Therapeutic Committees (PTCs)	External	2,5	3,0	1,0	5,5	2,5	1,5	3,0	7,0	1,5	Yes
Patients	Internal	0,0	0,0	1,0	0,0	2,5	2,0	1,0	5,5	0,5	No
World Health Organisation	External	5,0	3,0	1,0	8,0	3,0	3,0	3,0	9,0	2,0	Yes
Global Fund	External	5,0	3,0	1,0	8,0	3,0	3,0	3,0	9,0	2,0	Yes
PMPU (replenishment planning)	External	3,5	4,0	1,0	7,5	2,5	2,0	2,0	6,5	2,0	Yes
PMPU (supply planning)	External	3,0	3,5	1,0	6,5	2,0	1,5	1,5	5,0	2,5	Yes
Provincial Head of Department (Health)	External	3,5	3,0	1,0	6,5	3,0	3,0	3,0	9,0	3,0	Yes
SVS product owner	External	4,5	4,0	1,0	8,5	2,5	1,0	2,0	5,5	1,5	No
Technical team and network providers	External	1,5	2,5	1,0	4,0	2,0	1,5	1,0	4,5	1,5	No
Third-party distributors	External	1,0	1,0	1,0	2,0	2,0	1,5	1,0	4,5	1,0	No

Figure S.2: Stakeholder analysis for policy 2

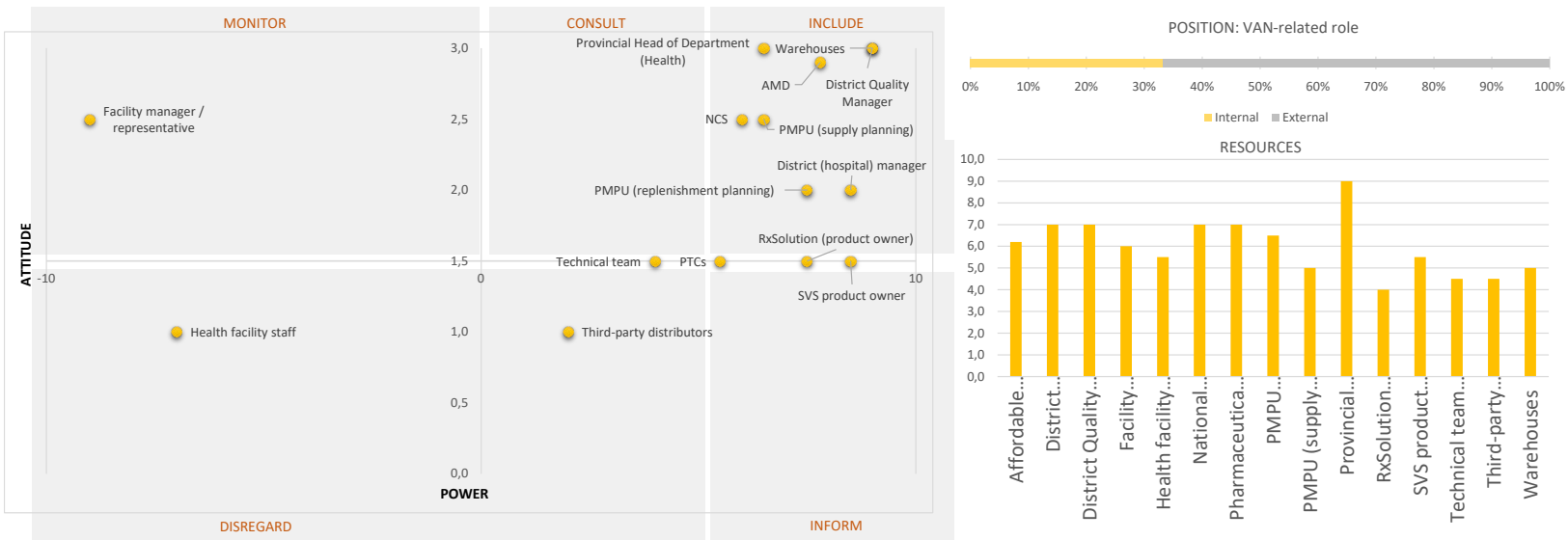| STAKEHOLDER ANALYSIS	POLICY 3: National policy for the transition to an electronic stock management system									
Stakeholders	Position	Knowledge	Interest	Support	Attitude	Financial Resources	Political Resources	Human Resources	Total Resources	Power	Opinion leaders
Affordable Medicines Directorate (AMD)	Internal	3,9	3,9	1,0	7,8	2,2	1	3	6,2	2,9	Yes
District (hospital) manager	External	4,5	4,0	1,0	8,5	2,0	3,0	2,0	7,0	2,0	No
District Quality Manager	External	5,0	4,0	1,0	9,0	2,0	2,0	3,0	7,0	3,0	Yes
Facility manager / representative	External	5,0	4,0	-1,0	-9,0	1,0	3,0	2,0	6,0	2,5	Yes
Health facility staff	External	3,5	3,5	-1,0	-7,0	0,0	3,0	2,5	5,5	1,0	Yes
National Surveilance Center (NSC)	External	2,0	4,0	1,0	6,0	3,0	2,0	2,0	7,0	2,5	Yes
Pharmaceutical Therapeutic Committees (PTCs)	External	2,5	3,0	1,0	5,5	2,5	1,5	3,0	7,0	1,5	Yes
PMPU (replenishment planning)	Internal	3,5	4,0	1,0	7,5	2,5	2,0	2,0	6,5	2,0	Yes
PMPU (supply planning)	Internal	3,0	3,5	1,0	6,5	2,0	1,5	1,5	5,0	2,5	Yes
Provincial Head of Department (Health)	External	3,5	3,0	1,0	6,5	3,0	3,0	3,0	9,0	3,0	Yes
RxSolution (product owner)	Internal	4,5	3,0	1,0	7,5	2,0	1,0	1,0	4,0	1,5	No
SVS product owner	Internal	4,5	4,0	1,0	8,5	2,5	1,0	2,0	5,5	1,5	No
Technical team and network providers	External	1,5	2,5	1,0	4,0	2,0	1,5	1,0	4,5	1,5	No
Third-party distributors	External	1,0	1,0	1,0	2,0	2,0	1,5	1,0	4,5	1,0	No
Warehouses	External	5,0	4,0	1,0	9,0	1,0	1,5	2,5	5,0	3,0	Yes

Figure S.3: Stakeholder analysis for policy 3

S.5 Policy impact analysis for inventory management policy options

In this section, the application of the policy impact analysis tool is illustrated and discussed. This section starts with the selection and breakdown of the analytical dimensions, then the policy impact analysis tool is set up and populated with inputs from the relevant SMEs. Finally, an interpretation of the analysis done in Phase 6 to address the policy problem identified during Phase 2 of this case study.

S.5.1 Selecting appropriate analytical dimensions and weightings for the inventory management case

The policy impact analysis is constructed by making use of the analytical dimensions as provided by Table 7.8. The dimensions for this case study is specifically selected to fit the aim of the policies. The policies are more technical and operational, thus, not all the analytical dimensions proposed by Table 7.8 were used. Figure S.4 provides the breakdown of the dimensions used for this case study.

The next step in this phase is to assign a weights to each analytical dimensions. In this case study, the weights were assigned to each analytical dimension (the first-level dimensions in Figure S.4) with the inputs from the SME, P15. The 'feasibility' and 'criticality' dimensions were given the highest weighting preference, 35% and 20% respectively. The reason or this was because the policies are aimed at implementing information systems and technology tools into the supply chain system. Understanding the impact these policies have with operability and influence on other supply chain components is vital. The third highest weighting preference is given to the 'acceptability' dimension with 15%. The reason for this was because the policies require change management processes, and how stakeholders react to these policies could potentially have a great impact on the outcomes of the policies. The rest of the dimensions were given either 10% or 5% preference.

S.5.2 Policy impact analysis table and discussion

The analytical dimensions were given a range metrics and scores to evaluate the different policy options based on the possible impact it could have on the pharmaceutical supply chain system. These metrics are developed from the scoring table (Table 7.9) in Chapter 7.

The policy impact analysis table for the inventory management function is presented Table S.5. The acceptability is scored according to the percentage of stakeholder in support of each policy. The support percentage for Policies 1 to 3 are: 89%, 46%, and 87% respectively. This means that each policy option is scored a '5' on the metric scale. The rest of the data in the table was populated after background research on past policies and their impact on the

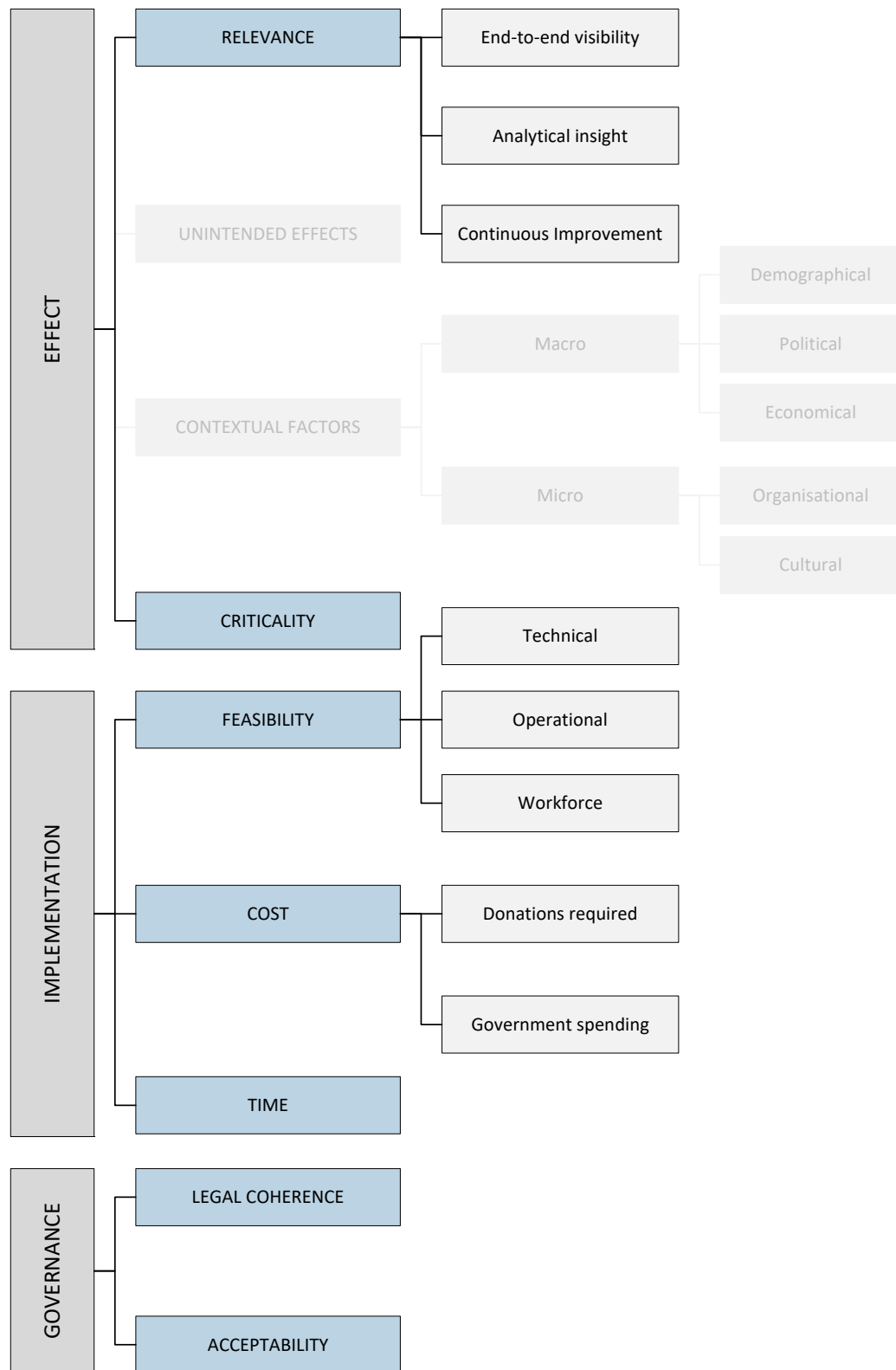**S.5 Policy impact analysis for inventory management policy options**

Figure S.4: Analytical dimensions constructed for the inventory management case study

South African system; however, little information was available. As this is a desktop review of the case study, the data populated are 'estimated' and was reviewed by SME, P15 for additional input. The outcomes from the evaluation table was then used to illustrate how the results can be interpret and how the complimenting policies were analysed.

In this analysis, the policies are not required to outrank each other. Here, the impact is considered for the implementation of all policies considered. The total score was calculated with a percentage of the maximum score it has achieved. Then the weighted score was calculated with the percentage of maximum score achieved. From literature, it was found that a weighted score is not required when options are not purposely analysed to outrank each other, but rather to analyse the impact of each option individually (Dodgson *et al.*, 2009). Therefore, in this analysis, the weighted score is not used for the analysis.

The outputs and insight produced by the preceding phases are use to develop policy decision plans and strategies. The strategies identified in this case study are discussed in the next section.

S.6 Inventory management policy decision and recommendations

From the outcomes in Table S.5, Policy 2 and 3 both did not have a high impact on the pharmaceutical supply chain, and does not have any risk factors which can be identified from the scores in the evaluation table. However, Policy 1 was scored relatively low and the risk factors are identified by the highlighted cells in Table S.5. The criticality was scored a '0', because the impact of implementing RxSolution in all provinces, and changing the algorithm to DDMRP will have a big impact on the rest of the replenishment processes, and subsequently, other inventory and supply planning functions. At an initial stage, implementing RxSolution across all provinces requires that the software should be installed and implemented across all facilities and the DDMRP algorithm will need to be updated. The RxSolution can only run one instance / algorithm at a time and needs to be physically installed at each point where the system operates. This require high efforts. Also, the cost to implement RxSolution at all operating points can become costly. The government will need to ensure that data coverage is available and that maintenance programmes are included with the use of the RxSolution. Finally, as mentioned in Phase 1 of this case study, South Africa has declared provinces to be autonomous with authority to pass their own law. The policy will require strategies (specifically with the stakeholders of provincial government) to manage how RxSolution will be set as the required replenishment management tools. Currently, some provinces are using other replenishment software tools. Incentives will need to be introduced in order for provinces to enable the use of RxSolution within their province.

Table S.5: Policy impact analysis evaluation table for the inventory management case study

Categories	EFFECT										
Weight	5%										20%
Dimensions	RELEVANCE			UNINTENDED EFFECTS	CONTEXTUAL FACTORS						CRITICALITY
	End-to-end visibility	Analytical insight	Continuous improvement		Demographical	Macro Political	Economical	Micro Organisational	Cultural		
Policy 1	5	5	3								0
Policy 2	4	3	3								3
Policy 3	5	4	3								5
Scoring Metrics	5 - Highly relevant 4 - Relevant 3 - Moderately relevant 2 - Slightly relevant 1 - Little/no relevance			5 - 0% → 20% 4 - 20% → 30 % 3 - 30% → 50% 2 - 50% → 70% 1 - 70% → 80%	3 - Low impact 2 - Moderate impact 1 - High impact						0 - Very high affect 1 - High affect 2 - Moderate affect 3 - Slight affect 4 - Little affect 5 - No affect

Categories	IMPLEMENTATION					GOVERNANCE			TOTAL SCORE	WEIGHTED SCORE	
Weight	35%			5%		10%	15%	10%			
Dimensions	FEASIBILITY			COST		TIME	Acceptability	Legal Coherence			
	Technical	Operational	Workforce	Donations required	Government spending					Total	% of max
Policy 1	1	1	3	3	1	4	5	2	33	27,65	55%
Policy 2	3	3	2	3	3	5	5	4	41	40,95	82%
Policy 3	2	2	2	3	2	4	5	4	41	38,50	77%
Scoring Metrics	3 - Feasible 2 - Moderately feasibly 1 - Slightly feasible 0 - Not feasible			3 - Low/no input required 2 - Moderate input required 1 - Big input required		5 - Weeks 4 - Months 3 - A year 2 - A few years 1 - Multiple years	5 - 80% → 100% 4 - 70% → 80% 3 - 50% → 70% 2 - 30% → 50% 1 - 20% → 30%	5 - No effort 4 - Low effort 3 - Moderate effort 2 - High effort 1 - very high effort			

S.6 Inventory management policy decision and recommendations

Because the VAN requires a system such as RxSolution to enable the end-to-end visibility and informed push supply chain approach, it is necessary to have this policy in order to enable such a system. For Policy 1, a clear strategy of how the RxSolution is planned to be implemented, needs to be designed. The analytical dimensions that show great risking impacts need to be managed. In the policy analysis landscape, it is common to expect the unexpected. Policy outcomes do not always follow the intended purpose, but this policy impact analysis provides the necessary insights for analysts to manage prior to implementing a policy. This is where risk management strategies can be addressed and thoroughly designed, as well as an implementation plan that does not allow any disruption to the current system.

In addition to these strategies, a stakeholder engagement plan needs to be designed for each policy (because all three policies are planned toe be implemented). However, to avoid redundant information and repetitive analyses, only one policy is selected for the illustration of the analysis. The analysis process is similar than the one discussed in the first case study, Appendix R. Policy 3, the national policy for the transition to an electronic stock management system, is used to illustrate and discuss the stakeholder engagement plan.

The first analysis is to identify the degree to which stakeholders are involved. In Figure S.3, a number of stakeholders will need to be involved in this policy process; facility managers and representatives should be monitored; health facility staff and third-party distributions can be disregarded from the policy process; and four stakeholder (groups) are equally distributed on the 'attitude' (horizontal) axis. The four stakeholder groups that are unclassified, are categorised accordingly:

SVS and RxSolution product owners: These stakeholders need to be included in the decision-making strategy. Although they do not have the power from a political perspective to influence the policy decision, they do have a big stake in the policy being implemented and should be included to provide assistance from a technology point.

Pharmaceutical Therapeutic Commitees (PTCs): They are responsible for ensuring that the national formularies and provincial formularies should be updated accordingly. This will then need to be embedded into the electronic system. The PTCs have a role to play in the operations; however, they are not negatively impacted by this and can thus be moved down to the 'keep informed' category. They will need to be kept updated on policy decisions, but does not necessarily need to provide input.

Technical team and service providers: From a technical and operations feasibility stand point, they would need to be moved to the consulting category. Their input on operations feasibility and technical feasibility can be insightful.

The health facility managers are a key role for the operationalisation of this policy. The would be responsible for managing and monitoring these operations and ensure that the facility staff are well educated and skilled. They would also bear the responsibility of these processes and will be held accountable. For them to possibly oppose this policy can become problematic. Similar to the health facility staff. For the implementation of the policy, double work would be required by both stakeholders, as the switch to a electronic system cannot be disruptive. The change in the current processes would require training and education, as well as more accountability from both stakeholders.

The health facility staff can still be disregarded from the policy decision-making processes, as they do not have the necessary power to change policy decisions. However, they could be informed on the future possibilities of the policy and that in the long term, the operation of such a system will allow them more time to focus on their clinical role. The health facility managers, however, will need to be monitored as they do have some degree of access to resources (the second type of analysis). Possible solutions would be to provide them with incentives for the first phase in of this policy. The third type of analysis is to look at the internal and external ratios between VAN-related roles. The number of VAN-related roles are in minority, therefore from a human resource perspective, there are not major change required within the organisational structure for this specific policy.

In conclusion, this case study provided another illustration of the PoliVAN logic model's applicability and provided insights on the flexibility of the PoliVAN logic model. No case or context is the same, but the insights and outcomes produced by the six phases shed light onto possible policy obstacles, solutions and strategies.

S.7   Appendix S: Conclusion

In this appendix, the application of the PoliVAN model proceeded systematically through the six phases, where detailed accounts of the different analyses within each phase of the PoliVAN model are presented. Some of the details presented in this appendix are not discussed in Chapter 8, because the case study refined the scope of the analysis as the case study proceeded through the six phases. The scope of the case studies are to illustrate the applicability and flexibility of the PoliVAN logic model. An attempt was made to strike a balance between demonstrating the applicability and the flexibility of the PoliVAN as comprehensively and thoroughly as possible whilst constraining the case study to a feasible scope

Altogether, the insights and the accumulation of information gathered were sufficient to make the necessary policy decisions and strategies. The key findings on the applicability, and especially the flexibility are further highlighted in Section 8.5.

Appendix T

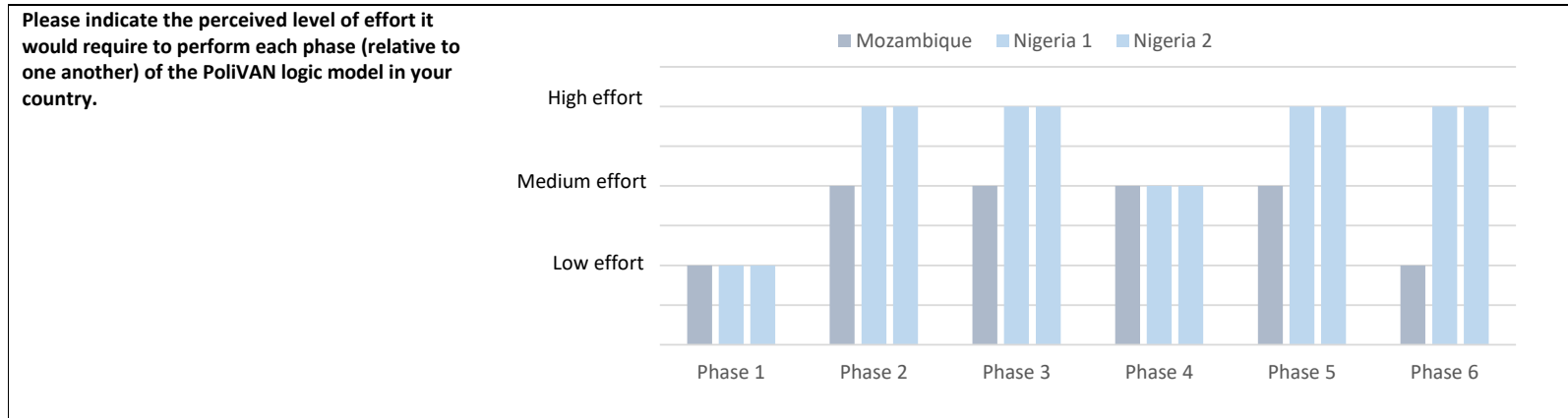# PoliVAN transferability questionnaire and result

In this appendix, the questionnaire detailing the feedback from sub-Saharan African VAN representatives is presented. This questionnaire forms part of the final validation stage in the evaluation strategy and the aim is to gain insight on the transferability of the PoliVAN logic model to other country contexts.

Table T.1: PoliVAN transferability questionnaire and feedback

SUB-SAHARAN AFRICAN COUNTRIES QUESTIONNAIRE	PARTICIPANTS' RESPONSE		
	P6	P17	P18
	Mozambique	Nigeria	
PART 1: VAN-RELATED QUESTIONS ABOUT YOUR COUNTRY			
Does your country have a VAN Operating Model?	"Yes"	"Yes"	"Yes"
If 'Yes', did your country make use of the Blueprint Reference Model (BPRM)?	"Yes"	"Yes"	"Yes"
How did your country find the policy guidelines from the BPRM when developing your VAN?	"N/A"	"Not too descriptive"	"I spoke to one of our advisors on the development team and he believes its incomplete."
Does your country have any policy analysis processes or strategies that are utilised when implementing new strategies in your pharmaceutical supply chain system?	"Yes"	"These are hand-off to VillageReach. They assist with the implementation of our VAN and policy requirements"	"Our VAN advisors sits within the organization which is Village Reach. They do our VAN implementation strategies."
PART 2: POLIVAN LOGIC MODEL CASE STUDY OUTCOMES			
If the PoliVAN logic model is able to provide a similar level of information regarding policies in your country, would you advise VAN-developing stakeholders in your country to utilise this approach? (Explain)	"Each country have its own specifications. I would encourage the use of this Model on developing VAN in my country, since its starts to access what the country have in terms of policies for VAN and Adapt of reformulate them to VAN."	"Yes - it would be useful to test this out though, but it seems to be generic for our country."	"Yes. I believe our country and Village Reach should implement this concept. I enjoyed reading the details and outcomes in the inventory management case study."
If your country decided to make use of the PoliVAN logic model, who would be the responsible role to utilise and govern the PoliVAN implementation?	"Actually VAN in Mozambique has been implemented with support of VillageReach which have expertise in this field. But I think the Central warehouse manager for medicine including vaccines. In Mozambique the counterpart for VillageReach is the MOH M&E Manager of the Immunization program, since VAN is being implemented specifically for vaccines."	"VillageReach will most likely take accountability and be responsible for the execution of the policy model."	"Village Reach"

| **Please indicate the perceived level of effort it would require to perform each phase (relative to one another) of the PoliVAN logic model in your country.** | |

PART 3: COUNTRY-SPECIFIC FACTORS ON THE POLIVAN LOGIC MODEL

Does your country have a detailed framework of your pharmaceutical supply chain functions (such as the PLF given in the pre-read document)?	"Yes"	"No"	"Yes"
If 'No', can the PLF guide your country on how to identify key operational functions in your supply chain?	-	"We use another, cyclic process form VillageReach, not as thoroughly designed as the presented PLF. This tool would be useful."	"We have a similar framework, which is cyclic and includes some components"
The legal hierarchy presented in the pre-read document provides a generic schematic of the relationship between policies and legislation documents. Is this framework a representative of the legislation structure in your country? Please discuss.	"Yes because in my country all policies, rules as well SOPs depends on the country legislation and regulations"	"We have a constitution with legislation (such as regulations, laws and rules similar to your hierarchy). Then there are four distinct law systems: English law, customary law, the Islamic law and the common law. The next type is the Judicial law with four case tiers."	"We have a legal hierarchy, but it is structured differently than the one given in the case study."
The stakeholder identification list aim to provide a generic categorisation of possible individuals, groups or organisations within a pharmaceutical supply chain system. Is it possible for your country to identify relevant stakeholders from this list? Please discuss.	"Yes"	"Yes" "We specificaly focus on cold chain management as well"	"Yes" "This is a very good list"

Appendix U

Bachelor's thesis project for Phase 5 in the PoliVAN

In this appendix, an overview of the supplementary study that aims to support the subjectivity regarding the policy impact analysis approach is discussed. This study is part of a Bachelor's thesis project which was performed under the guidance of the author in this study. The background and aim of this project is discussed, followed by the shortcomings identified from Phase 5 of the PoliVAN, and concludes with an illustration of the developed policy impact analysis model.

U.1   A summary of this study

This supplementary study highlights the shortcoming identified in Section 10.2 and aims to address this by investigating various "impact analysis dimensions, tools and methods available" Oosthuizen *et al.* (2019), to subsequently provide a comprehensive multi-criteria decision analysis approach that analyses the impact of the policy options from Phase 3 on the pharmaceutical system in a country (within the scope of VAN). Figure U.1 provides an illustration of this particular study's scope, how it fits within the PoliVAN, and at largely, the VAN initiative.

After a meticulous investigation of the PoliVAN's current policy impact analysis model and its high-level problem, it was highlighted that the "current method used to determine the scores and weighted impact of each analytical dimension...is subjective" (Oosthuizen *et al.*, 2019). This supplementary study conducted an analysis on ways to measure the impact of policies specifically on a pharmaceutical supply chain and placed emphasis on the dimension 'resilience'—the system's capacity to handle change and unexpected disturbances (Hafner et al., 2017). This finding led to further investigation of analytical dimensions that are associated with the resilience dimension. After further literature review and gap analysis studies, other analytic dimensions were highlighted—some similar than those from Phase 5 of the PoliVAN. This supplementary study then conducted a literature synthesis to identify the key analytical
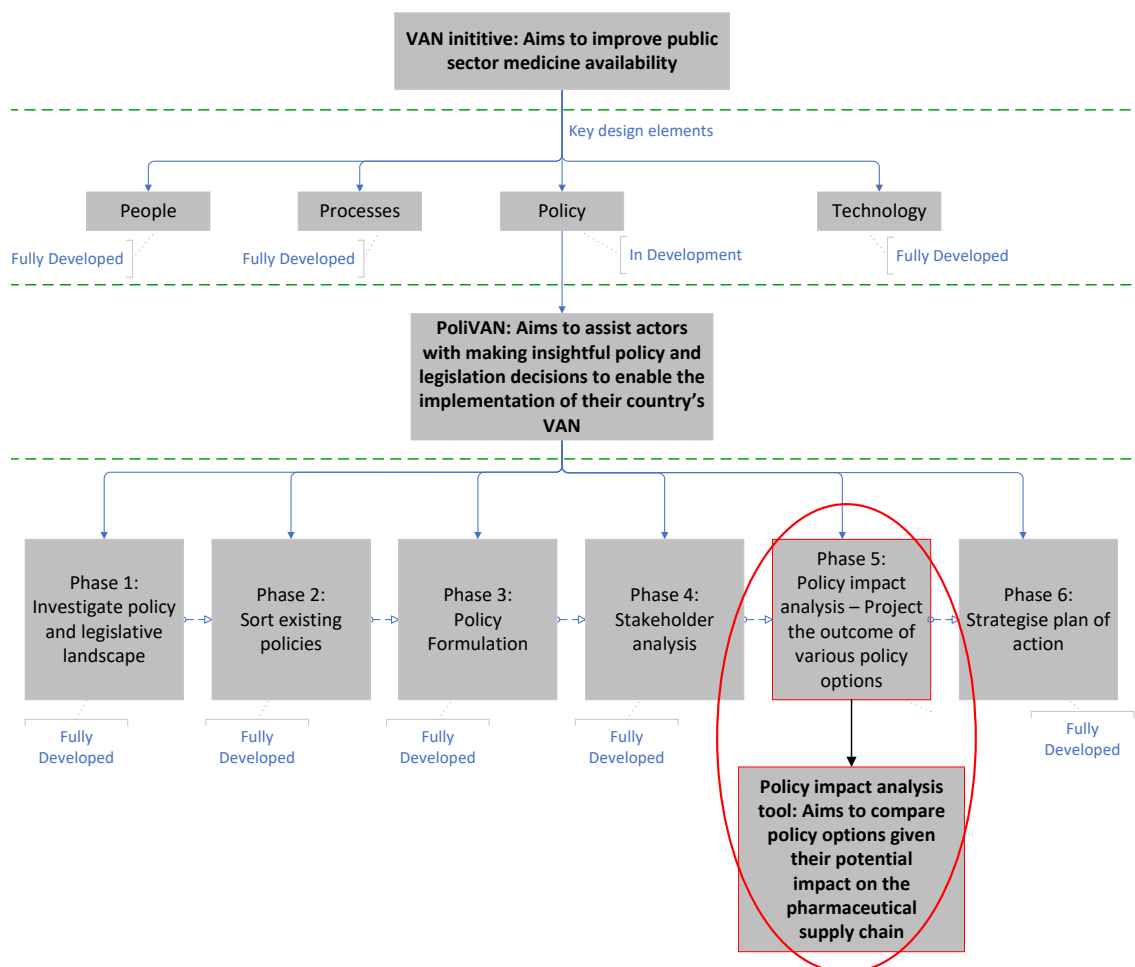
Figure U.1: The scope of the supplementary Bachelor's thesis project

dimensions that supports both the VAN initiative and the context of a pharmaceutical supply chain, which consequently builds on the current analytical dimensions proposed in Phase 5.

Once the analytical dimensions were formulated, the study investigated measures on how to score and assign weighting factors that are less subjective than that of the current method. After a thorough literature review, information synthesis and cross-examinations, it was concluded that the analytical hierarchy process (AHP)[1] is considered the best multi-criteria decision analysis approach for the PoliVAN (Oosthuizen *et al.*, 2019). This approach translate subjective scoring method into objective outcomes (Oosthuizen *et al.*, 2019). The AHP method is subsequently included into the design of the policy impact analysis tool and the proposed Phase 5 steps for the PoliVAN is illustrated (the extended view) in Figure U.2.

The process of the analyses, suggested in this phase, provides the sequential steps that progresses through three respective regions, each region defining the scope of the analysis

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[1]Saaty (2008) defines AHP as "a theory of measurement through pairwise comparisons that relies on the judgements of experts to derive priority scales".
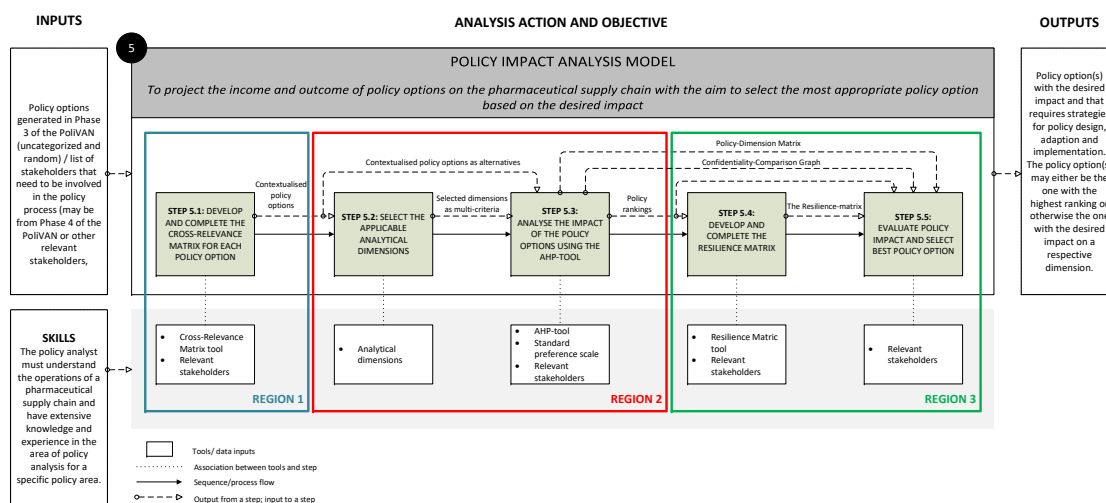
Figure U.2: The detailed steps within Phase 5 of the proposed policy impact analysis tool

to the specific context of the policy options (Oosthuizen *et al.*, 2019): *"(i) Region 1 their relevance to the VAN objectives, pharmaceutical objectives and operational components of the* [PLF]; *(ii) Region 2 their impact on pharmaceutical systems strengthening; and (iii) Region 3 their impact on the resilience of a pharmaceutical health system."* Similar to the generic step-wise guide illustrated in Figure 7.2, the inputs, outputs, steps, skills and tools are provided which subsequently fits within the current PoliVAN logic model. The details regarding each step and tool is not presented in this appendix. However, an overview of the input and output dashboards are illustrated in Figure U.3. The output dashboard illustrates the policy rankings based on the least impact it has on the pharmaceutical supply chain. The data inputs used is for illustrative purposes and are by no means connected to the outcomes presented in the case studies in Chapter 8.

U.2 Conclusion

This supplementary study investigated the shortcomings highlighted from Phase 5 of the PoliVAN and explores methods on how to improve the subjective nature of the current scoring approach. Additionally, the supplementary study refined the analytical dimensions and provided a method that systematically defines the scope of the impact analysis for the specific policy being analysed. This supplementary study will be examined in November 2019 and has not been applied to the case studies discussed in Chapter 8.
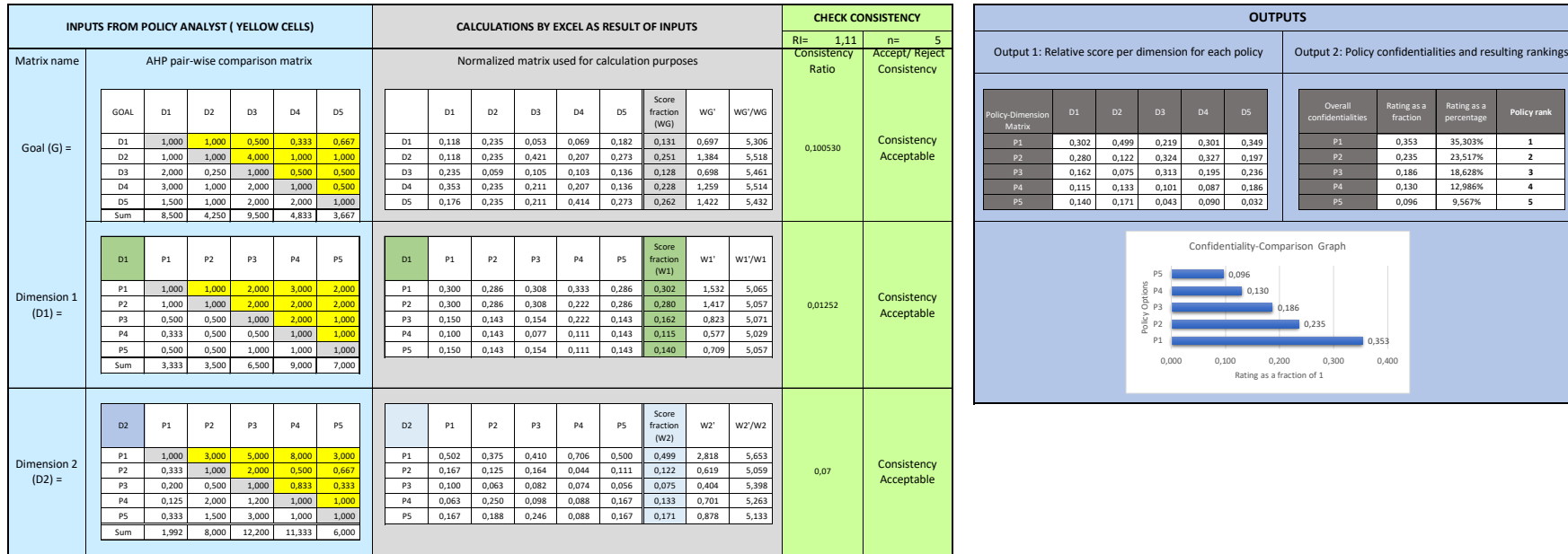
Figure U.3: A section overview formulated from the input and output dashboard