Financing of Medical Products in South Africa

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Thesis presented in partial fulfilment of the degree of Masters of Medicine in the Faculty of Medicine and Health Sciences at Stellenbosch University.

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December 2019

Declaration

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Abstract

Background:

Medical products (encompassing medicines and medical devices) are critical health system building blocks; access to medical products (ATM) impact clinical outcomes. However, cost and operational inefficiencies in the health system limits ATM. Funding strategies and policy reforms are key instruments in managing the supply and demand side determinants of ATM.

Objectives:

This study aimed to 1) analyse the South African(SA) regulatory framework for medical products; 2) review expenditure on medical products at Private, Public and Household levels; and 3) describe ATM using the WHO Building Blocks framework and 4) gauge the status of supply and demand side determinants of ATM.

Methodology:

A mixed methods study design was used to represent ATM complexity in the health system. USAID's Health System Assessment Approach was used to analyse the enabling legislative and regulatory landscape for ATM in SA. Unpublished National Treasury, provincial Departments of Health and Council for Medical Schemes Annual Reports were sources for the descriptive trend analysis of public and private sector medical products expenditure. Household out-of-pocket expenditure was analysed from Statistics SA national household survey data. With data from key informant interviews, a systems diagram was constructed. District Health information system and national survey data was used to present current system performance using supply and demand side indictors of ATM.

Results:

Medical products expenditure is a major cost driver in the private sector. Households with medical aid, spent more OOP on medical products than the uninsured; province, household size and income sources were not significant factors in estimating medical products expenditure. In the public sector, trends demonstrate increasing investment in medical products, however indicators of supply side ATM determinants show poor performance. In 2014, health contributed 0.9 %(R935) of total household expenditure; which does not constitute catastrophic expenditure levels. A larger proportion of total health spending is on medical products (0.7%) than outpatient medical services (0.6%) in average SA households; pharmaceutical expenditure dominates (90%) compared to therapeutic appliances and other medical products combined (10%). In uninsured households NC and LP provinces and Indian and White population groups were the only statistically significant variables in estimating expenditure. Male headed households spend more actual Rands on medical products than female headed households. A R31.00 decrease in expenditure for rural insured households

was calculated for each increase in expenditure by urban insured households. Households in FS, NW, EC and NC had the highest OOP expenditures on medical products. Households in LP had the lowest OOP expenditure on medical products in the survey period.

Conclusions and Recommendations:

There are opportunities in the scale up to UHC to implement policy options to increase ATM. Capacity building is needed to ensure equitable fiscal allocations, ability to absorb resources and optimise service delivery within government. Need for improved monitoring and data analytics of cost, access and utilisation of medical products at public health facilities; OOP spending on medical products in private sector in terms of outpatient and hospitalisation and survey data at household level spending. Managed care Organisations can contribute to ATM through quality and clinical governance in the private sector.

Acknowledgement

I would like to thank the following people:

My family, Collin, Szarya Shirlene, Sedira and Yemira Mamdoo for their love, inspiration, sacrifice and support.

My Supervisor, Dr Kerrin Begg, and other senior faculty members, Prof Lilian Dudley and Prof Hassan Mahomed among others.

All other staff members at the Division of Health Systems and Public Health, Stellenbosch University.

Collin Mamdoo, Cladnos Mapfumo and Carl Lombard for Biostatistical assistance.

Abbreviations

ATM	Access to Medical products
AMASA	Accessing Medicines in Africa and South Asia
ATMP	Advanced Therapeutic Medicinal Product
ADR	Adverse Drug Reaction
ACP-EU	African Caribbean and Pacific Group of States Secretariat –European Union
ASR	Annual Statutory returns
ART	Anti-Retroviral Therapy
ARV	Antiretroviral
bn	billion
CCMDD	Central Chronic Medicines Dispensing and Distribution
CPM	Centre for Pharmaceutical Management
CFO	Chief Financial Officer
COICOP	classification of individual Consumption According to Purpose
CDC	Community Day Clinic
CHC	Community Health Centre
CMS	Council for Medical Schemes
CHE	Current Health Expenditure
DOH	Department of Health
DSP	Designated Service provider
DHB	District Health Barometer
DHIS	District Health Information System
DU	Dwelling unit
EDO	Efficiency Discount Options
EUAL	Emergency Use Assessment and Listing
EML	Essential Medicines List
FTPL	Fix The Patent Laws
GHS	General Household Survey
GP	General Practitioner
GGM	Good Governance for Medicines
G&S	Goods and services
GDP	Gross Domestic Product
HOD	Head of Department
HiAP	Health in all Policies
HPSR	Health Policy and Systems Research
HPCSA	Health Professionals Council of South Africa
HSAA	Health system assessment approach
HSS	Health system strengthening
HST	Health Systems Trust
HTA	Health Technology Assessment
HMI	Healthcare Market Inquiry
HH	Household
HIV/AIDS	Human Immune Deficiency/Acquired Immune Deficiency Syndrome
HSRC	Human Science Research Council
IVD	In Vitro Diagnostics
IES	Income and Expenditure Survey
IOM	Institute of Medicine
FIP	International Pharmacy Federation
KI	Key informants
LCS	Living Conditions Survey
LMIC	Low and Middle Income Country

MSF	Management Sciences for Health
MSH	Management Sciences for Health
MSA	Medical Savings Account
MRSA	Medicines and Related Substances Act, 1965 (Act 101 of 1965)
MCC	Medicines Control Council
MDG	Millennium Development Gaol
M&E	Monitoring and Evaluation
NDOH	National Department of Health
NDP	National Drug Policy
NHI	National Health Insurance
NMPs	National Medicine Policies
NCE	New Chemical entity
NCD	Non Communicable Disease
OOP	Out of pocket
OTC	Over the counter
PTG	Pharmaceutical Task Group
PBM	Pharmacy Benefit management
PMB	Prescribed Minimum Benefits
PMTCT	Prevention of Mother to Child transmission
PHC	Primary Health Care
PSU	Proportional Sampling Unit
ZAR	Rands
RF	Rural Formal
SEP	Single Exit Price
SDH	Social Determinants of Health
SADHS	South African Demographic and Health survey
SAHPRA	South African Health Products Regulatory Authority
SAHR	South African Health review
SAPA	South African Pharmacy Association
SAPAM	Southern African Programme of Access to Medicines and Diagnostics
STG	Standard Treatment Guidelines
Stats SA	Statistics South Africa
SSA	Sub-Saharan Africa
SCM	Supply Chain Management
SDG	Sustainable Development Goals
THE	Total Health Expenditure
TAC	Treatment Action Campaign
UN	United Nations
UNDP	United Nations Development Program
USAID	United States Agency for International Development
USD	United States Dollar
UHC	Universal Health Coverage
UF	Urban Formal
UI	Urban Informal
WHO	World Health Organisation

Glossary

Medical device

“Medical device” means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) — (a) intended by the manufacturer to be used, alone or in combination, for humans or animals for one or more of the following: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) control of conception; (vi) disinfection of medical devices; or (vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and (b) which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means(1).

In Vitro Medical Devices (IVD)

‘In Vitro Diagnostic (IVD) means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes(1).

Medical equipment

Medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices(1).

Consumables medical supplies

Non-durable medical supplies that are usually disposable in nature; cannot withstand repeated use by more than one individual; are primarily and customarily used to serve a medical purpose; generally are not useful to a person in the absence of illness or injury; may be ordered and/or prescribed by a physician(2).

Health technology

Refers to the application of organised knowledge and skills in the form of (medical) devices, medicines, vaccines, procedures and systems developed to solve a health problem and to improve quality of lives. (WHA 60.29)(1)

Medical products / Health products

Products used for health related matters may be categorised into two major categories according to intent, i.e. those which aim to diagnose, to treat and to prevent disease and injury; and general health and wellness products. Health products which aim to diagnose, to treat and to prevent disease and injury include all medicines (allopathic and complementary) and medical devices (including in vitro diagnostic devices, IVDs). The regulation of safety and efficacy of medicines is well established for allopathic medicines and recently initiated for complementary medicines(3)

Medicine / Pharmaceutical / Drug

"Medicine" (a) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in — (i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or (ii) restoring, correcting or modifying any somatic or psychic or organic function in humans, and (b) includes any veterinary medicine(4).

COICOP (classification of individual Consumption According to Purpose) codes (5)

Medical Products, Appliances and Equipment

This group covers medicaments, prostheses, medical appliances and equipment and other health-related products purchased by individuals or households, either with or without a prescription, usually from dispensing chemists, pharmacists or medical equipment suppliers. They are intended for consumption or use outside a health facility or institution. Such products supplied directly to outpatients by medical, dental and paramedical practitioners or to in-patients by hospitals and the like are included in outpatient services (06.2) or hospital services (06.3).

Pharmaceutical products

Medicinal preparations, medicinal drugs, patent medicines, serums and vaccines, vitamins and minerals, cod liver oil and halibut liver oil, oral contraceptives. Excludes: veterinary products (09.3.4); articles for personal hygiene such as medicinal soaps (12.1.3).

Other medical products

Clinical thermometers, adhesive and non-adhesive bandages, hypodermic syringes, first-aid kits, hot-water bottles and ice bags, medical hosiery items such as elasticated stockings and knee supports, pregnancy tests, condoms and other mechanical contraceptive devices.

Therapeutic appliances and equipment

Corrective eyeglasses and contact lenses, hearing aids, glass eyes, artificial limbs and other prosthetic devices, orthopaedic braces and supports, orthopaedic footwear, surgical belts, trusses and supports, neck braces, medical massage equipment and health lamps, powered and unpowered wheelchairs and invalid carriages, ‘‘special’’ beds, crutches, electronic and other devices for monitoring blood pressure, etc.; – repair of such articles. Includes: dentures but not fitting costs. Excludes: hire of therapeutic equipment (06.2.3); protective goggles, belts and supports for sport (09.3.2); sunglasses not fitted with corrective lenses (12.3.2).

Outpatient Services

This group covers medical, dental and paramedical services delivered to outpatients by medical, dental and paramedical practitioners and auxiliaries. The services may be delivered at home, in individual or group consulting facilities, dispensaries or the outpatient clinics of hospitals and the like. Outpatient services include the medicaments, prostheses, medical appliances and equipment and other health-related products supplied directly to outpatients by medical, dental and paramedical practitioners and auxiliaries. Medical, dental and paramedical services provided to in-patients by hospitals and the like are included in hospital services (06.3).

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CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Good health is important to build traditions and norms for communities to flourish (6). Today however, what resonates is the association of health and productivity as a means to achieve economic growth to improve lives in society(7). Improving the health status of citizens is therefore a political and policy priority for South Africa. The Bill of Rights enshrined in the South African Constitution since 1996, recognises access to healthcare as a basic human right(8). In realising this right, access to healthcare services and professionals without medicines and medical devices (referred to as 'medical products') is of little practical significance(9).

Medical products save lives and help avoid catastrophic consequences to health status but they are expensive and need sustainable financing mechanisms to fund them consistently and reliably(9). Literature on access to medical products highlight regulation and financing as key system inputs in the value chain linking the pharmaceutical and health technology industries to the health sector(10).

Expenditure on medical products, pharmaceuticals in particular, is a major driver of cost for the State, after Compensation of Employees(11). In 2016, spending on medicines (R13bn) and medical supplies (R7bn) across all provinces in South Africa (SA) (12) served an estimated 45 million uninsured individuals (81% of total population) (9), who rely on the public sector to meet their healthcare needs. Medical products expenditure is also a major cost driver of healthcare in the private sector, where , R23.9bn (15.84%) was spent on prescribed medicines alone (13) in 2016 from total industry benefits paid (R151.21bn).

In the context of overall health spending, households in low and lower middle income countries in Sub-Saharan Africa (SSA), incurred most (more than 85%) of total health expenses Out Of Pocket(OOP) in 2009; the main expense (50 to 80%) of total spend is on medicines (14). Despite this, allopathic medicines are estimated to be underfunded in both public and private (about 20% overall expenditure) sectors in LMICs in 2004 (15).

Recognising the resource limitations and capacity constraints in South Africa, effective medical treatment and intervention demands innovative financing strategies and responsive health delivery systems (9). There is increasing demand and dependence on medicines in clinical practice brought about by increases in population size and life expectancy. Innovative new drug formulations present novel treatment modalities, but are expensive new market entrants. As multimorbidity increases, combination replaces monotherapy and acute episodic treatment is replaced by chronic management (9).

Access to medical products (ATM) is an essential part of the health service delivery but suffers the tensions between underfunding and overspending; medicines selection and rational use; pricing and cost; efficient supply and effective demand management (9). There are serious gaps in knowledge of financing and expenditure in medical products in SA although accessible and publicly available information is reported by public and private sectors and gathered from households routinely (30). Although pharmaceutical policy analysis and reviews have been undertaken in SA, more research is needed to define ATM within the context of the health system (98,132). This study critically reviews the literature on policies, laws and regulations that frame the interaction between the health technology industry and the health sector in South Africa and analyses the financing and expenditure of medical products, with a specific focus on allopathic medicines, in the health sector (public and private) and at household level. Linking the analyses, the health systems approach contextualises the discussion of ATM in South Africa.

1.2 Background

The anatomy of the clinical consultation has evolved to an extent where medical products are now indispensable in the encounter(9)and this is true also for allied health professions. Medical products can be defined within a broader framework of health technologies shown in Figure 1. The Medicines and Related Substances Control Act (1965) (referred to as 'The Medicines Act') and the Amendments, form the regulatory basis for all aspects of health technology in South Africa. The most recent Amendments (2008 and 2015) introduce medical device, complementary and traditional medicine regulation in South Africa(4).

Precise and consistent technical definitions are critical to classify health technologies according to risk and intended use, which determines applicable regulatory controls(1) . Although health technology encompasses blood products and Advanced Therapeutic Medicinal Products (ATMPs)(1) , which are innovative new therapies such as gene, tissue and cell technologies(146), these are considered beyond the scope of this study and have been omitted in the analysis.

Medical products introduce technical and economic challenges to health systems and raise concerns around sustainable financing, efficiency and equity. Harmonising regulatory requirements can decrease costs of compliance and product registration time, enabling faster access to medicines and medical devices, ultimately benefitting users(16).

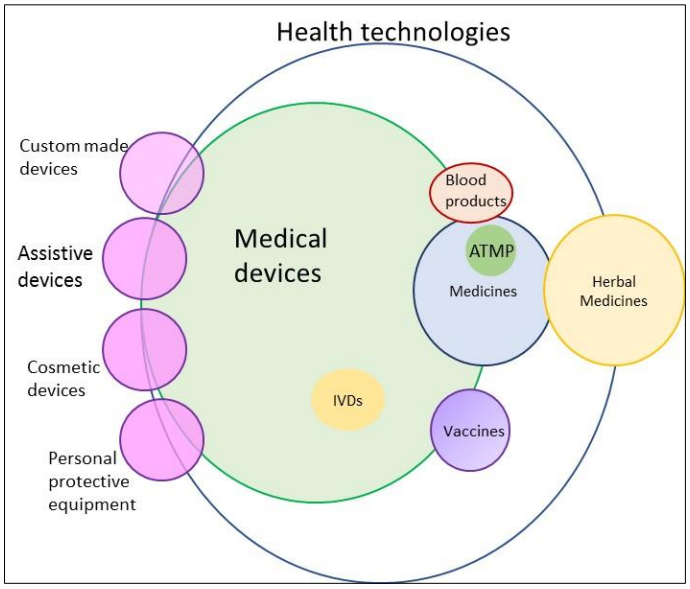


Figure 1 : Interrelation of medical products inside and outside healthcare

Source: Medicines Control Council, Borderline Products 2017(3)

A demonstration of the impact of ATM in the lives of South Africans, is the historical pharmaceutical industry action against the South African government's intention to provide access to lifesaving Antiretrovirals (ARVs). Pharmaceutical Manufacturers in SA sought to oppose parallel importation of low cost generics and manufacturing licences under the provisions of Section 22C in the Medicines' Act, for local generic manufacturing (17,18). In 1991, the average annual cost of (ARV) triple therapy per patient in Africa was approximately USD 12 000. Through cooperative agreements between industry and government, annual costs of ARVs fell to less than USD 1000 in 2003. This improved access to ARVs lead to increases in life expectancy at birth for South Africans from 54.9years in 2002 to 64yrs in 2017 (19). With an estimated 6.4 million people living with HIV/AIDS in South Africa in 2012 (20)and 7.52million in 2018(147), ATM requires an integrated health systems response with costly, resource- heavy inputs from service delivery, finance, human resources, health information and governance building blocks(21, 9).

The first South African National Drug Policy (NDP) in 1996 addressed health inequities and improved access to medicines for all South Africans, recognising the disparities between the consumption in the larger public (70% volume) and private (80% expenditure) in health sectors (22). In three decades of implementing National Medicine Policies (NMPs) across the globe, evidence points to policy and regulation as effective instruments to improve access, control expenditure, rationalise use and ensure quality of medicines(9). Where

health sector equity, social justice and service orientation converges with industry and market agendas , vulnerability to fraud, mismanagement, patent law infringements, information asymmetry and corruption pose real threats(9). Amartya Sen in Ruger's "Health and social Justice" recognises the role of public policy across sectors to promote health, aligned with the World Health Organization's (WHO) "health-in-all-policies" approach (23).

WHO-supported global policy changes have resulted in ATM increases from around 2.1 bn (1977) to an estimated 3.8 bn people(1997) (24). About fifty percent of the population in parts of Africa and South-East Asia in 2002 lacked access to essential medicines. The Report of the Commission on Macroeconomics and Health (2001) estimated that by 2015 over 10 million deaths per year could be averted by ensuring ATM(25).However in 2015, United Nations(UN) MDG target 8E progress reports ("In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries") found that low availability, high prices and poor affordability of medicines are still key impediments to treatment access in LMICs (26). WHO estimates that nearly two billion people (a third of the world's population) still do not receive a regular and consistent supply of crucial medicines in 2015 (27).

Beran et al suggest that increasing expenditure is an effective policy instrument to improve health outcomes, but cannot be successful without health systems strengthening(28). Several studies confirm that increased financial investment results in positive health outcomes in Africa (7,29,30,31) . Others argue that increased spending alone cannot not improve access emphasizing Social Determinants of Health (SDH) such as income per capita, income distribution, female education levels, ethnic fragmentation and religion, have profound effects on health outcomes(32,33). Increasing life expectancy and paradoxical increases in morbidity from a high burden of NCDs and chronic infectious diseases (e.g. HIV and TB) impact health policy and financing decisions. The epidemiological profile of the country should be a key determinant in funding decisions allocating equitable financial resources to greatest need(32). South Africa and other Low and Middle income countries (LMICs) share a high burden of disease which affects ATM in a variety of ways such as: differential access to acute and chronic medications; high demand in public sector; high cost in private sector; wide contrasts in patient experiences afforded by insurance coverage and geospatial health service delivery arrangements (33,34,35).

The literature review describes ATM using the health systems approach, to address barriers to access, discussing the relevance of emerging challenges in health policy and financing. Research suggests that access to health services has improved over the past two decades in South Africa however, a deeper understanding of service quality is needed to inform an appropriate systems and policy response(36). Therefore, the aim of the literature review is

to provide a critical analysis of access to medical products in health systems and highlight the links between policy, financing and ATM in South Africa.

1.3 Defining 'access to medical products' in the South African context

'Access to medical products' is defined as "having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk of the population"(37). Medicines in this context refers to pharmaceuticals or drugs and do not encompass complementary and traditional medicines(1,4).Most definitions recognise the role of time, distance, resources involved in seeking health care(38,39). Access is therefore multidimensional and complex which makes measurement complicated.

Enrolling patients onto treatment may improve coverage or uptake of services but without improvement in health outcomes it is not considered 'accesses. ATM therefore implies that individuals should possess both the ability and resources to obtain medicines when they are needed, to improve health. Although Penchansky and Thomas introduced five dimensions for access(40) in healthcare in 1981, most current descriptions emphasizes four dimensions: accessibility , affordability, availability, and acceptability(9, 41,42,43). Beran et al distinguish ATM from access to treatment by emphasizing the role of other health systems determinants such as infrastructure, health worker expertise, adequate funding of resources and poor information management(28), a burden experienced disproportionately in LMICs. ATM is therefore, inextricably linked to access to healthcare and is the premise on which this study is based.

'Access to care' viewed from the demand side perspective, is the empowerment or ability of an individual to use healthcare resources and represents an interaction between individuals, households, the community and the healthcare system(43). The 70th World Health Assembly (WHA) in 2017, refers to supply side definitions of ATM as multistage processes along the medical products value chain from "needs based research, development and innovation; quality manufacturing processes ; public health- oriented intellectual property and trade policies; selection, pricing and reimbursement policies; integrity and efficiency of procurement and supply; and appropriate prescribing and use"(44).

1.4 Health systems approaches to 'Access to medical products'

There is universal acknowledgement of the impact of ATM in health systems. The Sustainable Development Goals (SDG 3) and its predecessor, Millennium Development Goals (MDG 8) recognised the impact of ATM on the global health agenda. The UN 'High-

Level Panel on Access to Health Technologies'(44) in 2016, called for new approaches to health technology innovation, ensuring access that benefits all people. The 70th World Health Assembly in 2017 drew attention to the "global shortage of and lack of access to medicines and vaccines" despite the importance of ATM underlying public health strategies (44).

The health systems approach favours the utility of frameworks to describe complex environments, highlighting interactions between elements. The WHO Framework for Action (2007) (45) listed priorities for countries in ensuring ATM, focussing on overall health systems performance at a macro level. The framework emphasizes interaction of the six building blocks in strengthening health systems. The WHO Access framework (2004) (24), which pre-dated the health systems strengthening agenda of the 1990s, focusses on supply-side policy reforms . Four themes introduced here (rational use, sustainable financing, affordable prices and reliable health and supply systems) are incorporated in the Management Sciences for Health (MSH) Centre for Pharmaceutical Management (CPM) (2011) Framework (9).

The conceptual framework for assessing access to health services by Peters et al(42) in Figure 2 reinforces the relationship between quality and access to healthcare. The model recognises the influence of policy on the macro-context, showing the effects of illness on poverty and vulnerability. In this model, the supply and demand side dimensions of access create a measurement matrix for efficiency and performance. The MSH/CPM model for ATM adds the domains of quality (safety, efficacy and cost effectiveness) as an essential cross-cutting attribute of medical products. Access is seen as the result of the interaction of finance, information, service delivery, and governance building blocks in the health system (98).

Levesque's conceptual framework maintains the integrity of the access dimensions seen in other models but focuses on SDH. This model highlights the interface between user and health service along a pathway beginning with the user's capacity to convert a health need into a demand for service termed 'expressed utilisation'. Here access is the final outcome, contingent on the user's capacity to navigate and negotiate barriers to access(46) .

Viewed as a whole, the conceptualisation of access to healthcare and extensibly ATM is consistent across many models. Embedding ATM models within the health systems frameworks, based on evidence from successfully implemented programs, provides policy makers and health officials the knowledge base from which to identify leverage points for action (47). When the model is sufficiently robust, decision makers at different levels can interpose local knowledge and extrapolate results within defined system parameters, if they are able to assimilate their own capabilities within health system components (48). Effective

policies catalyse people and relationships in the system to act as inhibitors or enablers which transform organisational capacity on the supply side. This can greatly influence availability and acceptability (demand side) of ATM (48). The impact and consequences of equity, social justice, innovation, globalisation and politics , should inform ATM public health program design and goal setting (48).

Advocated by WHO for LMICs, Universal health coverage (UHC) goals of equity, financial risk protection and access to a comprehensive range of services, have proven elusive thus far. The NHI currently being implemented in South Africa, principled on risk sharing and cross subsidization, relies on a high degree of social solidarity which is questionable with historical and current untenable levels of inequality (49). Within-country differences such as decreased poverty levels, higher medical scheme membership and increased per capita health spending in Gauteng and Western Cape as compared to Limpopo and Eastern Cape exacerbate inequity(59,86,57,60). Equitable ATM is therefore, an appropriate goal within the South African setting(42).

1.5 Health systems assessment of 'Access to medical products'

Defined by the WHO, "Health is a complete state of physical and mental wellbeing not merely the absence of disease or infirmity"(50). In this sense, 'health' is defined as an outcome and healthcare is a determinant of health. Here, 'healthcare' refers to services delivered to either the public at large (e.g. campaigns for health promotion) or personal health services (clinical consultation and treatment). Health systems represent the structures, resource mobilisation and actions which influence health (outcome). In this study, ATM is viewed as an outcome. This outcome (ATM) is a product of the performance of the healthcare system. Thus, to assess healthcare performance, an evaluation of the delivery mechanisms of health services, is needed(51).

The extent to which access is achieved can be assessed through utilisation, patient satisfaction and extent of changes to service provision. 'Access' and 'coverage' have been used interchangeably to describe measurable targets of health system performance. Epidemiologists aspire to achieve maximum 'coverage' of an intervention in a target population; policy makers aspire towards achieving access to healthcare for an entire population(45). Given its complexity, an overall picture of access to medicines can be generated using a range of indicators that provide data on medicine availability and price, in both public and private sectors, in combination with key policy indicators.

Measurement guides improvement in health systems(52) which is required to address ATM shortcomings in South Africa. Quality data enables decision-makers to assess ATM and

make informed decisions to intervene. Monitoring of availability, quality and misuse of medical products can facilitate timely intervention and improve ATM. WHO supports the development and use of practical indicators, methods and systems for monitoring access to medicines and the use of this data to adapt and amend policies and practice but much more needs to be done to achieve this to fulfil the reporting requirements for the SDG 3.8 (53) Survey data has also been used successfully to analyse access to health(54).

ATM can be measured in four dimensions; accessibility, availability, affordability and acceptability, each with demand and supply side determinants. A study of access to General Practitioner (GP) primary health care (PHC) services in Australia singled out Acceptability (patient preference) and Availability (GP) as the most important dimensions(55).

In 1993, Institute of Medicine (IOM) set up a gauge for access to healthcare consisting of routinely collected information in the health system, tracked over time, providing a realistic impression of progress for policy and decision makers. The diagram below by Peters et al(42) provides a conceptual framework of practical utility in measuring access to health services. Factors affecting access to healthcare and ATM are closely linked and reflective of common systemic issues (52,56,28) and are therefore considered synonymously in this study.

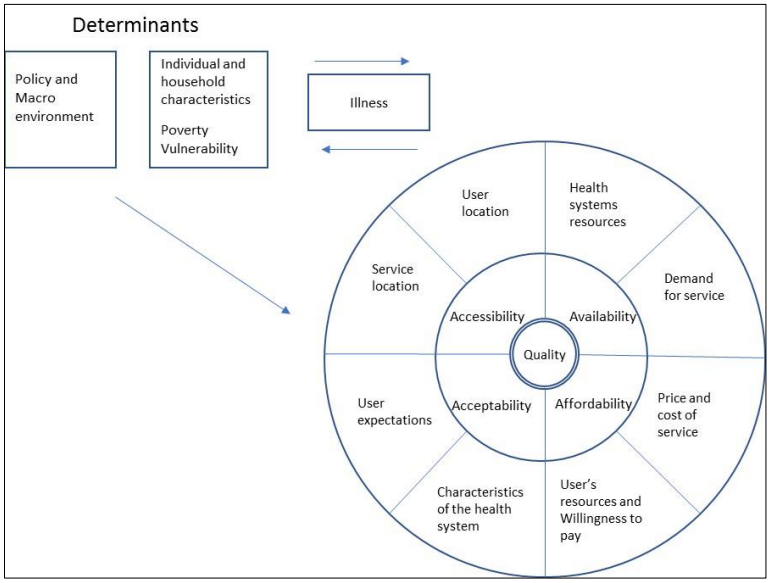


Figure 2: Conceptual framework used to assess health service

Source: Peters et al. (55)

The Peters et al. model combines supply and demand determinants of access to healthcare in the context of poverty and has utility for describing ATM in SA. Demand side determinants

of access are subject to differences in decision-making and health seeking behaviour at individual and community level; individuals make choices about their health and communities make decisions based on resources. However, an exploration of these factors at an individual level affecting behaviour, preference and choice are beyond the scope of this study.

Accessibility is defined as the geographic location or travel distance from or to a service delivery point(46). The South African Health and Demographic Survey (SADHS) in 2003 found that women of all ages, experienced problems accessing care. Two of the top three commonest barriers to access healthcare across all provinces and in all race groups was due to reliance on transport (31.8%) and distance (30.6%). The SADHS found that women living in Limpopo Province (LP) and those with children were particularly vulnerable to impeded access. This has deleterious effects on health status of mother and child as it impacts on uptake of immunisation and antenatal care(57). McIntyre and Ataguba (43) suggest that physical access to health facilities leads to increased utilisation of services which improve health outcomes. In 2008, the majority of South African households in urban areas (urban formal 52.4% and urban informal 53.4%) lived within a 2km radius of a health facility, except in traditional and formal rural areas, where most (64.3% and 76.3% respectively) lived more than 10km from a clinic(107, 56). However, the 2016 SADHS survey findings suggest that measures of access are shifting: women from non-urban areas were more likely to receive antenatal care from a skilled provider (96% vs 92%) as well as four or more ANC visits (80% vs 73%) than urban women (148).

Availability is the ability to receive the appropriate services when the need arises. From a user perspective, it refers to the appropriate type of care available to those who need it, such as hours of operation and waiting times that meet demands of users, as well as having the appropriate type of service providers and materials(46). Poor and inconsistent availability of medicines have immediate effects: inconvenience, actual and opportunity costs, no medication, incomplete regimen, less than required volumes and more burdensome alternatives. However the long term consequences are worse: incomplete vaccination schedule; treatment failure; catastrophic health expenditure and propagation of disease in the community(59).

Measures of Availability are: first point of contact for medical assistance; operating hours of facilities; waiting period (demand side) and medicine stock- out rates (supply side). In SA, public sector facilities continue to experience stock-outs of EML drugs. The “Stop Stock Outs” campaign organised by a consortium of 6 civil society organisations report serious stock outs of EML drugs (especially HIV/TB drugs) in PHC facilities across SA. Seventy percent of these stock outs last for more than a month. Routine paediatric vaccines were out of stock in 11% of facilities. Stock outs in PHC facilities increased from 2014 (25%) to 2015

(36%)(59). The District Health Information System (DHIS) data reflects that 78.4% of PHC facilities nationally had access to 90% of tracer medicines between 2016 and 2017(60). Although the requirement is to stock 90% of tracer medicines, only six districts were able to achieve this benchmark(60). Globally, the average public sector availability of generic medicines ranged from 29·4% to 54·4% across WHO regions(61). In the formal sector of LMICs, average availability of medicines is 35% in public facilities and 66% in the private sector, although prices are often unaffordable in the latter (62).

Affordability describes both the price of services (supply side) and the willingness and ability of users to pay for those services (demand side). Measures of affordability are users' expenditure threshold for use of services and household expenditure on medical products. The SADHS in 2003 found that, on average, women of all ages, race groups, provinces, regardless of marital status and education level, cited affordability as the biggest barrier to accessing healthcare. Limpopo province, rural settlement areas, Black African race group, no exposure to formal education, divorced or separated or widowed status, were positively associated with lack of access due to low affordability(57). However, by 2016, the GHS showed that affordability did not feature in the commonest causes of dissatisfaction among healthcare users (139).

Acceptability, from a health systems perspective, reflects the extent to which the health service and professionals cater to individuals' and communities' social and cultural expectations. Measures of acceptability are cleanliness of facilities; friendliness of staff and service satisfaction visit to a health facility (63). By these measures, the GHS 2016 found that service satisfaction and friendliness of staff were common reasons for patient dissatisfaction (139). Acceptability of medicines refers narrowly to the "overall ability of the patient and caregiver (defined as 'user') to use a medicinal product as intended (or authorised)" (64)and is not explored in this work.

1.6 Factors affecting 'Access to medical products' in South Africa

South Africa, among other LMICs, is experiencing an epidemiological transition as the dual chronic infectious disease epidemic of HIV/AIDs and TB is gradually being replaced by chronic diseases of lifestyle as leading causes of morbidity and mortality(65) . Sixty five percent (65%) of mortality in persons over the age of 45yrs was attributed to NCDs in 2012. Despite the effects of HIV/AIDS, life expectancy for South Africans at age 60 was 18.2yrs in 2012 (66). Globally, between 1950 and 2017, life expectancy increased from 48·1 years (46·5–49·6) to 70·5 years (70·1–70·8) for men and from 52·9 years (51·7–54·0) to 75·6 years (75·3–75·9) for women (149). Increasing longevity coupled with increased NCD

mortality and morbidity is expected to challenge existing models of healthcare provision and pharmaceutical utilisation and creates the opportunity for innovative approaches to ATM.

Infectious disease epidemics such as Ebola and Zika viral outbreaks, exposed the heightened vulnerability of health systems responses across the globe. The WHO's response procedure, Emergency Use Assessment and Listing (EUAL) fast tracks access to diagnostics, medicines and vaccines in public health emergencies. As a longer term strategy, WHO- African Caribbean and Pacific Group of States Secretariat (ACP) –European Union (EU) collaboration has the task of expanding access and availability, improving quality and safety, and supporting good governance in the pharmaceutical sector. Participation in regional and international collaborative efforts are going to be key towards a harmonised response to health systems challenges especially in LMICs(67).

Ethical issues in ATM surface at all levels where industry imperatives meet the public health agenda. Following the South African-turned-global controversy of drug patents and high pharmaceutical prices inhibiting access to life saving ARVs(68), the ethics of ATM has emphasized the need for policy and regulation of all health technologies . Ethical concerns range from poorly evidenced claims of effectiveness in product registrations by global companies, incentives to providers and professionals for selection and use of originator brands and specialised drugs or choice of health program (WHO Option A , B , B+ for the national PMTCT program) (67,68).

MDGs are not devoid of ethically charged concerns- speculation on the reasons for dropping MDG 8, which deals with facilitating ATM in developing countries through negotiation with pharmaceutical companies, suggest that the balance of power and politics were tipped(71). At a service delivery level, private providers may suffer the symptoms of poor regulation such as perverse incentives, unethical marketing, sampling and conflict of interest. Over-servicing of ageing or terminally ill members of medical schemes involves spiralling costs (72) involving pharmaceutical and surgical modes of treatment. Increased regulation is an effective tool to guide ethical practice in the health technology sector.

1.7 Effect of policy on 'Access to medical products' in South Africa

The nexus between the global health technology industry and the health sector is complex and serves important but diverse functions. The aim of State intervention through health policy and regulation is to align the actions of a network of intersectoral stakeholders, with nuanced perspectives, towards improving ATM. The objective of the global pharmaceutical industry is to innovate for profitability, market expansion and shareholder value. These divergent mandates are in conflict when the right to health is poised against access based on

high costs of drugs. The interaction of the health sector (public and private) with the health technology industry requires a unified robust governance framework consisting of legislation, regulation and policies in financing, human resources, service delivery and information system components. A summary of the applicable regulatory documents is given in Appendix A. In high income countries, medical product pricing and affordability predominate the policy direction. However, in LMICs with fragile heath systems, sustainable financing, selection , procurement, service delivery and universal access issues dominate (73).

Challenges with ATM in South Africa have been amplified by the media, social justice coalitions and the development sector by organisations (such as TAC, Section27, MSF, SAPAM, AMASA, SARAM and FTPL) (see Abbreviations) advocating change based on users' experience of ATM. These social coalitions are a powerful voice, setting the policy agenda in international trade and politics and acting as informal monitors of government performance in ATM as they raise the profile of citizens' demands(66,68,72,73).

The South African National Drug Policy (NDP) is based on WHO guidelines for developing a national drug policy(76). The NDP spans two decades of transition and gives strategic direction, objectives and goals for the interaction of the health sector with the pharmaceutical and medical device industry. The United Nations Development Program (UNDP) principles for good governance (Legitimacy and voice, Direction, Performance , Accountability and Fairness) forms the structural basis of the NDP (77) in recognition of the vulnerability of this sector to unethical practice and corruption involving international, national and local entities .

The SA NDP addresses the first 5 key generic elements of the WHO guidelines as shown in Table 1(9), and includes contextual issues that can be addressed through policy. These elements are, by themselves, not sufficient to ensure ATM, but create the environment for stewardship, where all stakeholders can be held accountable.

Table 1 : Summary of South African National Drug Policy, 1996

Principle	NDP Goal –Summary
Legislation and regulation	Establishing an independent regulatory authority with autonomy capable of enforcing penalties in transgressions. Registration, licensing, quality, compliance and enforcement, Pharmacovigilance and regulation of prescribing and distribution
Selection of essential medicines	Implement EML and standard treatment guidelines
Medicines supply	Ensure equitable access to medicines
Rational use of medicines	Promote appropriate use of medicines in clinical practice to improve quality of care
Affordability of medicines	Pricing , cost effectiveness, partnerships in the sector
Human resources Development	Capacity building of HR to enable NDP goals
Research and Advisory	Promote technical advisory groups covering key areas the sector
Technical cooperation between countries	Promote An example is the European medicines agency which regulates the pharmaceutical market across the EU.
Local manufacturing of medicines	Build local manufacturing capacity in generic drugs to lower cost of EML

Source: Author

Pharasi and Miot's reviews of medicines selection and procurement policies(78) suggest that South Africa has marked good progress towards implementing the health objectives of the NDP. These initiatives include medicines formularies and treatment guidelines in the private sector, Prescribed Minimum Benefits (PMB) definitions, and criteria for the use of medical products and centralised procurement in the NDOH. The extent of changes since NDP implementation has not been quantified although some independent efforts in 1998 (NDOH), 2003 (Human Sciences Research Council (HSRC)) and 2005 (NDOH/MSH collaboration) were made to evaluate specific aspects of the policy. Availability of medicines in PHC and reliable consistent supply of medical products continues to impact service delivery(79). In 2016, some medical device companies withdrew support to public sector citing payment delays and non-payment; corruption; and inconsistent tender practices. As the device industry comprises mainly small to medium enterprises unable to absorb irregular payment cycles, the result is decreased competition among suppliers. Heavy reliance on single suppliers interrupts regular supply and access to essential medicines. (80)

The cost- versus- access policy debate in medicines and healthcare has infiltrated the public domain domestically and abroad. However, WHO's Good Governance for Medicines (GGM) program claims that public access to information about pricing and quality in the pharmaceutical sector is lacking(81). The 'Medicines Act' Amendment (2002), introduced new definitions in the pharmaceutical regulatory lexicon for licencing, pricing committee and marketing controls. Policy initiatives targeted discriminatory practices, promotion of generics, rational drug use, single exit prices, fixed professional and dispensing fee regimens, regulatory price increases and establishment of clinical governance structures at service delivery levels as Pharmacy and Therapeutics committee (PTCs) (82,87).

Some of the most profound effects of policy changes since 1996 have been mandatory generic substitution augmented by local manufacturing capability. One such estimate in 2017, of the extent to which prices have dropped due to generics is 80% (83) However, there are claims of transfer of perversity from doctor to pharmacist . Despite the establishment of the pricing committee and the price registry, a transparent pricing system and public awareness of medical product pricing is not optimally realised. Control of rebates, discounts and bonuses has eliminated the rural-urban differentiated prices, prevented risk transfers by unit pricing and prevented bulk discounts for chain stores(84). Single exit price policies(SEP) have yielded about a 19% drop in the price of medicines(85).

There are some lingering concerns around aspects of implementation such as logistic fee controls, external reference pricing and incentive scheme controls. (86). In the public sector, the focus has shifted over the past two decades towards building capacity in the health system for ATM specifically through improved drug availability and rational use at service delivery level. The Medicines Control Council (MCC), superseded by SAHPRA in June 2017 has instituted a range of policies to address key issues in management of medical products, vaccines and technologies.

The selection of medicines appropriate for SA has involved adoption and use of STG/EMLs as well as the development of national strategic plans for priority health conditions. Manufacturing, procurement and distribution such as software to manage stock, Central Chronic Medicines Dispensing and Distribution (CCMDD) programme, regulations of the Preferential Procurement Policy Framework Act by the National Treasury to align BEE to healthcare procurement, as well as allocation of products for local production. Substantial investment has been made in the public sector by training cadres (pharmacy assistants, SCM, finance and clinical staff) at various interfaces of the pharmaceutical and medical supplies value chain to improve the process(87).

The emergence of multidrug resistant healthcare associated infections (HAI) in South Africa is linked to increased costs and poor patient outcomes in both public and private sectors.(88)

Although the media discourse emphasizes the patient preference and palliation(89), the role of expensive, aggressive treatment modalities, prolonged ICU and hospital stay , driving expenditure on medical products, is not clear . Without new antibiotic compounds in the pipeline for the next two decades, policies advocating rational use of available drugs are critical in public and private sectors(90). More health systems and policy research (HSPR) and economic evaluations could be used to compare cost effectiveness of clinical interventions.

Some newer cancer chemotherapy, orphan and specialised drugs, with contested clinical and cost effectiveness outcomes, are subjected to Managed Care Organisations (MCOs) evidence based rational drug use policies. One such example is the oncology drug under the registered trade name “Herceptin”, which prompted debates on risk sharing and outcomes based reimbursement models between Pharma and Funders(91). In South Africa, more is known about drug utilisation through research(92) than through praxis(93). Systems for reporting drug utilisation are disparate and lacking within and across the public and private health sectors(94).

Research in the pharmaceuticals sector in South Africa has focussed almost exclusively at discipline-level from medicine(95) , pharmacology(96) , economics , law(18), industrial engineering (97) , health management(98) , health advocacy (75) and public health focussing on a wide range of policy areas . Topic areas well represented by research are intellectual property, patent law, essential drugs, rational use, traditional medicines, procurement and supply chain for medical products, pricing and organisational capacity to regulate the pharmaceutical sector. In the context of South Africa’s quadruple burden of disease, access to specific drugs such as ARVs, TB and oncology drugs have been studied from a clinical perspective(97,98) Although some authors have addressed ATM in South Africa (100), few have presented it in relation to complex interactions of other health systems resources and therefore less pragmatic and sustainable solutions to real world implementation challenges have been found. Health Systems and Policy Research (HSPR) enables the ATM issue to be embedded within quality, resource planning and delivery debates on both supply and demand side of access. Within the current paradigm of reform towards UHC, Gray and Suleman suggest that evidence of ATM experience from LMICs should guide policy making in South Africa (101). To support this goal, a thrust of HSPR should be undertaken in South Africa for fresh ATM perspectives within health system complexities(48,101).

The WHO GGF points to role of organisational capacity building for regulation in the crucial area of medicines pricing, selection and registration by statutory bodies at national level which is evident in South Africa. Countries either lack policy initiatives or effective implementation or both(103).

This study presents a baseline assessment of pharmaceutical policy, regulation and laws using the Health System Assessment Approach (HSAA) as a guiding tool to gauge orientation to the ATM goal in South Africa. A major objective of this study is to produce a health systems diagram for ATM in SA based on the literature and qualitative data analysis, demonstrating the multidimensional interactions of the building blocks. The advantage of a health systems approach is to stakeholders who are able to identify their sphere of influence to leverage their contributions in strategic and sustained ways in the health system. Effects of policy and intervention on system resources are also made clearer through this approach. Innovative delivery models for ATM in South Africa , coupled with a HSPR flagstone, can have pragmatic implications for LMICs (73) .

1.8 Funding of medical products in South Africa

The new global medicines framework "Towards Access 2030" by WHO and the Lancet Commission on ATM calculates between US$77.4 and $151.9 billion per year (or $13 to $25 per capita) is needed to provide a basic package of 201 essential medicines for all LMICs(44). In 2002, it was estimated that over 70% of pharmaceuticals are publicly funded through reimbursement plans and other mechanisms in developed countries, in contrast to developing and transitional economies where 50 to 90% of medicines are OOP (25). In developing countries the budget for medicines corresponds to 24 to 66% of national health expenses, supporting the monitoring of access to medicines in these countries(27).

A study of pricing and affordability in developing and middle income countries by Cameron et al (62) showed that median government procurement prices for generic medicines were similar to international reference price. However, low procurement prices did not always translate into low patient prices and treatment was still unaffordable in many countries. Private sector patients paid 9–25 times international reference prices for lowest-priced generic products and over 20 times international reference prices for originator products across WHO regions. In the private sector, wholesale mark-ups ranged from 2% to 380%, whereas retail mark-ups ranged from 10% to 552%(62).

Private households' out-of-pocket payment on health as percentage of total health expenditure are the direct outlays of households, including gratuities and payments in-kind made to health practitioners and suppliers of pharmaceuticals, therapeutic appliances, and other goods and services, whose primary intent is to contribute to the restoration or to the enhancement of the health status of individuals or population groups. It includes household payments to public services, non-profit institutions or non-governmental organisations. It includes non-reimbursable cost sharing, deductibles, co-payments and fee-for service; excludes payments made by enterprises which deliver medical and paramedical benefits,

mandated by law or not, to their employees. It excludes payments for overseas treatment."(104)

The international pharmaceutical manufacturer and supplier global market was worth USD1,105 bn in 2016 and is projected to reach USD 1,485bn by 2021.(105) . The global pharmaceutical market is expected to reach USD 1400bn in 2019 (106) and only 10 countries in SSA (Algeria, Egypt, Kenya, Ivory Coast, Libya, Morocco, Nigeria, South Africa, Sudan, and Tunisia) hold the promise of a market size about USD60bn in 2020.(107)

The Top 10 corporations (Aspen, Adcock Ingram, Sanofi, Novartis, Pfizer, Cipla, Johnson and Johnson, Merck, Bayer and Roche) own 58% of the total pharmaceutical market share in South Africa; local companies make up 20.5% and global companies 37.5%. (106) In 2015, the generics market in SA was R11.7bn (35.3% market value;49.4% volume of sales) and originator drugs made up R16bn (48.2% market value; 29.7% volume of sales) (108). The total South African pharmaceutical market was valued at R44bn, split between private R34.2bn (86.7%) and public R6.8bn (13.3%) sectors in 2015(108) and is forecasted to grow by 38% to reach R47bn in 2020(83). In contrast , the national estimated drug expenditure in the public sector in 2000 was just R1.96bn(82).

There is much less analysis, research and discussion generated around medical products expenditure in the public sector. Information on medical products expenditure in the public sector is communicated in the Department of Health (DOH) Annual Reports and Medical Supplies Depot (MSD) Annual Reports reported by the provinces. Public sector expenditure data is held by a small group of district, provincial and national health managers whose specific role dictates involvement. It is not common for clinicians and managers at all levels to be involved and aware of budget and expenditure issues in the public sector(109). Expenditure on medical products is not commonly analysed in the public sector within the DOH (82)and efficiency is not often a matter of public knowledge, thus more research is needed in this area. Data from the private sector, referring to insured members of medical schemes, is available through statutory reporting to the CMS, industry reports from MCOs and analysis of claims data through 'switching' companies. Much of the data on pharmaceutical and medical device spending is contained in industry reports specifically focussing on prices, market share, forecasts of growth in new markets and trends in revenue. Annual reports of Pharmaceutical manufacturers or wholesalers provide sales data such as non-prescription ('over the counter') drugs, generics, originator brands and specialised medicines.

Additional sources of expenditure in medical products are through donations, such as the Fluconazole donation by Pfizer to the NDoH, and Conditional Grants for Tertiary services and HIV, from which about 60% is spent on ARVs(110). Medical schemes fund medicines

through the risk pool or medical savings accounts and on a case by case basis through an ex gratia process. Out of pocket expenditure for medical scheme beneficiaries arise out of co-payments based on six major mechanisms: differences between the dispensing fees, use of non DSPs , out–of-formulary medicines , reference price , maximum value OTC and set co-payments. Overall, in 2017, the differences between claimed and approved amounts was 1.6% (58).

Institutional arrangements for reimbursement in the medical schemes industry is complex: after registration with the newly formed SAHPRA regulator, pharmaceutical and medical device suppliers are expected to negotiate with MCOs to establish products within clinical protocols and formularies which correspond to medical schemes' funding criteria. This managed care gateway is based on rational drug use principles and evidence-based medical practice to manage demand in medical products (150). However, the results of these measures often disadvantage users through OOP payments with implications for ATM. User charges discourage use of chronic medications and affect vulnerable groups disproportionately (112). Influencing doctors by MCOs is an option to control expenditure but this usually has severe consequences to patients when quality of care is compromised in favour of aggressive cost savings (110, 111). Financing approaches and expenditure on medical products can have opposing effects on access. Tighter controls of expenditure in medical products can lead to lower prices resulting in delays in accessing newer health technologies. Liberal expenditure may incur user charges and this also has an effect on access(113).

The responses of the South African Medical Device Industry Association (SAMED) to the Healthcare market Inquiry (HMI) by the Competition Commission in 2016, summarizes major issues in medical devices expenditure. SAMED emphasize that medical devices are not the most significant cost driver in healthcare, using CMS data (2013) which points to 7% of total industry expenditure on medical devices. This was supported by Discovery Health Medical Scheme Administrator, demonstrated R3.1bn (8%) in-hospital expenditure of total surgical spend on medical devices, majority of which were in-hospital. SAMED suggest that surgical spend (which includes the use of medical devices) as a proportion of total hospital costs decreased from 2008 (21.5%) to 2013 (17.9%). A perspective offered by SAMED is that medical schemes set prices for the health technology industry and reject increases above inflation, disregarding effects of exchange rates on mostly (76%) imported goods(80).

In the response to the HMI, the pharmaceutical task group (PTG) industry liaison body reports that medicines account for 1.1% of the 10.9% increase in medical claims expenditure according to Medscheme (85). Mediclinic and Netcare report about 9% of a hospitalised patient's bill, is for medicines. From 2003 (22.3%), the expenditure on medicines for the private health industry decreased in 2013 (16%). This corroborates the report of the CMS

(2016/17) that private hospital (inpatient and theatre costs) (48%) and medical specialists (37%) are the top cost drivers in private healthcare(13).

In the HMI, PTG acknowledged a social commitment to supply medicines to the public sector but listed many challenges of conducting business with the State, including: unaccounted logistics costs; lower prices on bulk purchase; marginal income from the State based on irregular tenders and unorthodox practices such as further price negotiations after closure of the tender process(85). Therefore pharmaceutical sales in the presence of robust price regulation and low purchasing efficiency in the public sector, is heavily dependent on the South African private sector, with less than 20% of the population (insured), bearing the cost of doing business.

1.9 Conclusion

Financing and policy are the key mechanisms influencing access (42). The role of policy and sustainable finance has been shown in frameworks for access to highlight supply side contributions to ATM(9). ATM is most often dependent on access to healthcare built on a broad national strategic vision and a plan to address pricing, quality, essential medicines, rational drug use, efficient selection and procurement processes and reorientation of the health system. Health technologies are now an integral resource in the clinical care of patients and should be consistently available at the point-of-care. When financing arrangements in the public are not sustainable or consistent across districts or provinces, the most vulnerable are disadvantaged by fewer alternatives to access care, lack of agency to demand quality and perpetuation of inequity across society.

Alliance for Health Policy and Systems Research (WHO) 2012 set the international agenda for research in access to medicines based on limited contextual evidence and health systems understanding of ATM challenges particularly in LMICs. More research on health policy is needed as OOP spending was unsustainably high (50-90%). The disparities in OOP spending between public and private sectors in these countries was 35% versus 66%. National expenditure on medicines represent 20-60% of the total health budget (114) . Access to medicines in LMICs is high on the policy and research agenda (47). The WHO ‘World Medicines Situation 2011’, stresses that data to assess ATM can inform a range of policy actions to ensure that the obligation of the State to provide healthcare to all citizens, is realised (61).

The literature on medical products expenditure exists; however, it is not assimilated across sectors to present a high-level overview of medical products expenditure in South Africa. The results of this study will describe the policy, funding flows, expenditure trends and

analysis of medical products in South Africa. The objective of this work is to provide a descriptive overview of the major sources of funding for medical products in South Africa. This knowledge can be used to inform policy and health systems strengthening interventions to improve ATM for those whose need is greatest.

CHAPTER 2: METHODS

2.1. Problem Statement

Policy, finance and medical products are three building blocks at the forefront of service delivery and access to medicines. Existing work focusses on policy analysis and critical reviews of the pharmaceutical and health technology policies (115,101,87,116)but few studies acknowledge the health systems impacts(100) . More health policy and systems research(HPSR) is needed to understand the complex interaction of building blocks which produce ATM as an outcome particularly in view of a new wave of reforms ushering in universal health coverage(117).

Overall, health finance research covers broadly public, private and household health funding flows and is better described in the literature than medical products expenditure in SA. Few studies elaborate on the economic classification and component costs of healthcare such as hospitals, ambulatory care, medicines, medical devices and human resources yet this informs budgeting, impacts health inflation and influences access to healthcare(118).

Without studying the effects of leadership and governance and financing on health outcomes (represented by ATM in this study) the three main intrinsic health goals (Health, responsiveness and fairness of financing) are neither understood nor operationalised(119).

2.2. Study Rationale

The study builds on policy analysis and critical reviews on pharmaceutical and medical devices sector reforms since the advent of the National Drug Plan in 1996, by shifting the research priority towards pharmaceutical system performance. This work assesses progress made in SA through pharmaceutical reforms and advances the contextualisation of Access to medical products from a health systems perspective.

Public, private and household level expenditure on medical products is analysed using publicly accessible and routinely collected information. In this way, the study adds new and detailed insights into medical products expenditure in SA. This knowledge is critical for efficient use of scarce healthcare resources and overall effectiveness of the health system.

Importantly, this study presents an assessment of health system progress towards ATM using supply and demand side measures.

2.3. Study Aim

The aim of this study is to analyse and describe policy reforms and funding flows of medical products in South Africa. This will inform the development of new perspectives on access to medical products within the complexity of the health system.

2.4. Research Objectives

The specific research objectives were to:

- Assess the South African regulatory framework for medical products using the Health Systems Assessment Approach (HSAA) which evaluates Pharmaceutical Policy, Law and Regulation.
- Describe health expenditure on medical products in South Africa in public, private (supply-side) and household level (demand side) using available data.
- Develop a health systems framework for understanding, and evaluating 'Access to medical products' in the South African context, which describes regulation, funding, product, distribution and information flows.
- Analyse 'Access to medical products' in South Africa using four dimensions of access from supply and demand side perspectives.

2.5 Selection of Study Design and Research Approach

Descriptive and analytic methods were used in this study to understand the complexity of ATM in the SA health system, which is linked to the historical, political, sociodemographic and economic macro-context. The exploratory approach facilitated deep insights into concepts, assumptions, behaviours and interactions of the key elements of the health system.

This sequential exploratory mixed methods study was underpinned by data collection and data analysis processes. Secondary data sources were used to conduct descriptive and regression analyses. The quantitative analysis was done in two stages. In the first stage, descriptive statistics were produced from secondary administrative data such as Annual reports from CMS and DOH and survey data from Statistics South Africa (Stats SA). The second stage of quantitative analysis involved building a multiple regression model using survey data from the Income and Expenditure Survey (IES) 2000 conducted by Stats SA.

Household surveys can provide crucial information on how drug policies affect the individual, from the user's perspective(120).

The results of the quantitative data analysis was used to formulate an interview plan. Six key informant (KI) semi structured interviews were held; qualitative data was extracted from handwritten shorthand notes, captured, transcribed and analysed. The Figure below is a schematic representation of a sequential dominant- status mixed methods design.

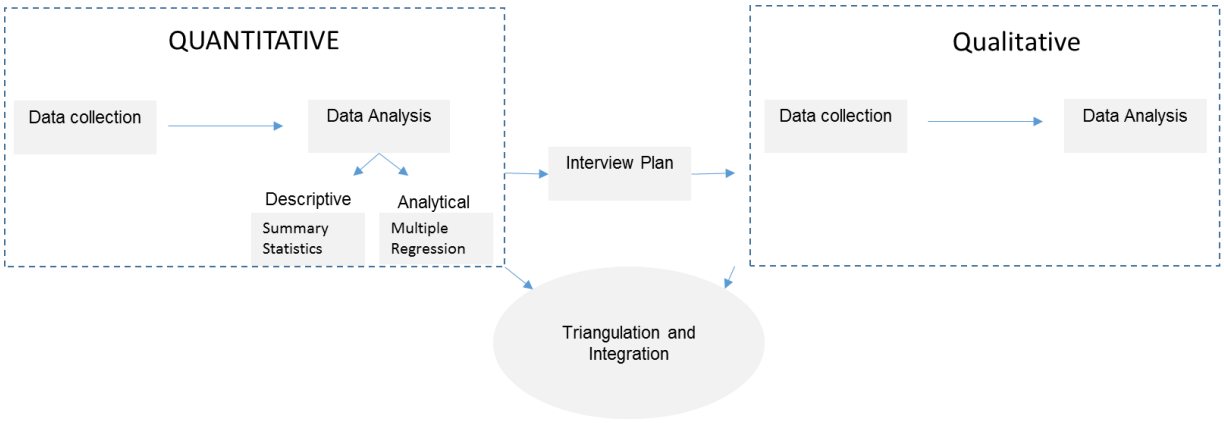


Figure 3 : Sequential explanatory mixed methods design

Source: Wu (121)

2.6 Data Sources

In this study primary and secondary data sources were used. For primary data collection, key informants (KIs) were identified based on relevant work or research experience in health technology and pharmaceutical systems, service delivery, policy, financing and willingness to participate in the study. Access to these individuals was negotiated through formal requests and informed consent for participation was obtained prior to the study. Six telephonic KI interviews were held using the semi structured interview format. Prior to each interview, the participant was given an option of voice recording or note taking as a means to capture the data; one interview was recorded with permission from the interviewee. The data was summarised and analysed in MS Excel spreadsheets, coded and categorised. Semantic and latent themes were reviewed with a second researcher. Emerging themes were summarised and tabulated. The qualitative data informed the development of the schematic diagram for ATM in the SA health system.

Secondary data formed the basis of the quantitative enquiry in this study. Private sector medical scheme expenditure data on medical products was extracted from Utilisation Annual Statutory Return (ASR) reports mandated by the Council for Medical Schemes (CMS). Additional medicines utilisation and expenditure in the private sector was obtained, with permission, from Mediscor (a Pharmacy benefit management company) industry analytic

reports, based on claims data of insured beneficiaries of selected medical schemes. Public sector expenditure was extracted from provincial government Annual reports and National Treasury reports which are freely available in the public domain through the respective websites. Expenditure data from these sources, were captured on MS Excel spreadsheets and descriptive statistical analyses were performed.

The household expenditure analysis used Stats SA survey microdata accessed with permission from the University of Cape Town Data repository (Datafirst)(122). The Stata v12 data files for each survey year were downloaded from the internet.

The literature review was conducted in PubMed, Scientific Electronic Library Online (SCIELO), Cochrane, Popline and Google Scholar. The institutional websites used were WHO, World Bank, MCC, HPCSA, SAPA, DOH, CMS, and Provincial government, Stats SA, HST and MSH. Annual reports, books, research publications, internal communiques, meeting reports, conference summaries, presentations both published and unpublished and other sources of grey literature were used. Where necessary access was obtained from organisations.

The policy assessment was based on the Health Systems Assessment Approach (HSAA) (2012 version) was developed by Health System 20/20, the Quality Assurance Project and Rational Pharmaceutical Management Plus/Management Sciences for Health. The manual was first published in 2007 through United States Agency for International Development (USAID) funding. It has been supported and implemented across 25 countries in Africa, Asia, Latin America and the Caribbean as well as USAID funded programs from 2006 to 2012. The HSAA has been used to inform national strategic plans, PEPFAR partnership frameworks, grant applications, and numerous other health systems strengthening and programmatic activities. In 2012, the HSAA manual was updated to reflect lessons learned through its application in more than 20 countries and thus validated as the appropriate tool for use in this study (123) .

A number of data sources were used to assess ATM. Routine data captured in the DHIS and reported in the District Health Barometer (DHB) (60) was used for public health services data. Household data was obtained from the General Household Survey(GHS) (2011-2016) microdata accessed through Datafirst(122).

2.7 Data Entry and Storage

Primary and secondary data collected in this study are subject to the Stellenbosch University's copyright regulations. Safe keeping of the data is the responsibility of the researcher for the duration of the study. Data obtained in the study is stored on a password

protected laptop which is the property of the Centre for Health Systems Strengthening. The data collected for the purposes of the study is subject to the provisions of the Protection of Personal Information Act (POPI).

2.8 Data Analysis Plan

MS Excel software (MS Office 360) was used to perform descriptive statistics on the expenditure data from secondary sources. The descriptive analyses were subject to the limited availability of data in the public and private sector and therefore the time periods of analysis vary. For the survey data, a multiple regression model was used to predict the effect of demographic variables on household spending on medical products in SA in IES 2000. STATA 15.0 was used for quantitative analysis, licensed under Stellenbosch University.

2.8.1 Data analysis for household expenditure on medical products

The IES and Living Conditions Survey (LCS) are nationally representative sample of households and have been used to collect information on household expenditure to inform the Consumer Price Index (CPI). The target population of the surveys consists of all private households or dwelling units (DU) in all nine provinces of South Africa and residents in workers' hostels or quarters and is therefore only representative of non-institutionalised and non-military persons or households in South Africa(124).

2.8.1.1 Survey methodology and data collection

The IES 2000 payment and recall method was replaced by a combination of payment, acquisition and diary/recall methods for durable items and services in IES 2005 and LCS2008. The aim of these changes was to improve utility and application of the data and to minimize biases in the methodology. Changes to the methods had a major effect on the results between 2000 and 2008(124) . The debate around the quality and utility of data from these national surveys, analysed by Burger and Yu , Casale, Muller and Posel , and Wittenberg in Yu(125) , highlights methodological issues relevant to the interpretation of the data.

The IES 2000 used the recall method to collect information on goods and services and identified according to the Standard Trade classification. From 2005, COICOP (Classification of Individual Consumption by Purpose) was introduced to classify expenditure items.

Households were asked Expenditure data from the surveys, which were annualised and inflation adjusted to ensure data comparability. Significant differences were noted between the IES 2000 and 2005 results. From 2008, a master sample design was employed across all household surveys which uses a two-stage, stratified design with probability–proportional-to-size (PPS) sampling within strata.

Although the methodology was changed between IES 2000 and LCS 2014, adjustments were made during the weighting process to offset any potential bias in change of sample design. Based on method integrity, household expenditure data in these surveys is comparable over years(124). The expenditure items captured in the LCS 2014 dataset could be mapped to the United Nations COICOP (5)codes and matched those of previous surveys. Furthermore, the questionnaire specifically asked for annual estimates of household expenditure on medical products that were not covered by medical aid, insurance or any schemes that were OOP.

2.8.1.2 Survey sample size

The sample sizes for periods relevant to this study were : IES 2000 (30 000 DUs); 2005 (24000 DUs); LCS 2008 (31 473 DUs); 2010 (31 419 DUs) and 2014 (30818 DUs)(126).

2.8.1.3 Study Variables

There are common questions and variables used in the IES, GHS and LCS. The modules of the survey data were first merged using unique identifiers to create a dataset for the survey year containing all variables of interest. The survey dataset was set up in STATA accounting for the two stage clustered survey design.

The outcome (dependent) variables were defined in the survey dataset as “expPMDmedaid” and “expPMDnomedaid” to represent medical scheme membership status. These variables represent household OOP expenditure on medical products. The expenditure items linked to these variables were mapped to COICOP codes. The COICOP codes included in the outcome variables from the Health (061) category(5) and included : expenditure on medicine with prescription; expenditure on medicine without prescription; pharmacy dispensing fees; pharmacy service fees; other medical products and therapeutic appliances (see Glossary for details of these categories).

This study reports on two main outcome variables the independent variables were descriptors of the demographic characteristics of the survey population. The independent variables included in the IES 2000 regression model were population group of head of

household (“Popgroup”) , province (“Province”), source of income (“incomesource”), settlement type (p0101q01) and number of persons in the household (“nopersons”) . There were five categories of “Population group” variable (Black/African, Coloured, Indian/Asian, White and Other). The size of the household was a discrete number. The variable “province” had 9 categories (WC, EC, NC, FS, KZN, NW, GP, MP and LP). The source of income variable had 9 main categories in 2000 and although 4 subcategories were added in 2014, they were easily mapped to the original IES 2000. Only six of the income source categories with the highest frequencies were included in the analysis.

2.8.2 Qualitative data analysis

The qualitative data was transcribed and coded and thematic analysis was conducted. The results of Phase one and two will be triangulated to validate the findings and to elicit emerging themes not introduced in the data collection and analysis phase. Data triangulation was done combining the results of the quantitative(expenditure data) and qualitative(KI interviews) data to identify agreement, partial agreement, silence , dissonance between findings from the different components of the study (127).

2.9 Ethical Considerations

The necessary authorisations and permissions were obtained to access documents routine financing and expenditure data. These were mainly in the form of industry reports of medical products expenditure data in the private sector. Access to data is listed as a major limitation in this study and discussed in Chapter 5. Anonymised routine data sources were used and therefore did not present any risks to patient confidentiality. There were no instances of patient identifiers in the data included in the analysis and therefore no risks to individual or organisations were presented. The Ethical approval for this study was obtained under the number HREC Reference #: N17/09/089.

This study was industry funded (Janssens Pharmaceutica) and mobilized a cross–faculty multidisciplinary research team towards improving policy and processes around financing and access to medical products. In the context of NHI, building capacity for policy and implementation whilst increasing public private partnership and collaboration, is a key competency. No actual or potential conflicts of interest have been declared by the author, company or participating faculties of the University of Stellenbosch. The research paper will be made available in the public domain for the benefit of all sectors of the health system. This study will be submitted as a Master’s research project by the author.

CHAPTER 3: RESULTS

3.1 Policy Summary and Analysis

Using the HSAA framework for Pharmaceutical policy, laws and regulations, the basis for an efficient health sector with access to medical products was analysed. The framework was not applied in its entirety; performance measurement criteria of the HSAA framework were omitted as this was not relevant to the study objectives. The criteria for assessment were objectively based on legal and regulatory requirements in the process to make medical products accessible to users of the health system. This framework was used in the WHO – SA NDOH collaboration in 2006 for the development of indicators to monitor country pharmaceutical situations and has been validated through its wide application (128).

The key findings of the HSAA framework applied to the "Medicines, Vaccines and health technology" building block of the SA health system is shown in Figs 5 and 6 (below). The aims of the NDP have been expressed in the regulatory landscape for ATM in South Africa since 1996 and the roadmap to achieve the instrumental health system goals (access, efficiency, effectiveness, quality, safety and equity) is in place. However, the NDP has not been revised since 1996 creating a void in some areas such as strategies for supply and procurement; the role of the MSD, province and district, especially in view of the NHI's objective of strategic purchasing; systems for pharmaceutical and medical device registration that consider capacity constraints, product life cycles, post marketing requirements (medical devices); provisions for licensing scenarios and conformity assessments.

Policies and guidelines for pharmaceutical registration and quality control in South Africa, are implemented and operational and can be extended to include medical devices. Until 2017, medical devices were unregulated but the advent of SAHPRA through the enactment of the Amendments 2008 and 2015 has laid the foundation for implementation. Systems for post marketing surveillance, pharmacovigilance, licensing, inspection and control have been established but need effective implementation. Lastly, the HSAA framework reinforces the lack of adequate monitoring and evaluation (M&E) mechanisms to address progress towards ATM, performance of stakeholders, quality and financing.

Table 2 : HSAA Policy Summary Framework Part 1

Existence of an National Medicines Plan or other government document that sets objectives and strategies for the pharmaceutical sector based on priority health problems
The NDOH set up a committee in 1994 and with technical assistance from WHO and Action Programme on Essential Drugs, the first NDP was implemented in 1996. The policy addresses inequitable access to essential drugs, quality of care, rising comparative drug prices, evidence of irrational drug use, losses through mismanagement, wastage, poor security, cost-ineffective procurement and logistics and undesirable industry incentive schemes (22). The Standard Treatment Guidelines and Essential Drugs List (later referred to as 'Essential Medicines List') series comprises :PHC (1996,1998,2006,2012,2015 editions); Paediatrics (1998,2006,2013,2017 editions); Adult Hospital (1998,2006,2012,2015 editions). Although WHO recommends more frequent updates, it is more feasible to conduct updates on a 5 yearly basis accounting for implementation time. Most differences between SA and WHO EML are found in the Adult Hospital list(2012) although the PHC(2008) and Paediatric lists(2013) align (154).

Regulatory framework - Medicines and Related Substances Control Act (1965) as amended (1997) (2008) (2015).	
Principles for selecting medicines , including donations	Regulations (R 1102 , 1210,524,657,1090,1256,766,714,264) Standard Treatment Guidelines and Essential Medicines List Establishment and function of Pharmacy and Therapeutics Committee Policy Section 21 Authorization Antimicrobial resistance Strategic framework HPCSA Guidelines for Good Practice in Healthcare Professions. HPCSA Code of conduct for Health Professionals Policy on Overservicing, Perverse incentives and related matters
Strategies for Supply and Procurement	
Promotion of rational use of pharmaceuticals	
Economic and financing mechanisms	PFMA(1999),Public service Act(1994) ; Promotion of Administrative Justice Act(2000) ; Division of Revenue Act(2003) ; Broad Based Black Economic Empowerment Act(2003); MFMA(2003) ; Appropriations Act ;Consumer Protection Act (2008); Patents Act (1978); Competition Act(1998); Copyright Act(1998) See Annexure for complete list
Control of premises for Distribution	Pharmacy Act (1974) as amended 1997; 2000; 2015. Good Pharmacy Practice code , Good Manufacturing Practice , Good Wholesale Practice
Role of Health professionals	Health Professions Act(1974)as amended 2003;2007
Monitoring and Evaluation	Applicable policies, regulations and laws ; Norms and Standards regulation (National Health Act)

Existence of a National Drug Regulating Authority responsible for the promulgation and enforcement of regulations
The newly formed South African Health products Regulatory Authority (SAPHRA) replaces the previous Medicines Control Council, created through the NDP and enacted in the 1997 Amendment of the Medicines Act. SAHPRA an organ of state, is subject to the Public Finance Management Act (PFMA) (1999), reports to the Minister of Health but holds final authority of all functions. It has monetary autonomy, generating revenue from the service and function of the organization and only partly subsidized by the National Treasury. Whereas the MCC mandate was as follows , SAPHRA is expected to take over these functions with extension to health technology : Registration of medicines based on safety efficacy and quality ; Approval of clinical trials ; Monitoring of safety ; Response to signals ; Licensing manufacturers, wholesalers and distributors ; Ensuring compliance ; Provision of information to oversee medicines, scheduled substances(155).

Source: Author, Using HSAA framework(123)

Table 3: HSAA Policy Summary Framework Part 2

Mechanisms exist for licensing, inspection and control
Section 22C of the "Medicines" Act Amendment (2008 ad 2015) has extended licensing of medical devices. Classification of Medical devices is critical to the licensing process. SAPHRA is responsible for licensing, inspection and control of medicines and medical products. Two policies have been implemented by the MCC: License to Act as a Wholesaler of Medical Devices & IVDs; Guidelines for License to Manufacture, Import or Export. Some of the supporting policies for these functions are : Hazardous Substances Act – electro medical and radiation devices; Standards Act (2008) ; National Regulator for Compulsory Specifications Act [NRCS Act] ; Metrology Act ; SANAS: accredit inspection & certification bodies ; Foodstuffs, Cosmetics, Disinfectants Act. The intent of the licensing process is to establish relevant quality assurance criteria for manufacture of medical devices in South Africa ; Identify requirements for importation of medium to high risk and high risk medical devices; establish relevant distribution practices for distributors in South Africa ; establish a database of all medical devices imported and manufactured in South Africa by risk classification, by manufacturer or by distributor ; maintain details of Manufacturers, Distributors & respective Authorised Representatives(156)

Existence of a system for pharmaceutical registration
The registration process includes product efficacy, quality, safety and packaging instructions as contained in the regulations, however, there is some concern around the turnaround times for this process by the former MCC (157). The registration backlog in South Africa refers to a decision taken for all drugs on the EML, most of which are generics, to be offered a "fast track "process of registration. Multiple applications for the generic equivalent of a single drug were received. This provision has been omitted in the new Amendment Act(86). Efforts towards pooled procurement and regional standardization and Harmonization , under the African Medicine Registration Harmonization Initiative(AMRHI), offers increased availability of quality controlled medical products and increased market size (158). There main problems with registration in African countries are registration costs and commerce related reasons : retention costs, GMP inspection fees and GMP inspection requirements resulting in withdrawal of such essential drugs as allergy, anti-infective, gastroenterology, HIV/AIDS, cardiovascular, metabolic disorders, pain management, psychiatry and gynaecology(159).

Existence of a post-marketing surveillance system
The policy response to a post marketing surveillance system, is the MCC Guideline "Reporting Of Post-Marketing Adverse Drug Reactions To Human Medicinal Products In South Africa" which has been in place since 2003 and revised in 2015(160). A National decentralized targeted spontaneous reporting (TSR) for specific drugs or patient groups was established to promote a multidisciplinary approach towards medical errors and systems failures. active surveillance for adverse reactions within existing cohort studies (two provincial systems) and cohort event monitoring (CEM) (two systems for patients receiving antiretroviral (ARV) medicines) were in place in 2012(161). The Draft National Strategic plan on HIV/AIDS, TB and STI 2017-2022 seeks to implement the national pregnancy exposure registry and birth defect surveillance programme at sentinel sites to assess safety profiles of commonly used drugs in pregnancy(162).

Existence of A Pharmacovigilance System
The policy "Reporting of Post-Marketing Adverse Drug Reactions to Human Medicinal Products in South Africa" overseen by SAPHRA has been implemented since 2003 and relates to PV and ADR reporting. Under reporting of ADRs is likely in South Africa as most health professionals, including pharmacists, do not have the capacity to identify or report ADRs. In 2012, it was agreed that data on ADRs were being collected by multiple programs and this warranted coordination at National level. A national Pharmacovigilance (PV) Strategic plan was proposed. Programs to report Immunization, HIV/TB and specific clinical specialties (paediatric HIV and dermatology) were noted in 2012(160). Approximately 16 percent of deaths in inpatient medical wards can be attributed to ADRs and an estimated 50 percent are preventable, impacting on patient safety and quality of care and highlighting the need to capacitate HCWs in management of ADRs(151,160,163)

Source: Author, Using HSAA framework(123)

3.2 Funding and Expenditure on Medical Products in South Africa

3.2.1 National Health expenditure

An overview of the National Total Health Expenditure (THE) provides an understanding of the principles, strategic priorities and politics of SA. The Global Health Observatory Data Repository reports SA national estimates of expenditure on health showing health budget allocation as a percentage of GDP peaked between 2012 and 2014 (9%) and declined from 2014 (8.7%; R145.7bn) to 2016 (8.5%; R168.4bn) as seen in Figure 4. Public sector investment in health as a percentage of GDP, increased from 2005 (3.4%) to 2011(4.1 %), before reaching 4% in 2016. Table 4 shows THE, private, public and OOP expenditure on health. Overall, change in proportional spending between public and private sector is not overt; incremental domestic general government spending on health(GGHE-D) as a percentage of Current Health Expenditure(CHE) (53.6%) is met with stabilising domestic private sector health spending(PVT-D) (44%) in 2016 as opposed to GGHE-D (41.1%) and PVT-D(57.6%) about a decade ago in 2005. In 2005 , public sector per capita health expenditure was USD 145.4(29%) lower than the private sector(USD 203.8 per capita) however, this was reversed in 2015 ; private sector per capita health expenditure was USD 207.2(17.8%) lower compared to the public sector (USD 252.1). Although a steady decrease in OOP health spending as %CHE from 2005 (12.4%) to 2015(7.7%) was seen, OOP spending per capita, which is population based, showed more variation.

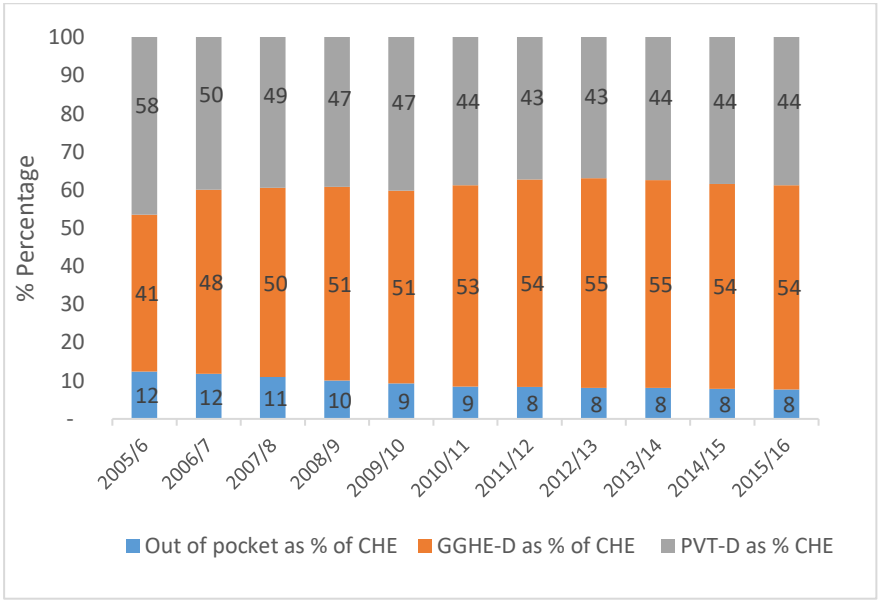


Figure 4: National Health Account Expenditure Estimates, South Africa

Source: Author, based on Global Health Observatory Data Repository; Provincial Budgets and Expenditure review 2005-2011 and 2010-2016

3.2.2 Private sector (insured) expenditure on medical products

3.2.2.1 Medicines Expenditure by professional category

In 2016, as shown in Figure 5(Table 5) the total industry benefits paid in respect of medicines in the private sector was about R24bn. Medicines amounting to R21bn (89%) was dispensed by pharmacists and R1.3bn (5%) by GPs, making up 94% percent of all medicines dispensed in the private sector. Only 5% of medicine expenditure was incurred by medical specialists, support and allied and other health professionals (such as surgical specialities, radiology, pathology, anaesthetists, dental and medical technologists and dentists) combined

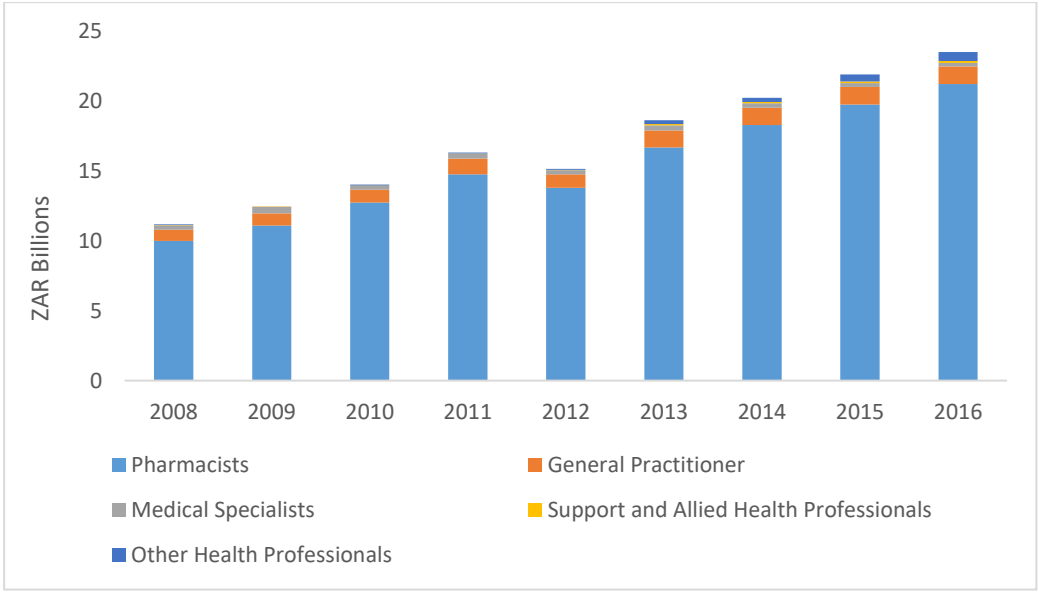


Figure 5 : Private sector (Insured) expenditure on medicines by Health Professional

Source : Author, based on CMS data (123)

Medicines expenditure incurred in “other health services” contributing 2% to the total spend includes blood transfusion services, ambulance, Foreign Service, travel clinics, clinical services, group practices and hospitals or clinics.

3.2.2.2 Medical products Expenditure by Hospital type

Figures 6 and 7 represent total medical scheme expenditure on medicines, consumables and equipment in private and provincial hospitals. The term ‘private hospitals’ here encompasses day clinics and unattached operating theatres and Fee-for-service (FFS) hospitals(129), distinguished from provincial(public sector) hospitals which are routinely used by members of low cost medical scheme options. There are vast differences in the nature of expenditure between these two types of hospitals. In 2010, private medical scheme members using provincial hospitals contributed 13.5% to total medical schemes’ industry expenditure on medical products, compared to 86.5% of expenditure incurred in private hospitals. Table 6 shows that over the period from 2011 to 2013, private hospitals consumed 98-99% of total industry expenditure on medical products.

In 2013, private hospitals spent R3.7bn on medicines, R1.8bn on consumables and R632 million on medicines as shown in Figure 6. Of the total spent on private hospitals, medicines constituted the highest proportional expenditure (60%), followed by consumables (30%) and equipment (10%), consistent from 2010 to 2013.

Figure 7 and Table 6 shows private sector medical products expenditure in provincial hospitals. In 2010, the medical schemes spent the largest proportion on consumables (75.7%, R 39.5m), followed by medicines (22.7%, R11.8m) and least on equipment (1.5%, R740 000). This pattern changed drastically in 2011; the highest spend was on equipment, followed by medicines and lastly consumables. By 2013 the pattern of private sector medical products expenditure in provincial hospitals was similar to that of private hospitals; medicines (48%, R9.6m); consumables (44%, R8.8m) and equipment (7%, R1.4m). The reporting format for private sector medical products expenditure changed in 2013, affecting line listing and economic classification of expenditure published in CMS Annual reports and limiting comparability of data.

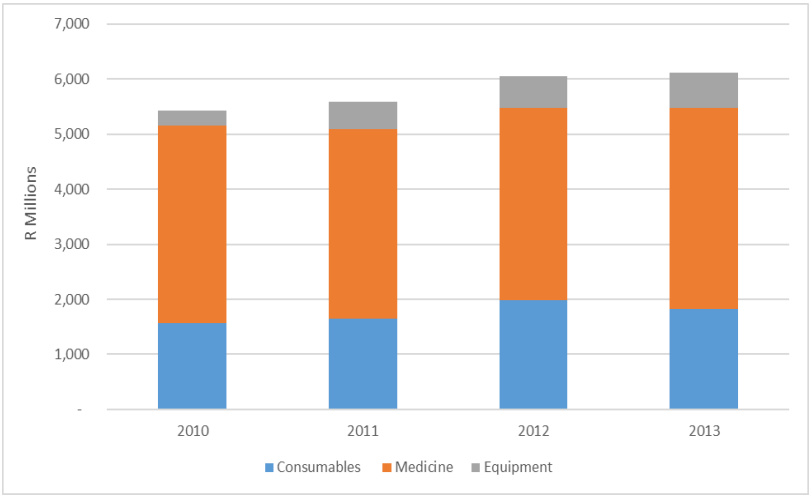


Figure 6: Private sector (insured) expenditure on medical products in private hospitals 2010-2013

Source: CMS Annual Reports 2010-2013

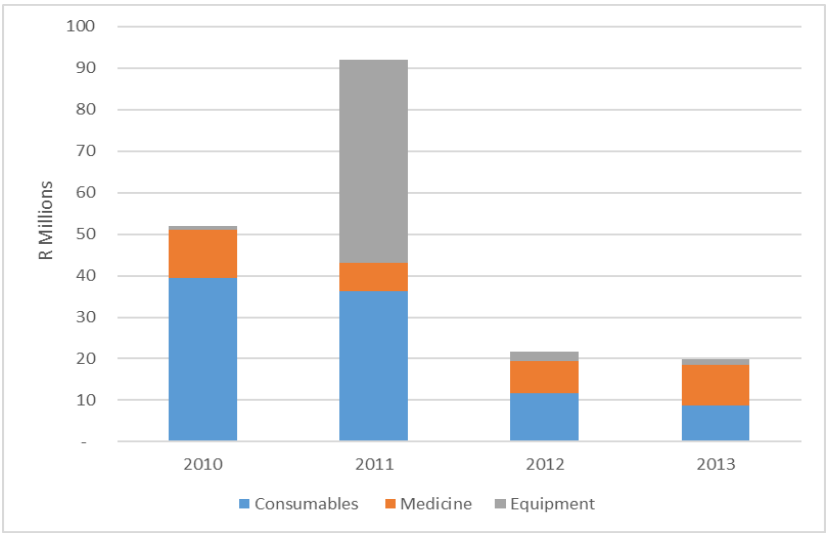


Figure 7: Private sector (insured) expenditure on medical products in provincial (State) hospitals 2010-2103

Source: CMS Annual Reports 2010-2013

3.2.2.3 Medicines expenditure by source of funds in private sector (Insured)

A higher proportion of expenditure on medicines, as shown in the Figure 8(Table 7), was from pooled risk funds (ranging between 77%-80%) than from members' medical saving

accounts (ranging between 19%-23%) during the period 2008 to 2016. In 8 years, medicines expenditure from risk funds doubled from R9bn (2008) to R18.4bn (2016); medicines expenditure from medical savings accounts, increased by a factor of 2.5 from 2008(R2.2bn) to 2016 (R5.6 bn).

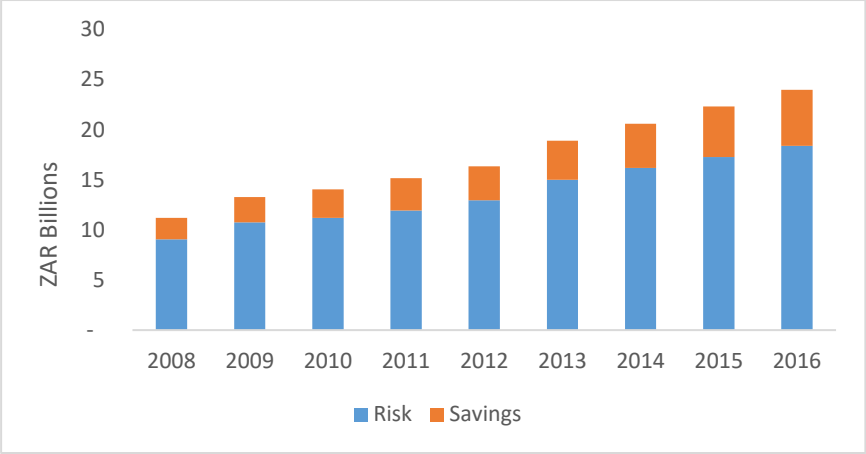


Figure 8 : Private sector (insured) expenditure on medicines by source of funds 2008-2016

Source: CMS Annual Report 2008-2016

3.2.2.4. Medicines expenditure by medical scheme benefit management (Mediscor)

The pharmaceutical benefits of SA fee-for-service medical schemes are managed by Pharmaceutical Benefit Management (PBM) companies performing MCO functions. Tables 8 and 9 are based on data extracted from publicly available industry reports from Mediscor, a PBM company, accredited by the CMS, representing a number of medical schemes. The dataset presented in these tables was based on approximately one million beneficiaries(58) . 'Prevalence' refers to utilising beneficiaries as a percentage of total beneficiaries and 'Intensity' refers to the number of items per utilising beneficiary.

The average cost per beneficiary of the medical schemes sampled in this dataset, was R2617 per annum in 2016. The average cost per item for 2016 was R150 and each utilising beneficiary (which in 2016 was 81% of the sample schemes population) was issued an average of 21.5 items for the year. In the years 2014 to 2017, this trend is consistent. Most commonly prescribed medicines by volume were acute(49%), PMB (29%)and OTC (14.4%) in 2016(58) .The top 10 therapeutic groups by volume are associated with acute infectious diseases (antibiotics, NSAIDs, antacids, analgesics etc.)

Mediscor beneficiary utilisation data shows that existing medicines constitute 98% of medical schemes' expenditure and New Chemical Entities (NCEs) account for less than 2% of total

expenditure. NCEs are new chemicals submitted for registration for a new indication, or a previously known chemical in a drug which is newly recognised for its commercial value (152). This pattern was also reflected in terms of the volume of medicines dispensed. The average cost per item from 2014 to 2017 increased year-on year from R138 to the value of R165 although this was not the case for NCEs. Average cost per item increased from R555 (2014) over just three years to R906 (2017). The uptake and utilisation of NCEs was around 2%, with the majority (80%) of beneficiaries using existing medicines. The average number of NCEs dispensed to beneficiaries ranged between 2.5-3.3 items per annum and 21 items for existing medicines.

Table 4: National Health Financing Indicators South Africa 2005-2015

Indicator	2005/6	2006/7	2007/8	2008/9	2009/10	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16
Total Health Expenditure (THE) as % GDP	8.7	8.4	8.5	8.7	8.9	8.7	8.9	9	9	8.7	8.5
Public Health Expenditure as % GDP	3.4	3.4	3.4	3.7	3.7	4.1	4.1	4.4	4.4	4.3	4.2
Out of pocket as % of CHE	12.4	11.8	11.0	10.1	9.3	8.5	8.4	8.1	8.1	7.9	7.7
GGHE-D as % of CHE	41.1	48.3	49.6	50.7	50.5	52.8	54.4	55	54.5	53.7	53.6
PVT-D as % CHE	57.6	50.2	48.6	46.9	46.7	44.2	43.1	43	43.5	43.7	44
GGHE-D Expenditure per capita USD	145.4	175	191.5	188.7	208.7	284.8	325.2	318.7	287.2	273.8	252.1
PVT-D Health Expenditure per capita USD	203.8	181.8	187.6	174.7	192.7	238.7	257.5	249.3	229.0	223.0	207.2
Out of pocket per capita USD	43.7	42.7	42.6	37.8	38.2	45.9	50.2	47.1	42.5	40.3	36.2
Public health expenditure per capita ZAR	1722	1852	1953	2058	2134	2709	2915	2934	3021	3011	3011

Source: Global Health Observatory Data Repository; Provincial Budgets and Expenditure review 2005-2011 and 2010-2016, National Treasury, Provincial and local government database, Estimates of National Expenditure, Council for Medical Schemes, Road accident Fund and South African Reserve Bank

Table 5: Private sector (insured) expenditure on medicines by Health Professional category 2008-2016

Professional Category	2008	2009	2010	2011	2012	2013	2014	2015	2016
Pharmacists	10,007,914,000	11,108,357,000	12,742,782,000	14,775,873,896	13,816,244,350	16,699,706,683	18,290,506,792	19,778,776,612	21,225,169,130
General Practitioner	788,812,000	861,059,000	929,498,000	1,113,136,158	955,597,539	1,214,697,346	1,259,936,843	1,243,989,704	1,259,596,690
Medical Specialists	325,068,000	495,008,000	286,480,000	357,227,092	307,005,921	373,474,144	301,918,086	291,985,581	252,655,799
Support and Allied Health Professional	23,265,000	25,468,000	15,650,000	24,612,570	20,940,334	74,010,728	89,601,874	105,147,679	138,508,155
Other Health Professionals	60,256,000	NC	65,766,000	69,170,480	61,028,538	279,920,474	314,764,696	496,516,268	642,819,192

Source: CMS Annual Report 2009-2016)

Table 6 : Private sector (Insured) expenditure on medical products by hospital type 2010-2013

Hospital type	Item	2010	2011	2012	2013
Private Hospitals	Consumables	1,576,051,000	1,646,784,556	1,981,711,619	1,819,138,246
	Medicine	3,578,407,000	3,445,570,451	3,494,236,437	3,658,873,417
	Equipment	273,672,000	503,755,870	582,062,295	632,106,288
Provincial(State) Hospital	Consumables	39,351,000	36,346,285	11,639,483	8,803,271
	Medicine	11,800,000	6,683,079	7,721,329	9,621,453
	Equipment	796,000,000	49,049,853	2,370,749	1,402,228

Source: CMS Annual Report (2010-2013)

Table 7: Private sector (insured) expenditure on medicines by source of funds 2008-2016

Source of funds	2008	2009	2010	2011	2012	2013	2014	2015	2016
Risk	9,048,304,000	10,757,169,000	11,202,641,000	11,919,079,163	12,941,658,248	14,994,887,131	16,194,876,467	17,252,731,129	18,386,208,103
Savings	2,157,011,000	2,532,996,000	2,837,534,000	3,241,737,519	3,398,361,948	3,914,828,270	4,394,904,417	5,069,041,594	5,571,376,464

Source: CMS Annual Reports 2008-2016

Table 8 : Private sector (Mediscor) data on medicines expenditure 2012-2017

Key expenditure indicators (Annual)	2014	2015	2016	2017
Average cost per beneficiary	2526	2616	2617	NA
Average cost per item	140	150	150	165
Average # items per utilising beneficiary	22	21.9	21.5	21.8

Source: Mediscor Medicines Review 2015-2017

Table 9 : Private sector (Mediscor) data on New Chemical Entities (NCE) expenditure 2014-2017

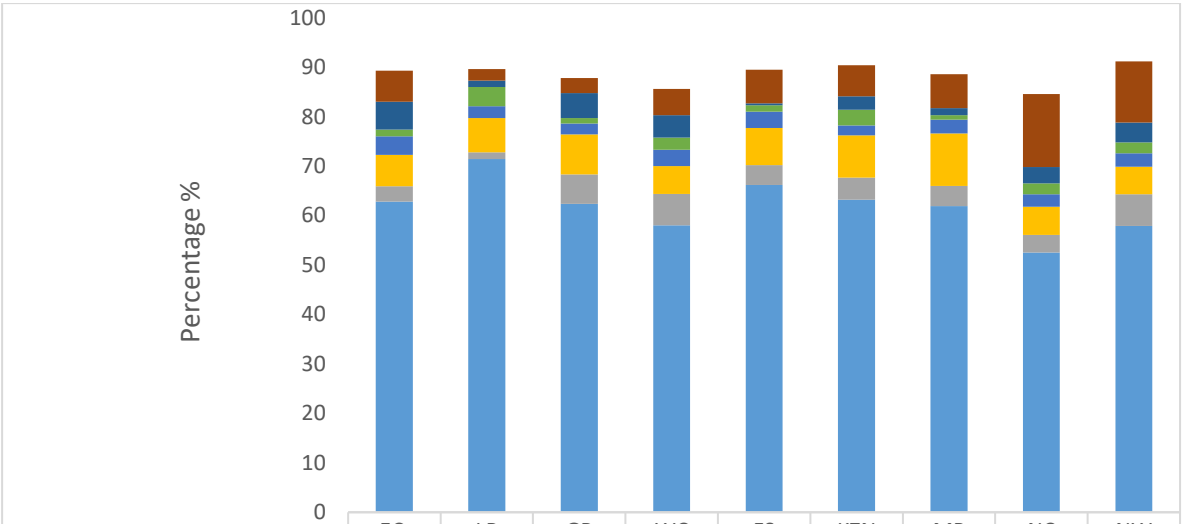
NCEs vs Existing medicines	2014		2015		2016		2017	
	New	Existing	New	Existing	New	Existing	New	Existing
% Expenditure	1.4	98.6	1.9	98.1	1.7	98.3	1.8	98.2
% Volume	0.4	99.6	0.4	99.6	0.4	99.6	0.3	99.7
Cost per item(ZAR)	555	138	737	148	604	148	906	165
% Prevalence	2	82	2.4	79.5	2.7	81	2.3	78.8
%Intensity	3.3	21.9	2.8	21.9	2.7	21.4	2.5	21.8

Source: Mediscor Medicines Review 2015-2017

3.2.3 Public sector expenditure on medical products

3.2.3.1 Overall public sector medical products expenditure – 2013

Medical supplies as a line item is comprised of medical devices and diagnostic equipment under R5000. Figure 9 and Table 11 presents a 'snapshot' of the provincial breakdown of operational budgets across SA in 2013. In this year, Mpumalanga (MP), KwaZulu Natal (KZN) and Gauteng Province (GP) respectively, recorded the highest proportional expenditures for medicines; the mean(SD) medicines expenditure across all provinces in 2013 was 7.3%(1.66)of the operational. The median medicines expenditure was 6.9% in 2013.



	EC	LP	GP	WC	FS	KZN	MP	NC	NW
Payments for Capital assets	6,3	2,3	3	5,3	6,8	6,3	6,9	14,8	12,4
Property payments	5,6	1,3	5,1	4,5	0,4	2,7	1,4	3,3	4
Inventory : Agency and support/outsourced services	1,4	3,9	1,1	2,5	1,3	3,2	0,9	2,2	2,2
Inventory : Laboratory costs	3,7	2,4	2,2	3,3	3,3	2	2,8	2,5	2,7
Inventory : Medicines	6,4	6,9	8,1	5,6	7,5	8,5	10,6	5,7	5,6
Inventory : Medical Supplies	3,1	1,4	5,9	6,4	4	4,5	4,1	3,6	6,4
Compensation of employees	62,8	71,4	62,4	58	66,2	63,2	61,9	52,5	57,9

Figure 9 : Public sector operational health expenditure by Province, 2013

Source: Author, based on National Treasury Report 2013

North West (NW) and Western Cape (WC) provinces held joint first position for medical supplies expenditure followed by GP and KZN respectively. The mean (SD) for medical supplies expenditure was 4.3% (1.65) of the operational budget with a median of 4.1%. Although there were differences between the provinces, overall, there was consistency in the public sector around expenditure on medical products. Medical products in the public sector

consumed a median of 6% of the goods and services budgets in the provincial Departments of Health.

3.2.3.2 Public sector expenditure on medicines by province

Figure 10 and Table 12 shows expenditure on medicines in each province from 2011 to 2016. Missing data entries for LP, NC and MP were noted and therefore any summary drawn from this data is to be interpreted with caution. The median change in expenditure from 2011 to 2016 was 5.3%, however, the outlier was a 16.6% increase between 2013 and 2014. KZN (R3.5bn; 29%) and GP (R3.1bn; 25%) incurred the highest expenditure on medicines in 2016. These two provinces alone accounted for 54 % of national expenditure (R12.3bn) on medicines; WC and EC combined constituted 22% of the total spend. In 2015, the national expenditure on medicines in the private sector was R10.9bn. The median increase year on year was 12% from 2011 to 2016. Incremental investment in medicines is noted in all provinces over the last 6 years. KZN, GP and EC respectively consistently account for the top three provincial expenditure on medicines, while NC, LP and NW/FS represent the lowest expenditure on medicines. In 2011, the national expenditure on medicines was R6.3bn and in 5 years, this doubled to R12.3bn in 2016, despite the absence of expenditure data from the MP province.

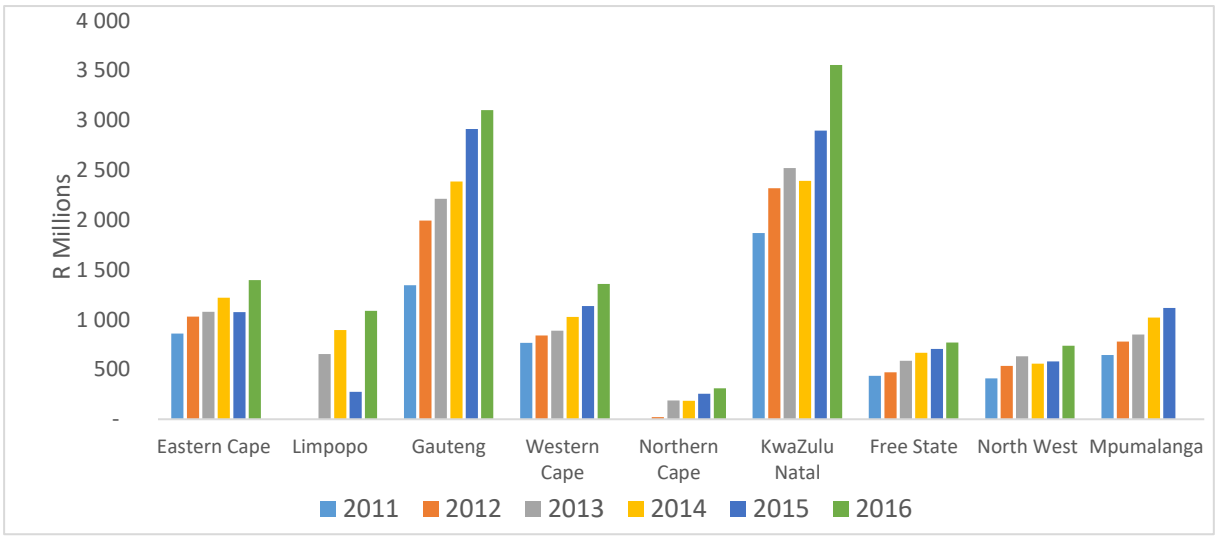


Figure 10 : Public sector expenditure on medicines by Province 2011-2016

Source: Provincial Annual Reports 2011- 2016

3.2.3.3 Public sector proportional expenditure on medical supplies

Expenditure on medical supplies per province from 2011 to 2016 is shown in Figure 11 and Table 13. Missing data entries for MP were noted and therefore any summary drawn from

this data should be interpreted with caution. The total expenditure on medical supplies in the public sector in 2016 was R6.7bn. The three provinces with highest expenditure were GP (R2bn), KZN (R1.5bn) and WC (R1.3bn) respectively, constitute 73 %(R4.9bn) of the total national expenditure on medical supplies in 2016. The top three provinces' expenditure trend was consistent in the review period. GP and KZN alone account for 53% (R3.5bn) of total national spending on medical supplies. The median change in the expenditure year-on-year was 1% however, in 2013, there was a reduction in expenditure by 13%, which had a knock-on effect in 2014, where a 12% increase was seen. The lowest expenditure was in NC (R158m), consistent with lower levels in prior years; R110m (2013), R124m (2014) and R117m (2015). In 2011, the national expenditure on medical supplies was R6.3bn and in 2016 the expenditure was R6.7bn, considering the absence of data for MP province.

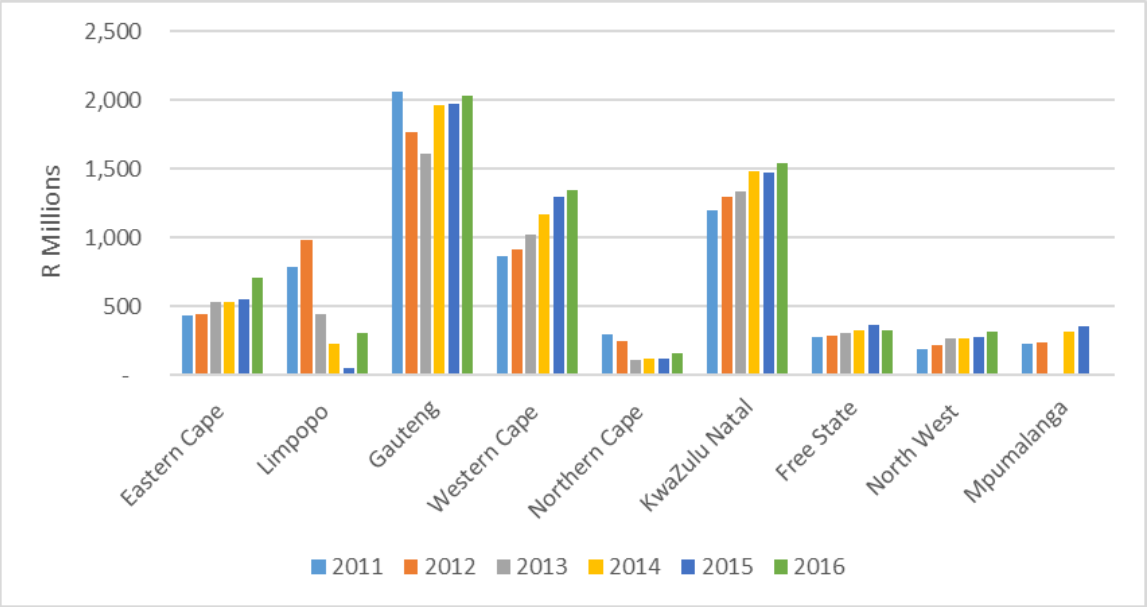


Figure 11 : Public sector expenditure on medical supplies by Province 2011-2016

Source: Provincial Annual Reports 2011- 2016

The proportional expenditure across the provinces shows that GP (30%), KZN (23%), and WC (20%) dominate the spending on medical supplies. As seen with medicines expenditure, NW and FS (5%), LP (4%), NC (2%) shared the lowest proportions of the total national spending on medical supplies.

3.2.3.4 Expenditure on medical products across all provinces

Public sector expenditure on medicines and medical supplies across all provinces from 2011 to 2016 is seen in Figure 12(Table 10). This data was sourced from National Treasury Provincial Reports and therefore differs slightly from data presented in Figures 10 and 11 above (Public sector medicines and medical supplies) and Tables12 and 13 below.

Furthermore, mid- term estimates and not actuals in the period from 2014 to 2016 were included in Figure 12(Table 10). The average proportional expenditure on medicines (63%) and medical supplies (37%) from 2010 to 2016.

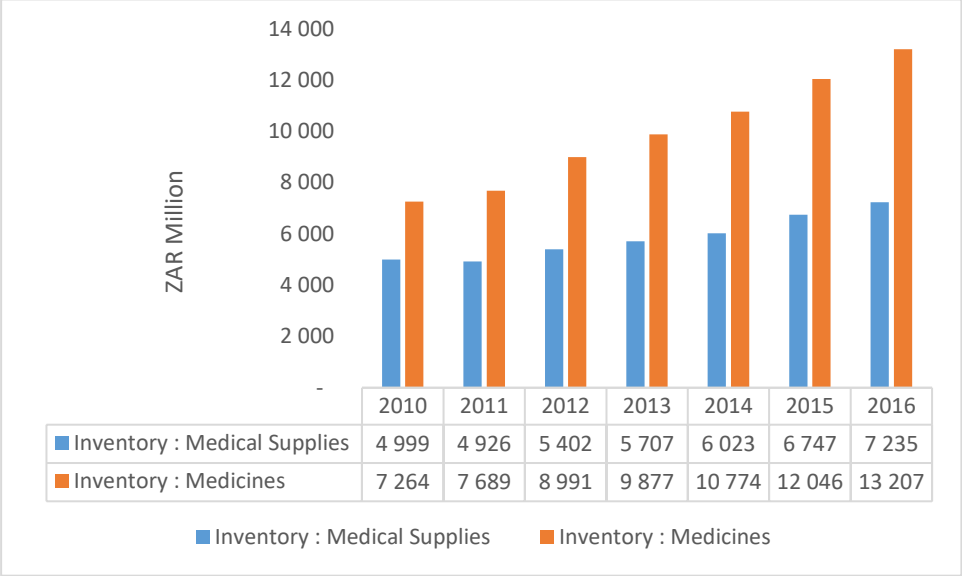


Figure 12: Public sector expenditure on medical products, All Provinces 2010-2016

Source: National Treasury Provincial Budget Review 2016

Table 10: Public sector expenditure on medical products, All Provinces 2010-2016

Economic classification ZAR (million)	2010	2011	2012	2013	2014	2015	2016
Inventory : Medical Supplies	4,999	4,926	5,402	5,707	6,023	6,747	7,235
Inventory : Medicines	7,264	7,689	8,991	9,877	10,774	12,046	13,207

Source: National Treasury, Provincial Budget Review, 2013

Table 11 : Public Sector operational expenditure on medical products by Province 2013

Economic classification (%)	EC	LP	GP	WC	FS	KZN	MP	NC	NW
Compensation of employees	62.8	71.4	62.4	58	66.2	63.2	61.9	52.5	57.9
Goods and Services	28.1	22.4	29.4	31.1	25.3	27.8	27.8	30.2	28.3
Inventory : Medical Supplies	3.1	1.4	5.9	6.4	4	4.5	4.1	3.6	6.4
Inventory : Medicines	6.4	6.9	8.1	5.6	7.5	8.5	10.6	5.7	5.6
Inventory : Laboratory costs	3.7	2.4	2.2	3.3	3.3	2	2.8	2.5	2.7
Inventory : Agency and support/outsourced services	1.4	3.9	1.1	2.5	1.3	3.2	0.9	2.2	2.2
Property payments	5.6	1.3	5.1	4.5	0.4	2.7	1.4	3.3	4
Payments for Capital assets	6.3	2.3	3	5.3	6.8	6.3	6.9	14.8	12.4

Source: National Treasury, Provincial Budget Review, 2013

Table 12 : Public sector expenditure on medicines by Province 2011-2016

Medicines Expenditure (ZAR)	2011	2012	2013	2014	2015	2016
Eastern Cape	861,342,000	1,030,925,000	1,077,780,000	1,218,920,000	1,073,766,000	1,396,440,000
Limpopo	NR*	NR	655,339,000	896,814,000	274,292,000	1,088,944,000
Gauteng	1,345,473,000	1,992,800,000	2,213,556,000	2,387,454,000	2,913,796,000	3,101,764,000
Western Cape	766,304,000	839,937,000	890,182,000	1,028,175,000	1,136,188,000	1,357,475,000
Northern Cape	NR	21,471,000	190,140,000	186,748,000	254,965,000	311,074,000
KwaZulu Natal	1,868,079,000	2,317,380,000	2,520,817,000	2,392,761,000	2,895,380,000	3,554,428,000
Free State	436,832,000	469,762,000	587,261,000	667,761,000	706,238,000	769,499,000
North West	409,468,000	535,591,000	632,565,000	558,631,000	580,064,000	736,331,000
Mpumalanga	645,706,000	779,215,000	850,983,000	1,020,330,000	1,118,218,000	NR
Mean	904,743,429	998,385,125	1,068,735,889	1,150,843,778	1,216,989,667	1,539,494,375
Standard Deviation	489116752.4	728936780.3	735105667.7	721601291.6	955315860.2	1089966516
Median	766,304,000	809,576,000	850,983,000	1,020,330,000	1,073,766,000	1,223,720,758
Total Annual	6,333,204,000	7,987,081,000	9,618,623,000	10,357,594,000	10,952,907,000	12,315,955,000

*Source: Author, based on Provincial Annual Reports, All Provinces, 2011-2016 *Not reported*

Table 13 : Public sector expenditure on medical supplies by Province 2011-2016

Medical Supplies (ZAR)	2011	2012	2013	2014	2015	2016
Eastern Cape	438,442,000	446,168,000	532,711,000	537,674,000	557,292,000	714,642,000
Limpopo	785,157,000	988,876,000	442,862,000	225,493,000	56,634,000	307,208,000
Gauteng	2,066,011,000	1,766,582,000	1,607,522,000	1,964,383,000	1,971,892,000	2,030,336,000
Western Cape	865,583,000	911,550,000	1,026,400,000	1,174,505,000	1,298,695,000	1,344,775,000
Northern Cape	297,439,000	253,411,000	110,901,000	124,602,000	117,249,000	158,512,000
KwaZulu Natal	1,199,821,000	1,293,502,000	1,339,984,000	1,481,668,000	1,479,150,000	1,541,848,000
Free State	279,267,000	286,395,000	307,872,000	331,387,000	371,482,000	329,636,000
North West	195,437,000	221,364,000	267,414,000	264,897,000	283,034,000	322,378,000
Mpumalanga	227,484,000	239,568,000	NR	320,387,000	355,748,000	NR
Mean	706,071,222	711,935,111	704,458,250	713,888,444	721,241,778	843,666,875
Standard Deviation	615,983,379	558,210,766	550,531,154	660,016,468	684,957,758	702,708,274
Median	438,442,000	446,168,000	487,786,500	331,387,000	371,482,000	522,139,000
Total Annual	6,354,641,000	6,407,416,000	5,635,666,000	6,424,996,000	6,491,176,000	6,749,335,000

*Source: Author, based on Provincial Annual Reports, All Provinces, 2011-2016 *Not reported*

3.2.4. Household expenditure on medical products in South Africa

The results of the study of household survey data to determine household expenditure on medical products was based on survey data from the IES 2005, 2010 and LCS 2008 and 2014. In the IES 2005, 2010 and LCS 2014, it was possible to examine disaggregated

expenditure on ‘pharmaceutical’, ‘therapeutic appliances and equipment’ and ‘other medical products’ categories, however, this classification was not consistent in the LCS 2008.

In the four surveys from 2005 to 2014, SA households spent more on medical products than outpatient health services. The median household expenditure on medical products, which included pharmaceuticals , appliances and equipment was 0.7% of the total household expenditure on health , which in real terms was an average annualized R542(SD 193.4). In contrast, during the same period, the median expenditure on outpatient health services was 0.6% of total household spending on health (R493; SD 183.3) as seen in Table 14.

Figure 13 shows average SA household expenditure by expenditure groups demonstrating that pharmaceuticals constitute a larger proportion of household expenditure than therapeutic appliances and equipment and other medical products over the period 2005 to 2014.

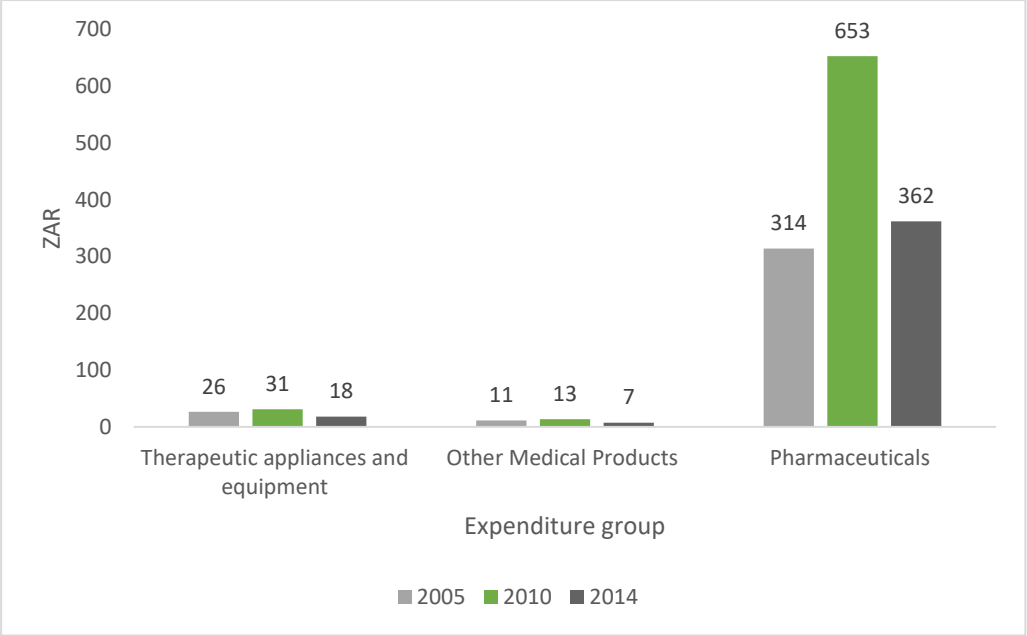


Figure 13: Household OOP expenditure on medical products by expenditure group

Source: IES2005, IES 2010 and LCS2014

3.2.4.1 Household expenditure on medical products by sex of Household head

Median spending in male headed households was 0.65% as compared to 0.7% for female headed households over the survey periods from 2005 to 2014 as shown in Figure 14(Table 14). Changes to the questionnaire in 2008 impacted the data collected on medical products expenditure; female headed households spent more (1.2%) on medical products than male headed households (0.9%) in that year. Figure 14 show females headed households spent less on medical products, in real terms, across all survey years. The average spent by female headed households was R404.8 (SD165) and that of males was R622 (SD216).

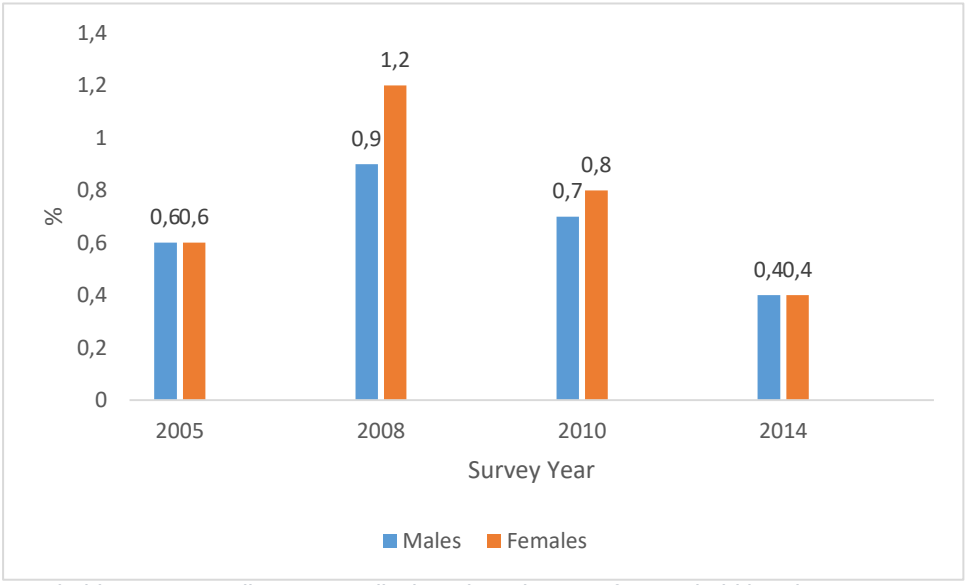


Figure 14 : Household OOP expenditure on medical products by sex of Household head

Source: IES 2005, LCS 2008, IES 2010 and LCS2014

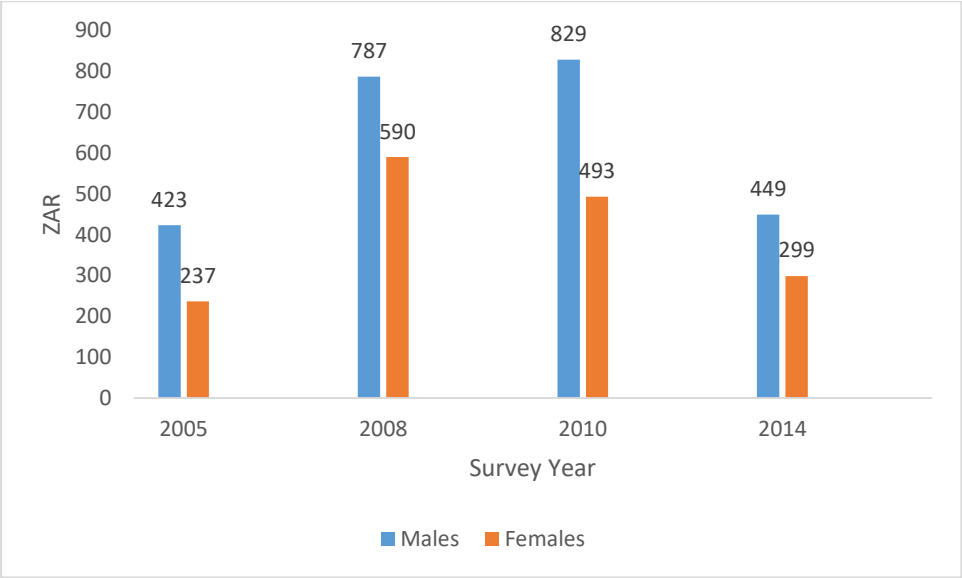


Figure 15: Household OOP expenditure on medical products, by Sex of HH head, real values(R)

Source: IES 2005, LCS 2008, IES 2010 and LCS2014

3.2.4.2. Household expenditure on medical products by settlement type

The IES 2005 survey distinguishes only two settlement types namely urban and rural; this was changed in the LCS 2008 to urban formal (UF), urban informal (UI), rural formal (RF) and traditional areas. Urban households allocated an average of 0.8% of household expenditure on medical products over the period 2005-2014 in the four surveys, compared to 0.7% in rural households as seen in Figure 16(Table 15). Both urban and rural households spent more on medical products than outpatient services. Urban informal households spent 66% less than urban formal households on medical products; rural formal households spent 41% less than urban formal. The average urban household spent R940 per year over the survey periods compared to rural households (R585) on medical products.

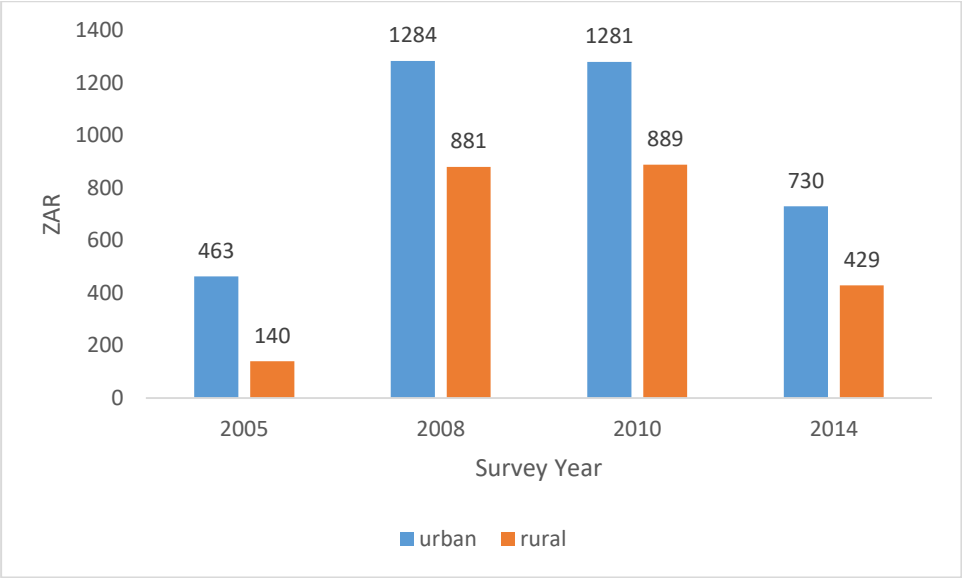


Figure 16 : Household OOP expenditure on medical products, by Settlement type

Source: IES 2005, LCS 2008, IES 2010 and LCS2014

3.2.4.3 Household expenditure on medical products by province

The average household across all provinces spent 0.6% of total household expenditure on medical products in the survey periods from 2005 to 2014, as shown in Figure 17(Table 18). In 2005, households committed a larger proportion of household expenditure to outpatient services than medical products, except in the FS province where medical products formed 1% and outpatient services 0.9%. This trend was unchanged in 2014 with a higher proportional spending on outpatient services. The average expenditure in real terms from 2005 to 2014 was R536 (SD 193) as shown in Figure 17. The provinces with the highest household expenditure on medical products in 2005 were FS (0.9%), NW and EC (0.7%), WC/NC/KZN/GP (0.6%). Although the average household expenditure on medical products across SA had decreased between 2005 and 2014, the highest household expenditure was in FS (0.8%), WC/NC (0.5%), and KZN (0.4%) in 2014.

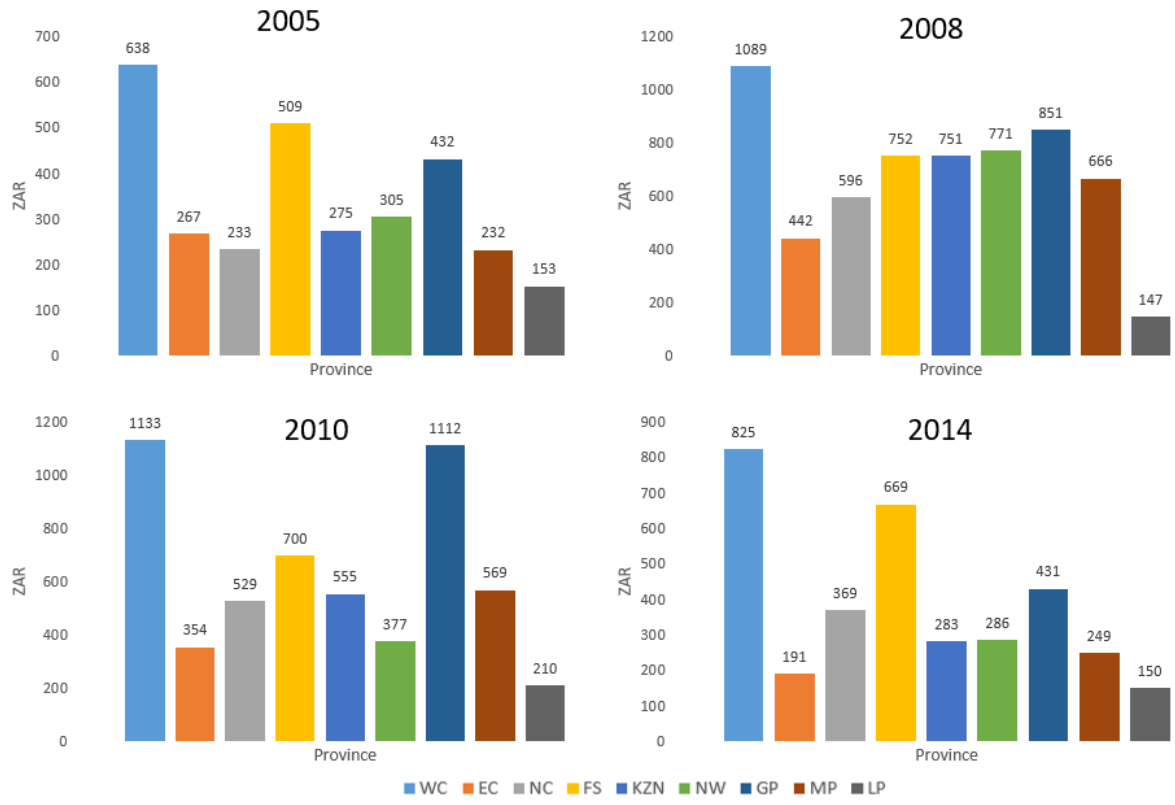


Figure 17 : Household OOP expenditure on medical products by Province

Source: IES 2005, LCS 2008, IES 2010 and LCS2014

3.2.4.4 Household expenditure on medical products by expenditure deciles

From 2005 to 2014, household OOP expenditure on outpatient services (0.5%) was lower than that of medical products (0.7%). Changes in average household spending on medical products, in real terms, were not linear from 2005 (R350), 2008(R392), 2010(R697) and 2014 (R387), as shown in Table 17. In 2005, the average spending on medical products was R350 (median R136) ranging between the minimum R41 in the lowest decile to the maximum R1797 in the highest expenditure decile. The average spending on medical products across all expenditure deciles in 2014 was R387 (median R 187), however, this varied greatly between the lowest decile (R46) and highest decile (R1668).

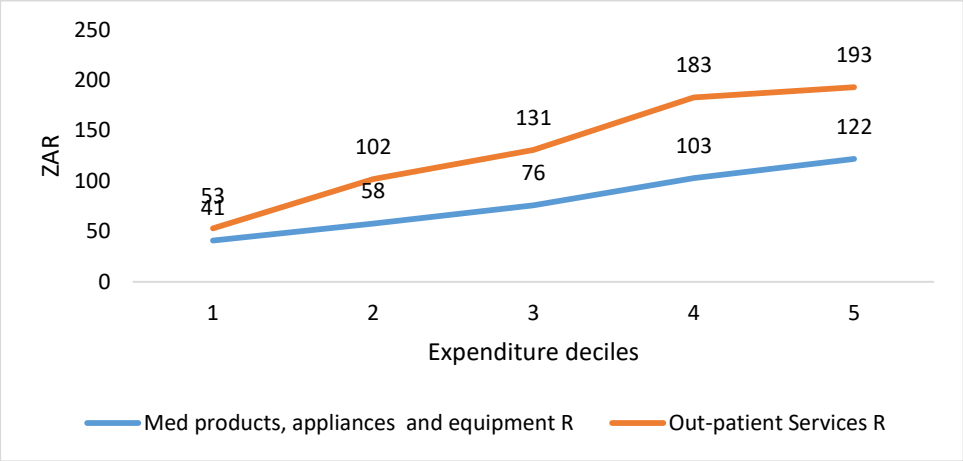


Figure 18 : Household OOP expenditure on medical products by Lowest Expenditure deciles

Source: IES 2005

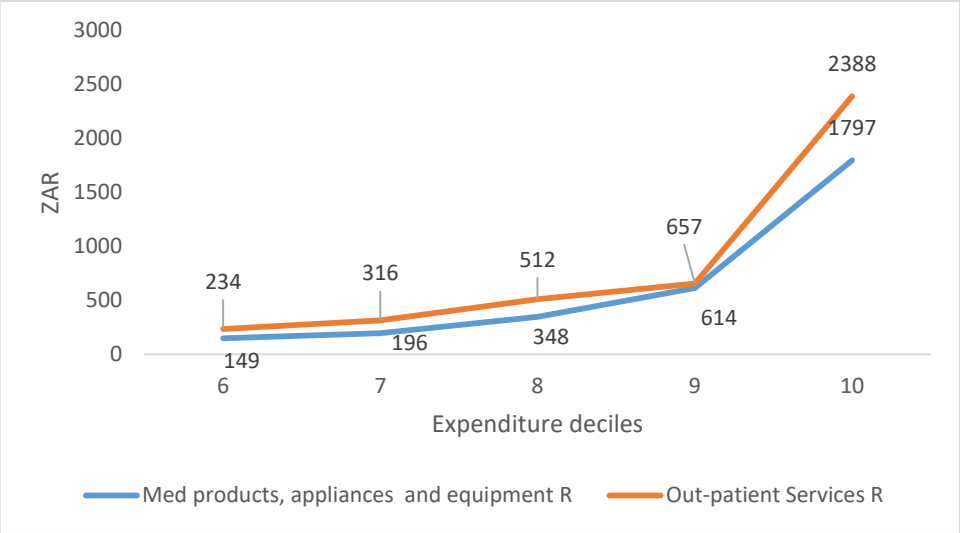


Figure 19 : Household OOP expenditure on medical products by Highest Expenditure deciles

Source: IES 2005

Figures 18 and 19 shows the unequal distribution of expenditure on medical products between the lowest and highest five expenditure deciles in 2005. The average spent on medical products in the lowest 5 deciles in 2005 was R156 (SD 100) compared with the average spent in the upper five deciles which was R916 (SD 826). These values were widely dispersed around the mean. Expenditure on outpatient services was similar to that of medical products except in the two highest expenditure deciles, (i.e. expenditure deciles 9 and 10) where outpatient services spending steeply increased, widening the gap between services and medical products expenditure. Between decile 9 and 10, expenditure on services increases relative to that of medical products. A similar widening of the gap between expenditure on services and medical products at household level is also seen between the deciles 4 and 5.

3.2.4.5 Household expenditure on medical products by income deciles

In 2005, both lower and upper income deciles spent 0.6% of total expenditure on ambulatory care (out of hospital) spending on medical products, as seen in the Figure 20(Table 16). In 2005, a higher proportion of ambulatory care expenditure was spent on outpatient care. The lower 5 income deciles spent an annual average of R181 (SD 95) in the survey periods from 2005 to 2014. The upper 5 income deciles spent an annual average of R866 (SD 736) between 2005 and 2014 although there was wide variation around the mean.

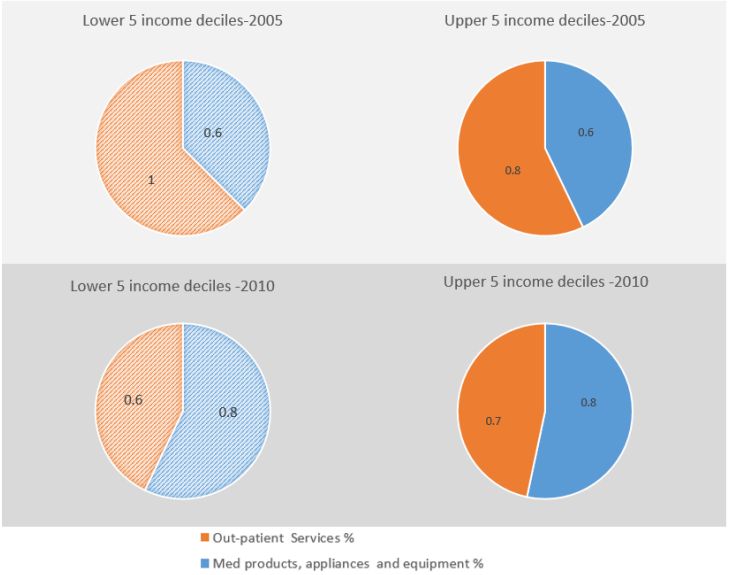


Figure 20 : Household OOP expenditure on medical products by Income deciles

Source: IES 2010

Table 14 : Household OOP expenditure on medical products by Sex of Household head

Household expenditure on medical products by sex of household head 2005-2014												
Average household consumption by 3rd expenditure group and gender of household head	2005			2008			2010			2014		
	M	F	Total	M	F	Total	M	F	Total	M	F	Total
Med products, appliances and equipment %	0.6	0.6	**0.6**	0.9	1.2	**1.0**	0.7	0.8	**0.7**	0.4	0.4	**0.4**
Med products, appliances and equipment R	423	237	**351**	787	590	**709**	829	493	**697**	449	299	**387**
Therapeutic appliances and equipment R	33	15	**26**	·	·	·	39	18	**31**	24	10	**18**
Other Medical Products R	13	8	**11**	·	·	·	18	6	**13**	8	5	**7**
Pharmaceuticals R	377	214	**314**	·	·	·	772	469	**653**	417	283	**362**
Out-patient Services %	0.9	0.8	**0.9**	0.3	0.3	**0.3**	0.7	0.6	**0.7**	0.5	0.4	**0.5**
Out-patient Services R	573	327	**477**	252	141	**208**	827	363	**644**	652	327	**517**
Source : IES 2005,LCS2008,IES2010,LCS2014, Stats SA							*(M=Males, F=Females)*					

Table 15: Household OOP expenditure on medical products by Settlement type

Household expenditure on medical products by settlement type 2005-2014																	
Average household consumption by 3rd expenditure group and settlement type	2005			2008					2010					2014			
	Urban	Rural	Total	UF	UI	Trad	RF	Total	UF	UI	Trad	RF	Total	UF	UI	Trad	RF	Total
Med products, appliances and equipment %	0.6	0.6	**0.6**	0.9	1.3	1.1	1.1	**1**	0.7	0.9	0.6	0.8	**0.7**	0.4	0.5	0.3	0.4	**0.4**
Out-patient Services %	0.8	1.1	**0.9**	0.3	0.1	0.2	0.3	**0.3**	0.7	0.6	0.6	0.4	**0.7**	0.5	0.4	0.3	0.6	**0.5**
Med products, appliances and equipment R	463	140	**351**	950	334	350	531	**709**	978	303	249	640	**697**	532	198	133	296	**387**
Therapeutic appliances and equipment R	37	5	**26**	·	·	·	·	·	50	4	3	17	**31**	28	1	1	25	**18**
Other Medical Products R	14	5	**11**	·	·	·	·	·	20	8	3	5	**13**	9	1	4	1	**7**
Pharmaceuticals R	411	131	**314**	·	·	·	·	·	909	291	244	618	**653**	495	196	128	270	**362**
Out-patient Services R	581	283	**477**	313	28	58	129	**208**	933	220	234	303	**644**	739	142	155	427	**517**
Source : IES 2005,LCS2008,IES2010,LCS2014, Stats SA									*(UF=Urban Formal, UI= Urban Informal, Trad= Traditional, RF=Rural Formal)*									

Table 16 : Household OOP expenditure on medical products by Income decile

Household expenditure on medical products by income decile 2005 -2010																					
Average household consumption by 3rd expenditure group and Income Deciles	2005											2010									
	Low	2	3	4	5	6	7	8	9	High	Total	Low	2	3	4	5	6	7	8	9	High	Total
Med products, appliances and equipment %	0.5	0.6	0.6	0.6	0.6	0.5	0.5	0.6	0.6	0.7	0.7	1.1	0.9	0.7	0.8	0.8	0.8	0.8	0.8	0.7	0.7	0.7
Out-patient Services %	0.7	1.0	1.0	1.0	1.0	1.1	0.8	0.8	0.7	0.9	0.9	0.5	0.6	0.5	0.6	0.6	0.7	0.7	0.8	0.7	0.7	0.7
Med products, appliances and equipment R	60	88	92	117	137	150	188	327	691	1657	351	241	220	227	292	339	397	548	815	1289	2598	697
Therapeutic appliances and equipment R	1	2	1	12	1	4	6	22	70	143	26	32	3	4	8	9	21	14	54	47	116	31
Other Medical Products R	3	4	3	5	4	7	9	13	11	51	11	46	2	2	10	3	4	7	8	18	34	13
Pharmaceuticals	56	81	88	100	132	139	173	292	610	1463	314	163	216	222	274	327	373	528	752	1224	2448	653
Out-patient Services R	84	141	175	196	228	307	285	416	728	2213	477	110	153	163	199	252	337	460	783	1294	2690	644
Source : IES 2005, IES2010, Stats SA																						

Table 17 : Household OOP expenditure on medical products by Expenditure deciles

Household expenditure on medical products by expenditure deciles 2005-2014

Average household consumption by 3rd expenditure group and expenditure deciles	2005											2008											2010											2014										
	Low	2	3	4	5	6	7	8	9	High	Total	Low	2	3	4	5	6	7	8	9	High	Total	Low	2	3	4	5	6	7	8	9	High	Total	Low	2	3	4	5	6	7	8	9	High	Total
Med products, appliances and equipment %	0.7	0.6	0.6	0.6	0.6	0.6	0.6	0.7	0.6	0.6	**0.6**	1	1.1	1.3	1.4	1.4	1.3	1.2	1	0.9	0.9	**1**	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.7	**0.7**	0.4	0	0.4	0.4	0.4	0.4	0.5	0.4	0.4	0.3	**0.4**
Out-patient Services %	0.9	1	1	1.1	0.9	0.9	0.9	1	0.7	0.9	**0.9**	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.3	0.4	**0.3**	0.7	0.7	0.6	0.6	0.6	0.6	0.6	0.6	0.7	0.8	**0.7**	0.4	0	0.4	0.4	0.4	0.4	0.5	0.4	0.4	0.6	**0.5**
Med products, appliances and equipment R	41	58	76	103	122	149	196	348	614	1797	**351**	90	160	252	320	415	481	628	792	1138	2810	**709**	88	149	190	231	277	364	528	763	1381	2997	**697**	46	75	111	136	170	203	351	388	723	1668	**387**
Therapeutic appliances and equipment R	1	0	1	3	1	2	9	23	54	167	**26**	·	·	·	·	·	·	·	·	·	·	·	·	·	2	3	5	3	13	40	98	143	**31**	·	1	·	1	1	1	7	8	20	143	**18**
Other Medical Products R	2	2	3	5	5	6	8	14	13	52	**11**	·	·	·	·	·	·	·	·	·	·	·	1	2	1	3	4	4	9	9	62	37	**13**	·	1	1	3	2	13	8	9	11	22	**7**
Pharmaceuticals R	38	56	71	96	115	142	179	310	548	1578	**314**	·	·	·	·	·	·	·	·	·	·	·	87	147	187	226	268	357	506	714	1221	2817	**653**	46	72	110	132	167	189	337	371	691	1502	**362**
Out-patient Services R	53	102	131	183	193	234	316	512	657	2388	**477**	10	18	23	25	34	49	73	134	457	1255	**208**	69	111	142	178	212	267	393	561	1150	3359	**644**	43	76	104	124	166	213	360	437	765	2886	**517**

Source : IES 2005,LCS2008,IES2010,LCS2014, Stats SA

Table 18 : Household OOP expenditure on medical products by Province

Household expenditure on medical products by province 2005-2014

Average household consumption by 3rd expenditure group and Province	2005										2008										2010										2014									
	WC	EC	NC	FS	KZN	NW	GP	MP	LP	Total	WC	EC	NC	FS	KZN	NW	GP	MP	LP	Total	WC	EC	NC	FS	KZN	NW	GP	MP	LP	Total	WC	EC	NC	FS	KZN	NW	GP	MP	LP	Total
Med products, appliances and equipment %	0.6	0.7	0.6	1	0.6	0.7	0.6	0.5	0.5	**0.6**	1	0.9	1	1.5	1.3	1.4	0.8	1.2	0.4	**1**	0.9	0.6	0.7	1	0.7	0.5	0.8	0.7	0.4	**0.7**	0.5	0.3	0.5	0.8	0.4	0.4	0.3	0.3	0.2	**0.4**
Out-patient Services %	0.7	0.8	0.7	0.9	0.9	0.8	1	0.8	0.8	**0.9**	0.4	0.2	0.2	0.4	0.2	0.2	0.3	0.2	0.1	**0.3**	0.9	0.3	0.5	0.8	0.6	0.4	0.8	0.7	0.3	**0.7**	0.8	0.3	0.5	1.3	0.5	0.3	0.4	0.4	0.2	**0.5**
Med products, appliances and equipment R	638	267	233	509	275	305	432	232	153	**351**	1089	442	596	752	751	771	851	666	147	**709**	1133	354	529	700	555	377	1112	569	210	**697**	825	191	369	669	283	286	431	249	150	**387**
Therapeutic appliances and equipment R	56	24	7	112	25	21	5	9	8	**26**	·	·	·	·	·	·	·	·	·	·	52	8	45	54	28	14	50	7	4	**31**	55	7	31	33	3	5	25	1	3	**18**
Other Medical Products R	23	8	8	8	9	6	14	12	5	**11**	·	·	·	·	·	·	·	·	·	·	14	1	3	15	8	4	29	13	4	**13**	9	7	3	10	3	4	10	7	4	**7**
Pharmaceuticals R	559	235	218	389	241	277	412	211	140	**314**	·	·	·	·	·	·	·	·	·	·	1067	344	482	632	520	359	1032	548	202	**653**	761	177	335	625	277	277	396	240	143	**362**
Out-patient Services R	691	311	258	432	414	366	742	350	236	**477**	500	78	105	225	122	119	325	125	39	**208**	1171	200	398	605	493	333	1066	595	166	**644**	1258	239	429	1098	387	239	539	339	130	**517**

Source : IES 2005,LCS2008,IES2010,LCS2014, Stats SA

(WC=Western Cape, EC= Eastern Cape, NC=Northern Cape, FS=Free State, KZN=KwaZuluNatal,NW=North West,GP=Gauteng Province, MP=Mpumalanga, LP=Limpopo Province)

3.2.4.6 Summary of Multiple Regression Analysis

A multiple regression analysis was conducted to predict the effect of demographic variables on household OOP expenditure on medical products. Household survey data was comparable only from 2005 -2014 and excluded any prior surveys therefore, the IES2000 was used in this inferential statistical analysis, to understand the trajectory of household spending on medical products prior to 2005 (124,125). In total 26 182 observations were recorded across 18 strata and 2956 PSUs in the IES2000 household survey. Table 19 summarises the descriptive statistics for OOP medical products expenditure in households based on membership status of medical aid schemes.

The sample was composed of majority Black/African households (75%), White (14%), Coloured (8.3%) and Indian/Asian (2.5%). More urban households were sampled (64%) as compared to rural (36%). Most families consisted of 1-5 members (78%). Twenty percent of families in the sample had between 6-10 members and only 2% had more than 10 members per household. The main income sources were regular income (69%), salaries and wages (21.4%), regular receipts from grants and funds (8.27%), nett profit from business (3.14%) and Alimony (1.97%).

The highest average annual spending in 2000 was seen in the White population group (R611.8 per year in medical scheme members and R224.3 in non-medical scheme members) followed by Indians/Asians (R146 in members and R85.3 in non-members). Black/African households spent the least on medical products regardless of membership status (around R21 per annum). Across all population groups, households with non-members incurred less OOP expenditure on medical products than members of medical schemes

Households in GP and WC were the highest spenders in both public and private sectors. Households in LP, NW and EC incurred the lowest OOP expenditure on medical products. Across all provinces, households without medical aid or insurance incurred less OOP expenditure on medical products compared to members of medical schemes. Uninsured households in LP reported an average annual expenditure of R7.8 on medical products, while GP insured households in GP spent R178.9 per annum.

Insured households in urban areas spent more per annum (R956.8) on average than insured rural households (R439) and this urban-rural pattern was repeated in the uninsured households.

Table 19: Descriptive Statistics - Income and Expenditure Survey 2000

n=26 182

	%	Mean ZAR Private	SD	Mean ZAR Public	SD
Population group of HH head					
Black/African	75	20.5	270.9	21.1	122.8
Coloured	8.3	40.1	302.8	57.4	352.5
Indian/Asian	2.5	146.6	576.3	85.3	280.4
White	14	611.8	1327.6	224.3	682.9
Other	0.25	218.7	529.5	47.4	97.2
Province					
WC	9.5	175.8	824.4	109.9	49.2
EC	14.4	54.9	473.2	24.7	204.7
NC	4.6	98.1	1241.5	42.6	417.4
FS	7.8	124	892.7	60.2	739.2
KZN	18.9	89.1	635.1	47.1	254.8
NW	10.1	47.4	468.2	30.1	271.2
GP	13	178.9	804.4	80.5	362.2
MP	9.1	71.9	520.1	40.2	291.9
LP	12.8	27.3	389.3	7.8	72.5
Settlement type					
Urban	64	956.8	1742	396.9	752.2
Rural	36	439.1	706.9	234.9	791.6
Income Sources					
Salaries and Wages	21.46	1076.8	2268.1	435.3	879.8
Net Profit	3.14	1343.2	2736.4	456.4	830.4
Interest received	0.14	345.9	68	283.4	294.2
Regular receipts	8.09	1292.9	1348.7	1224.6	1371.1
Alimony	1.97	448.4	644	90.1	102.3
Regular allowances	1.4	1882	3416.8	78.4	126.9
Total regular income	63.62	877.4	1599.9	321.8	615.3
Household size					
1		935.9	1738.6	396	767.4
2		588.2	919.7	101	113.6
3		488.5	251.4	74.7	30
4					
5		146	153.8	69	80.9

Source: Author, IES 2000 using Stata v15 (STATACORP)

The regression models for OOP medical products expenditure in households with and without medical aid based on the IES 2000, is given in Appendix C and D respectively. The regression model was able to predict only 7.9% of the variability seen in expenditure on medical products in insured households.

Province and household size were not predictors of average household OOP expenditure on medical products. The average annual household expenditure on medical products for insured households increases on average by R109 for Indians/Asian (p=0.005) and R590 for White (p<0.000) population groups, as compared to Black/African population group, holding all other variables constant. The average OOP expenditure on medical products in insured households decreases by R31 for rural settlement type (p=0.002) as compared to urban settlement type, holding all other variables constant. The average household expenditure on medical products by medical scheme members decreases by R322 where the income source is subsistence farming (p=0.032) and by R151 where royalties are the income source (p=0.013) holding all other variables constant.

In households with non-members of medical schemes, the regression model was able to predict on 6.8% of the variability seen in OOP expenditure on medical products. In the NC (p=0.004) and LP (p=0.041) in uninsured households, decreases in medical products expenditure by R50 and R38 respectively, as compared to the Western Cape is seen, adjusting and holding constant, all other variables in the model. Household size, settlement type and income source were not predictors of average OOP expenditure on medical products in uninsured households. The average household OOP expenditure on medical products in uninsured households increases by R56 in Indians/Asian (p=0.001) population group and by R187 in White (p<0.001) population groups, as compared to Black African population group, holding all other variables constant.

3.3 Summary of Qualitative Data

3.3.1 Overview of interviews

The six key informant interviews yielded qualitative data that confirmed assumptions and publicly held views of ATM in SA. Interestingly, the information highlighted concerns and challenges of practical significance that was not well documented in the prevailing literature.

The KIs were adept at relating their professional activities within the ATM context and articulating their roles and contribution to the overall health system ATM goals. Each interviewee was well placed within their professional remit, to offer in-depth insights into funding, policy, governance, HR, health technology, supply and procurement and health information management (i.e. health system building blocks). Two perspectives of ATM

emerged – the strategic and the operational levels. The differences between the public and private sectors are highlighted in the themes.

Three KIs were well versed in ATM research, analytics and consultancy. Their interviews confirmed the major themes elicited in the literature review on health technology, policy, finance and ATM. They were executive level decision makers, industry and opinion leaders. The interview covered the urgent, complex, and controversial issues of medical products policy, funding and access.

Three interviewees were professionally engaged at an operational level within the health system and offered unique views, many of which were undocumented, of the challenges and opportunities in human resources and service delivery. These KIs were employed in critical roles at or near the frontline of service delivery, a vantage point from which knowledge translation and policy implementation could be assessed. Each KI related the complexity of operations enabling the realisation of ATM, by adopting pragmatic approaches rooted in management, public administration and policies to exploit resources optimally.

There was coherence around many of the themes elicited through the KI interviews and the critical literature review conducted. The KIs were able to provide experiences, empirical and anecdotal evidence of the policy process, regulation and implementation. The preliminary quantitative results could be 'verified' as these impressions were intuitively known and well accepted in the industry. The findings of the qualitative interviews were coherent with the themes identified in the policy and health systems ATM literature. Additionally, the quantitative data reinforced the emergent knowledge with respect to medical products expenditure (from CMS and DOH reports) and household survey data.

The NDP was accepted as a strategic document that spearheaded reforms in ATM. All agreed that there were many success of the NDP, but were aware of the delays and failures of implementation. KIs agreed that regulation was necessary for medical products, but there was some dissonance in what should be prioritised. The implementation of the NHI received mixed responses with most KIs identifying the opportunity for further reform and bemoaning the lack of clarity around the details of implementation. There was consensus that NHI has the potential to overhaul the current health system but concerns abound about capacity of the regulator, health system functions (financing and service delivery), human resources and information system.

The operational level issues raised were also confirmatory of the literature. Supply chain management in the public sector was the dominant theme. KIs had detailed knowledge of process bottlenecks and resource constraints and shared many management -driven solutions and best practices within their contexts. The KIs were perceived as experts in their respective fields but were unable to execute on improvement initiatives based of lack of

management, resource and time constraints. Table 20 below summarises the key themes highlighted in the interviews.

The public and private sector themes are given below in Tables 21 and 22.

Table 20: Emerging themes from Key informant interviews

Industry/Sector	Content Area	Themes
Public Sector	District and Provincial Management	Financing, procurement, clinical governance, rational use, reporting , MSD capacity, training HR, SCM, stock outs. Policy, procurement, clinical governance , rational use, finance, reporting process, Sub district capacity to manage procurement and SCM
Private Sector	Retail pharmacy	Generic utilisation, Generic uptake as pharmacy performance criteria. MCO incentives for retail pharmacies(Designated Service Providers) , OOP spending in private , Top 5 generic and originators in private, Consult in public buy in private, locals vs foreign nationals, average cost chronic self funding
Private Sector	Provider Management	Managed care funding , Registration delays,SEP, inhibitory regulation, regulatory authority capacity constraint ,formulary limitations , providers input costs , co-payments , government capacity, NHI
Academic	Research	Regulation , Policy SEP,price setting, dispensing fee, NHI,access to PMD,clinical governance ,capacity of SAHPRA,public financing of medicines and devices, MSD capacity, private financing ,managed care , rational drug use , pharmacy practice
Private Sector	Health Technology Assessment	Device registration, licencing ,classification of medical devices, capacity of SAHPRA, product registration, price controls, cost effectiveness , public sector procurement, managed care funding , HTA, NHI

Source: Author, based on key informant interviews

Table 21: Summary of Public Sector themes

Procurement and SCM	Clinics have a specification committee with clinical representatives to understand the equipment technical description and needs. Requests for procurement must be vetted by cost containment committees at facility level . District hospitals have a Bid Evaluation Committee. Sub districts need to be capacitated to conduct these meetings. At facility level orders are repeated due to non delivery and charged multiple times .Suppliers provide medicines with soon-to-be expired stock. Stocks outs result when suppliers are unable to meet the demand or if there is only one . IT systems(such JAC and WINRTM) is useful to manage pharmaceutical utilisation . Serious challenges with availability of essential medicines; Umtata depot not accredited by Pharmacy Council. Courier services struggle to deliver in vast rural areas. Controls are poor and services not efficiently rendered. Cold chain not maintained. "Couriers left vaccines with security guard of facility". Fridge at facility used to keep food for staff and not for medicines. Essential drugs out of stock causes repercussions on patients. the 9 Depots are incompatible with each other as they employ different software and data cannot be aggregated. there is a new national data management system on pilot in NC, LP,MP. this will bring in a single public management system, recording tenders, database of orders despatched to companies. IQIVIA has public sector data by pharmaceutical brand and work out generic vs patent drug utilisation with ATC codes.
Rational Use	Clinical audits at PHC facilities explain over expenditure. Example of intervention in District hospital is to use Flagyl oral instead of IV(more expensive). Provincial PTC conducts a review of EML and monitors drug utilisation, clinical governance, Antimicrobial resistance(AMR) and imposes restriction on prescriber levels . CHCs have clinical governance meetings. Family physicians forum discusses rational Drug use. Metro clinic governance forum also discusses drug use and expenditure. clinician networks discuss appropriate use of medicines and AMR protocols. clinical governance in pharmacy practice is not punitive- intended to build capacity as a learning organization. The WC province conducts a Medicines Utilisation Evaluation on a quarterly basis where reports on ATC classification, Provincial Top 20 by volume and expenditure and other clinical governance issues are raised.
Capacity of MSD	Serious challenges with availability of essential medicines; Umtata depot not accredited by Pharmacy Council. Courier services struggle to deliver in vast rural areas. Controls are poor and services not efficiently rendered. Cold chain not maintained. "Couriers left vaccines with security guard of facility". Fridge at facility used to keep food for staff and not for medicines. Essential drugs out of stock causes repercussions on patients. the 9 Depots are incompatible with each other as they employ different software and data cannot be aggregated. there is a new national data management system on pilot in NC, LP,MP. this will bring in a single public management system, recording tenders, database of orders despatched to companies. IQIVIA has public sector data by pharmaceutical brand and work out generic vs patent drug utilisation with ATC codes.
Human resources	No District pharmacist is on staff establishment which makes permanent appointment challenging . High volume centres have Pharmacy assistants . Some facilities depend on NGOs/partners to provide access to pharmacists or Pharmacy Assistants. no community based collection points for CCMDD as no Pharmacy Assistants. Not enough nurses trained on Drug supply management . CHW are not registered with Pharmacy council and cannot dispense medicines . DOH staff manage CDU distribution points in the community.
Data and Reporting	No software(Delta 9 or Rx solution) reliably implemented to report on utilisation. These IT systems available at tertiary hospitals. Lost to Follow up patients(increased) was compared to drug costs(increased). Medicines utilisation evaluation report is a formal system generated account of drugs by expenditure and volume on a quarterly basis. ATC classification report and expenditure reports are generated on quarterly basis. and presented at M&E committee, CFO,PTC and finally the HOD.
Expenditure	District health Expenditure review meetings are held monthly in with the DMT. Procurement process for institutions is well described . Institutional and District draw up cost containment plans . After internal interrogation and approval against budget, order is captured on LOGIS . Over expenditure arises from duplicative orders.
Budget	Medicines and medical supplies are paid out of the Provincial Equitable share which is ring fenced for "non negotiables" in the operational budget. District budgets are allocated from Provincial Head Office and District managers have little or no participation in forecasting. Central, Regional, Academic and Specialised hospitals have their own budgets and order medicines directly from the Depot. PHC facilities are managed by the District. Medicine expenditure is paid from MSD to Suppliers. Medical equipment that is not capital expenditure can be bought under 'Goods and Services' . If the medical device or equipment is less than R5000 no procurement process is needed; if above R5000 the item must be procured through National or provincial tenders. "National threshold for procurement not realistic".

Table 22: Summary of Private Sector themes

Finance	Provinces work on a virtual budget and delayed payments are expected. For consumables, it is a 'free for all'. A three quote or "Requests for Quote" basis is used in the absence of tenders. 'Squeaky wheel gets the most grease'. Public sector tenders are problematic and not transparent .Few suppliers are invited to bid. Suppliers listed on the National Database are more likely to win tender bids. Market forces prevail based on the price point. Equipment is negotiated at cost. State tenders were introduce in 1985. Some equipment have variable demands. Consignment trays used in theatre are produced on demand and processing of payment occurs after use. Hidden costs of these (call out, transport, standby, human resource) is not included. Private sector financing of medical devices is complex. Medical products have a NAPPI code. MCOs determine funding criteria of the device and advise the medical scheme. At the retail pharmacies a 4 tier dispensing fee exists. In the State, change from fiscal federalism in 1996 to Provincial equitable share in relation to population movement e.g. how does that impact GP/WC where in-migration occurs? Medicines do not have ring fenced budget therefore not easy to analyse expenditure as there are no BAS (Basic accounting system) mechanisms to track itemised expenditure. Medicines form roughly 10% of total health expenses from aggregated provincial expenditure. Conditional grants are used for ARVs/vaccines but the money can be spent elsewhere. As a country South Africa spends R350bn on healthcare but the consumption volume and expenditure between public and private is skewed. New trends ageing population and multimorbidity and NCD implies that expenditure is increasing. Newer biological drugs are expensive.
Policy	Medical devices have no regulated pricing model, suppliers set the price. Medical aid (MCOs) expect new technologies to enter at old prices and price within the category. If supplier demands a premium, he must demonstrate incremental cost vs incremental effect. Data is needed for cost effectiveness studies. Cost data is a perennial challenge in South Africa. Cost information is not in the public domain. MRSA amendment was postponed due to PMA court action and was promulgated in 2003, pricing regulations came in a year later. Policy changes since 2004 are ban on bonuses and incentives, single exit price annual maximum increment, cessation of samples and discounts. No clarity yet on international benchmarking and external reference pricing- imply higher prices .Uncertainty exists around the capacity for Pharmacoeconomics in South Africa.
Access to medical products /Pharmacy practice	Outdated funding protocols affect ATM. New technologies which do not have any existing comparators need information and evidence of efficacy. Insufficient cost and clinical data to make a case for funding results in restricted ATM. Process of review of devices has long lead times while most HTA takes 3months to 2 years. Defined by geographical accessibility, economic ability, acceptability and availability. Barriers to Access is OOP from medical scheme members. New biological drugs are restricted in private sector through MCOs and not available in public sector. PHC clinics should have 100% availability. Gains have been made but logistical problems persist. Where drug availability is consistent, treatment outcomes can improve. In private excreta payments on a case by case basis allows ATM. Some newer concepts would be introduction of collaborative practice options for pharmacists, similar to international efforts where task shifting has been successful. These pharmacy dependent prescriber arrangements could be useful in clinical settings such as INR based warfarin adjustment; IV antibiotics to oral switching. This will promote rational use. The Pharmacy council should have the scope of these services listed. Private pharmacies are incentivised by MCOs to be preferred providers and account for utilisation and cost. Patients struggling with poor ATM access in public sector, buy chronic meds OOP in private. The opportunity costs of waiting at a clinic with poor availability of meds is too high.
SAPHRA capacity/Regulation	Concerns abound over capacity of new regulator to manage the accreditation, licensing, quality, pricing functions. SAPHRA will be more diverse. MCC had limited capacity. Long lead times for registration process (5-10years) outlasting the product life cycle. There is no clarity around who will be involved in research, review and assessment process. Will they build internal capacity or rely on external support? What will this cost? Does the staff have the capacity to adjudicate decisions? A committee (Regulatory Oversight Committee) will be established to support staff decisions. Decisions pertaining to medical devices will rely on benchmarking in other parts of the world. Regulation of medical devices in SA in lacking or implementation is poor. Establishment licences from August 2017 have huge implications for companies. Technology and devices with an electrical supply and active interaction and contact with the body fall under Hazardous Substances Act and controlled by Department of Radiation Controls. A licence is required to sell equipment thus medical device companies must identify their scope of operation and register accordingly.
Rational Drug use	MCOs provide clinical governance but private hospitals do focus on tertiary level of care. A single line of treatment can cost R33mil. Cancer chemotherapy agents are expensive. Products are registered on thin data and use is extended to unregistered indications. "Private sector is no worse than public". MCOs have helped to curb cost and drive clinical governance. Some issues in both sectors are AMR, MDR organisms, overuse of newer analogues of Insulin. In private antidepressants and antipsychotic use is wide and usually not covered by chronic therefore expensive. These impact quality of care to patients. Chronic authorisation for medication tries to ensure patients have ATM. Some CDL algorithms are out of date. Despite MCOs efforts to drive rational use and increase cost effectiveness of treatment options, there is no data going back to providers. GPs and pharmacists increased generic utilisation.
NHI	What are the priorities of NHI? How will it affect the PMB legislation? PMB is currently under review. Benefit review and benefit definition process has begun. Concerns are who will conduct the assessment? What quality of information will be available? "How will we upskill local people". Zero rate all EML from VAT. Australian HTA system raises the question of future of State tender system. Not clear on mechanisms of active contracting and sophisticated capitation scheme. Concern over capacity in the District to contract. NHI commission will contract on a national basis. OHSC critical to ensure that only accredited pharmacies. State contracts are 'subsidized' through private sector prices.

3.4 Health Systems approach to Access to medical products in South Africa

The health systems approach involves an integrated understanding of the interaction of the building blocks in realising the goal of access to medicines. Figure 21 is based on a focussed literature review of supply chain, logistics, procurement and regulatory frameworks (76, 66, 117, 9) for medical products, combined with qualitative data from interviews.

3.4.1 Medicines, Vaccines and Technology Product flow

Medical product suppliers use national wholesalers, local manufacturers and distributions networks, which are regulated by SAHPRA. Medical products are procured in the public sector predominantly on national or provincial tenders but also on a quotation basis. Medical Supplies Depot (MSD) procure, supply and deliver medical products to health facilities however, there are serious efficiency concerns resulting in direct engagement with wholesalers and distributors. Product flows in the private sector occurs directly to providers (wholesalers) and provider organisations (retailers) however, medical schemes acting through MCOs exert considerable influence on reimbursement thereby impacting ATM. Individuals access medical products through direct OOP payments at private retail pharmacies.

3.4.2 Health Financing

In the public sector, health services are funded by National Treasury allocations to NDOH and transferred to provinces using the Provincial Equitable Share (PES) formula and conditional grants. Large donations in the public sector, such as the South African 2000 Diflucan partnership, is a vehicle for funding of medical products in developing countries. Provinces allocate budgets to District health services which are responsible for PHC. (130) while larger institutions like, central, regional, specialised hospitals have their own operational budgets. In the private sector, medical schemes reimburse services provided to members by providers (dispensing clinicians) or retail pharmacies in accordance with benefit design and managed care protocols. OOP in SA occur when consumers self-fund their health expenditure or when scheme members incur co-payments, deductibles and balance billing.

3.4.3 Health information and Service Delivery

Data is generated from service delivery interfaces at clinics, hospitals (district or provincial) in the public sector. Although the process of digitization is underway, paper based routine monthly data is captured and validated as it ascends from clinic level through the DHIS to District, Provincial and National DOH. At the point of service in the private sector, claims, reimbursement and logistical data is generated, for MCOs through switching companies.

The medical schemes industry regulator (CMS) reports consolidated industry results based on statutory data reporting by medical schemes.

3.4.4. Human Resources for Health

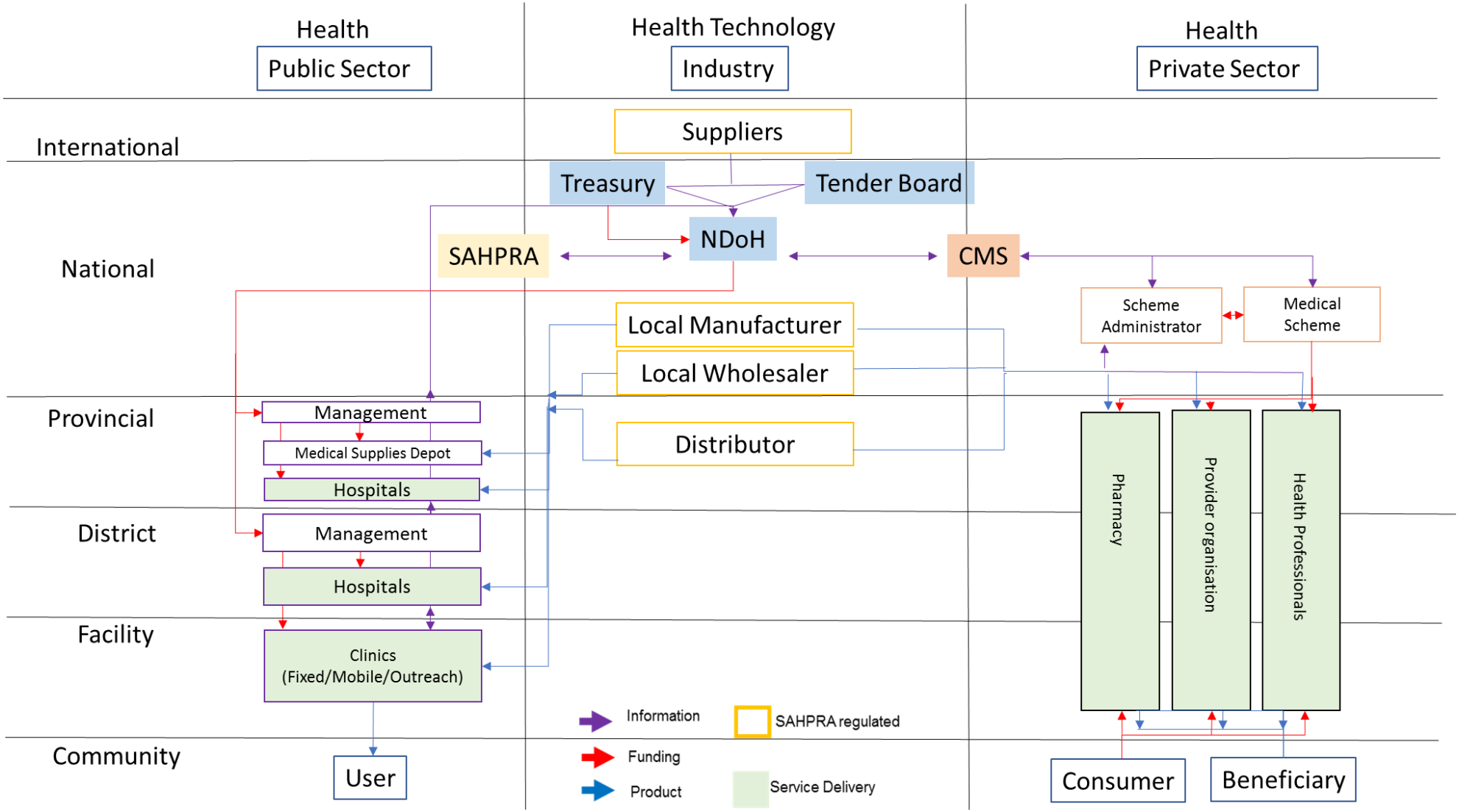
The International Pharmacy Federation (FIP)(131) showed in the Global Workforce Report in 2012 that an HR focus in Supply chain management (SCM) is needed to address the link between a lack of pharmacy personnel and inequalities in access to medicines. Strong supply chains are essential for positive health outcomes and require a competent, recognized and supported supply chain workforce with significant technical and managerial capacity. This requires systematic approaches to plan, finance, develop, support, and retain the national workforce. In the SA context, the nurse driven PHC services in the public sector requires that nurses, in addition to their primary clinical roles, dispense medication and maintain responsibility for stock flow management. A cadre of 'Pharmacy assistants' were created to address the shortage of registered pharmacists in the country(132). In 2014, there were 13 364 registered pharmacists in SA and 4516 employed in the private sector(132). In the private sector, there are fewer dispensing doctors, both GP and specialists. With the advent of oral oncology drugs and IV treatments, medical oncologists have become, in effect, dispensing doctors as they claim service fees(58).

3.4.5 Governance and Leadership

NDoH provides stewardship in the health system however the executing authority in the SA public health system lies with the Provincial health department. NDoH provides leadership, policy development and regulatory oversight across the health sector through various agencies established in law. SAHPRA is the regulatory body, established in terms of the MRSA (1965) and Amendments (2008 and 2015) , as a public entity outside the NDoH responsible for the accreditation, licensing, quality, pricing, research practice, evaluation of medical products and medical devices. The CMS is the statutory regulator of the medical schemes industry providing oversight to not-for-profit medical schemes and their contracted MCOs. Medical schemes play the role of Funders of private healthcare for the insured while the role of MCOs is governance and clinical risk mitigation. HPCSA, Nursing and Pharmacy Councils regulate health professionals' and pharmacists' practice.

Figure 21 below demonstrates the interaction of the health system building blocks in the South African context in relation to ATM.

Figure 21: Health systems diagram for ATM in South Africa



Source: Author

3.5 Assessing Access to medical products in South Africa

3.5.1 Assessing supply-side determinants of ATM

A dashboard of DHIS service indicators was compiled to assess supply side determinants of ATM. These indicators served as proxy measures of accessibility, availability, acceptability and affordability. Based on the DHIS data source, these results are more relevant to ATM in the public sector.

The PHC utilisation rate shows that the average public sector client visits the PHC facility more than once per year. From 2000 to 2015, the national PHC utilisation rate increased from 1.9 to 2.3 visits per year, which infers improved accessibility of services (153).

Availability of medical products at PHC level was assessed by the indicator 'Tracer item stock out rate' as seen in Table 23. The indicator is defined as the proportion of all fixed clinics, Community Health Centre (CHC) or Community Day Clinics (CDC) with a stock out of any tracer drug. Stock out rates increased between 2011 (10.5%) to 2014 (23.6%) and decreased in 2015 (22.6%). The second indicator refers specifically to HIV/AIDS and TB drugs, in recognition of the importance of treatment adherence, patient compliance and drug availability impacting patient health outcomes. The three consecutive years show an unacceptably high percentage of stock outs in these essential drugs.

"Acceptability "was assessed using the GHS indicator, "Percentage of users of public health services very satisfied with the service they receive". This measure of Acceptability was used in both demand and supply side assessments. The GHS data showed that average satisfaction experienced in the private sector was higher than in the public sector. Table 23 shows that from 2009 to 2015, the proportion of users satisfied with public health facilities has increased from 54.5% to 57.6%.

Table 23 shows the access dimension "Affordability", represented by "PHC expenditure and real values per headcount". This value includes services and medical products at PHC level. . Increasing expenditure per headcount is an indication of supply-side investment from R317 to R389 towards PHC and ATM at an average 5.7% change from 2013 to 2017.

Table 23 : Supply side dimensions of Access

Accessibility

Access Dimension	Measure	2000	2005	2010	2015
Accessibility - Health infrastructure Service location	PHC utilisation rate	1.9	2.2	2.4	2.3

Source : SAHR 2017

Availability

Access Dimension	Measure	2011	2012	2013	2014	2015
Availability -System resource inputs Drugs/equipment / healthcare workers	Tracer item stock- out rate (fixed clinic)	10.5	16.4	18.2	23.6	22.6
	Any ARV and /or TB drug stock out rate	.	.	21.5	25	25

Source : SAHR 2017

Acceptability

Access Dimension	Measure	2009	2010*	2012	2015
Acceptability -Responsiveness to user Characteristics of health service	% Users of public health services very satisfied with services received	54.5	55.9	57.3	57.6

*Source : SAHR 2017, *GHS 2010*

Affordability

Access Dimension	Measure	2013	2014	2015	2016	2017
Affordability- Sustainable financing Costs and price of services	PHC expenditure per headcount %change (ZAR)	7.1(317)	2(323)	6.6(344)	6.7(367)	6.1(389)

Source : DHB 2017

Source: DHB 2017, GHS 2010, SAHR 2017

3.5.2 Assessing demand-side determinants of ATM

In order to assess demand–side determinants of ATM, the nationally representative GHS 2011-2016 data was used and the average sample size over this period was 24 064.

“Acceptability” was assessed using patient satisfaction as shown in Table 24 About 80% of South Africans surveyed in the GHS from 2011 to 2016 were satisfied with the service they received at the last visit to a health facility, public or private. There was minimal variation around the mean for this measure.

“Accessibility” was measured by ‘travel time to health facility’. More than 80% of South Africans live less than 30 minutes from a health facility and this proportion has been increasing over the past 5 years. The commonest modes of transport to health facilities were by foot (49%), taxi (26%) and own transport (20%).

In the surveys, respondents were asked if they would use the health facility nearest to their dwelling. Approximately 90% of respondents chose a health facility in closest proximity to their residence. Of the 10% who do not use the nearest health facility, less than 1% (0.11%) cited affordability (too expensive) as the reason. When asked the reasons for not visiting a health facility for recent illness, only 0.08% replied that seeking health services were too expensive (unaffordable). These responses indicate that few people are constrained by affordability in seeking healthcare services.

Two measures of "Availability" were used in this assessment. The interview question asked why respondents would not use their nearest health facility. A small proportion of respondents (1.25%) claimed that long waiting times was a deterrent to access and even fewer (0.69%) reported that important drugs were not available.

Table 24 : Demand Side determinants of Access

Dimension of Access(Demand Side)	2011	2012	2013	2014	2015	2016	Mean(SD)
	%	%	%	%	%	%	
Acceptability							
Service satisfaction during the visit							
Satisfied	80.49	78.71	81.72	81.46	80.01	79.49	80.3(1.1)
Dissatisfied	6.82	8.82	7.06	7.29	7.67	7.38	7.5(0.7)
Accessibility							
Travel time to health facility							
<30 minutes	79.1	78.73	81.09	80.6	81.16	82.66	80.5(1.4)
>30 minutes	20.03	20.05	17.9	18.01	17.86	16.7	18.4(1.3)
Means of transport							
Walking	50.47	49.42	49.13	49.42	48.34	49.65	49.13(0.6)
Taxi/Sedan taxi/Bakkie taxi	27.02	25.57	25.63	25.04	27.58	27.07	26.3(1.0)
Bus	1.13	1.09	1.16	1.19	1.06	1.01	1.16(0.0)
Train	0.15	0.26	0.1	0.2	0.19	0.19	0.1(0.0)
Own transport	18.77	20.8	21.2	20.95	20.2	19.72	20.2(0.9)
Bicycle/motorcycle	0.12	0.17	0.16	0.18	0.24	0.19	0.17(0.0)
Other	1.53	1.76	1.7	2.15	1.52	1.54	1.7(0.2)
Unspecified	0.82	0.94	0.92	0.87	0.86	0.64	0.92(0.1)
Affordability							
Too expensive (Not nearest Facility)	0.2	0.13	0.13	0.08	0.05	0.11	0.11(0.0)
Too expensive (Not Consulting)	0.11	0.09	0.07	0.08	0.08	0.07	0.08(0.0)
Availability							
Long waiting time	1.44	1.35	1.16	1.03	1.15	1.42	1.25(0.1)
Drugs that were needed, not available	1.08	0.79	0.65	0.58	0.53	0.53	0.69(0.2)

Source: Pooled version of GHS 2010-2016

CHAPTER 4: DISCUSSION

4.1 Health Policy assessment for Access to Medical Products

The HSAA framework applied in this study describes the policy landscape for medical products and assess the extent of reforms needed to enable ATM. This study found that South African policies hold the necessary actions and intent to achieve universal and equitable access to medical products when benchmarked against internationally accepted models. Three distinct policy thrusts emerged in this study - medical products regulation, pharmacy practice and health systems strengthening (HSS) which help to understand the complex interaction of the health system to produce ATM. This categorisation has utility in mapping existing policy and holds appeal to policy makers by highlighting gaps in content areas. Key informants interviewed in this study were well versed in policy and therefore able to participate in advocacy, research and consultancy at senior levels in industry, public and private health sectors and academia.

Key informants acknowledged substantial reforms in products regulation and pharmacy practice, arising out of the NDP in 1996 but stressed the failure of implementation of these well intentioned policies. The literature review, HSAA assessment and qualitative data suggest that HSS efforts have been applied through disparate policies in finance, information management, human resource and service delivery building blocks, and implemented in vertical programs, when what is proven effective, is an integrated policy response to create synergy around ATM (114). Key informants identified barriers to ATM and referred to inter-sectoral collaboration(133) between public and private sectors and government departments and agencies such as National Treasury, Social Development, Roads and Infrastructure, Human Settlements, Trade and Industry, among others, to address the SDH.

In this environment, the pace of innovation in practice and products, not only dictates policy but quickly renders it obsolete. The literature review and qualitative interviews in this study, highlighted two major perspectives - ‘strategic and operational levels ‘in public and private sectors. Over the two decades of NDP implementation, the literature highlights successful policy outcomes in medicines pricing and selection, procurement and distribution, rational use, harmonisation, financial and human resource deployment, governance and scholarship around medical products. The full extent of gains from key ATM policies is yet to be achieved (134)(87), reinforcing the qualitative theme that many SA governance frameworks and models, although progressive, lack implementation and operational success.

A number of policy gaps have been identified in this study, such as: medical device price regulation; capacity for HTA and pharmacoeconomic evaluations; registration process of medical products; uptake of STG/EML across public and private sectors; adverse events

reporting of IVDs; rational use of medicines and IVDs in the context of universal coverage under NHI, intersectoral collaboration and anticipated regulations arising out of the Medicines Act Amendments 2008 and 2015.

4.2 Health financing for Access to medical products

4.2.1. Public sector expenditure on medical products

A pivotal contribution of the NDP and other strategic health sector reforms since 1996, was to catalyse the commitment towards sustainable public financing of medical products. The paradox of increasing government spending on health and shrinking private sector spending in SA over the last decade, as presented in this study, is reassuring that equity and allocative efficiency principles are at work. Econex (118) suggests that the DOH lacks efficiency in public expenditure and administration and effectiveness in health outcomes. Bidzha et al (132,7) show that public investment is not sufficient, to improve health outcomes in SA, accounting for SDH and burden of disease while Bletcher et al claim(136) that the prioritisation of medicine spending has been one of the DOH's greatest successes. As demonstrated in this study, there has been increased annual spending on medicines (6.7% above inflation) from 2005 to 2012, mostly due to the ARV rollout.

Overall, provinces spent about 6% of the operational budget on medical products. In 2016, the total expenditure on medical supplies in the public sector was estimated at R7.2bn (actual R6.7bn based on missing data for MP). . Data quality was a serious concern as missing entries for "medical supplies" line items were frequently encountered. The study showed that high disease burden provinces (e.g. KZN, GP and EC) (134, 135) consistently lead medical products expenditure at provincial level in the public sector, leaving NC, LP and NW/FS at the bottom. Beyond the geospatial, socioeconomic and disease burden challenges of these provinces, the absorptive capacity to optimise fiscal resources in the production of health (outcomes and access) is of concern (137).

At district level, PHC budgets have grown by 4.1% (real per annum) from 2014 to 2016 driven by HIV in particular and chronic disease spending however PHC headcounts have slowed possibly due to the CCMDD but this effect is not quantifiable in the DHIS. In addition to HIV conditional grants, NHI pilot districts received direct NHI conditional grants which were not factored into the Provincial budgets. Therefore actual PHC expenditure may be higher than reported in the DHIS, as there are NHI pilots in each province (60). Real PHC expenditure per headcount has grown annually between 2005 and 2016 by 6.5%. investment in district health services (DHS) have increased from 35.1% in 1996 to 46.1% of total provincial expenditure in 2016 following the shift of the ARV rollout from hospitals to

PHC. Consequently, contraction in provincial hospitals and stabilisation of central hospitals' expenditure has been recorded(60), marking the shift towards primary health care.

In this study private sector expenditure on medical products was shown to outweigh that in the public sector by multiples. Real expenditure on medical products in the public sector is lower (about 8% of operational budgets) relative to the private sector through medical schemes (15.3%) and when compared to OECD countries (20%)(60). Despite the paucity of data describing disaggregated expenditure in the public sector , Annual Reports of provincial DOHs indicate that overall, medicines and medical supplies consume approximately 11% of total budgets (12) at provincial expenditure level. To further illustrate the point that public and private expenditure on medical products is grossly uneven, the provincial and local government expenditure per capita in 2016 was R1054 (60) including service fees and medical products (138) compared to R2617 (average cost per beneficiary) in the same year on medicines alone in the Mediscor sample(58).

4.2.2 Private sector expenditure on medical products

Overall in the private sector, the study demonstrated that industry expenditure on medical products is exorbitant at R24bn on medicines only in 2016 covering a population of 8.8 million members(13) out of the SA population estimated in 2016 at 55 million(139).

Most medicines were dispensed by pharmacists (89%) and only 5% by GPs, which is easily understood when viewed in context with Mediscor's sample data(58) showing the dis-incentivising average differences between claimed (dispensing fee) and approved (scheme rate reimbursement) amounts which are lowest for pharmacies (1.8%) and highest for GPs(3.3%). These results bring the debate on what constitutes the professional remit of GPs and Pharmacists pertaining to point of care screening, diagnosing, prescribing, treating and dispensing, sharply into focus. The qualitative data finds that discussions are already underway to expand the scope of Pharmacist services to include collaborative practice, task shifting and pharmacy–dependent prescriber arrangements.

The study results show that 99% more is spent on medical products in private hospitals as compared to provincial hospitals, for medical scheme members on low cost options but this skewness is due to the huge difference in denominators. In 2016, there were only 549 787 beneficiaries on low cost options of medical schemes of the total South African scheme population of approximately 8.8million (13). The advent of Efficiency Discount Options (EDO), (47 in total in 2016), is based on discounted contributions and network provider limitations (i.e. use of designated service providers (DSPs)). Since gross contribution increases in medical schemes are based on numbers of actual principal members plus adult and child dependents, there is an opportunity to increase membership through affordable member contributions in EDOs. The health system effect of this is improved access to

private healthcare and at a lowered medicines cost by increasing utilisation of provincial hospitals(13).

Medical products expenditure analysed by source of funds, showed that medicine expenditure from schemes' risk funds doubled over 8 years while increases from members' savings more than doubled (2.5 times) in the same period. There are no known mechanisms to ring-fence members' savings accounts for acute medicines only despite legislation (Section 10(6) of Medical Schemes Act) prohibiting their use for PMB medicines. Increasing dependence on MSAs as a source of medicines funding without checks and balances is problematic as acute, non PMB chronic and OTC medicines attract the highest co-payment differentials(58). In 2015, the CMS implemented a formal process to actively identify the sources of OOP for scheme members. Reports show current estimates of medical scheme members' contributions to total cost of healthcare are around 18.7%, while the scheme covers 81.3%, calling into question the ethics of cost sharing. A quarter of all OOP expenses in medical scheme members were for medicines(104).

The average cost per beneficiary on medicines shows a steady increase year on year. The average cost of medicines alone in the private sector in 2016 was R150 per item, compared to the total average annual cost of OOP medical products expenditure by households in 2014 (R387) . This unequal spending is indicative of broader societal influences affecting income and expenditure disparities in SA(140). In addition to the spiralling cost of existing drugs, the Mediscor data flagged price escalations of NCEs in three years from 2014 to 2017, the average cost of these drugs has almost doubled from R555 to R906.

4.2.3 Household level expenditure on medical products

The LCS 2014 estimated that overall annual household consumption expenditure in SA was R1.72 trillion. In 2014/15 the average South African household spent R103 293 and proportionally on housing (32.6%), transport (16.3%), miscellaneous goods and services (14.7%) and food (12.9%). Health as a main expenditure group, contributed 0.9 %(R935) of total expenditure(126).

However, health expenditure in these surveys reflects only health services and medical products as OOP expenditure by households and does not account for medical aid or medical insurance premiums and contributions paid by the household for healthcare. Insurance premiums paid by households are captured within the "Miscellaneous goods and services" expenditure group. This explains why the average South Africa household expenditure appears to be low, averaging 1.34% from 1995 to 2014(126). Based on average household annual income , expenditure on ambulatory healthcare (services and medical

products) in SA, is far below the catastrophic health expenditure threshold of 10-15% of a household's income(140, 141,104).

In this study, we showed that over the survey periods 2005, 2010, 2008 and 2014, a larger proportion of total health spending is on medical products (0.7%) than outpatient medical services (0.6%) in average SA households. Within the aggregated medical products category, pharmaceutical expenditure dominates (90%) compared to therapeutic appliances and other medical products combined, constituting 10%. Overall, the unadjusted means for household OOP on medical products was greater in those who were medical scheme members than the uninsured households across province, population group, settlement type, and income source. Critically, the regression model showed that households without medical aid, spent less OOP on medical products than those with medical cover. The province, household size and income sources were not significant factors in estimating expenditure for members of medical schemes. For non-members of medical schemes, province (NC and LP), and Indian/Asian and White population groups were the only statistically significant variables in estimating expenditure in the model.

In the 2005 to 2014 surveys, the study showed that female headed households spend, on average, proportionally more on medical products than male headed households. However, in real (monetary) terms this is reversed; male headed households spend more actual Rands on medical products than female headed households. In 2010, The average household income for male-headed households was R151 186, while for female-headed households this average was far lower at R70 830(142).

The addition of the IES 2000 analysis was useful in setting the historical context of household medical expenditure. Rural households spent less, both in real terms and proportionally on medical products than urban households. As compared to outpatient services, medical products accounted for a larger proportion of the household expenditure on health in rural and urban households. The multivariate regression model showed a statistically significant effect on rural insured household expenditure; A R31 decrease in expenditure for rural insured households was seen for every increase in expenditure by urban insured households. However, for non-members of medical schemes, settlement type was not a predictor of household expenditure. The differences in the annual expenditure on medical products unadjusted means for urban insured and uninsured households was R559.9 in 2000. Vast differences between urban and rural insured households were also noted.

FS, NW, EC and NC provinces had the highest OOP expenditures on medical products. Households in LP had the lowest OOP expenditure on medical products in the survey period. This result is rooted in the effect of SDH and social deprivation within these provinces. The

EC province has the highest rate of maternal (52%) and employment deprivation (47.3); NC has the highest education deprivation (30%) and LP has the highest rate of living environment deprivation (71.9%) in SA. FS, although not the highest, has higher than national rates for education deprivation (23.4%). The regression analysis confirmed that province had no significant effect on OOP spending on medical products for members of medical schemes, holding all other variables constant. However, two provinces (NC and LP) were significantly associated with OOP expenditure for non-insured households. No reasons for the conflicting levels of OOP expenditure in socially deprived provinces of SA were advanced in this study, however, this is an important area of future research arising out of this work. Unadjusted means for the survey data in 2000 showed gross disparities in OOP expenditure with richer provinces like WC and GP spending more (R175.8 and 178.9 respectively) compared to LP and NW (R27.3 and R47.4resp).

Households across the expenditure deciles spent more on outpatient services than on medical products. This was most apparent in the highest two expenditure deciles, where the expenditure on ambulatory care increases dramatically. A similar result was obtained when analysing income deciles – the differences in expenditure between the lower and higher income deciles were inflated at the higher end of the income spectrum. Despite changes to the health system through investment and reform and the effects of inflation and market forces, households from the highest expenditure decile spent 36 times more annually on medical products than the lowest decile in 2014.

In 2014, Black/African headed households spent proportionally higher OOP (43%) than White headed households(35%) on medicines(126). In 2014 the GHS recorded lowest medical scheme coverage in Black/African (10.6%) households as compared to White households(76.9%) alluding to the protective effect of medical scheme membership on increases in medicine prices. However, medical scheme membership may not be an option for the majority (87,6% of the SA population) of Black/Africans who, in 2014, earned less than R71 479per annum (lower limit of upper income quintile) and almost half (48%) of whom were in quintile 1 and 2(126). The regression model predicted statistically significant increases in OOP spending by Indian/Asian and White population groups as compared to Black/African population group in 2000. Also in 2000, White households who were insured spent 30 times more OOP than insured Black/African households on medical products.

4.3 Health Systems Strengthening for Access to Medical Products

This study shows that most South African households have access to healthcare services and live sufficiently close to health facilities so that they are able to access the facilities by foot. PHC utilisation rate is increasing in SA and is used here as a proxy measure for accessibility(143) although its multidimensional complexity includes other factors such as

family education level, financial status, perception of health and cultural beliefs(140, 56). In the private sector, access to healthcare is facilitated by financial risk protection mainly through insurance and medical aid. In 2016, medical scheme members visited GPs an average of 3.6 times per year (2016) (13); below WHO recommendation of 5 visits per year and above the current public sector PHC utilization rate of 2.3 times in 2016. For every 1000 members, a GP was consulted 731 times(13). Inpatient utilisation in private is 180 per 1000 scheme members in 2016, exceeding WHO recommendations of 10-15 hospital discharges per 100 population (11,139).

The results show that availability of medicines is a persistent challenge to effective PHC and ATM in SA. The literature and qualitative interviews confirm that there are serious disruptions to the medical products supply chain which impact quality of care and ATM. Three provinces with the highest number and longest duration of stock-outs in the SSOP study in 2015 were MP, FS and GP, which incurred the highest expenditure on medicines (10.6%, 7.5% and 8.1% respectively) in 2013 as reported in this study, beyond the median expenditure for all other provinces (6.9%) underscoring serious deficiencies in provincial supply chain management.

Affordability of medical products is achieved through supply-side mechanisms ensuring sustainable financing and investment in PHC expenditure. The relationship between expenditure, service delivery and performance, may not be directly correlated and is dependent on more than funding alone (137). This study shows that district health services and PHC expenditure per headcount is equitably financed to drive access to healthcare. HIV/AIDS is a driver of PHC expenditure. HIV/AIDS expenditure increased by 38% (8.4%) per annum in real terms over past 5 years, while non-HIV PHC expenditure has increased by 13% (3%) per annum(136). The CCMDD programme has decreased the PHC headcounts by decanting patients from PHC facilities and thus impacted PHC expenditure per headcount(60) while improving ATM.

The study results show that only half of the patients using the public sector, find the service acceptable. The reasons for this low acceptability must be addressed as it affects access to healthcare and ATM.

Overall, from this analysis of demand side determinants, there is stable progress towards ATM in SA from 2011 to 2016. The supply-side analysis shows that while there is achievement in accessibility through infrastructure and affordability through PHC investment, urgency is needed to address availability and acceptability of ATM in SA.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

Pharmaceutical regulatory framework in South Africa is vast and encompasses the key elements needed to implemented health systems changes for access to medicines. The reforms have been extensive and have had far reaching effects. Expenditure in both private and public sectors on medical products, is increasing but not comparable. Despite substantial progress in ATM there are supply-side issues needing urgent response such as drug availability and quality of care in the public sector and the rising cost of OOP payments.

The legacy of entrenched divisions in the population infiltrates all levels of the health system, affecting resource allocation and impacting supply and demand side determinants of access to care. Equity and ATM forms a positive reinforcing loop and to interrupt this cycle health system stakeholders must actively address the differences between urban and rural, high and low income quintiles, men and women, PHC and secondary hospitals and interprovincial (e.g. WC and LP) differences in ATM. In this study, supply side factors are shown to exacerbate inadequate access to medicines and qualitative data suggest that these are amenable to change through operational efficiencies.

Demand side determinants stem from deeply rooted inequalities in socioeconomic status, human settlement education and cultural practices; which require political will, resources and social mobilisation.

The strategic importance of South Africa for the pharmaceutical and medical devices sector, is a leverage point for South African policymakers to facilitate harmonizing efforts to build capacity in regional health systems. This study has broad implications for health systems in LMICs in SSA embarking on reforms to embrace changes that the global pharmaceutical and health technology supply chain impose.

The contribution of this study was the mixed methods design to capture the complexity of the health system and add new ways in HSPR to explore multifaceted issues, such as ATM, with pragmatic significance. This study therefore moves beyond analysis of ATM, to create a synthesis of information, uniting disparate sources of data.

Significantly, a major contribution of this study, is the extent to which new insights can be drawn from publicly available and routinely collected data. Indeed, all sources of secondary data used in this study are in the public domain. This study advances the synthesis of varying sources of data to reflect health system complexity and thus contributes to the methodological diversity of HPSR in SA.

5.2 Limitations

This study did not involve the use of analytical tools or techniques routinely used in economics sciences. Therefore calculations performed are not adjusted for headline or health inflation and do not account for exchange, real and nominal rates.

The multiple regression was used in this study to explore the relationship between household OOP expenditure on medical products and a number of demographic independent variables of interest. This regression analysis ignores the asymmetry of response distributions common with expenditure data and the large mass of observations with zero cost. Therefore further bio statistical analyses are recommended to study the effects of the factors on the model.

Public sector expenditure at PHC and hospital level allocated to service areas is not easily accessible and do not form part of statutory reporting requirements yet programmatic budgeting will facilitate economic analyses and costing studies. Disaggregated expenditure data for public sector is not available and where data is in the public domain, there are serious challenges with the quality, comparability and consistency.

Data in provincial Annual reports based on BAS is inconsistent and threatens reliability of inter-district or provincial comparison. This is often caused by misclassification of goods and services in the BAS system. An example of this is misclassification of expenditure line items, reported in the NC Annual Financial Statement Report disclosure notes (2012).

Cumulative effects of access to care and expenditure on healthcare comparisons were drawn from annual household surveys but do not capture the effects of intervening events such as illness, trauma on health and disability.

The contribution of industry suppliers and manufacturers to stocks-outs and therefore ATM was not explored in this study.

In-depth analysis from an economics perspective on private and public sector expenditure requires microdata and is an entirely separate pursuit, larger than the scope of this project.

5.3 Recommendations

These recommendations are based on quantitative and (mainly) qualitative data presented in this study.

- Policy makers in SA have a unique opportunity to institute reform in the scale up to UHC. Innovative pricing models, public private partnerships, sustainable financing and delivery of services and increased investment in health technology are some of the policy options to increase ATM.
- Supply side availability of medicines has not been realised despite pressure to perform in this area. Civil society has been actively engaged around the human rights' aspects or lack of access to medical products however, clinic committees (PHC level) and hospital Boards (hospital level) and Ward councillors are key resources yet to be mobilised effectively as a push factor for political accountability.
- Medical schemes and MCOs drive provider behaviour motivated by cost containment and profit maximisation, using mechanism such as preferred provider networks, payment incentives and performance rating. The CMS Circular 13 of 2014 (150), which defines and clarifies the scope of managed care services, in their role as facilitators of appropriate and cost-effective 'relevant' (150) healthcare services. Funders in SA therefore have the mandate to pursue more enterprising and sustainable goals such as access, equity and quality in the private sector which promotes ATM within a broader clinical governance agenda.
- Capacity building of healthcare managers within the district and provincial management echelons is needed to ensure equitable fiscal allocations, absorption of financial resources which translate into optimised service delivery, without which, ATM cannot be realised. This can be achieved through the enforcement of a legislative framework, such as those reforms currently proposed under the NHI Scheme, that provides for sustainable financing, access, quality and equity.
- As a prelude to the NHI, enhanced strategic information management capacity to monitor cost and utilisation of medicines and medical devices at health facilities and evaluate cost effectiveness of health technologies. As a first step, tracking this information through existing SCM platforms, will be necessary to manage the supply, use and control of medical products.

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Annexure A: SA Regulatory map Part 1

Table 25 : SA regulatory landscape Part 1

Other Government Departments		Health
Laws	Policies	Laws
Appropriations Act,	Advertising regulations	Academic Health Centres Act, 1993
Basic Conditions of Employment Act, 1997	Procurement policies	Allied Health Professions Act, 1982*
Broad Based Black Economic Empowerment Act, 2003	Supply chain management policies	Choice on Termination of Pregnancy Act, 1996*
Child Care Act, 1983	Trade-related aspects of Intellectual Property rights	Constitution of the Republic of South Africa Act, 1996
Compensation of Occupation Injuries and Diseases Act, 1993 Competitions Act, 1998	Treasury Regulations	Council for Medical Schemes Levy Act, 2000 Dental Technicians Act, 1979
Conventional Penalties Act, 1962 Copyright Act,1998 Design Act,1993 Division of Revenue Act, 2003		Foodstuff, Cosmetics and Disinfectants Act, 1972* Hazardous Substances Act, 1973 Health Professions Act , 1974*,2007 Human Tissue Act, 1983
Intergovernmental Fiscal relations Act, 1997		Medical Schemes Act, 1995
Labour Relations Act, 1996 Legal Metrology Act, 2014		Medicines and Related Substances Control Act, 1965, 1997,2008,2015 Mental Health Care Act, 2002
Measurement Units and Measurement Standards Act, 2006. Merchandise Marks Act, 1941		National Health Act, 2003 National Health Laboratory Services Act, 2000
Municipal Finance Management Act, 2003 Occupational Health and Safety Act,1993 Patents Act, 1978		Nursing Act, 2005 Occupational Disease in Mines and Works , 1973 Pharmacy Act, 1974 *,1997,2000,2015
Prevention and Combatting Corruption Act , 2004		South African Medical Research Council Act, 1991
Promotion of Access to Information Act, 2000		Sterilisation Act, 1998
Promotion of Administrative Justice Act, 2000		Tobacco Products Control Amendment Act, 2008
Promotion of Equality and the prevention of Unfair Discrimination Act, 2000 Protected Disclosures Act, 2000		
Protection of Personal Information Act, 2013 Public Finance Management Act, 1999 Public Service Act, 1994 Public Service Commission Act , 1997 Skills Development Act,1998 P State Information Technology Act,1998 State Liability Act, 1957 Trademark Act, 1993		

Source: Author

Annexure B: SA Regulatory map Part 2

Table 26 : SA Regulatory landscape Part 2

Health		
Pharmacy Policies	Policies -Governance and Leadership/ Finance /Human Resource building blocks	Regulations
National Drug Policy, 1996	RDP White paper, 1994	Access to and control of medical devices and IVDs
PHC Package Part 1 & 2, 2000	National health plan for South Africa , 1995	Adverse Drug Reactions
Good Pharmacy Practice	White paper on transformation of the public service , 1995	Advertising of medicines
National policy on Establishment and function of PTC,2015	Policy for the development of a district health systems for South Farica,1995	Appeal against the decision of the Director-General or Council
Good Manufacturing Practice	Restructuring of the national health system for universal primary healthcare, 1996	Application for amendment to a medicine register
Good Pharmacy Practice	White paper on transformation of the health system in South Africa, 1997	Application for registration of a medicine
Standard Treatment Guidelines and Essential Medicines List	White paper on transforming public service delivery(Batho Pele),1997	Batch release for biological medicines
Medical Device Quality Management, 2017	Patient rights Charter,1999	Categories and classification of medicines
Conflict of Interest Declaration, 2011	Health Strategic Framework 1999-2004	Compliance with Regulations
Regulations for Norms and Standards of Health establishments , 2015	Policy on Quality in healthcare for South Africa , 2007	Conduct of clinical trials for humans
Access and Control of Medical Devices and IVDS	District Health management Information System policy, 2011	Control of medicines in hospitals
Antimicrobial Resistance Strategic Framework 2014-2024	National Development plan ,2012	Destruction of medicines
HPCSA Code of Conduct for Health Professionals	National Strategic Plan 2012-2013	Expedited registration process for medicines for human use
Council for Medical Schemes Circular Generics/ICD10 Dictionary in PMB	National Strategic plan 2012-2020	Importation of medicines into the Republic
Council for Medical Schemes Circular 13 of 2014: Managed health care services	National HAST Strategic plan 2012-2016	Importation or exportation of specified Schedule 5, Schedules 6, 7 or 8 medicines or substances
Council for Medical Schemes Circular 13 of 2014: Managed health care services	Human Resources for Health 2012-2017	Information that must appear in the register for medicines
PHC Supervisors Manual, 2009	National Development Plan 2030	Information to be furnished annually to the Director- General by the holder of a permit to import or export Schedules 6 & 7 substances
Ideal clinic initiative , 2012	White Paper on National Health Insurance , 2017	Investigations
Good Wholesale practice	Office of Health Standards and Compliance (NHAA)2013	Labelling for Veterinary medicine
God Manufacturing practice		Labelling of medicines for human use
		Licence to compound and dispense medicines
		Licence to manufacture, act as a wholesaler or distributor of medicines
		Method of taking samples during investigations, the certificate to be issued and reporting of analysis results
		Obtaining of pethidine or preparations or admixtures thereof by registered midwives
		Offences and Penalties
		Package inserts for medicines for human use
		Package inserts for veterinary medicines
		Parallel importation of medicines
		Particulars to be published in the Gazette
		Particulars which must appear on a prescription or order for a medicine
		Patient Information Leaflet
		Period of validity of licence issued in terms of regulations 18 and 19
		Permits in terms of s 22A(9) of the Act
		Possession of small quantities of Scheduled substances for personal medicinal use by persons entering or departing, from the Republic
		Prescription Book
		Pricing Committee
		Register of specified Schedules 5, Schedule 5 and 6 medicines
		Registration certificate
		Repackaging of medicines into patient ready packs
		Requirements for therapeutic equivalence
		Returns to be furnished in respect of specified Schedule 5, Schedule 6, 7 and 8 substances
		Rules relating to the conduct of business of the Council
		Seizure of medicines
		Skills of members of the Council and its committees
		The conditions for and the quantity not to be exceeded by a pharmacist in compounding a medicine for sale in the retail trade
		The manner of and conditions for allowing international tendering
		Transmission of medicines through the Republic
		Transparent pricing systems for medicines and substances
		Use of medicines for the prevention of malaria
		Labelling , advertising and composition of cosmetics

Source: Author

Annexure C: Regression table -Private sector

Survey: Linear regression

Number of strata	= 18	Number of obs	= 26,182
Number of PSUs	= 2,956	Population size	= 11,211,426
		Design df	= 2,938
		F(24, 2915)	= 7.64
		Prob > F	= 0.0000
		R-squared	= 0.0799

ExpPMDmedAid	Coef.	Linearized Std. Err.	t	P>|t|	[95% Conf.	Interval]
Province						
2	27.82198	53.92	0.52	0.606	-77.90283	133.5468
3	-31.27632	49.72678	-0.63	0.529	-128.7792	66.22656
4	39.52001	59.534	0.66	0.507	-77.21259	156.2526
5	38.25435	56.97755	0.67	0.502	-73.46562	149.9743
6	25.09465	54.24342	0.46	0.644	-81.26431	131.4536
7	53.26664	63.69186	0.84	0.403	-71.61856	178.1518
8	35.0215	56.46577	0.62	0.535	-75.69498	145.738
9	39.96739	54.54595	0.73	0.464	-66.98477	146.9195
Nopersons	.6410192	2.265994	0.28	0.777	-3.802077	5.084116
popgroup						
2	40.39519	36.32919	1.11	0.266	-30.83805	111.6284
3	109.6173	38.64084	2.84	0.005	33.85144	185.3832
4	590.1593	56.55481	10.44	0.000	479.2682	701.0504
5	210.4265	116.145	1.81	0.070	-17.30737	438.1604
9	22.04719	35.41837	0.62	0.534	-47.40015	91.49453
2.p0101q01	-31.07094	9.850024	-3.15	0.002	-50.38458	-11.75729
incomesource						
2	-25.91142	61.71927	-0.42	0.675	-146.9288	95.10598
3	-177.4587	100.1149	-1.77	0.076	-373.7612	18.84383
4	-322.067	149.7716	-2.15	0.032	-615.735	-28.39913
5	-135.72	193.5763	-0.70	0.483	-515.2789	243.8389
6	-151.9387	61.25039	-2.48	0.013	-272.0367	-31.84069
7	2.611855	51.93863	0.05	0.960	-99.22794	104.4516
8	18.94055	69.24821	0.27	0.784	-116.8394	154.7205
9	-34.44379	36.82553	-0.94	0.350	-106.6502	37.76266
99	8.670502	28.05176	0.31	0.757	-46.3326	63.6736
_cons	-10.05263	51.59853	-0.19	0.846	-111.2256	91.12032

Annexure D: Regression table -Public sector

Survey: Linear regression

Number of strata	= 18	Number of obs	= 26,182
Number of PSUs	= 2,956	Population size	= 11,211,426
		Design df	= 2,938
		F(24, 2915)	= 8.81
		Prob > F	= 0.0000
		R-squared	= 0.0685

ExpPMDnome-d	Coef.	Linearized Std. Err.	t	P>|t|	[95% Conf.	Interval]
Province						
2	-33.96471	18.07898	-1.88	0.060	-69.41346	1.484034
3	-49.8203	17.43305	-2.86	0.004	-84.00253	-15.63807
4	-18.8309	24.36308	-0.77	0.440	-66.60133	28.93953
5	-20.02862	20.21407	-0.99	0.322	-59.6638	19.60656
6	-31.59125	19.12118	-1.65	0.099	-69.08353	5.901021
7	-4.697849	23.0015	-0.20	0.838	-49.79854	40.40285
8	-18.61704	20.11175	-0.93	0.355	-58.05159	20.8175
9	-37.83779	18.51852	-2.04	0.041	-74.14839	-1.527197
Nopersons	1.042538	1.041949	1.00	0.317	-1.000487	3.085563
popgroup						
2	20.4853	14.73322	1.39	0.165	-8.403172	49.37378
3	56.09496	17.0852	3.28	0.001	22.59479	89.59513
4	187.1436	23.20564	8.06	0.000	141.6426	232.6445
5	11.33931	34.90312	0.32	0.745	-57.09775	79.77636
9	.0102227	13.23921	0.00	0.999	-25.94884	25.96929
2.p0101q01	-6.520838	4.967474	-1.31	0.189	-16.26092	3.219246
incomesource						
2	34.07419	32.95124	1.03	0.301	-30.53567	98.68406
3	2827.007	2561.164	1.10	0.270	-2194.851	7848.866
4	29.64865	181.5103	0.16	0.870	-326.2517	385.549
5	121.9944	111.3082	1.10	0.273	-96.25552	340.2443
6	-19.9311	18.85001	-1.06	0.290	-56.89166	17.02947
7	51.14251	34.14917	1.50	0.134	-15.81622	118.1012
8	7.29712	10.63733	0.69	0.493	-13.56025	28.15449
9	-13.77006	10.70427	-1.29	0.198	-34.75868	7.218567
99	15.723	9.026249	1.74	0.082	-1.975417	33.42141
_cons	27.18273	20.53055	1.32	0.186	-13.073	67.43846