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# Research on Pharmaceutical Pricing Policies

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## AUTHORS

Haroon Wadee (Team Leader), Nomvula Marawa (Sector Specialist), Linton Reddy (Researcher), Sajid Sherif (Analyst), Amanda Jitsing (Project Director)

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## PHOTO CREDIT

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## LIST OF ACRONYMS

API	Active Pharmaceutical Ingredient
ARV	Anti-retroviral
ATC	Anatomical Therapeutic Chemical
BPS	Board of Pharmaceutical Benefits
CCSA	Competition Commission of South Africa
CFDA	Chinese Food and Drug Administration
CIPC	Companies and Intellectual Property Commission
CMED	Câmara de Regulação do Mercado de Medicamentos
CPI	Consumer Price Index
DPCO	Drug Price Control Order
DPME	Department of Planning, Monitoring and Evaluation
DRG	Diagnosis-related group
DSP	Designated Service Providers
EDL	Essential Drug List
EML	Essential Medicines List
ERP	External reference pricing
FDA	Food and Drug Administration
FPP	Finished Pharmaceutical Product
HIV	Human Immunodeficiency Virus
HMI	Health Market Inquiry
IP	Intellectual Property
IRP	International Reference Pricing
MCC	Medicines Control Council
MIS	Management Information System
MoHRSS	Ministry of Human Resources and Social Security
MPC	Master Procurement Catalogue
MPR	Medicine Price Registry
NDoH	National Department of Health
NDP	National Development Plan
NDPC	National Drug Policy Committee
NDRC	National Development and Reform Commission
NHA	National Health Act
NHCO	National Health Commission Office
NHFPC	National Health and Family Planning Commission
NHI	National Health Inquiry
NHS	National Health System
NIS	National Innovation System
NLEM	National List of Medicines
NPC	National Planning Commission
NPPA	National Pharmaceutical Pricing Authority
NRDL	National Reimbursable Drug List
OHPP	Office of Health Products Procurement
OHSC	Office of Health Standards and Compliance
OOP	Out of pocket expenditure
PFMA	Public Finance Management Act
PHC	Primary Health Care
PMA	Pharmaceutical Manufacturers Association
PSC	Project Steering Committee
R&D	Research and Development
RDP	Reconstruction and Development Programme
SADC	Southern African Development Community
SAHPRA	South African Health Products Regulatory Association
SAHR	South African Health Review
SAMMDRA	South African Medicines and Medical Devices Regulatory Authority
SDG	Sustainable Development Goals

SDH	Social Determinants of Health
SEP	Single Exit Price
SEPA	Single Exit Price Adjustment
SHI	Social Health Insurance
SMME	Small, Medium and Micro Enterprises
SOI	Statement of Issues
TB	Tuberculosis
TL	Turkish Lira
TRIPS	Trade-Related Aspects of Intellectual Property Rights Agreement
UHC	Universal Health Coverage
UN	United Nations
UPFS	Uniform Patient Fee System
VAT	Value Added Tax
WHO	World Health Organization
WTO	World Trade Organization



## EXECUTIVE SUMMARY

### Background

**About 30% of the total pharmaceutical expenditure is in the public sector.**

All South Africans need medicines at some point in their lives, whether it is to treat a simple cold, cure an acute illness or manage chronic disease. Making sure that all citizens have access to affordable medicines is indispensable to the proper functioning of the healthcare system. In 2018, South Africa spent R413.7 billion on healthcare services across the public and private sectors. Of this, close to R47.1 billion was spent on pharmaceutical products, which accounted for about 11.3% of total health expenditure. While pharmaceutical expenditure per capita stands at about R778, the private sector typically spends ten times more than the public health system on medicines for each patient. Even with medical aids and free public health services, South Africans still spent about R 7.2 billion on Out-Of-Pocket (OOP) payments on pharmaceutical products.

Like most developing countries, the availability, access to and affordability of medicines has been and remains an important health policy issue in South Africa. At the height of the HIV/AIDs pandemic in South Africa in mid-2000s, the price of Anti-Retroviral (ARV) drugs was amongst the highest in the world, limiting access to life-saving treatment for millions of people and reducing the life expectancy of the population.<sup>1</sup> Since then, the South African government has reduced the prices of medicines through pooled purchasing within the public health system and price regulation in the private sector.

Nevertheless, the rapidly rising cost of health services is a significant concern for policymakers in South Africa as it accounts for a considerable proportion of expenditure among low-income households in South Africa. The National Planning Commission (NPC) was established to promote the implementation of the National Development Plan and the achievement of its objectives. Access to affordable medicines is critical to delivering on the National Development Plan's goal of extending the life expectancy of all South Africans to 70 years.

Against this background, the National Planning Commission's Quality of Life Workstream has decided to commission an analysis on the drivers of medicine prices and their influence on the attainment of universal health care coverage goals.

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<sup>1</sup> (Brand South Africa, 2010)

Whereas the government has taken concrete steps towards universal health coverage with the tabling of the National Health Bill (No 11 of 2019), at this stage, there is not enough information on exactly how the fund will purchase medicines. Nonetheless, some of the findings and lessons from this study might be relevant to a medicine pricing policy under the NHI.

Four key research questions were identified at the outset to guide this study:



**How does the policy and regulatory framework in South Africa governing medicine pricing work?**



**How does South Africa's pharmacy pricing regulatory regime compare to other countries?**



**What are the main factors within the pharmaceutical sector that impact on medicine prices?**



**How much is OOP expenditure spent on medicines by citizens and residents?**

## **Methodology**

This study uses a mixed-methods approach combining qualitative and quantitative analyses. It began with a review of the policy and legislative framework. This was followed by a synthesis of the empirical evidence on medicine pricing in South Africa and an international benchmarking study. Qualitative data was gathered through a series of semi-structured interview with 26 key informants from the public and private sectors as well as civil society. Descriptive statistics were used to examine the SEP and compare prices across countries. The final choice of countries for the price comparison was decided based on their level of development, type of health system and the availability of data. The study also uses inferential statistics to test the relationship between the different components of the SEP. Specifically, regressions were performed to test the relationship between the manufacturer and logistics components of the SEP to determine whether market power was influencing the observed trends.

## **Main findings**

***RQ 1: How do the policy and regulatory framework in South Africa governing medicine pricing work?***

**Medicine prices in the public sector are determined through a combination of competitive tendering and bulk purchasing.**

The pharmaceutical sector is governed by a complex set of laws, regulations and policies that influence the prices of medicines. Prices are determined and set differently in the public and private sectors. In the public sector, medicines are procured through a competitive tendering process, governed by the PFMA (1999). Under public sector procurement rules, government must take the lowest cost product that meets their specifications, maximises black economic empowerment and promotes local manufacturing. In many respects, these sometimes-conflicting objectives all have an impact on price. While, international manufacturers might be able to offer the lowest price to the state, awarding points for economic empowerment and local content in the procurement process improves the competitiveness of local pharmaceutical companies.

The price of pharmaceutical products in the private sector is regulated through the Single Exit Price SEP prescribed in the Medicines and Related Substances Control Act (1967) (hereinafter the “Medicines Act”) as amended. Before the amendments to the Medicine Act, pharmaceutical companies charged customers different prices for the same drug based on the maximum price they were willing to pay. The Medicines Act contains several provisions that aim to improve transparency and reduce the prices of medicines. The Act prohibits pharmaceutical companies from using financial and other incentives to market their products to pharmacists and prescribing doctors. It also outlaws discounts and rebates to distributors and retailers.

There are also several contested provisions in the Amendment Act. Compulsory licensing is one of these provisions and currently subject to a legal challenge and has yet to come into effect. While this provision in the Act would effectively allow the Minister to implement the TRIPS agreement<sup>2</sup> which allows countries some flexibility to license other manufacturers of drugs in the case of a national emergency.<sup>3</sup> While South Africa is a signatory to the TRIPS agreement, the Patent Act’s (1978) conditions for a compulsory license are fairly strict. The rights of the patent holder can only be suspended when there is clear evidence that the patent is being abused. However, while the Competition Act (1998) has mechanisms to control the abuse of dominance associated with the market power granted to patent holders, these provisions have not yet been tested in the pharmaceutical industry.

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<sup>2</sup> The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an agreement signed by WTO members.

<sup>3</sup> (WTO, 2019)

**In the private sector, medicine prices are regulated through the Single Exit Price.**

In addition to price regulation, the Act introduces a form of conduct regulation that is designed to enhance transparency and prevent rent-seeking behaviours. This includes prohibitions on: the use of non-financial incentives (e.g. gifts) by pharmaceutical manufacturers to push their products. The Act places an obligation on pharmacists to substitute the branded product for the generic alternative unless otherwise specified by the prescribing doctor.

The SEP is the regulated maximum price that patients should pay for their medicines. The SEP consists of three components: (i) the ex-manufacturer price, (ii) logistics fee, and (iii) VAT. The ex-manufacturer price is the proposal put forward by the manufacturer for new drugs. Originally, the Pricing Regulations envisaged a two-stage process to setting the price of the SEP. In the first stage, pharmaceutical companies submit their ex-manufacturers price, logistics fee and VAT to the Pricing Committee. In the second stage, the Pricing Committee was supposed to benchmark the prices proposed by manufacturers against comparable jurisdictions. Despite regulations for an ERP methodology being published as far back as 2007, they were only finalised in 2014 but have not been promulgated yet. This is because the pharmaceutical industry has objected to the basket of comparison countries proposed by government and the use of the lowest instead of the average price of medicines as the benchmark.

The final price that consumers pay for their medicines is the sum of the SEP and dispensing fee. The dispensing fee is regulated and consists of a fixed and variable component. At present, the structure of the dispensing fee is regressive. In other words, the dispensing fee makes up a higher proportion of the total cost of lower-priced medicines.

While, South Africa has a regulatory framework in place, the uneven implementation of the legislation and regulation has had unintended consequences. On one hand, the SEP has fostered greater price transparency and eliminated some the incentives for pharmaceutical companies to 'push' their products. On the other hand, because of the stalled implementation of the ERP, South Africans might be paying more for certain drugs when assessed against comparable countries.

The key shortcoming in the policy and regulatory framework is that manufacturers have an incentive to price as high as financially viable for small quantities. Since manufacturers' prices are strictly regulated irrespective of quantities sold, they have an incentive to price as high as would be financially viable when selling small quantities. The Medicines

Act contributes to this problem by not providing enabling legislation for regulators to challenge manufacturers' prices if they deem it too high.

R1.1

- Strengthen the regulatory powers of the Pricing Committee to allow them to interrogate and negotiate prices of originator and generic drugs with manufacturers.

R1.2

- Strengthen the disclosure obligations of manufacturers to provide information on costs, volumes and the actual (not just planned) logistics fees to the Pricing Committee.

R1.3

- Conduct a regulatory impact assessment on the current regulations relating to the dispensing fee to determine how its regressive nature impacts on the affordability of medicines (especially lower-priced ones) across the income quintiles.

***RQ2: How does South Africa's pharmacy pricing regulatory regime compare to other countries?***

**ERP refers to the practice of determining the price of a medicine in one country by comparing it with the prices of the same medication in comparable countries.**

Three of the eight comparator countries have adopted ERP to determine medicine prices. This pricing approach has to some extent enabled them to constrain the growth in medicine prices. India, which has amongst the cheapest prices in the world, uses a price control mechanism where the National Pharmaceutical Pricing Authority sets the ceiling price for each drug. The regulated price is fixed at the weighted average price of brands that have more than 1% market share. Like the SEP, the price ceilings in India determine the maximum allowable price. However, a key difference between South African and India is that since many of the medicines are produced locally, price competition amongst Indian manufacturers tends to drive down medicine prices.

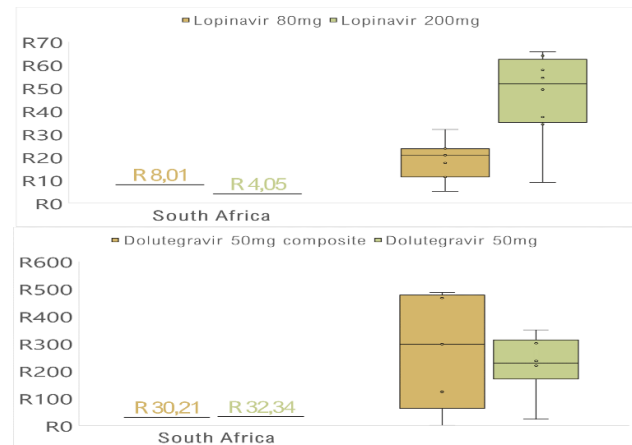
In addition, there is a move in developed countries such as Sweden, the UK and France to use value-based pricing – a technique that takes the effects of the drug on health outcomes measured against its costs. The international review also revealed that countries are reviewing and updating their patent laws to allow for compulsory licensing. There have been 108 attempts to issue compulsory licensing for 40 pharmaceuticals in 27 countries since 1995.

The international comparison reveals that South Africa has done well in bringing down the price of ARVs (Exhibit 1), and alongside India, has the

**After India, South Africa has the lowest prices in the world for ARVs but ranks among the highest for lifestyle diabetes and cardiac diseases**

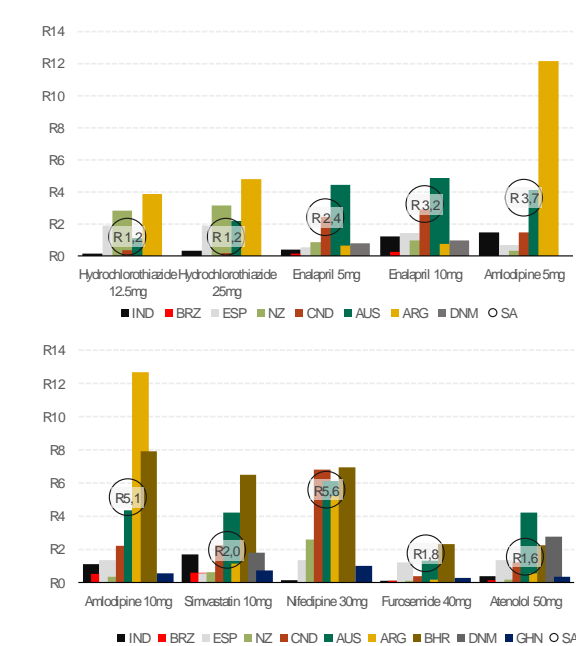
lowest prices in the world. However, prices for drugs treating non-communicable diseases such as lifestyle diabetes (non-insulin treatment) and cardiac diseases remain relatively high compared to other countries (Exhibit 2). For instance, cardiac drugs are being sold locally at a higher price than many comparator countries. Lower prices are not exclusive to high- or low-income countries which indicates potential for South Africa to bring prices closer to some of its BRICS counterparts.

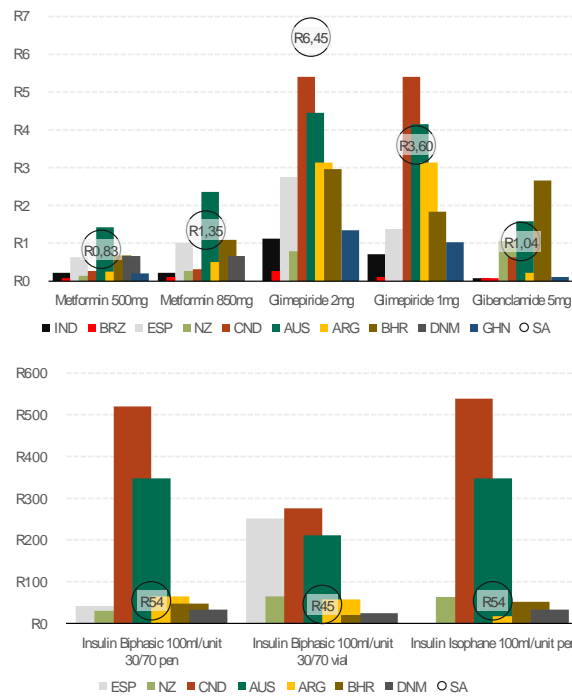
**Exhibit 1: Cross country unit price comparison for ARV drugs, 2019**



Source: Medicine Price Registry; Country formularies, 2019

**Exhibit 2: Cross country unit price comparison for Cardiac and Diabetes Therapy drugs, 2019**





Source: Medicine Price Registry, 2019. Country formularies, 2019. Own calculations.

Given, the growth in mortality rates from non-communicable lifestyle diseases, the higher demand for these drugs together with the higher prices, is likely to increase pharmaceutical expenditure going forward.

R2.1

- The NDoH should take steps to issue the regulations on ERP. In the interim, the department should monitor the SEP of drugs against the basket of comparator countries, especially those used to treat non-communicable diseases.

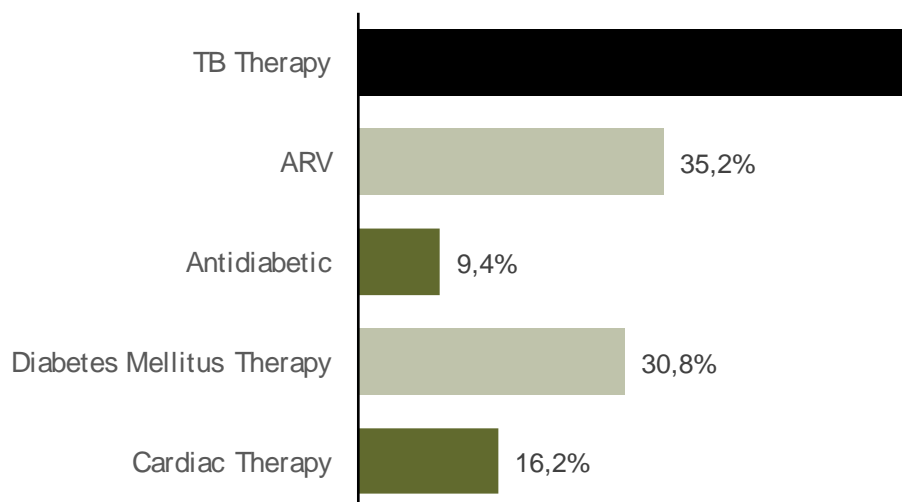
**RQ3: What are the main factors within the pharmaceutical sector that impact on medicine prices?**

**Pricing policy and regulation**

Pricing policy is distinct between the public and private sectors, reflected in the price differential (see Exhibit 3). The graph shows the extent to which pooled procurement can reduce the cost of drugs. In the public sector, antidiabetic drugs, for example, are purchased for less than a tenth

of private sector prices. International prices tend to be higher than public sector prices but lower than SEPs.<sup>4, 5</sup>

**Exhibit 3: Average of public prices as percentage of SEP manufacturer component by therapeutic category, 2019**



Source : Master Procurement Catalogue, 2019. Own calculations.

**Public sector prices are considerably lower than the SEP across all therapeutic categories analysed.**

Although bulk purchasing is likely the major contributor to the price differential between the public and private sector prices, without information on quantities purchased in the private sector, it is not possible to assess the extent to which economies of scale lower public sector prices.

Has the SEP resulted in reasonable prices? Evidence on the pricing outcomes is mixed. A recent international study found that medicine prices in South Africa are the 45<sup>th</sup> lowest in the world. Other studies suggest that private sector prices are relatively high in South Africa.<sup>6</sup> Given the findings from the international benchmarking exercise and various stakeholder interactions, a fair conclusion is that prices in South Africa can be high for some drugs and low for others. Reasons for this tend to be varied across interviews, but there is some consensus that the inability to interrogate the prices proposed by manufacturers might contribute to relatively higher SEP compared to other countries.

<sup>4</sup> (Cassar & Suleman, 2019)

<sup>5</sup> This is consistent within the analysis sample as well.

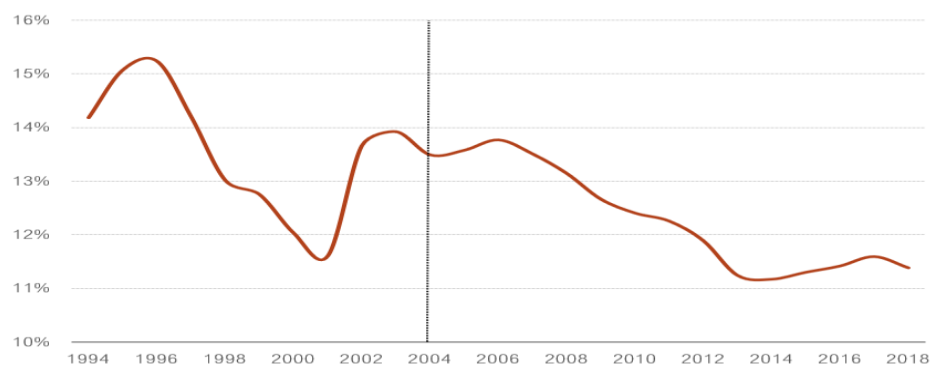
<sup>6</sup> (Cassar & Suleman, 2019)



**The introduction of the SEP has contributed to the decline in the share of pharmaceutical expenditure as a percentage of total health expenditure.**

Despite these challenges, the SEP has been seemingly successful in removing unethical practices and standardising prices across the value chain. Furthermore, the share of pharmaceutical expenditure as a proportion of total expenditure declined after the implementation of the SEP in 2004 (Exhibit 4). Academic literature also supports this finding.<sup>7</sup> This is one indication that the SEP has worked to reduce the cost of medicines in the private sector. Despite this, there are questions around whether the decline in prices is enough to achieve the health goals of the country.

**Exhibit 4: Pharmaceutical expenditure as a percentage of total healthcare expenditure, 1994-2019**



*Source : Master Procurement Catalogue, 2019. Own calculations.*

Pricing in the private sector also faces other challenges related to regulation. The logistics fee component of the SEP is unregulated, which has raised concerns around the efficiency of pricing. Regression analysis revealed indicative evidence of price play between the manufacturer price and logistics fee. This finding corroborates findings by Bangalee & Suleman (2016) who purport that manufacturers may pay greater logistics fees to incentivise the marketing of their drugs or constrict logistics fees if they supply high demand drugs, such as medicines on the Essential Medicines List.

Concerns around the dispensing fee also tend to centre around power relations, in this case between dispensers and medical scheme funders. The dispensing fee is a regulated regressive price band based on the price of medicines. It does leave room for a high dispensing fee to be levied on low priced medication. However, medical schemes negotiate down the dispensing fee, meaning that it is unlikely for widespread abuse

<sup>7</sup> (Moodley & Suleman, 2019)

of the regulation. Nevertheless, non-medical scheme patients may be exposed to high dispensing fees since they pay OOP expenses.

R3.1

- The NDoH should build capacity within government to implement the ERP and carry out pharmaco-economic analyses in the short-term to determine the appropriate price of medicines. Over the medium to long term, government should consider adopting a value-based pricing methodology.

R3.2

- The NDoH should develop and implement a monitoring system that collects consistent and longitudinal data on the prices, volumes and costs of medicines across therapeutic categories, and by generic and originator.

R3.3

- The NDoH should fast track setting up an independent body (similar to NICE<sup>8</sup>) or integrating the function into SAHPRA to undertake the pharmaco-economic and value-based pricing assessments.

R3.4

- The NDoH should fast track the establish of the real-time medicine inventory monitoring system to provide the information it needs to better forecast demand for drugs in the public sector.

### Market structure and competition

The pharmaceutical value chain consists of distinct (and related) activities including research and development, drug substance development, manufacturing, wholesaling, distribution and marketing<sup>9</sup>. Firms may be present in one or more of these segments of the value chain. The current market structure of the pharmaceutical industry appears to be highly fragmented, as at 2015, approximately 276 companies were licensed to import, manufacture, distribute or export pharmaceutical products.

There are high levels of market concentration in the manufacturing of originators.<sup>10</sup> The manufacture of generics has lower levels of concentration, which implies greater competition. However, careful

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<sup>8</sup> The National Institute for Health and Care Excellence (NICE) in the UK provides national guidance and advice to improve health and social care. As part of its mandate, it undertakes value-based pricing and cost-effectiveness analyses.

<sup>9</sup> (SAHPRA, 2017)

<sup>10</sup> Helen Suzman Foundation, 2017

attention must be given to those companies producing originator drugs which are directly/indirectly active in the supply of generic drugs.

Based on publicly available information, the market for Cardiac and Diabetes Mellitus drugs reflects an oligopolistic structure, characterised by a few firms supplying large quantities. There is a higher degree of competition in the supply of ARV's.

**At manufacturing and retail level, market concentration levels are high but there are countervailing pressures that prevent participants from exercising their market power**

At the distribution level, there is not enough information to assess the concentration levels. In this segment of the value chain, firms which distribute pharmaceuticals are not integrated with the pharmaceutical sector.

At the retail level, high levels of concentration exist with Dischem and Clicks having a combined market share of close to 40%. However, this market power is moderated by the buying power of medical schemes. Through their Designated Service Provider (DSP) arrangements and formularies, medical schemes can negotiate lower dispensing fees.

Overall, the lack of firm-level information makes it difficult to assess the current market structure and its influence on competition outcomes. Although there may be different areas or pockets of greater competition occurring across the value chain (e.g. in the supply of generics). However, we remain cognisant that factors such as the regulatory and policy environment (IP, SEP) are strong contributors to the current competitive landscape. At present, the lack of transparency around critical aspects of the price build-up may also have unintended consequences for the market.

The delays in market authorisations of new drugs and generics further entrench the power of incumbents in markets with few suppliers. The full impact of the delays by SAHPRA on the supply of medicines is difficult to gauge, as information on the types of drugs awaiting regulatory approval by therapeutic category is not publicly available. Nevertheless, likely, the backlog of 18 000 applications is severely constraining the supply of medicines.

**R3.5**

- The NPC should commission a detailed market assessment for the different segments of the pharmaceutical value chain based on actual

information about market participants and their relative market shares.<sup>11</sup>

**R3.6**

- SAHPRA must publish more granular information on the applications backlog, including a detailed analysis of the backlog by therapeutic category and medicine type (generic versus originator).

**R3.7**

- SAHPRA should develop and publish its action plan (in response to the recommendations from the backlog eradication project) that outlines how it intends to address the backlog and by when.

### **R&D and Intellectual Property Laws**

Investments in R&D within the pharmaceutical industry maximise societal welfare by increasing access to new drugs, encouraging incremental innovation to reduce side-effects and increase therapeutic value. To this end there several policies and strategies aimed at bolstering the country's innovation agenda.

The lack of coordination across the various departments responsible for health innovation is slowing down the pace of sector development. Overcoming key barriers in governance and commitment to R&D policies is generally slow with greater coordination and collaboration required to effect healthcare goals.

**R3.8**

- The DST, in collaboration with the NDOH and DTI, should develop a sector strategy to steer and coordinate the government's efforts to promote R&D in the pharmaceutical industry.

There is also a lack of a coherent industrial policy to foster the strengthening and development of the local pharmaceutical industry and to develop a state-owned pharmaceutical manufacturer (despite the stated policy intent). Patent laws are much stricter than the TRIPS, and thus might be a stumbling block to the introduction of compulsory licensing in South Africa. At the same time, one of the goals of government is to

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<sup>11</sup> The aim of this analysis is not duplicate the work of the Health Market Inquiry but to strengthen the policymakers understanding of the value chain.

expand local manufacturing, and this clear statement of intent articulates the expected outcomes, and what government departments need to do.

**R3.9**

- The DTI should take steps to align the current Patents Act (1978) with the TRIPS regime.

Finally, there is little capacity in South Africa for producing active pharmaceutical ingredients (APIs) at scale. At present, South African pharmaceutical companies mainly focus on reformulation or repackaging of medicines and APIs. While it is unlikely that South Africa will develop the capacity to manufacture APIs at scale and compete with large suppliers like India and China, it does nevertheless account for a quarter of the global ARV market in low- and middle-income countries. There is, therefore, an opportunity for the state to promote the local manufacturing of APIs required for ARVs.

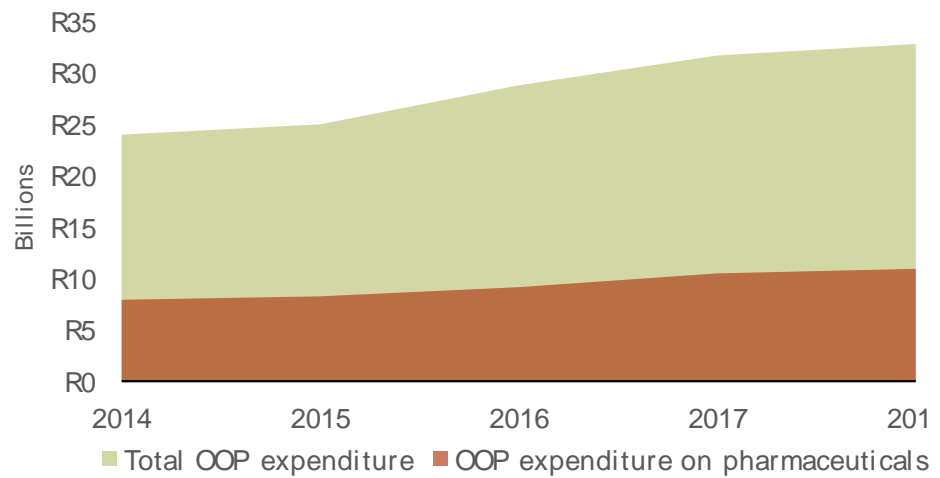
**R3.10**

- The DTI should develop an industrial strategy for the pharmaceutical industry that outlines the steps it will take to develop local manufacturing capacity for high priority drugs (where appropriate) and APIs linked to South Africa's burden of disease.

***RQ4: How much OOP expenditure is spent on medicines by citizens and residents?***

OOP expenditure for medicines is on the increase and under-reported across income quintiles within both the insured population and the public sector dependent population. Pharmaceuticals make up a significant portion of OOP – 32.9% in 2018 and appears to be increasing steadily over time. This is particularly worrying as OOP payments affect both public and private sector patients as well as those with medical scheme coverage.

**Exhibit 5: Annual OOP expenditure for medical scheme users, 2014-2019<sup>12</sup>**



Source: CMS Annual report 2018/19

**R4.1**

- Statistics SA and the CMS should collect disaggregated data on the OOP payments by households across different quintiles. Specifically, the data should collect information on their expenditure by therapeutic category.

South Africa’s public sector procurement system has been highly effective in reducing medicine prices. However, there is still some way to go in the private sector, where the SEP remains relatively high, as measured against other countries. For this to happen, a broader set of reforms that strengthens the regulatory system, improves data collection and enhances monitoring is needed.

<sup>12</sup> “Out-of-pocket payments have been calculated as the difference between the claim amount billed and the amount that was paid from medical scheme risk, including the amount paid from the medical savings account. This is an understatement of the true out-of-pocket expenditure incurred by medical scheme members, since not all out-of-pocket claims are submitted to the medical scheme. In 2018, the total out-of-pocket expenditure amounted to R32.9 billion – up from the R31.8 billion in 2017. This represents 19.0% of the total benefits paid” (Council for Medical Schemes, 2018)

# 1 INTRODUCTION

## 1.1 Background

The rapidly rising cost of health services is a concern for policymakers throughout the world. Spending on pharmaceutical products is a key driver of healthcare costs and accounts for between 20% to 60% of health expenditure in low-and-middle-income countries.<sup>13</sup> In developing countries, low-income households tend to purchase medicines through Out-of-Pocket (OOP) payments, making pharmaceutical products, a significant expense for these families. For many low-income households, the choice is often between buying medicines or foregoing necessities. However, the lack of access to affordable, appropriate and safe medication can reduce the lifespan of populations, increase the burden on the healthcare system and reduce productivity. The availability of affordable medicines is, therefore, a critical aspect of well-functioning health systems.

South Africa's expenditure on health services is comparable to upper-middle-income countries on a per capita basis. In 2018, South Africa spent R413.7 billion on healthcare services across both the public and private sectors. Of this, close to R47.1 billion was spent on pharmaceutical products, which accounted for about 11.3% of total health expenditure.<sup>14</sup> However, because the health system is fragmented, these figures mask stark differences between the public and private sector in the country.

South Africa's healthcare system has an over-stretched and somewhat poorly resourced public health system that serves 82% of the country's 58.8 million population, and a growing but smaller private sector that provides health services to the middle and upper class. In 2018, the public sector spent about R8.5 billion on medicines and accounted for only about 18% of total pharmaceutical expenditure. The rest of the spending on pharmaceutical products happened in the private sector. While pharmaceutical expenditure per capita stands at about R778, the private sector typically spends ten times more than the public health system on medicines per patient. Even with medical aids and free public health services, South Africans spent about R 7.2 billion on OOP payments for pharmaceutical, or roughly R 862 per person in 2015.<sup>15</sup>

Like most developing countries, the availability, access to and affordability of medicines has been and remains an important health policy issue in South Africa. At the height of the HIV/AIDS pandemic in South Africa in mid-2000s, the price of Anti-Retroviral (ARV) drugs was amongst the highest in the world, limiting access to life-saving treatment for millions of people.<sup>16</sup> Since then, the South African government has reduced the cost of medicines through pooled purchasing within the public health system and price regulation in the private sector.

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<sup>13</sup> (World Health Organisation, 2015)

<sup>14</sup> SARB data

<sup>15</sup> At a national level, OOP expenditure data on pharmaceuticals is not readily available. This estimate is from the most recent Living Conditions Survey, conducted by Stats SA.

<sup>16</sup> (Brand South Africa, 2010)

In 2004, the government introduced a transparent pricing scheme for medicines, including a Single Exit Price (SEP) for medicines sold in the private sector, to put a stop to discounts and additional levies on medicines. The SEP is the price at which a manufacturer must sell their pharmaceutical products to all pharmacies, irrespective of volume sold. The SEP consists of an ex-manufacturer price, a logistics fee and Value Added Tax (VAT). As a form of price regulation, the SEP ensures that companies do not use a bonus system, rebate system or any other incentive scheme. The regulatory framework also introduces forms of conduct regulation that prohibits the gifting of medicine samples and encourages generic substitution.

Before the introduction of the SEP, medicine prices were mostly unregulated; and there were concerns that the lack of transparency and inconsistent pricing strategies were contributing to medical inflation, which averaged about 9% between 1999 and 2003.<sup>17</sup> The SEP addressed these issues by reducing medicine price inflation, improving medicine price transparency, and ensuring patients pay the same price for medicines irrespective of where they buy them – from pharmacies, hospitals or dispensing doctors.

By regulating the price of medicines, the government has effectively done away with the ability of pharmaceutical companies to price discriminate between different purchasers in the private sector.<sup>18,19</sup> In addition to the SEP, pharmacists or dispensing doctors can charge a dispensing fee as a mark-up on their services. The dispensing fee consists of a fixed and variable component. Whereas the fixed component covers the minimum levy, the variable component is expressed as a percentage of the SEP of the medicine purchased. Therefore, the higher the SEP, the higher the maximum dispensing fee that can be charged to the customer, although the variable component is a regressive percentage for higher-priced medication. In other words, the dispensing fee accounts for a higher proportion of the total cost of cheaper medicines.

While there is some empirical evidence to support the notion that the SEP has reduced medicine prices<sup>20</sup>, there are still concerns about availability and affordability of pharmaceutical products in South Africa. Specifically, there is very little information on how well the prices submitted by manufacturers compare to prices in other countries, and whether South Africans are paying too much for medicines or getting them relatively cheaply.

In line with its mandate to implement the provisions of the National Development Plan (NDP), the National Planning Commission (NPC) commissioned Trade and Industrial Policy Strategies

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<sup>17</sup> SARB Data

<sup>18</sup> The SEP applies only to scheduled medication; over the counter medicines such as paracetamol are not subject to SEP.

<sup>19</sup> Medicines and Related Substances Act (No.101 of 1965): The Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances: Amendment. Government Gazette, July 2012.

<sup>20</sup> See Bangalee & Suleman, A Comparative Study on Medicine Pricing in Brazil, Russia, India, China and South Africa, 2018



(TIPs), a think tank, to examine the spending on State services and its influence on the cost of living of low-income households.

The report found that household spending on health care was considerably higher than education. The share of household health expenditure rose from 2.7% for the poorest 40% to 9.1% for the wealthiest 20%. OOP expenses absorbed almost the same share of spending for all three groups, at around 1.5%. This includes expenditure on medicines. In addition, the expenditure on health insurance accounted for 1.3% for the most marginalised 40%, 3.4% for the next 40%, and 7.7% for the richest quintile.

## 1.2 Scope

With poor households spending a large part of their income on health services and medicines, the NPC's Quality of Life Workstream has decided to commission an analysis on the drivers of the cost of medicines and their influence on the achievement of Universal Health Care (UHC) coverage goals.

The National Health Insurance Bill (No 11 of 2009) is a critical step towards UHC. In its latest iteration, the Bill establishes a fund to procure medicines actively and creates a Benefits Advisory Committee (BAC) to advise on the purchasing of medicines. Thus, while this research piece focuses on the current pharmaceutical pricing policies, in all likelihood, the National Health Insurance (NHI) scheme is likely to change the way medicine prices are determined fundamentally. While this research draws out lessons in pricing policies and regulations for the NHI, a full review of implications of current pricing policies for the Fund is beyond the scope of this assignment.

## 1.3 Research objectives

In line with the Terms of Reference, the specific objectives of this research project are to:

- Scope and analyse the existing literature on the drivers influencing the cost of medicines, explicating the current debates and arguments on this matter.
- Scope and analyse the policy, legislation and regulatory framework that governs the pharmaceutical industry, especially the following, but not limited to these areas:
  - Examine patent applications for pharmaceutical products and the allegations of abuse of market dominance by patent-holding companies and their impact on the cost of medicines.
  - Reflect on the factors contributing to poor investment in the pharmaceuticals industry.
  - Reflect on the link (if any) between health policies and industrial policies aimed at stimulating and/or protecting local manufacturing.
- Undertake an international benchmarking analysis in this area, using both developed and developing countries as case studies.

## 1.4 Report structure

The report is structured as follows:

- **Section 1** provides the background to this research study and sets out the research objectives.
- **Section 2** briefly outlines the methodology employed for the research assignment.
- **Section 3** reviews the policy and legislative context.
- **Section 4** contains an overview of the pharmaceutical value chain and the expenditure on medicines in South Africa.
- **Section 5** highlights the key findings from the international benchmarking exercise.
- **Section 6** presents the key findings from the research based on an analysis of quantitative data and information gathered from interviews.
- **Section 7** analyses OOP payments over time.
- **Section 8** concludes this research paper, draws out policy lessons and makes recommendations on potential policy changes.

## 2 METHODOLOGY

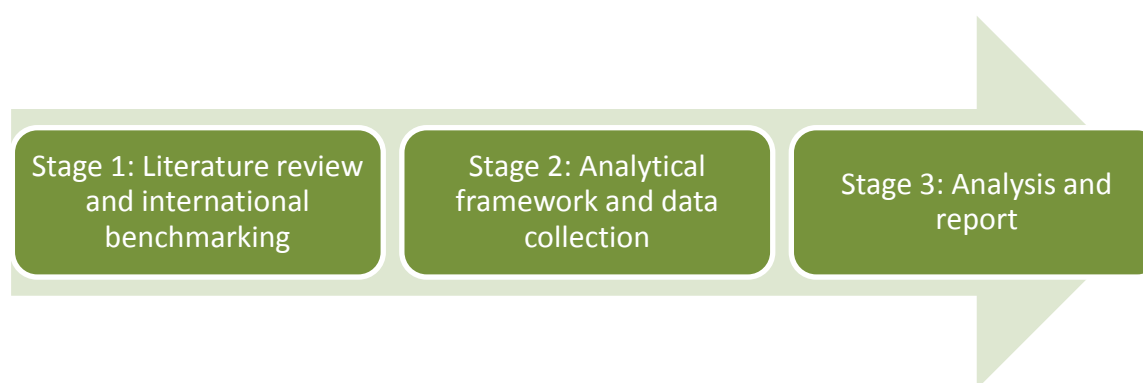
This study examines the approach to regulating the pharmaceutical prices of both originator and generic medication in South Africa and analyses the effects of regulation on prices. It also identifies the key drivers of costs and their impact on South African pharmaceutical prices.

The main research questions that drive this study are:

- How does the **policy and regulatory framework** in South Africa governing medicine pricing work?
  - What is the rationale behind the current medicine pricing regulation?
  - How has the policy and regulatory framework evolved?
- How does South Africa's **pharmaceutical pricing regulatory regime** compare to other countries? Specifically:
  - How are medicine prices regulated in other countries?
  - Are there differences between public and private sector pricing practices in comparator countries?
  - Are there differences in pricing practices between unified and competitive health systems in comparator countries?
- What are the main factors within the pharmaceutical sector that impact on medicine prices? Specifically,
  - What is South Africa's **approach to price regulation**?
  - What are the main differences between the way medicines are **procured and priced** in the public and private sector?
  - How has price regulation **affected the prices of medication**?
  - How does the **market structure and competition** across the different segments of the pharmaceutical industry influence pricing?
  - How much does the pharmaceutical sector spend on **Research & Development** in South Africa, and how does this expenditure impact on the pricing of medicines?
  - How does access to **Active Pharmaceutical Ingredients (APIs)** impact on the local manufacturing?
  - How do current **Intellectual Property (IP) laws and patent processes** influence medicine prices?
- How much **OOP expenditure** is spent on medicines by citizens and residents?
  - How does the OOP expenditure impact on citizens in different income quintiles?

The study was conducted in three stages:

**Figure 1: Project stages**



Source: DNA Economics

## 2.1 Literature review and international benchmarking

The project started with an inception meeting between the Department of Planning, Monitoring and Evaluation (DPME) and project team on 2 October 2019. The agreements on the scope of this project were captured in a final inception report submitted to the DPME on the 16 October 2019. In the first stage of this project, the project team completed a document and literature review which:

- provided an overview of the current policy, legislative and regulatory environment governing drug and medicine pricing policy;
- reviewed the implications of trade policies, competition and market structure on medicine pricing based on existing research; and
- benchmarked the medicine pricing policies and regulatory framework of eight countries (Brazil, China, France, Ghana, India, Thailand, Turkey and Sweden) to the South African experience.

## 2.2 Analytical framework and data collection

This study adopted a mixed-methods approach using both qualitative and quantitative data. For the qualitative assessment, the study completed semi-structured interviews with a range of key informants from both the public and private sector.

In selecting the key informants, researchers took care to include a diverse range of stakeholders from government, public entities, regulatory bodies, industry representative bodies, institutions of higher learning as well as private sector representatives. Of the total number of 30 interviews planned, 26 have been completed.<sup>21</sup> A complete list of the categories of key informants can be found in Appendix 1.

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<sup>21</sup> The research team, with assistance from the DPME, have done their best to secure all 30 interviews. Doing so proved challenging given the time of year this study was being conducted. This was highlighted as a risk in the inception report.

To analyse the effects of the SEP on prices, we collected the following information:

- Longitudinal SEP data for purposively sampled drugs (generic and brand name) informed by burden-of-disease data and key healthcare tracers for communicable and non-communicable diseases). The medicines sampled included those used in the treatment of HIV/AIDS, Tuberculosis, Diabetes and Coronary Heart Disease.
- Cross-sectional tender-price data (including the generic and brand name) informed by burden-of-disease and key healthcare tracers for communicable and non-communicable diseases.
- Time series aggregated data on pharmaceutical imports and exports.

### **Box 1: Sampling approach**

The National Treasury's Master Procurement Catalogue (MPC) contains a list of drugs, their tender prices and quantity purchased by the public sector. For the analysis, within selected therapeutic categories (Coronary, Diabetes, HIV and TB drugs), the research team selected the top ten drugs, by quantity. These medicines account for the high expenditure and signal the greatest demand, at least in the public sector. Several in-sample drugs purchased by National Treasury were from different companies, resulting in some of the sampled drugs having more than one supplier.

In-sample drugs were then matched with drugs listed on the Medicine Price Registry (MPR), which lists SEP prices for each company supplying the drug.<sup>22</sup> The matching exercise was successful for all ten company-drug combinations for the Cardiac, Diabetes and HIV therapeutic categories. Only four drugs were matched for Tuberculosis, likely due to the various types of TB drugs on the market used to treat the various strains of the disease. Diabetes drugs are split into two categories, Diabetes Mellitus and antidiabetic. The main difference between these two categories of medicines is that the former is in tablet form and cheaper whereas the latter is in an injectable form (i.e. insulin) and is more expensive. Three out of the four antidiabetic drugs are originators and four out of the ten HIV drugs are originators. All other medicines in the sample are generics.

Using this approach as the basis for the analysis, the sample tends to vary slightly. When analysing South African prices relative to international comparators, for drugs that have more than one company supplying them, the company supplying the largest quantity to National Treasury was selected for price comparison. Private sector (SEP) prices listed on the MPR were used for comparison.

When analysing the SEP locally, all company-drug combinations were included in the sample. A panel of all unique combinations was constructed over the period between 2013 and 2019. There are 62 unique company-drug combinations with 380 observations. While not all company-drug combinations were found across all seven years, missing values does not undermine the validity of the analysis.

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<sup>22</sup> Data available [here](#)

## 2.3 Analysis and reporting

### 2.3.1 Analysis

Information gathered from the semi-structured interviews was analysed thematically by researchers to draw out key insights. For the quantitative analysis, datasets were cleaned, consolidated and analysed. The analysis analysed the different components of the SEP across therapeutic categories as well as trends over time. In addition, an econometric analysis, in the form of regressions, was used to explore the dynamics of the manufacturer price and logistics fee, and their potential relationship with the SEP. Regressions are statistical techniques that attempts to establish the strength of the relations between two or more variables of interest. In this case, regression analysis was used to determine whether there is a relationship between the manufacturer's price and logistics fee. Any statistically significant relationship might point to the power of market participants to influence prices.

For this study, the research team used the Pooled Ordinary Least of Squares and Fixed Effects estimators to estimate the relationship between different components of the SEP, using the panel data set constructed specifically for this project. The research team conducted two sets of regressions.<sup>23</sup>

The first set of regressions considered the joint effect of a year-on-year increase (decrease) in the manufacturer price and a year-on-year decrease (increase) in the logistics fee on the SEP. The joint effect is estimated by interacting binary variables that control for an increase in the manufacturer price and a decrease in the logistics fee.

Parallel regressions are estimated accounting for the opposite scenario, a decrease in the manufacturer price and increase in the logistics fee. A statistically significant result indicates which component of the SEP – manufacturer price or logistics fee – drives the SEP. This might imply that manufacturers and distributors are interfering with components of the SEP.

The second set of regression models estimates the effect of the logistics fee in the preceding period (lagged once) on the current manufacturer price. This relationship is also estimated in reverse; the effect of the previous manufacturer price (lagged once) on the current logistics fee. Significant relationships in these regressions indicate price-play between manufacturers and distributors across periods and would suggest that there are factors – outside of the SEP framework – that are affecting prices.

### 2.3.2 Reporting

The findings from the analysis have been written up into the first draft of the report. The results and findings were presented to the DPME and NPC on 29 January 2020. This final report incorporates the comments from this validation workshop.

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## 2.1 Limitations of this research

- Data on the pharmaceutical sector is somewhat limited, and the research has been constrained by the lack of information on the quantity of products sold in the private sector over time. Without having access to data on the volumes of pharmaceutical products sold, it is difficult to assess the extent to which quantity and/or prices are driving total pharmaceutical expenditure. Beyond healthcare expenditure, volume data also sheds light on consumption patterns to determine whether there has been a change in the uptake of generic and originator medicines.
- Where data was available, the relatively small sample size limits the scope of statistical analyses that can be conducted. Moreover, small samples affect the extent to which we are able to infer a relationship between the components of the SEP and other variables.
- Securing interviews at the end and beginning of the calendar year (given the delays in the awarding of this project) has also been a challenge. With the assistance of the DPME, the research team has been successful in conducting more than 80% of the planned number of interviews (26 out of 30).
- Finally, the research team and the DPME were unable to secure price, volume, authorisation and product category data from the South African Health Products Regulatory Authority (SAHPRA) and the Council for Medical Schemes (CMS). This information would have enriched the analysis.

### 3 POLICY AND LEGISLATIVE REVIEW

The pharmaceutical sector is governed by a complex set of laws, regulations and policies that influence how it operates and sets prices. Whereas some legislation aims to protect consumers, limit rent-seeking behaviours of pharmaceutical companies (through price regulation) and ensure the safety of medicines, other policies aim to promote research and development and increase industrial production. While in principle, the regulatory framework is meant to work coherently to achieve the intended regulatory outcomes, in practice, there are trade-offs between expanding the local pharmaceutical production, ensuring the continued sustainability of the industry, encouraging investment in R&D while making sure that medicines remain affordable to consumers.

This section of the report summarises the main policy, legislative and regulatory provisions that influence medicine pricing in South Africa. It helps to contextualise the subsequent findings on the effectiveness of the current regulatory regime governing pharmaceutical prices.

#### 3.1 Historical overview

South African policymakers have long been concerned about the high costs of medicines, particularly given the country's reliance on imports of pharmaceutical products. Under the apartheid government, three commissions were appointed to investigate the high costs of healthcare, including medicines.<sup>24</sup> While each of these commissions had a specific mandate, their findings were broadly similar and remain relevant today.<sup>25</sup>

All three Commissions found that patent legislation contributed to high prices. As early as 1961, the Snyman Commission, and later the Steenkamp Commission (1978) recommended compulsory licencing for medicines. Compulsory licencing happens when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself. Compulsory licencing is allowed under the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPs) and countries are free to determine the grounds for compulsory licencing and determine what a national emergency is.<sup>26</sup>

By implementing a compulsory licencing regime, the government can reduce the cost of medicines by permitting more firms to produce a particular drug, effectively bypassing the originator's patent based on a public interest argument. The three commissions also recommended the increased use of generic substitution as a way of reducing the cost of medication. The provisions around generic substitution only became legal in 2003, almost two decades later.

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<sup>24</sup> The Commissions were the Snyman Commission (1961), the Steenkamp Commission (1978) and the Brown Commission (1985).

<sup>25</sup> (Gray A. L., 2009)

<sup>26</sup> (WTO, 2019)

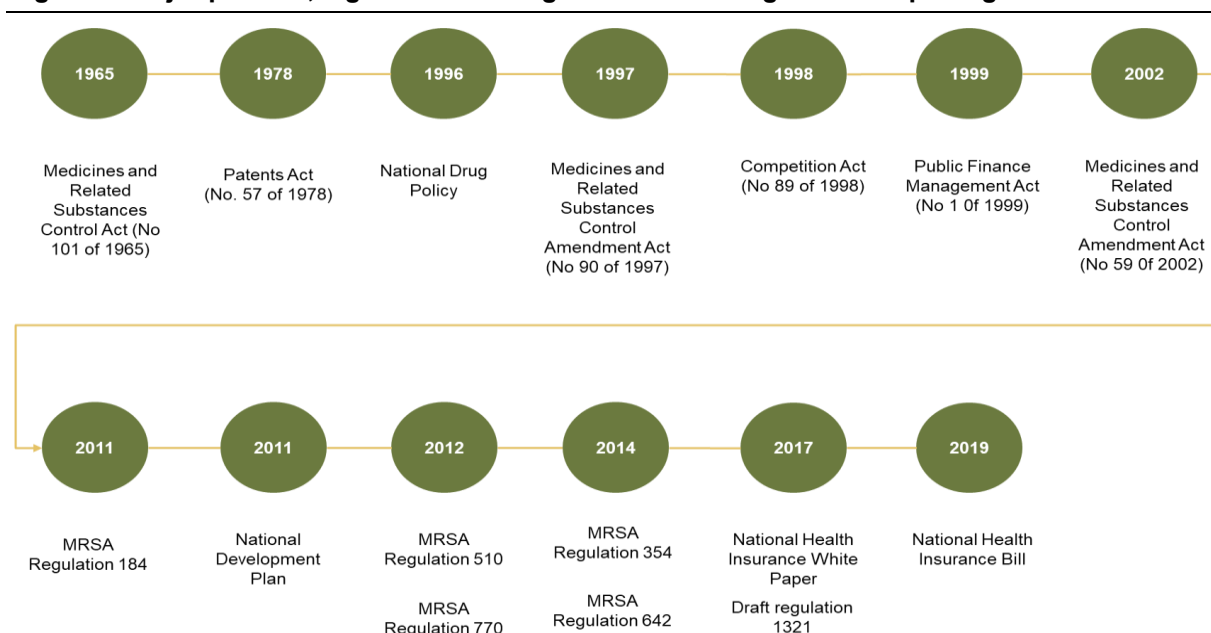


Other valuable recommendations such as curtailing excessive promotion of all types of medicines and the prohibitions around gifting and ‘bonusing’ of medicines to pharmacists, medical practitioners and dentists that enable pharmaceutical companies to market their products aggressively. These practices enable pharmaceutical companies to influence the prescribing and dispensing behaviours of doctors and pharmacists, at the expense of the patient. The one recommendation from the Browne Commission (1985) that was subsequently implemented was to establish a public sector tender process for the procurement of medicines.<sup>27</sup> This recommendation has helped to reduce prices in the public sector by fostering greater competition between generic and originator medicines and across different manufacturers.

### 3.2 Policy, legislation and regulation

There are several pieces of legislation that influence demand and supply of pharmaceutical products. While there are health-specific sector policies and regulations such as the Medicines and Related Substances Act (No. 101 of 1965), other cross-cutting pieces of legislation such as the Patents Act (No. 57 of 1978) and the Public Finance Management Act (No. 1 of 1999) (PFMA) also influence the prices of medicines. Therefore, the pricing outcomes seen in the public and private sector are often the result of an interplay between various pieces of legislation and regulation.

**Figure 2: Major policies, legislation and regulations affecting medicine pricing**



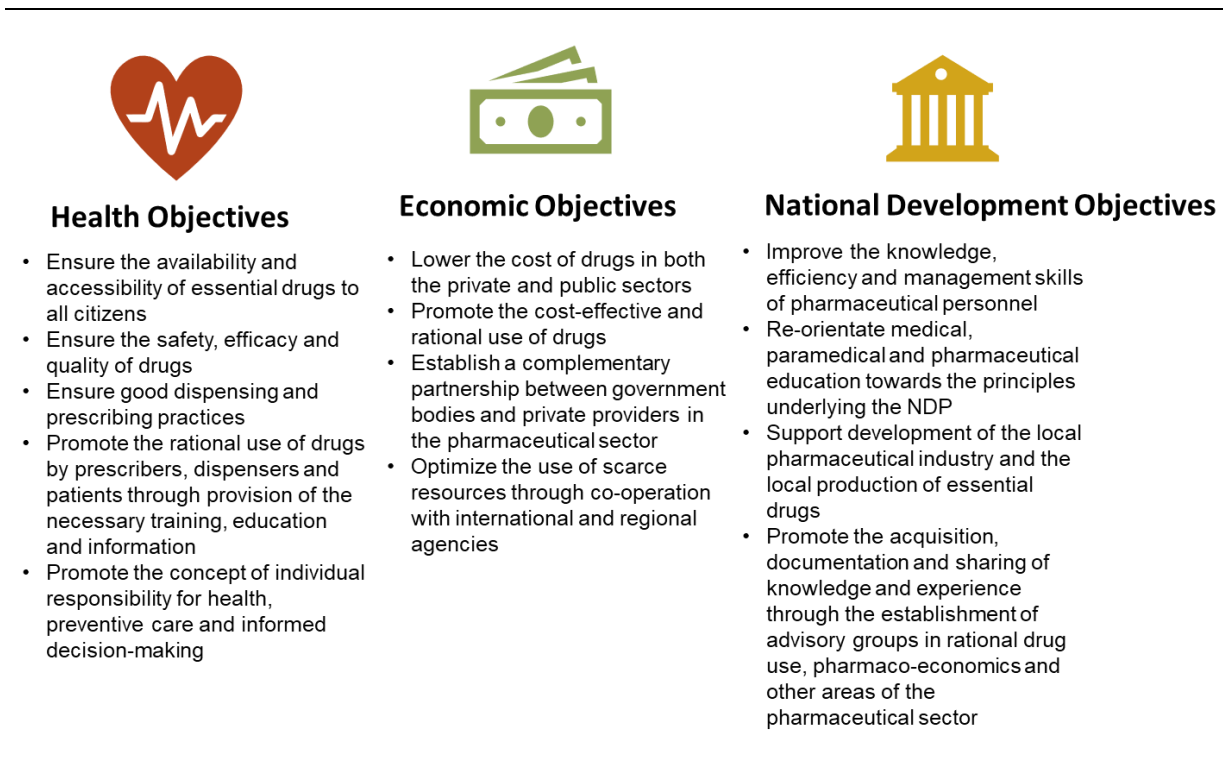
Source: DNA Economics

<sup>27</sup> (Gray A. L., 2009)

### 3.2.1 National Drug Policy (1996)

Although dated, the National Drug Policy (1996) continues to guide the implementation of the regulatory framework governing medicine pricing in South Africa. With regards to medicines, the National Drug policy sets out specific objectives categorised under three broad goals that would inform subsequent policy and regulation.

**Figure 3: Overview of the objectives of the National Drug Policy (1996)**



Source: National Drug Policy (1996)

The National Drug Policy proposed several interventions that were subsequently incorporated in legislation to regulate and monitor medicine pricing.<sup>28</sup> The first set of interventions revolved around establishing the capacity to regulate. The Drug Policy proposed that the Ministry of Health establish a pricing committee with clearly defined functions to monitor and regulate drug prices. The policy also called for the establishment of price regulation to:

- Improve the transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals.
- Introduce and enforce a non-discriminatory pricing system within the private sector.
- Replace the wholesale and retail percentage mark-up system with a fixed professional fee.

<sup>28</sup> (National Department of Health, 1996)

- Establish a database to monitor costs compared with other developing and developed countries, effectively shifting price regulation towards external reference pricing.
- Enable the public sector to supply the private sector with lower-cost drugs to pass on the bulk discounts to consumers.
- Promote generics, including generic substitution, while maintaining a negative list<sup>29</sup>.
- Control through regulation of marketing practices.

Many aspects of the NDP were implemented through amendments to the Medicines and Related Substances Control Act (1967) and the promulgation of regulations. However, there are still parts of the NDP that have not been implemented. This uneven implementation of the NDP has influenced the development of the industry and the pricing outcomes seen over the last two decades, and in ways that might not be aligned to the original intention of the policymaker, as the rest of the report shows.

### *3.2.2 Medicines and Related Substances Control Act (1967) as amended*

The manufacturing, supply and dispensation of medicines were regulated under the Medicines and Related Substances Control Act (No 101 of 1965) (hereinafter referred to as the “Medicines Act”), which came into effect in 1967. Significant changes designed to promote the availability and control of medicine prices were incorporated in the Medicines and Related Substances Control Amendment Act (No 90 of 1997).<sup>30</sup> Together with the first set of regulations issued under the Amendment Act (from now on referred to as the “General Regulations”), the amendments to the Act dealt with several issues, including:

- Measures to ensure the supply of cheaper medicines, including introducing competition through parallel importation.
- A transparent pricing system that, for the first time, requires openness and accountability in the setting of drug prices.
- Introducing a fee-for-service system at various levels in the medicine supply chain, with the government setting the upper level of the “appropriate” fees.
- Promoting the use of generic medicines once branded products are no longer protected by patent, including the mandatory generic substitution of off-patent medicines.
- Fast-track procedures for the registration of essential medicines.

Unsurprising, the amendments to the Medicines and Related Substances Control Amendment Act drew a strong response from the industry. The main issue was that the amendment and regulations were perceived as an unjustifiable infringement on the intellectual property rights of pharmaceutical manufacturers.<sup>31</sup> The Pharmaceutical Manufacturers’ Association (PMA) representing most pharmaceutical companies in South Africa challenged the law in court. Eventually, the Association withdrew its court challenge after the government and civil society

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<sup>29</sup> A negative list refers to a list of drugs that could not be substituted by the pharmacist at the patient’s request, but where the prescribed brand would have to be supplied

<sup>30</sup> (Republic of South Africa, 1997)

<sup>31</sup> (Section 27, 2010)

defended the Act. It took another three years before the law came into full force. Some of this delay was because regulations had to be drafted, consulted on and promulgated. In addition, certain minor amendments to the Medicines Act were needed, that culminated with the promulgation of the Medicines and Related Substances Amendment Act 59 of 2002.

The 1997 amendments to the Medicines and Related Substances Control Act came into force on 2 May 2003 and the full package of reform was brought into effect on 2 May 2004. However, some provisions of the law have still not taken effect as a result of a partially successful legal challenge to the validity of the Pricing Regulations issued under section 22G of the Act.

The Medicines Act contains specific provisions that allow the Minister of Health to take action that results in the supply of cheaper medicines. Specifically, section 15C gives the Minister the power to “prescribe conditions for the supply of more affordable medicines in certain circumstances”.<sup>32</sup> While the circumstances under which the Minister can invoke this clause are not elucidated in the Act, the two mechanisms through which price reductions can be achieved are highly contested. The first mechanism is laid out in Section 15C(a) of the Act, which appears to give the Minister extensive powers to override exclusive rights in patents. This conflicts with the provisions of the Patents Act (No. 57 of 1978), which protects the rights of the patent holders. The second mechanism is contained in Section 15C(b) that permits parallel importation.

## **Licensing**

Some analysts claim that Section 15C(a) permits compulsory licensing and that it may even go so far as to override patents completely. Predictably, section 15C was at the heart of the PMA’s court challenge. But by late 2005, the extent of the Minister’s powers in the paragraph remained unclear, and the General Regulations do not give effect to the paragraph, meaning that it cannot be used in practice. Further, because the PMA withdrew their court challenge, the High Court did not have an opportunity to provide a proper interpretation of the provision. In addition, the government has publicly declared that section 15C(a) would not be used for compulsory licensing.

## **Parallel importation**

Regulation 7 explains under what conditions parallel importation can take place including:

- The types of medicines can be imported under section 15C(b) (i.e. only patented medicines can be imported).
- The application requirements for a licence for the parallel import of medicines.
- The powers of the Minister around the approval of import licences.

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<sup>32</sup> (Republic of South Africa, 1997)

The process is complex, dealing with issues of safety, quality and efficacy, as well as affordability. By late 2006, no medicines have been imported into South Africa under Regulation 7, probably as a result of the difficult processes that must be followed.<sup>33</sup>

### **Transparency and accountability**

Before the 1997 amendments to the Act, drug manufacturers were free to set their own prices and had no legal duty to explain how these prices were calculated. In a truly competitive market, where demand is elastic because of the presence of substitutes in the market, competition should drive down prices. However, in the pharmaceutical industry, where manufacturers are guaranteed market exclusivity by patents, the lack of transparency and accountability can result in excessive pricing and profiteering.

The Act introduces price and conduct<sup>34</sup> regulation to achieve greater transparency and limit rent-seeking behaviours. Specific provisions in the Act that establish the system of price and conduct regulation include:

- Sections 18A and 18B prohibit the use of financial and other incentives that drug companies use to ensure that their products were prescribed and dispensed.
- It also prohibits practices such as discounts and rebates that often resulted in cheaper medicines for people in larger metropolitan areas of the country, while denying the same benefits to poor people in rural areas, small towns and under-resourced areas.
- Section 22G authorises the setting up of a Pricing Committee, whose primary task is to advise the Minister of Health on a transparent pricing system. The Pricing Committee's work is guided by the General Regulations.
- Section 22G also introduces the concept of the single exit price (SEP) as “the only price at which manufacturers shall sell medicines... to any person other than the state”.<sup>35</sup>

The Pricing Regulations, issued by the Minister on the recommendation of the Pricing Committee, established the parameters of the transparent pricing system and a single exit price. They were promulgated on 30 April 2004, with effect from 2 May 2004. However, their full implementation was delayed by a dispute over their constitutionality that eventually reached the Constitutional Court.

### **Single Exit Price**

Under the Pricing Regulations, there is a two-stage approach to setting the SEP. In the first stage, the average price at which individual units of medicine were sold in the private sector in 2003 was established. Effectively, this means that each tablet or capsule of medicine and a

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<sup>33</sup> There is no publicly available data on parallel importation of medicines subsequent to 2006.

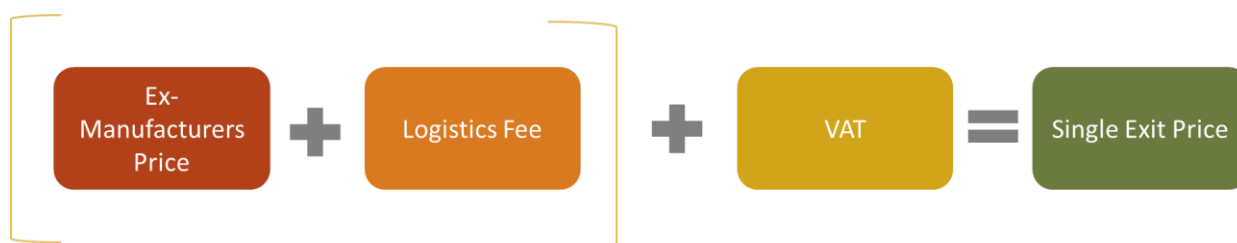
<sup>34</sup> Conduct regulation refers to all measures taken to regulate the behaviours of organisations, their employees and limit the adverse regulatory outcomes on individuals or the broader society. Thus, the Medicines and Related Substances Control Amendment Act prohibition of incentives to pharmacists and dispensing doctors is a form of conduct regulation.

<sup>35</sup> (Republic of South Africa, 1997)

particular dosage cost the same, regardless of package size. This component is referred to as the ex-manufacturer's price and is the first component of the SEP. The second component of the SEP is a logistics fee, negotiated between the manufacturer and distributor or wholesaler for their services. Finally, VAT is levied on the manufacturer's and logistics components of the price (see Figure 4).

SEP only applies to the private sector. The calculation of the SEP is relatively simple. The manufacturer price can be adjusted once a year. The Ministry of Health calculates the adjustment by accounting for inflation as well as exchange rate changes over the year. Manufacturers can choose whether to increase their prices by the adjustment put forth by the Department of Health. However, in cases where there has been some form of incremental innovation (e.g. change in dosage or ingredients), manufacturers can apply for an extraordinary increase.

**Figure 4: Components of the SEP**



Source: DNA Economics

In the second stage, the government was supposed to compare South African prices to comparator countries. Effectively, this regulation introduces external reference pricing as a method for adjusting medicine prices. External reference pricing is the practice of comparing pharmaceutical prices across countries. There are various methods applied and different country baskets used.<sup>36</sup> In October 2006, the National Department of Health published draft regulations on international benchmarking for public comment. The regulations were expected to be finalised in 2007 but were only published in May 2014 (7 years later) and outlined the proposed methodology for International Benchmarking of Medicine Prices in South Africa.<sup>37</sup> At the time of writing, these regulations had not come into effect because they are subject to a legal dispute.

The Pricing Regulations also gives the Director-General of Health certain powers to investigate whether medicines are reasonably priced, including a power to ask drug companies to justify

<sup>36</sup> (OECD, 2006)

<sup>37</sup> Medicines and Related Substance Act (Act No 101 of 1965) Regulations relating to a transparent pricing system for medicines for medicines and scheduled substances (benchmark methodology), May 2014.

their prices. While the Director-General can ask companies to explain their pricing strategies, he or she does not have a real power to take meaningful action after determining that a medicine price was unreasonable.

### **Appropriate professional fees**

Another driver of the cost of medicines in South Africa is the professional fees paid to different role-players in the value chain. Section 22G (2) of the Act allows the Minister to regulate:

- Wholesaler and distributor fees.
- Dispensing fees for pharmacists and dispensing health practitioners licensed under section 22C.
- Dispensing fees for “any other person selling Schedule 0 medicines”. For instance, vitamins are classified as Schedule 0 medicines.

However, the Pricing Regulations regulated dispensing fees only for pharmacists and dispensing health practitioners, drawing a clear distinction between the charges of pharmacists and those of dispensing doctors and other non-pharmacists. Fees for the sale of Schedule 0 medicines, and wholesaler and distributor fees, remained unregulated.

### **Promoting the use of generic medicines**

Generic substitution can reduce unnecessary expenditure on medicines. In the past, because of large financial incentives, clinicians were alleged to have prescribed branded medicines that have little to no added health benefits, but which cost significantly more than generic alternatives.

In keeping with the National Drug Policy, the Medicines Act aims to promote the use of generic medicines, especially once patent protection for brand name products has expired. It does this through the provisions on generic substitution in section 22F that also apply to generic products produced under a voluntary or compulsory licence. Section 22F uses the term “interchangeable multi-source medicines” to describe generic medicines.

The law requires that generic substitution should take place when a health care provider such as a doctor or nurse prescribes a branded product that costs the same or more than a generic alternative. In such a case, the person dispensing must:

- substitute the branded product with the generic alternative; and
- take reasonable steps to inform the prescribing healthcare provider that generic substitution has taken place.

The Medicines Act defines generics as “medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed”.



However, where generic substitution cannot take place, the branded product must be dispensed:

- if the prescribing healthcare provider has written that the branded medicine is non-substitutable.
- if the MCC (now SAHPRA) has stated that the branded medicine is non-substitutable.
- if the user clearly instructs the pharmacist or another health practitioner to dispense the branded product.

### **Fast-tracking registration of essential medicines**

The 1997 amendments to the Medicines Act introduced an Essential Drug List (EDL) to the regulatory regime. Medicines on this list are made available at no cost in the public health sector, depending on the appropriate level of care to be provided by a particular health facility. In 1998 the Department of Health published the Standard Treatment Guidelines and EDLs for Primary Health Care (updated in 2003), Hospital-Level Care (adults) and Hospital Level Care (paediatrics). These lists inform the purchasing decisions of national and provincial governments in South Africa, who are concurrently responsible for the delivery of health services. Under section 15(2)(b) of the Medicines Act, all medicines on the EDL, as well as all other medicines that “in the opinion of the Minister ... are essential for national health”, are “subject to such procedures as may be prescribed to expedite the registration”.<sup>38</sup>

#### **3.2.3 *The Patents Act (1978)***

The Patents Act (1978) seeks to protect the intellectual property rights of patent holders. Patent protections are particularly important in the pharmaceutical industry, where the costs of R&D are high, and the market exclusivity granted by patents allow companies to recoup the initial investments in R&D. However, unlike other consumer goods, medicines are essential products that provide life-saving treatment to the population, and therefore there are strong arguments for suspending intellectual property rights if it is in the public interest to do so.

The Patent Act (1978) recognises the need for some flexibility while safeguarding intellectual property rights. Section 56 of the Act allows “any interested person” to apply to the court for a compulsory licence. But section 56 may be used only when it can be shown “that the rights in a patent are being abused”. This provision makes it more challenging to use because patent abuse is often difficult to prove and is sometimes defined quite narrowly by courts.

Nevertheless, in terms of the TRIPS to which South Africa is a signatory, the government can issue a compulsory license to anyone provided it is in the greater public interest. As mentioned earlier, the TRIPS agreement leaves it up to the government to define the term public purpose. Some analysts argue that the term “public purpose” can be broadly defined to include the

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<sup>38</sup> (Republic of South Africa, 1997)



taking of steps that result in lower drug prices in the private sector and thereby increase access to essential medicines.

Even in cases where medicines are not excessively priced, a compulsory licence may also be used to ensure the sustainability of supply, by increasing the number of companies who manufacture the product. It appears that there is an increasing momentum to use the flexibility built into the TRIPS around the world for compulsory licensing of medicines. Kyung-Book Son and Tae-Jin Lee report that there have been about 108 attempts to issue compulsory licensing for 40 pharmaceuticals in 27 countries since 1995. Most of these attempts were in the developing world in Asian, Latin American and African countries, and mainly for HIV/AIDS medicines.<sup>39</sup>

While Section 56 is what many people refer to as TRIPS+, meaning that it provides greater patent protection than TRIPS requires. However, in South Africa, there is one example where section 56 has been used to help secure voluntary licences for the importation of generic medicines.

#### *3.2.4 The Competition Act (1998)*

The use of patents that grant exclusive access to markets might, in some instances have anti-competitive effects. While it is generally accepted that the exercise of rights in a patent does not automatically give rise to what the law recognises as "anti-competitive", a firm abusing the market power might fall foul of the Competition Act. There are two types of regulatory mechanisms in the Competition Act that control the exercise of rights in a patent – the "abuse of dominance" and "restrictive practices" provisions that give rise to harm. In terms of Sections 8 and 9 of the Competition Act, abuse of dominance and restrictive prices can take the form of excessive pricing, or charging prices that cannot be objectively justified, refusing to licence generic manufacturers, engaging in prohibited price discrimination.

#### *3.2.5 Public Finance Management Act (1999)*

The PFMA (1999) specifies how the government should procure goods and services. With regards to medicines, the PFMA uses competitive tendering to ensure the government gets the best price and value for money for their purchases. The PFMA and its regulations prescribe the supply chain management process in detail. At present, tenders for medicines and the EML are arranged nationally by the Department of Health in collaboration with the National Treasury, through a transversal contract, although provinces can issue their tenders for medicines not on the EML. Several reports, including one commissioned by the Department of Health, highlight the inefficiencies and delays in the procurement process that ultimately leads to stockouts in the public health system. These include weak demand and inventory management.<sup>40</sup> Nevertheless, it appears that pooled purchasing, where the state harnesses its buying power has helped to bring down the price of certain drugs such as HIV/AIDS

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<sup>39</sup> (Son & Lee, 2018)

<sup>40</sup> (MSH, 2010)

medicines. In addition to the PFMA, the Preference Procurement Framework Act (PPFA) outlines the requirements for procurement from black empowered enterprises.

Although the PFMA requires the government to choose the lowest cost option for medicines, this economic objective can come into conflict with an industrial policy that seeks to strengthen the domestic pharmaceutical industry by giving black firms preferential access to public sector markets, possibly at a premium price.

### *3.2.6 National Development Plan: 2030*

The National Development Plan: 2030 sets out the overarching objectives of the health system as follows:

- Raising the life expectancy of South Africans to at least 70 years;
- Ensuring that the generation of under the 20s is mostly free of HIV;
- Significantly reducing the burden of disease; and
- Achieving an infant mortality rate of fewer than 20 deaths per thousand live births, including an under-5 mortality rate of less than 30 per thousand<sup>41</sup>.

Access to affordable, appropriate and effective medicines is critical to the achievement of these objectives. In particular, given South African's quadruple burden of diseases and the emergence of Non-Communicable Diseases, the availability and affordability of chronic medication will become increasingly important in the health system.

## **3.3 Policy reforms and new developments**

### *3.3.1 National Health Insurance Bill*

The NHI Bill brings about significant reforms to the South African healthcare system. The Bill gives effect to Section 27 of the Constitution by establishing a financing mechanism to provide universal access to quality health care services for all South Africans, irrespective of their ability to pay. The draft NHI bill is a major step towards setting up the funding and financing mechanisms, and seeks to:

- Establish an NHI Fund and to set out its powers, functions and governance structures.
- Provide a framework for the strategic purchasing of health care services and medicines by the NHI Fund for all beneficiaries.
- Create mechanisms for the equitable, effective and efficient utilisation of the resources of the NHI Fund to meet the health needs of the population.

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<sup>41</sup> (National Planning Commission, 2012)

- Preclude or limit undesirable, unethical and unlawful practices in relation to the NHI Fund and its beneficiaries<sup>42</sup>.

While details on the exact functioning of the NHI fund are scant at this stage, the fund may have enough buying power to negotiate prices with manufacturers, wholesalers, retailers and dispensing clinicians. Moreover, under an NHI scheme, key issues such as how patients will be reimbursed for medications and co-payment arrangements (a form of risk-sharing) will need to be ironed out further.

Equally important, as a funder, the NHI will have to decide on the medicines that will be funded and their relative pharmacological benefits. Many of these decisions will fall to the proposed Office of Health Products Procurement (OHPP)<sup>43</sup>, a structure established in the Bill to handle the procurement of medicines and technology. The NHI Bill and subsequent amendments to S22G of the Medicines Act, now require the Minister to work in consultation with the OHPP when determining regulations including on the appointment of the pricing committee and setting of the SEP.<sup>44</sup>

This suggests that the SEP will continue to play a role in drug pricing policy going forward into the NHI. Expressly noted in the amendments to S22G(b) of the Act:

*“(b) by the substitution in subsection (3) for paragraph (a) of the following paragraph:*

*(a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed by the Office of Health Products Procurement contemplated in subsection (1), and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to **[any person other than the State] the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019, or any other person.**”<sup>45</sup>*[own emphasis]**

### 3.3.2 Legislated external reference pricing

In light of the amendments to the legislation that effectively craft a role for the SEP under the NHI, it is worthwhile considering its provision for External Reference Pricing (ERP), otherwise

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<sup>42</sup> Beneficiaries refer to all citizens irrespective of whether they use services or not. This is the essence of UHC for all, built on the foundation of equal access for equal need. This captures the paradigmatic shift away from a system where access is determined according to income and ability to pay towards one based on need.

<sup>43</sup> The Office of Health Products Procurement is located with the fund and its role is primarily to oversee the public procurement of health-related products. The functions of the Office include; setting the parameters for public procurement, retaining responsibility for the central facilitation and coordination of functions relating to the public procurement of health-related products and extend towards accreditation of service providers and ensuring compliance. See Section 38 of NHI Bill, accessed on: [https://www.gov.za/sites/default/files/gcis\\_document/201908/national-health-insurance-bill-b-11-2019.pdf](https://www.gov.za/sites/default/files/gcis_document/201908/national-health-insurance-bill-b-11-2019.pdf)

<sup>44</sup> (Republic of South Africa, 2019)

<sup>45</sup> (Republic of South Africa, 2019)

known as international benchmarking. As mentioned earlier, the External Reference Pricing allows countries to compare the national prices of medicines to international prices.

International benchmarking has been a source of contention between the pharmaceutical industry and policymakers. This is demonstrated by substantial delays in the process due to legal disputes and stiff lobbying. The methodology for international benchmarking was published as far back as 2007, updated in 2010 and the most recent Gazette published in 2014. The latest methodology (2014) is quite detailed but is still incomplete. For example, it only provides a methodology for originator drugs that have fewer than two generic competitors. A methodology for benchmarking originator drug prices for drugs with more than one generic competitor has yet to be published the Minister of Health.<sup>46</sup>

According to the latest gazette in 2014, the proposed methodology for ERP recommends that the lowest price for an originator drug across five countries – South Africa, Australia, Canada, New Zealand and Spain – be the benchmark.<sup>47</sup> The basket of countries may come under review biannually, and additional countries may be included in the basket. The government proposed a two-phase implementation for the ERP where the first phase will use the average price in the basket of countries as the benchmark for the first two years. The second phase will use the lowest price as the benchmark.<sup>48</sup>

The choice of countries was mainly determined by the countries' systems for pricing and regulating drugs. However, the choice and number of countries selected were constrained by access to reliable pricing data.<sup>49</sup> While the current selection of countries has adequate systems and accessible price data, the structure of their health systems, burden of disease and socioeconomic profile differs considerably from South Africa. As the burden of disease affects the demand for pharmaceuticals, it follows that the pricing outcomes will also be influenced by the volumes of medication needed in those countries.

The National Department of Health (NDoH) Pricing Committee views international benchmarking as a key intervention required to remove inappropriate price distortions resulting from market segmentation and structural weaknesses in the purchasing model prevalent in the South African private healthcare market.

The Committee is of the view that international benchmarking should be applied both to existing originator medicines and new originator medicines. It also recognises that the prices of different drugs are subject to distortion to greater or lesser degrees and that across the

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<sup>46</sup> (Government Gazette No. 37625, 2014)

<sup>47</sup> The benchmark is set at the ex-manufacturer price. The methodology stipulates that prices be converted to South African Rands, using the average exchange rate for the pair of countries over the past 12 months.

<sup>48</sup> (Government Gazette No. 37625, 2014)

<sup>49</sup> The 2010 Gazette listed characteristics (internal and external reference pricing, signatory to TRIPS, use of pharmacoeconomic evaluations, public spending on healthcare greater than 60% of total healthcare expenditure, and a member of the pharmaceutical inspection cooperation scheme) for choosing comparator countries. Countries such as Belgium, Hungary, The Netherlands, Poland and Portugal met such criteria but were excluded based on inaccessible medicine prices.

board price cuts or long-term price freezes will be unfair to products that are not presently distorted. For this reason, the Committee believes that international benchmarking is better to generalised price cuts as it is able to discriminate between prices with and without significant distortion.<sup>50</sup>

### **3.4 A critical review of the policy and legislative framework**

While South Africa has a reasonably good policy, legislation and regulation, there are slightly conflicting provisions within the regulatory framework that lead to uncertain and unintended outcomes. The regulatory framework has been particularly successful in promoting greater price transparency, reducing the prices of medicines in the private sector (through the SEP) and public sector (through the competitive tendering and pooled purchasing).

However, there remains some misalignment between IP laws, health legislation and the country's WTO commitments. Hence, while Section 15C(a) of the Medicines Act allows the Minister to override exclusive rights, the provisions of the Patents Act prevents compulsory licensing unless there is a clear case that the patent holder has abused their rights. Moreover, while the TRIPS agreement creates sufficient room for policymakers to pursue compulsory licencing in the public interest, as opposed to the stricter criterion of Section 56 of the Patents Act, so far, there is little progress in aligning the country's IP laws with international commitments. One explanation for this, articulated by some key informants during interviews, is that there is a lack of political will to bring into effect the provisions relating to compulsory licensing. Another view is that the Medicines Act itself is not clear enough on how and under what conditions compulsory licensing can take place.

The pharmaceutical pricing policy is distinct between the public and private sector. The PFMA, which governs how medicines are to be procured in the public sector, is based on a competitive tendering process. This inherently drives competition among suppliers to the state. Suppliers, therefore, have an incentive to price as low as possible; otherwise they face the risk of losing tenders. While market competition is beneficial in bringing down prices within the public sector, some argue that such price competition makes it difficult for local firms to compete with more significant international players. Moreover, some interviewees noted that the PFMA and PPPFA are not doing enough to encourage the development of local manufacturing capacity. Although the PPPFA awards points to black empowered manufacturers, the advantages conferred through preferential procurement may not be sufficient to overcome the price differences between local and international manufacturers.

Whereas competitive tendering the public sector drives down prices, there is an incentive for manufacturers to offer the highest possible price that they think the market will take as the SEP. Since the SEP stipulates the exact price at which drugs are to be sold – no matter the quantity – manufacturers have an incentive to price as high as would be financially viable when selling small quantities. This is one of the pitfalls of setting maximum price ceilings for goods

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<sup>50</sup> (Medicines and Related Substances Act, 2010)

and services with inelastic demand. Medicines tend to be price inelastic since they are necessities with few (if any) substitutes. On the demand side, this means that consumers will demand similar quantities even if prices were to increase but this also means that suppliers can increase prices without decreasing the quantity, they sell by much, increasing revenue. However, with the introduction of the regulated price (SEP), suppliers have an incentive to set the price as high as possible from the outset, especially for those products with few substitutes to capture the consumer surplus.

To prevent this, the legislative framework designed the SEP as a two-stage price-setting approach. Whereas, in the first stage, the manufacturers must submit their prices to the pricing committee, the second stage that involved an ERP was designed to moderate the prices, and reduce the risk of excessive pricing that could harm consumers through an international benchmarking exercise. However, the transition towards ERP has stalled as a result of the challenges to the legislation. Although there are other mechanisms in the legislation to foster price transparency, they are not particularly useful regulatory tools. For instance, although Director-General of Health has the power to investigate prices, he or she does not have a real power to take meaningful action after determining that the price of a medicine is unreasonable.

Similarly, the logistics fee is set by the Pricing Committee based on the manufacturer's submission. This leaves manufacturers with the flexibility to negotiate their logistics fee without any independent review or parameters to guide the setting of the logistics fee.

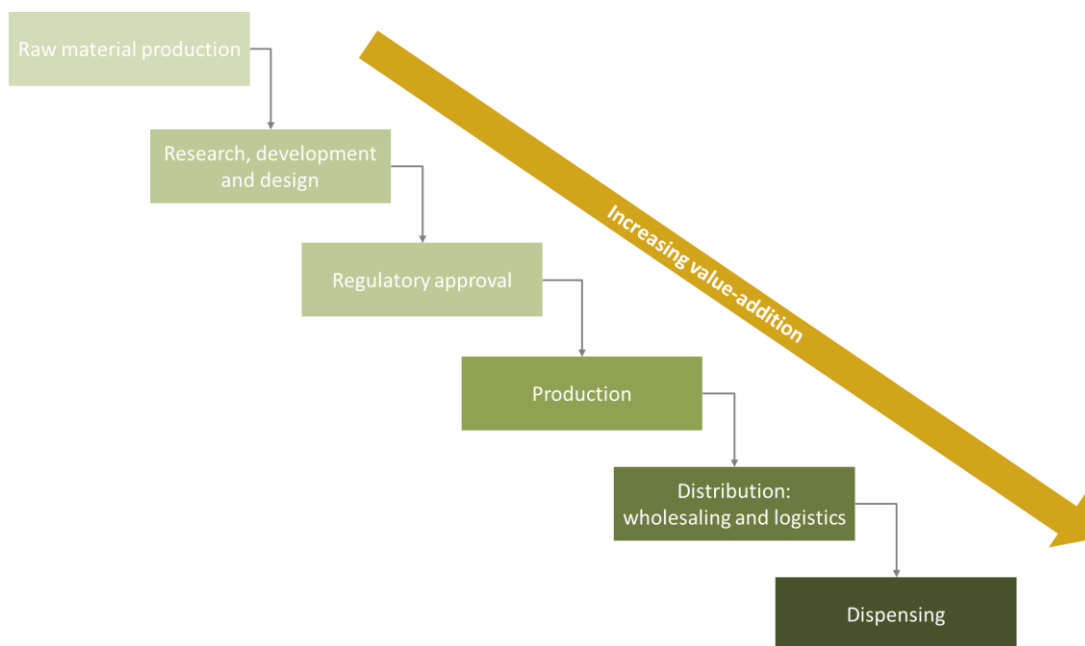
The structure of the dispensing fee, as determined by regulation, is regressive. Since the lowest tier starts at R113.71, the dispensing fee for the lowest price medication can be very high as a percentage of the SEP. As mentioned before, the dispensing fee accounts for a relatively higher proportion of the total cost of low-priced medicines. Thus, if generics are cheaper than originators, then it follows that the dispensing fee accounts for a higher percentage of the total cost of generics. That being said, the dispensing fee must also account for the need to compensate qualified professionals for dispensing.

## 4 THE PHARMACEUTICAL INDUSTRY IN SOUTH AFRICA

### 4.1 Understanding the pharmaceutical value chain

The pharmaceutical value chain consists of distinct yet related activities. A firm may be active through some or all activities across the value chain. The following diagram below captures the various value chain activities. While the key activities typically comprise of manufacturing, distribution and dispensing (retail), there are several activities contained within these broad activities that are worth highlighting for the South African context. This is not an exhaustive representation of a value chain; however, based on the research, the following key activities have been alluded to by various stakeholders.

**Figure 5: Key stages in the pharmaceutical value chain**



Source: DNA Economics

#### 4.1.1 Pharmaceutical raw materials

Pharmaceutical raw materials are the ingredients required to manufacture medicines. These raw materials include active ingredients such as API's, inactive ingredients such as excipients and packaging materials. In pharmaceutical production, API's are responsible for drug action. Globally, China and India are the leading producers of raw materials and API's, and most drug manufacturers tend to purchase raw materials from these two countries. There is some supply from Germany and Switzerland; however, this is minimal in relation to supply from Asia. North America, Europe and Asia primarily supply excipients which are essentially drug carriers. Most of the packaging materials come from North America and Europe.

## 4.1.2 Manufacturing

The manufacturing stage in the value chain consists of different activities: research and design, regulatory approval, clinical trials and production.

### 4.1.2.1 Research, Development and Design

Once a manufacturer has identified a candidate drug, the research and design process occurs. In this phase, manufacturers will review a substantial body of medical information (previous research, outcomes of clinical trials etc.) and undertake several tests to establish the therapeutic suitability of the drug. For originators, the R&D cost differs substantially to generics as there is an exploratory element to the research, whereas for generics, the cost of R&D is sunk as the drug is generally off patent. Globally, most R&D activities are conducted at universities. For instance, the Department of Science and Technology has an incubator at North-West University, which is researching clinical pathways.

### 4.1.2.2 Regulatory approval

Prior to the commercialization of the drug, regulatory approval is required. To register a drug, SAPHRA will require information relating to safety, efficacy and quality.

The regulator also sets out the legal framework for clinical trials and is responsible for the regulation of the clinical trial. No drugs will be approved until clinical trials have been conducted and outcomes vetted by the regulator. While clinical trials can take on different types (for example, randomised control trials versus blind trials); generally, they comprise of four phases. The Department of Health identifies the following four phases as part of good clinical practice.<sup>51</sup>

- **Phase 1** is typically the first trials of a new active ingredient or formulation and is often carried out on healthy participants. This phase seeks to establish a preliminary evaluation of safety within the general population.
- **Phase 2** trials are conducted on a limited number of participants, and in some instances within a comparative (placebo-controlled design). During this phase, the therapeutic activity and the effects of the drug are established, and the appropriate dosages or regimens are determined.
- **Phase 3** trials are conducted in larger patient groups and seek to establish the short- and long-term safety-efficacy balance of formulations of the active ingredient, and its overall therapeutic value. Under this phase, the pattern and profile of any adverse reactions from the drug being investigated. Phase 3 trials require the trial environment to be close as possible to the normal conditions of use.

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<sup>51</sup> (DOH, 2006)



- **Phase 4** trials are studies which are conducted after the marketing of the product. During this phase, manufacturers will assess the efficacy of the drug relative to the basis on which the drug was approved.

During the regulatory approval phase manufacturers may also apply for patent protection. However, this process is not confined to this phase, and patent protection may be sought before manufacturing (albeit subject to regulatory approval).

#### **4.1.2.3 Production**

Production of pharmaceuticals can occur through different arrangements. In the first instance, there are vertically integrated firms which self-produce and thereby retain responsibility for all related processes. Firms may offshore production to other countries, where the manufacturer will obtain a finished and packaged product for sale into the respective market. Firms may also engage in fixed local manufacturing, whereby volumes are outsourced to local manufacturers subject to service level agreements.

#### **4.1.2.4 Distribution (wholesaling and logistics)**

Post manufacturing, the distribution of pharmaceuticals occurs. This includes the transportation and handling of medicines from manufacturer to end-user, either a hospital, retail pharmacy, or dispensing doctor. Factors such as the nature of the medication, whether special storage conditions are required (i.e. temperature-controlled storage for vaccines), or geography can impact on distribution. Wholesaling of pharmaceuticals can occur directly to the end-user through an in-house distribution arm or indirectly through a third-party supplier. Most large manufacturers do however possess an in-house distribution arm which effectively purchases the product from the manufacturing arm for distribution to the end-user.

#### **4.1.2.5 Dispensing/Retail**

This entails the sale of medication to patients, which can be further delineated between prescription or over the counter (OTC) medication. At this level, pharmacies play an integral role, in terms of providing the correct dosage and form, providing generic substitution advice and ensuring patient understanding and awareness.

## **4.2 Size of industry**

The South African pharmaceutical industry, being the largest in Africa, is estimated to be worth approximately R50 billion.<sup>52</sup> Around 30% of expenditure on pharmaceuticals accrue to the public sector, although the exact amount spent on pharmaceuticals and the percentage split

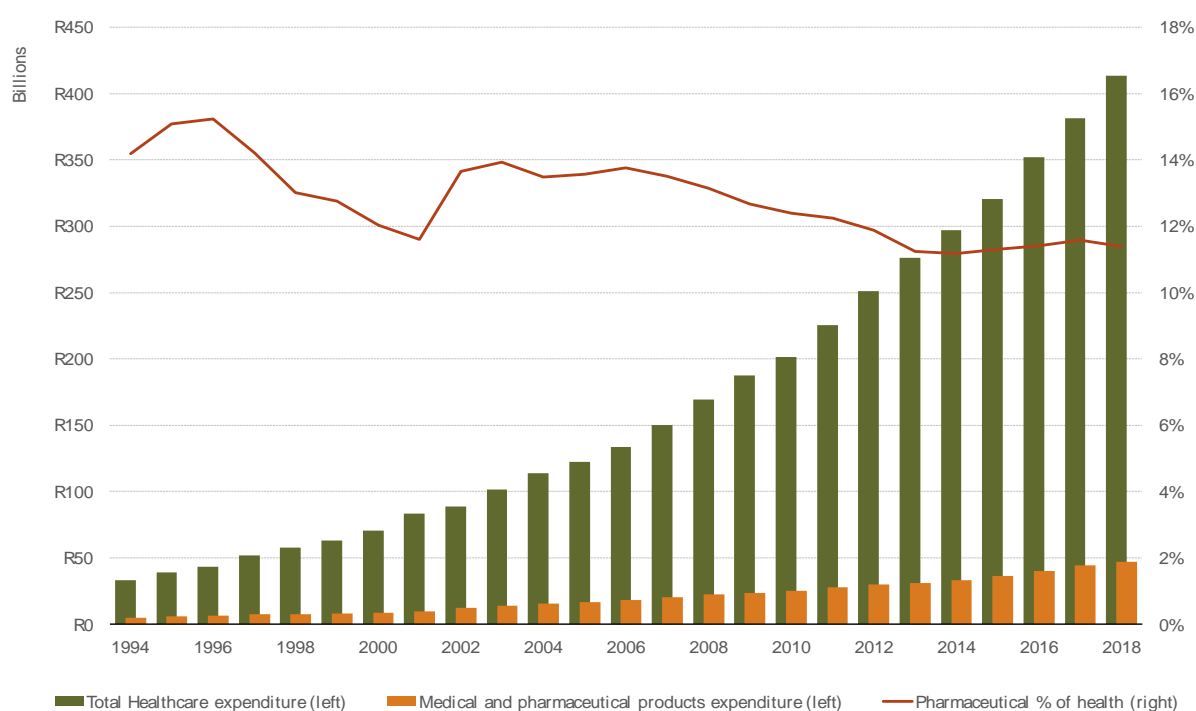
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<sup>52</sup> (Industry Insights, 2019)

between the public and private sector is not known.<sup>53</sup> In 2015, the DTI estimated the industry to be valued at R44 billion, with the public sector only accounting for 13.3%.<sup>54,55</sup>

Figure 6 shows total healthcare and pharmaceuticals expenditure in South Africa and the share of pharmaceuticals in healthcare between 1994 and 2019.<sup>56</sup> Pharmaceutical expenditure as a percentage of total healthcare has declined since the implementation of the SEP in 2004 (13.49%) to 11.38% in 2018. This might suggest that the SEP has managed to bring down medicine prices, although without information on the volumes of pharmaceutical products sold, we cannot attribute the decline in expenditure to the SEP.

**Figure 6: Total healthcare and pharmaceuticals expenditure, 1994-2019**



Source: SARB, 2019

South Africa ranks fifth in Africa for the highest per capita expenditure on pharmaceuticals.<sup>57</sup> Per capita expenditure has shown an increasing trend over the period between 1994 and 2018, depicted in Figure 7. The figure illustrates that real growth in expenditure has been positive since 2011, reaching a high of 5.99% in 2016. The growth in pharmaceutical expenditure is

<sup>53</sup> (The Helen Suzman Foundation, 2018)

<sup>54</sup> (the dti, 2015)

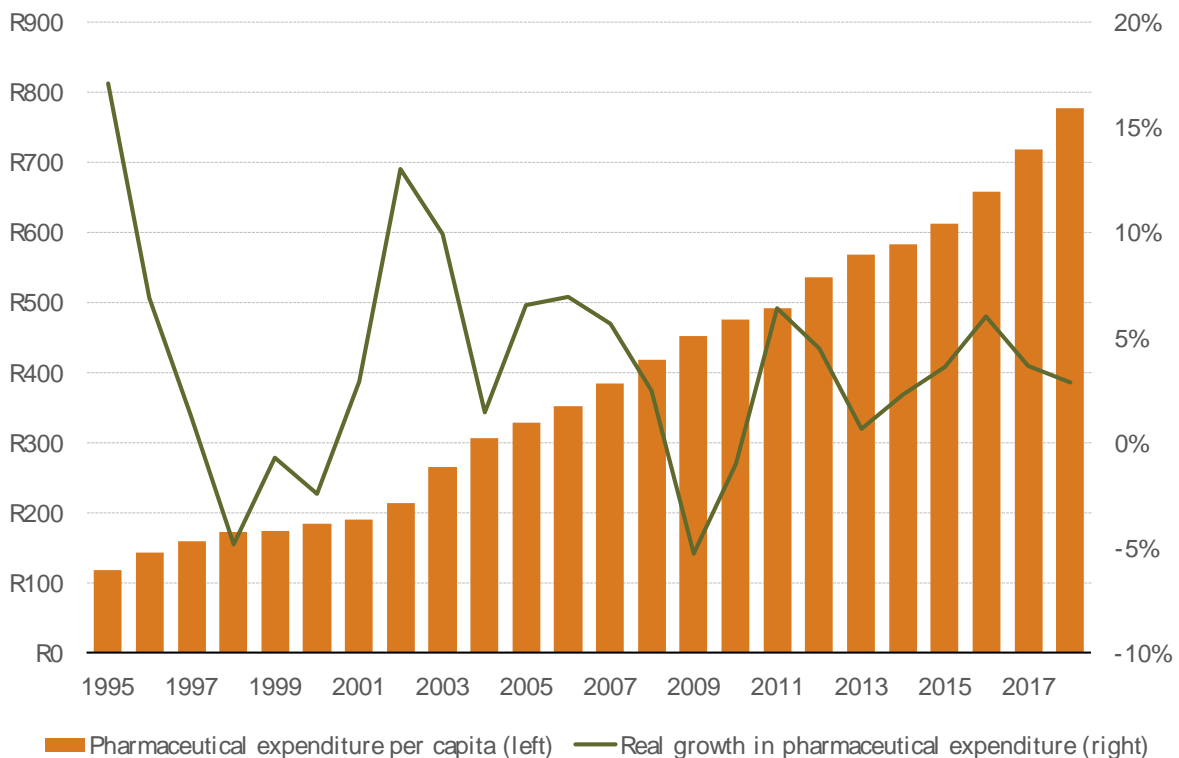
<sup>55</sup> Other estimates suggest that the State's share of pharmaceutical is 18% (Planting, 2018).

<sup>56</sup> Time series data on pharmaceutical expenditure only is not available. The SARB provides household consumption data on pharmaceuticals inclusive of medical products. SARB data on pharmaceutical expenditure is narrower than Stat SA's definition. These estimates are in line with other approximations of pharmaceuticals expenditure.

<sup>57</sup> (the dti, 2015)

likely to have increased in 2019, relative to 2018, since the annual Single Exit Price Adjustment (SEPA) gazetted for 2019 was 3.78% whereas that for 2018 was 1.2%.<sup>58</sup> The higher price adjustment is partly a reflection of the depreciation of the South African rand against our major trading partners.

**Figure 7: Per capita pharmaceutical expenditure and real growth, 1994-2018**



Source: SARB, 2019

The trend in real growth of pharmaceutical expenditure reflects the expected consequence of the SEP. In the years following SEP implementation, growth rates declined such that even negative rates were recorded for 2009 (-5.28%) and 2010 (-0.99%). Since then, real growth has been positive, potentially indicating increased consumption of pharmaceutical products. The rising real growth in pharmaceutical expenditure also coincides with a period where the depreciation of the rand against all major currency from the countries where South Africa imports pharmaceutical products.

### 4.3 Market structure

As discussed earlier in this report, the pharmaceutical value chain consists of distinct yet related activities including raw material production, research and development, manufacturing, wholesaling, distribution and marketing. There is very little information in the public domain on the structure of the markets in each stage of the value chain. However, the pharmaceutical

<sup>58</sup> (Planting, 2018).

industry does, however, appear to be highly fragmented with a diverse range of players active at some or across all levels of the value chain. As at 2015, approximately 276 companies were licenced to import, manufacture, distribute or export pharmaceuticals.<sup>59</sup>

The manufacturing and retail levels exhibit high levels of concentration. At the manufacturing level, most manufacturers are active across the four therapeutic categories analysed in this report (i.e. Anti-retrovirals, Diabetes Mellitus, Cardiac Therapy and TB), some possess stronger market positions within specific therapeutic categories, which implies that there may be high levels of concentration in the supply of certain drugs. Despite the lack of information in the public domain, there are some useful insights about the structure of the pharmaceutical industry in the Health Market Inquiry report and the Helen Suzman Foundation submission to the health inquiry.

In 2018, the Competition Commission published a Herfindahl-Hirschman Index (HHI) of 3 003 for the pharmaceutical sector.<sup>60</sup><sup>61</sup> The market is concentrated at the manufacturing level with Aspen Pharmacare and Adcock Ingram accounting for 16% and 10% of market share respectively. Market share data by the originator and generic brands are not readily available in the public domain. However, 2015 estimates suggested that generics were valued at R11.7 billion and originators at R16 billion, representing 35.3% and 49.4% of the market in value and 49.4% and 29.7% in volume, respectively.<sup>62</sup> It is assumed that the rest of the market was made up of Over-the-Counter (OTC) drugs, biologics and biosimilars.

Similarly, in 2017, the Helen Suzman foundation found there were 173 manufacturers supplying medicines to the public and private sectors.<sup>63</sup> Figure 8 shows the suppliers' product mix, which indicates a relatively similar number of the originator and generic suppliers, although this does not account for the size of companies.

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<sup>59</sup> (The Helen Suzman Foundation, 2018)

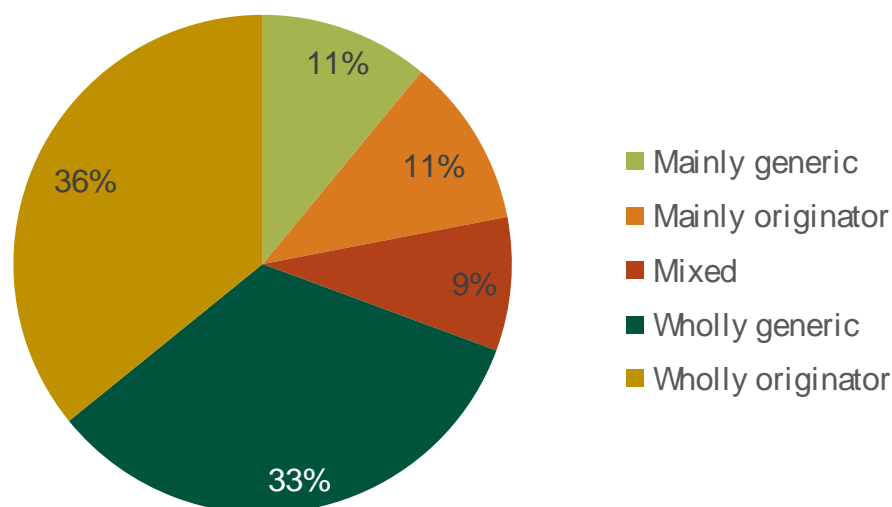
<sup>60</sup> The Commission states that a highly concentrated industry exhibits an HHI greater than 2 500 (Competition Commission, 2018).

<sup>61</sup> The Herfindahl-Hirschman Index (HHI) is a measure of market concentration that range from close to zero to 10,000. A market with an HHI of less than 1,500 is considered to be a competitive marketplace, an HHI of 1,500 to 2,500 to be a moderately concentrated marketplace, and an HHI of 2,500 or greater to be a highly concentrated marketplace.

<sup>62</sup> (the dti, 2015)

<sup>63</sup> Manufacturers are listed on the Master Procurement Catalogue (public) and the Medicine Price Registry (private).

**Figure 8: Pharmaceutical manufacturers by product supplied, 2017**



Source: Helen Suzman Foundation, 2017

Note: Mainly=more than 80%; Mixed=at least 20% generics and at least 20% originators.

Given South Africa’s current two-tiered healthcare system, Table 1 attempts to compare the extent of the originator and generic supply into the public and private sectors. The table revealed that, in 2017, all manufacturers had products listed in the public and private sector, limiting the extent to which we were able to assess the interplay between originator/generic usage within the two sectors. Nevertheless, in percentage terms, there is an indication of more significant supply of originators strictly into the private sector.

**Table 1: Number of originator and generics products by sector, 2017**

Sector	Total Originators	Total Generics
Public and Private	2 954	3 274
Private only	1 175	1 841
<b>Total</b>	<b>4 129</b>	<b>5 115</b>

Source: Helen Suzman Foundation, 2019

In the distribution component of the value chain, there are firms which are not integrated but distribute pharmaceuticals. There is almost no information on the distribution of pharmaceutical in South Africa in the public domain. Nevertheless, there is some evidence to suggest that the market for distribution is much more fragmented but also more competitive.

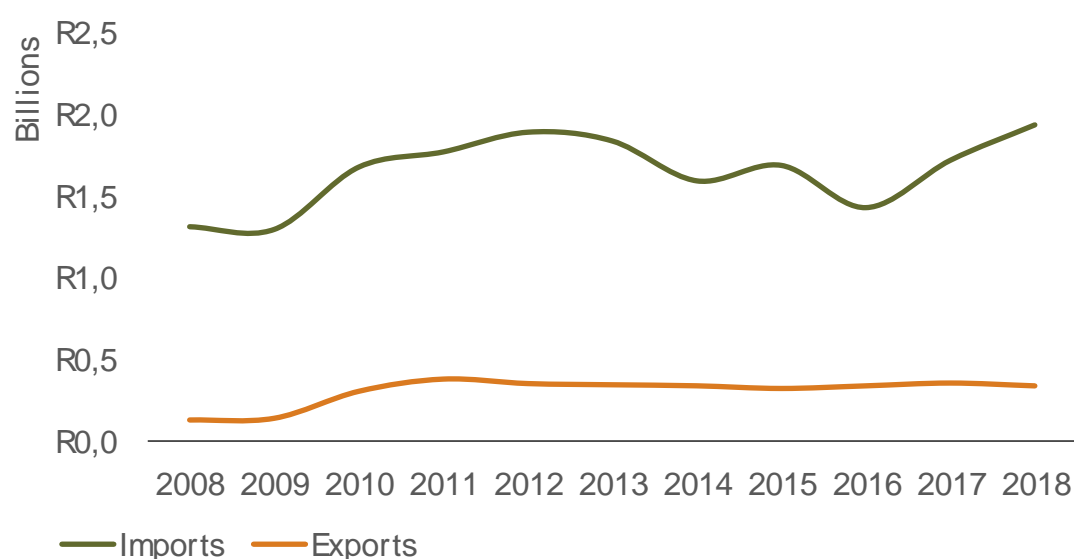
At the dispensing (retail) level, previous studies show a high market concentration with Dis-Chem and Clicks, accounting for 22% and 20.8% of the retail market, respectively. Estimates provided by a retailer corroborates this, with Dischem and Click estimated to have a combined market share of approximately 40%, independents cumulatively 48%, and Pick n Pay, Shoprite Medirite and Spar having a combined market share of 2%.

#### 4.4 Trade in pharmaceuticals

Local manufacture of medicines is limited to ARVs and select essential medicines (generics). Multinational corporations using South Africa as a base for trade within the region may be attracted to South Africa as it is the only SADC nation which meets the WHO’s Good Manufacturing Standards.<sup>64</sup>

Nevertheless, limited manufacturing capacity is reflected in South Africa’s reliance on imports, which peaked at R1.93 billion in 2018, depicted in Figure 9. Exports are quite low (R0.33 billion), the majority of which go to SADC countries, as shown in Figure 11. As such, South Africa faces a large and seemingly burgeoning trade deficit for pharmaceuticals.

**Figure 9: Imports and exports for South Africa, 2008-2018**



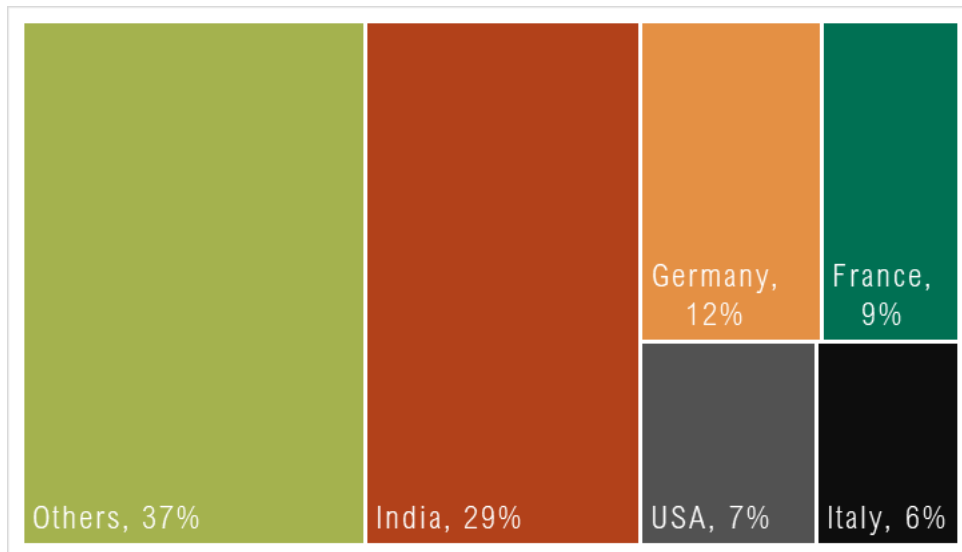
Source: ITC Trade Map, 2019

In its broadest categorisation, pharmaceuticals constitute South Africa’s sixth-largest import.<sup>65</sup> The top five countries from which South Africa imported pharmaceuticals in 2018 was India, Germany, France, United States of America and Italy. These nations accounted for 63% of total imports, with India alone accounting for 29%. Overall, trade in pharmaceuticals contributes to the trade deficit, with a single BRICS (India) member state supplying almost 1.7 times more than total exports.

<sup>64</sup> (the dti, 2015)

<sup>65</sup> The estimates presented in Figure 9 exclude items such as cosmetics and vitamins that do not fall within the scope of this study.

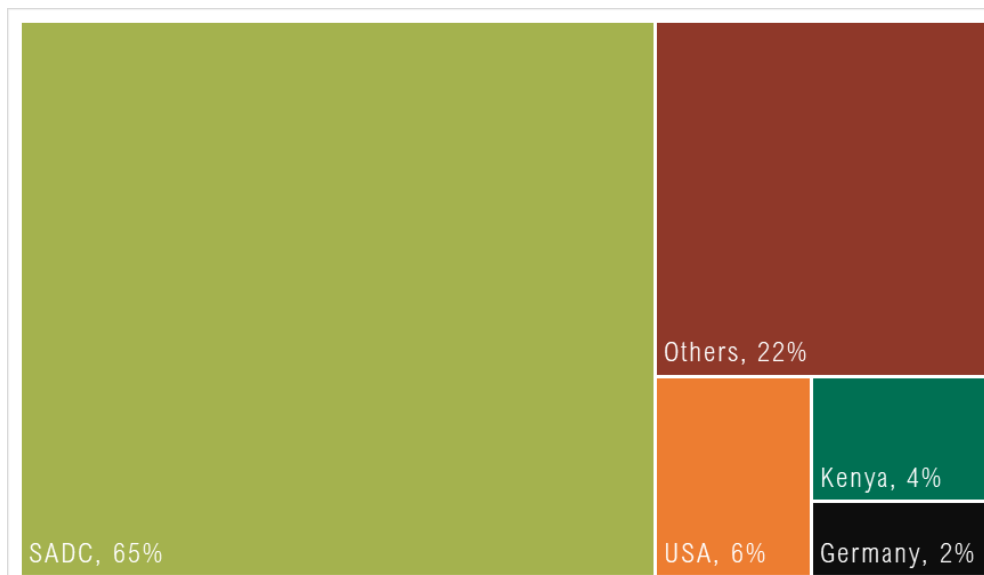
**Figure 10: South African imports by country, 2018**



Source: ITC Trade Map, 2019

As expected, South Africa exports pharmaceutical products to the rest of the SADC region. While the value of pharmaceutical exports is low, these trade statistics might also include re-exports, and therefore are not a reliable estimate of how many medicines manufactured in South Africa are exported to other markets.

**Figure 11: South African exports by country, 2018**

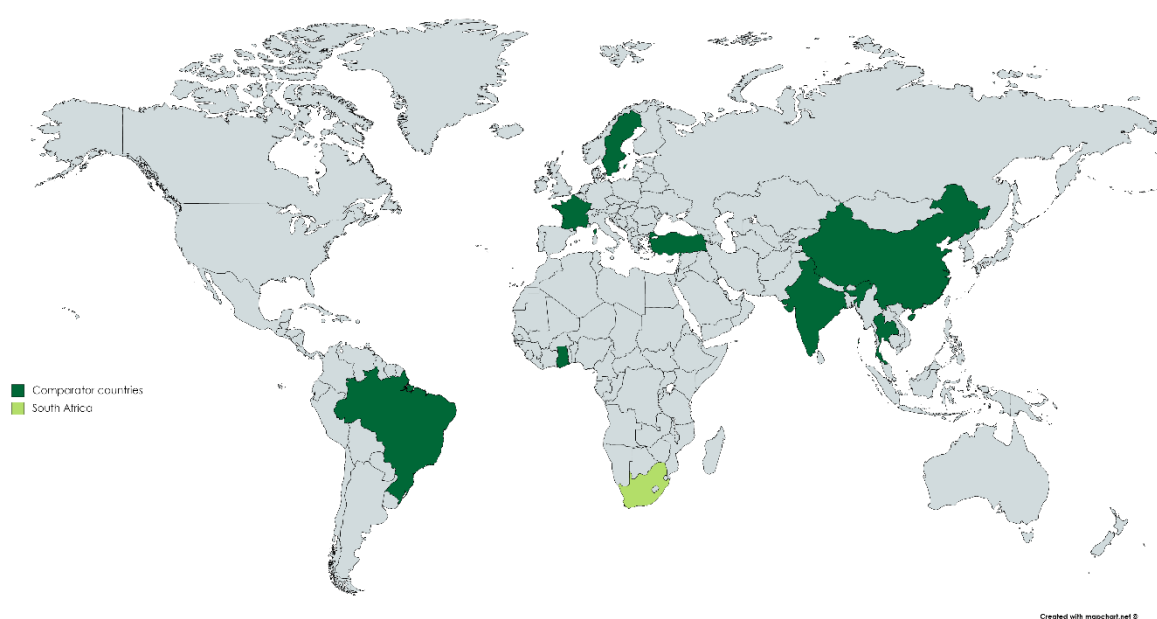


Source: ITC Trade Map, 2019

## 5 INTERNATIONAL BENCHMARKING

This section compares the pharmaceutical pricing policies and regulatory framework in South Africa to eight countries. The comparator countries were selected based on the type of healthcare system (unified versus pluralistic), level of development, strategic contribution of the pharmaceutical industry and regulatory approaches. Eight countries were selected for the country comparison, including France, China, Thailand, India, Brazil, Sweden, Ghana and Turkey (see Figure 12). The literature review, submitted as a separate report, provides a detailed analysis of the pharmaceutical pricing policies in each country. This section summarises the main lessons and findings from the literature review.

**Figure 12: Comparator countries**



Source: DNA Economics

### 5.1 Overview of country health systems

The type of health system influences pharmaceutical pricing policies. In the table below, we describe the main features of the health system in each of the comparator countries.

**Figure 13: Key features and characteristics of comparator countries**

Country	Key features and characteristics
France	The French healthcare system, taking the form of a statutory national healthcare scheme, consists of three main types of health insurance funds which are financed via general taxation. The funds cover both public and private healthcare providers inclusive of doctors and other medical specialists. There are 101 primary health insurance funds, 1 common social security fund and 5 social security funds. The National Agency for the Safety of Medicines and Health Products regulates pharmaceutical regulation and provides market authorisation.
China	China has three main insurance schemes for: (1) rural residents, (2) unemployed urban residents and (3) employed and retired urban residents. Funding across schemes varies



Country	Key features and characteristics
	substantially and so too do the scheme benefits. The four authorities that exert the most influences on the pharmaceutical industry are: The National Health and Family Planning Commission (NHFPC), the National Development and Reform Commission (NDRC), the Ministry of Human Resources and Social Security (MoHRSS) and the Chinese Food and Drug Administration (CFDA).
Thailand	Thailand's health system consists of both public and private health services. Since the early 2000's, Thailand's health sector underwent reforms, primarily to restructure the national insurance market. Currently, national insurance is provided/overseen by 3 schemes; the civil servants' medical scheme under the finance ministry; the social security scheme under the labour ministry and universal coverage scheme under the public health ministry <sup>66</sup> .
India	India has a two-tiered/mixed healthcare system comprising of both public and private healthcare provision. The public health sector is focused on providing primary healthcare needs, mainly to rural areas. Private sector provision is concentrated mainly on secondary and tertiary services, to citizens in the urban/metro areas. The private sector dominates India's healthcare sector with an estimated 80% of total services provided through this channel. The National Pharmaceutical Pricing Authority (NPPA) ensures that the Drug Price Control Policy (DCPO) is implemented.
Brazil	Health care provision occurs through a dual system, of public and private healthcare providers. Brazil provides free universal healthcare (Unified Health System) to its citizens as a constitutional right. The Unified Health system focuses on primary healthcare which is offered free at the point of services. Additionally, the Unified Health systems provide various hospital services including heart surgery, medical imaging and laboratory diagnostics. It also focusses on vaccinations, prevention campaigns, basic dental care and 90% subsidisation of many essential medicines. Public health care services are provided through a combination of public and public/private partnerships. Private healthcare provision is concentrated mainly in hospitals and through some walk-in clinics. Pharmaceutical prices in Brazil are the responsibility of the Câmara de Regulação do Mercado de Medicamentos (CMED). The CMED sets prices and exerts direct control.
Ghana	Ghana implemented NHI in 2003 to improve access and reduce the economic burden on households. Under NHI, providers have to be accredited and are reimbursed using negotiated rates. Private providers, however, cannot be forced or co-opted into the NHI.
Sweden	The Swedish healthcare system is predominantly a tax-funded system with PHC as its bedrock at a decentralised county council and regional level <sup>67</sup> . The system is, in essence, a National Health Service system premised on the notion of equal access for equal need. The health system is premised on principles of human value, need and social solidarity <sup>68</sup> and most importantly – especially with regards medicine pricing – cost-effectiveness analysis. Healthcare is not entirely free at the point of service delivery, and co-payments do exist at different levels with caps in place to protect the public. At the council level, population members can register with either private or public providers accredited to county councils for the provision of PHC. Most hospital care is publicly provided, and in some cases where there are gaps, private hospital care is contracted.
Turkey	Turkey began the implementation of the Turkish Health Transformation Programme (HTP) in 2003, moving towards UHC under a single-payer mechanism. <sup>69</sup> The health sector reform was part of a system overhaul with a conscious shift towards centralised healthcare financing. Most healthcare was provided on an out-of-pocket basis, and the transition saw a shift towards the family physician model reimbursed through the single-payer arrangement.

<sup>66</sup> (World Health Organization, 2019)

<sup>67</sup>[https://www.tlv.se/download/18.60fc571b1618606ac975dd4d/1533558140914/international\\_prisjamforelse\\_av\\_lakemedel\\_2017\\_rapport\\_engelska180213.pdf](https://www.tlv.se/download/18.60fc571b1618606ac975dd4d/1533558140914/international_prisjamforelse_av_lakemedel_2017_rapport_engelska180213.pdf)

<sup>68</sup> Paris, V. and A. Belloni (2013), "Value in Pharmaceutical Pricing", OECD Health Working Papers, No. 63, OECD

<sup>69</sup> (Yilmaz, et al, 2016)

Country	Key features and characteristics

## 5.2 Pricing policies differ by type of health system

Except for India and Thailand, other comparator countries had some form of National Health System. Whereas each national health system is configured differently ranging from France's 106 distinct funders to Turkey's single-payer system, they all aim to achieve universal coverage. There is some scope of private sector participation within national health systems, as in the case of Brazil, where 25% of the population has complementary private health insurance. Within these national health systems, funders have monopsonistic power and frequently leverage their bulk purchasing power to negotiate prices with manufacturers. In Turkey for instance, the SSI – the single-payer – has the power to negotiate prices with pharmaceutical companies.<sup>70</sup> In France, with its multiple funds, the prices of medicines that offer significant therapeutic benefits are set by the National Agency for the Safety of Medicines and Health Products using external reference pricing which compares prices in France to prices of identical products in Germany, the United Kingdom, Italy and Spain.<sup>71</sup>

Like South Africa, India and Thailand have pluralistic systems where the public and private health sectors operate side by side. In a similar way to South Africa, India exerts direct control over drug prices to curb the cost of medicines. Under its Drug Pricing Control Order (DCPO), the National Pharmaceutical Pricing Authority sets the ceiling price for each drug. The regulated price is fixed at the weighted average price of brands that have more than 1% market share. Medicine pricing in Thailand is mostly unregulated, and as a result, there is considerable variability in the prices of drugs within the public and private sectors. Even for the lowest-priced generics, median mark-ups were 80% in the public sector and 96% in the private sector, making expensive relatively expensive in Thailand.<sup>72</sup> In many ways, the situation in Thailand was similar to that of South Africa before the introduction of the SEP.

## 5.3 External reference pricing tends to control the price

According to the WHO, external reference pricing (ERP) can be defined as follows: *“the practice of using the price(s) of a medicine in one or several countries to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country”*.<sup>73</sup> Therefore, changes in drug prices in one country can affect the price in other countries.

Countries included in the reference basket must be comparable to the referencing country to ensure ERP is appropriate. Comparability tends to be determined by countries' pricing systems, economic status and burden of disease. Further crucial aspects are whether prices

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<sup>70</sup> (Yilmaz, et al, 2016)

<sup>71</sup> (Ruggeri & Nolte, 2013)

<sup>72</sup> (Sooksriwong, et al., 2009)

<sup>73</sup> (WHO, 2013)

are for exact comparator drugs and if published prices are actual versus negotiated prices.<sup>74</sup> Countries are selected on multiple criteria. Whereas, Canada's ERP methodology selected countries having similar economic indicators as comparators, Mexico uses a varying basket of countries per drug. Countries which have the highest sales for each drug are included in Mexico's basket of country comparators.<sup>75</sup>

France, Turkey and Brazil all use a form of ERP. Although the methodologies for calculating the external reference pricing differ, all three countries have pricing policies to prevent them from paying more than their comparison countries. While ERP is used to set the maximum allowable price for new medicines in Brazil<sup>76</sup>, Turkey's SSI uses this methodology to inform price negotiations with manufacturers. Likewise, in France, the Economic Committee for Health Products uses this information to negotiate prices for drugs with manufacturers for medicines that are reimbursed by funders.<sup>77</sup> In France, ERP ensures quick access to innovative drugs of moderate and high therapeutic value and limits higher expenditure for low therapeutic value-added drugs.<sup>78</sup> Aside from being a tool for price negotiation, ERP is also used to determine the reimbursable amounts paid by funders.

The reference price is often used to price generics as well, albeit at a lower price. In Brazil, for example, the regulation stipulates that generics must be priced at least 35% lower than the reference price for originator medication.<sup>79</sup> In France, generics are priced 60% below the on-patent originator reference price.<sup>80</sup>

ERP promotes transparency and is generally associated with lower prices. It is also simple to implement relative to alternative pricing mechanisms such as value-based pricing. ERP, however, can be associated with negative consequences. One such study found that ERP restricted R&D in high-income countries and delayed access in lower-income countries.<sup>81</sup> In general, ERP appears to reduce information asymmetries between funders and manufacturers, giving the former the information they need to negotiate prices.

#### **5.4 Generic substitution is encouraged as a form of conduct regulation**

Pharmaceutical products are unique in many respects. The decision to buy a drug is made by the physician who prescribes it, and seldom the user. This leads to a situation where the physician makes the purchasing decision and might not always prescribe the most cost-effective choice of drug for the principal, the patient. Physician behaviours are influenced by a

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<sup>74</sup> (WHO, 2015)

<sup>75</sup> (OECD, 2006)

<sup>76</sup> (Bangalee & Suleman, 2018) quoting (Ultrapar, 2016)

<sup>77</sup> (Mateu & Guerlain, 2019)

<sup>78</sup> (Ruggeri & Nolte, 2013)

<sup>79</sup> (Bangalee & Suleman, 2018)

<sup>80</sup> (Ruggeri & Nolte, 2013)

<sup>81</sup> (Persson & Jonsson, 2016)

range of factors, including promotional activities of pharmaceutical companies and prescription guidelines.

Hence, while price regulation is necessary, it is not enough by itself to bring about changes to prices. Conduct regulation that is a regulation that promotes changes in behaviours is equally essential. Five of the eight countries all have policies that encourage generic substitution. In Sweden, community pharmacists are obliged to dispense the least expensive generic medicine or parallel import medicine available in the pharmacy, unless the prescribers disallow substitution.

Although not a necessary form of regulation, the Brazilian government has actively promoted generic competition that has led to more aggressive discounting in pharmaceutical prices.<sup>82</sup> In Turkey's single-payer system, co-payments incentivise consumers to use generics by increasing the percentage of the cost of medicines covered if they opt for generics. Despite the clear economic benefits and imperative that comes with generic substitution, the experience is mixed, and the impacts on patients are likely to differ across countries.

## **5.5 Rebates and zero mark-up policies also reduce the cost of medicines to patients**

France and China use a range of regulatory approaches to limit the cost of medicines. Pharmaceutical firm revenues are controlled in France using rebates, for the market as a whole and therapeutic classes.<sup>83</sup> Rebates require manufacturers to take responsibility for (over) marketing their products. French authorities gauge an appropriate volume of sales for certain drugs which is intended to promote efficiency in the market and prevent overuse<sup>84</sup>. To reduce OOP, China has implemented zero mark-up policies on medicines listed in the National Essential Medicine System. A zero-mark up policy aims to curb the incentive by doctors (whose remuneration is linked to hospital profits) to over-prescribe medication and reduce the high levels of OOP in China.<sup>85</sup>

## **5.6 Value-based pricing is emerging as a new form of price regulation**

Only Sweden from the group of comparator countries has implemented a full value-based pricing system. Sweden has moved away from reference pricing and uses cost-effectiveness analysis to inform value-based pricing with regards to new drugs entering the market, as well as pricing originators and generics, with generic substitution a key facet of medicine pricing in the country. Whereas value-based pricing is considerably more challenging to implement than external reference pricing methodologies, it can help countries determine the clinical and cost-effectiveness of new drugs, and price them in a way that maximises societal welfare. To implement value-based pricing, countries need a considerable capacity to conduct the cost-

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<sup>82</sup> (Bangalee & Suleman, 2018)

<sup>83</sup> (Morgan, 2016)

<sup>84</sup> (Sauvage, 2008)

<sup>85</sup> (Hu & Mossialos, 2016)

effectiveness and clinical assessments to determine the explicit value of the drug to patients. Value-based pricing also plays an important role in determining which drugs are included on EDLs.

## 5.7 Patents laws are changing to allow for compulsory licensing

Two of the eight countries are reviewing or updating their patent laws to allow for compulsory licensing. Thailand has revised its patent law to provide for compulsory licensing of drugs. This ensures that for essential drugs, the government is no longer held captive by private manufacturers.<sup>86</sup> Between 1970 and 2005, India did not have any product patent legislation to protect the intellectual property rights of patent holders. Without restrictions on the ability to replicate intellectual property, the Indian pharmaceutical industry developed quickly over this period. But with India, assenting to the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the country was required to promulgate a patent law. Revisions to the Patents Act were made to allow for compulsory licensing. In 2012, the Indian government issued the country's first compulsory license against a foreign company's patented drug.

## 5.8 How do local medicine prices compare to international prices?

This section compares the South African private sector unit prices (SEP) to international prices.<sup>87</sup> Comparator drugs were selected based on the closest match to account for differences in countries' drug profiles. All prices were collected in December 2019 from country/state formularies, which are frequently updated.<sup>88</sup> To ensure that international prices are comparable to South African ones, the research team estimated the retail prices that the end-user would pay. This includes the manufacturer's prices, dispensing fees and any applicable taxes on goods. The results of the analysis are reported by therapeutic categories: cardiac therapy, diabetes, ARVs and TB. Note that the comparison countries in this section differ to those used for the policy framework comparisons in the previous section because price data is not always publicly available for all these countries.

Price comparisons can be tricky and need to be explained further. For this analysis, pricing data was often obtained from a formulary, which are negotiated prices in countries with a UHC system. South African private sector prices might not immediately seem like direct comparators to these negotiated prices. However, in a UHC system, where prices are negotiated and listed on a formulary, these prices become the *de facto* price for the country. Thus, while the SEP might not be entirely comparable to negotiated prices in a UHC, it is a close comparison. More importantly, the following analysis intends to illustrate where local prices lie compared to a

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<sup>86</sup> (Shivam, et al., 2012)

<sup>87</sup> South African unit prices reflect the maximum retail price using the 4-tiered pharmacy dispensing and profit bands.

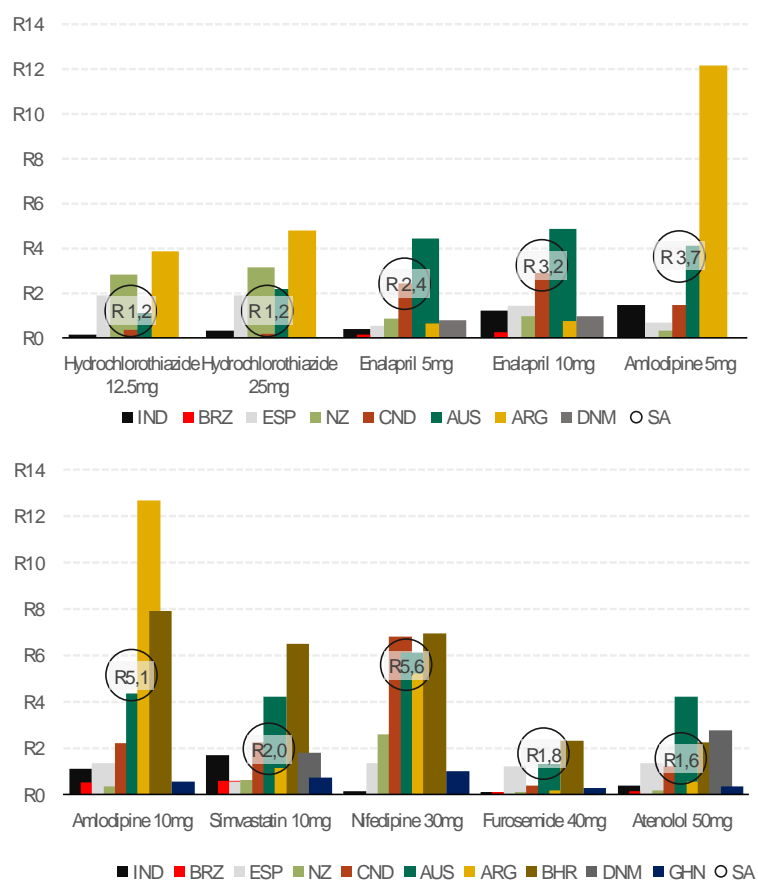
<sup>88</sup> All country prices reflect retail prices. Retail prices were calculated for some countries when only the manufacturer price was available.

range of international prices which includes pluralistic and single-payer health systems. The analysis is below by therapeutic category.

### 5.8.1 Cardiac Therapy

Figure 14 presents unit cost comparisons for cardiac therapy drugs. Prices in India, Brazil, Spain and New Zealand are notably lower than South African prices for most of the cardiac drugs sampled. Australian and Bahrain<sup>89</sup> prices tend to be higher than local prices, whereas South Africa fares differently across drugs in comparison to Canada and Argentina. On balance, the figure shows that cardiac drugs are being sold locally at a higher price than many comparator countries.

**Figure 14: Cross country unit price comparison for Cardiac Therapy drugs, 2019**



Source: Medicine Price Registry, 2019. Country formularies, 2019. Own calculations.

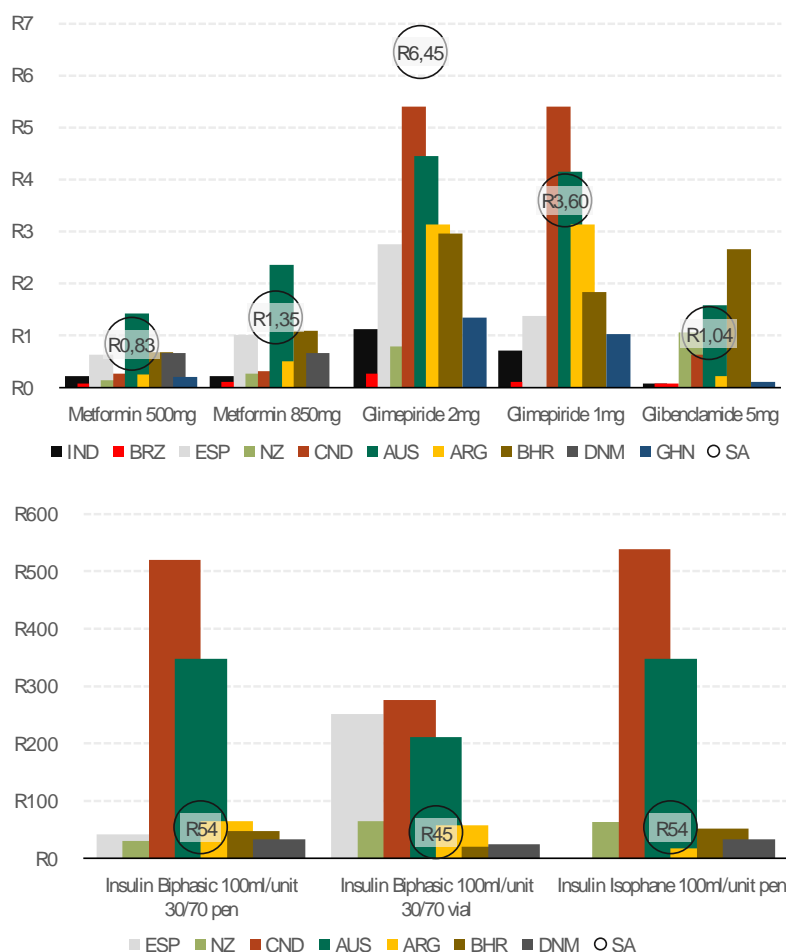
### 5.8.2 Diabetes Mellitus

Figure 15 shows that Diabetes Mellitus drugs are also priced high in South Africa relative to the comparator countries. As with cardiac drugs, prices tend to be lower for Diabetes Mellitus drugs in India, Brazil, Spain and New Zealand and higher in Australia. Lower prices are not

<sup>89</sup> Bahrain was removed from the upper panel of Figure 14 due to very high prices affecting the display.

exclusive to high- or low-income countries which indicate the potential for South Africa to bring prices closer to some of its BRICS partners. Antidiabetic drugs are priced similarly across countries – for the most part – except for substantially higher prices in Canada and Australia.

**Figure 15: Cross country unit price comparison for Diabetes Mellitus and Antidiabetic Therapy drugs, 2019**



Source: Medicine Price Registry, 2019. Country formularies, 2019. Own calculations.

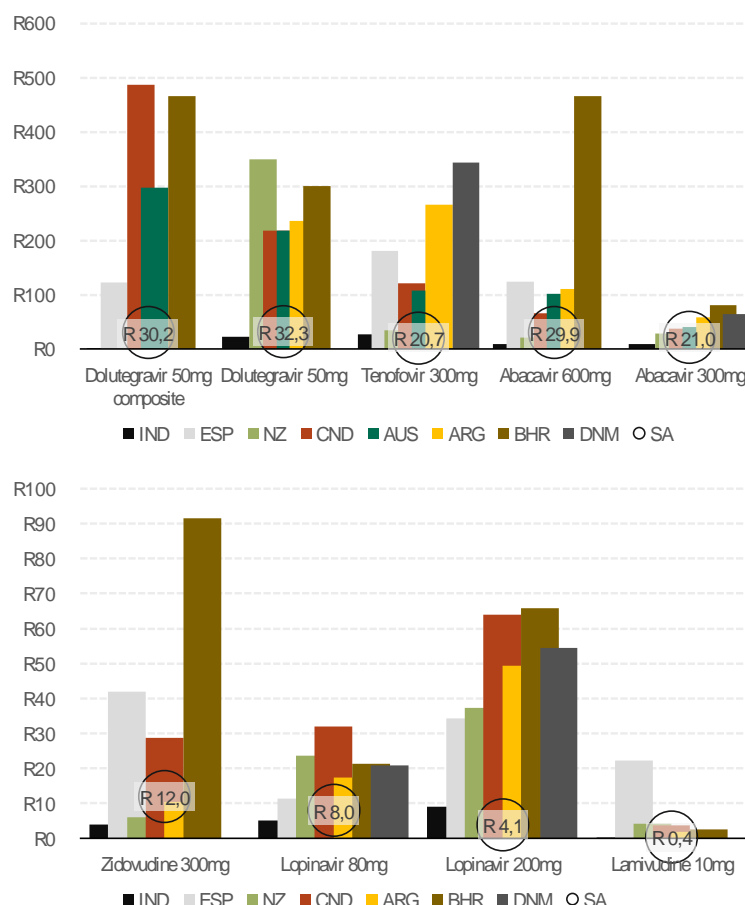
### 5.8.3 Antiretrovirals

ARVs retail cheapest in India, followed by South Africa, illustrated in Figure 16. Low local prices are expected given the size of demand in a country with a high prevalence rate. That said, the low prices seen in these two countries reflect different approaches to pricing policy. The Indian government issued a compulsory license for ARV drugs to fight the rapidly increasing deaths from HIV/AIDS in the country. This allowed manufacturers of generic medicines to enter the market and contributed to lowering the price of this category of medicines.<sup>90</sup> Similarly, in South Africa, some manufacturers have been granted a voluntary licence to produce ARV drugs

<sup>90</sup> (Hoen, Berger, & Moon, 2011)

although it is unclear whether it had the intended effect. In contrast, the South African government has used its considerable purchasing to negotiate large discounts on the unit prices of ARVs in 2010.<sup>91</sup>

**Figure 16: Cross country unit price comparison for ARV drugs, 2019<sup>92</sup>**



Source: Medicine Price Registry, 2019. Country formularies, 2019. Own calculations.

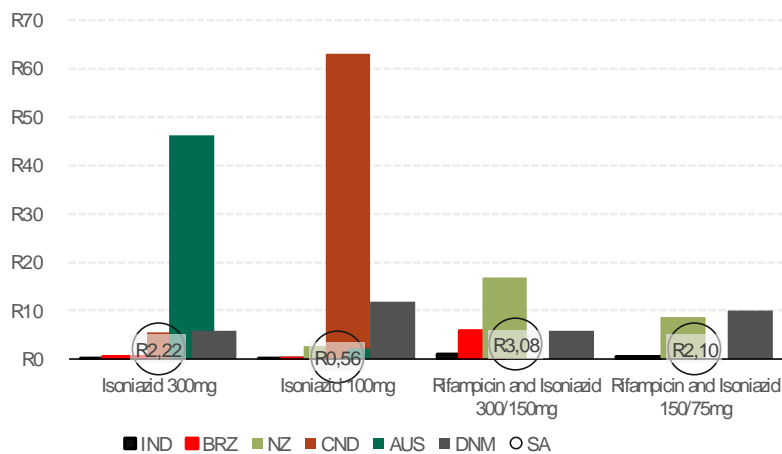
This is also the case for TB drugs depicted in Figure 17, although Brazil is only slightly more expensive than South Africa. Overall, where South Africa ranks depends on the type of drug. ARVs and TB drugs are cheaper in South Africa than most comparator countries. Due to high demand, economies of scale in purchasing likely keeps prices lower. India and Brazil tend to be cheapest across all therapeutic categories and Australia, Argentina and Bahrain the most expensive. Differences with other countries seem to be volume driven.

<sup>91</sup> (Brand South Africa, 2010)

<sup>92</sup> Australia omitted because high prices affected display.



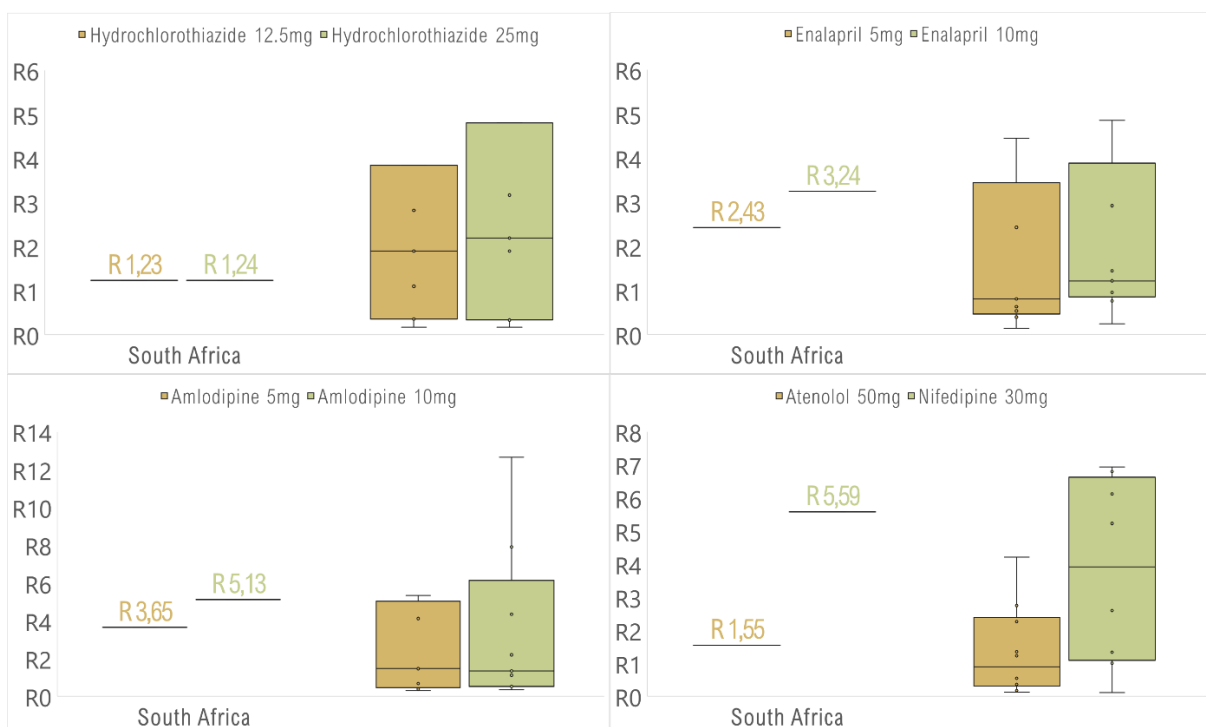
**Figure 17: Cross country unit price comparison for TB Therapy, 2019**



Source: Medicine Price Registry, 2019. Country formularies, 2019. Own calculations.

Figure 18 presents a closer look at the spread of Cardiac drug prices. South Africa is generally priced above the median and tends to be on the upper end of the distribution. In other words, Cardiac drugs in South Africa tend to be more expensive than comparison countries.

**Figure 18: Box plots of Cardiac drugs (unit prices), 2019**

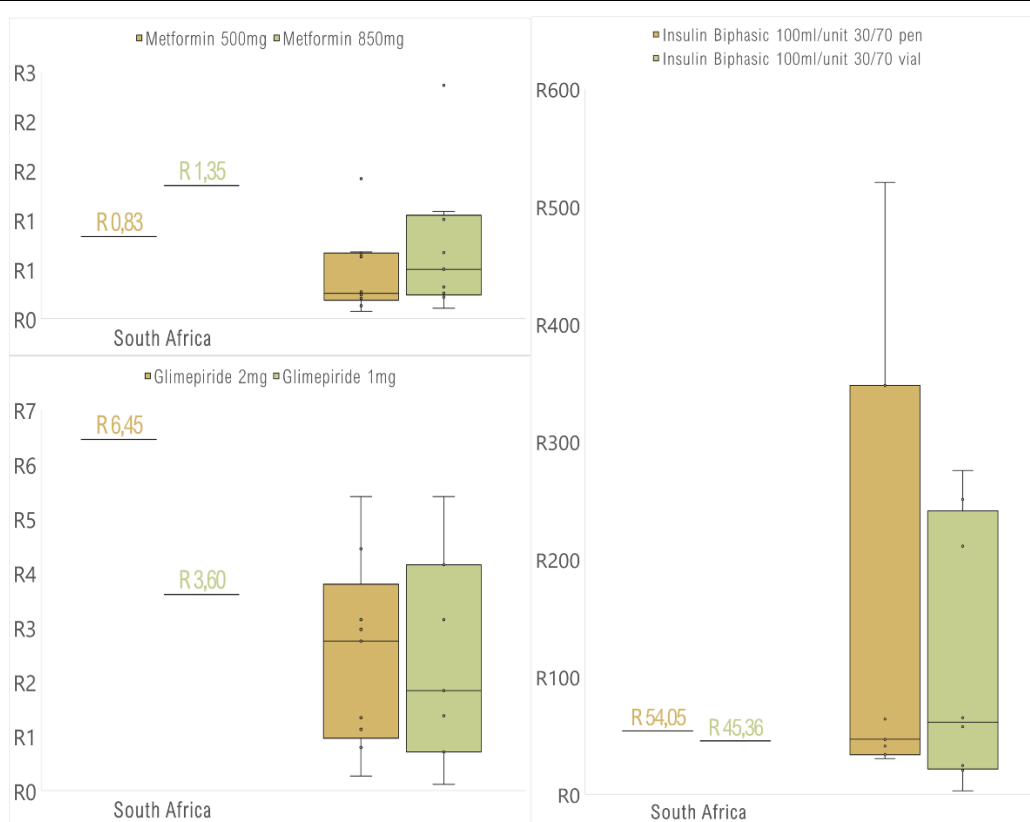


Source: Medicine Price Registry, 2019. Country formularies, 2019. Own calculations.

The left panel of Figure 19 indicates that Diabetes Mellitus drugs are even more highly priced in comparison to cardiac drugs based on their respective cross-country comparators. Excessive retail prices in South Africa are supported by three out of the four Diabetes Mellitus drugs being outliers, indicated by the unit prices for South Africa lying above the ‘whiskers’. This is particularly concerning given the rise in non-communicable diseases such as Diabetes in South Africa.

The distribution of antidiabetic drugs is skewed by the high prices in Canada and Australia. South African prices are relatively low for these drugs as the local unit price is at and just above the mean for the two insulin drugs presented on the right panel of Figure 19.

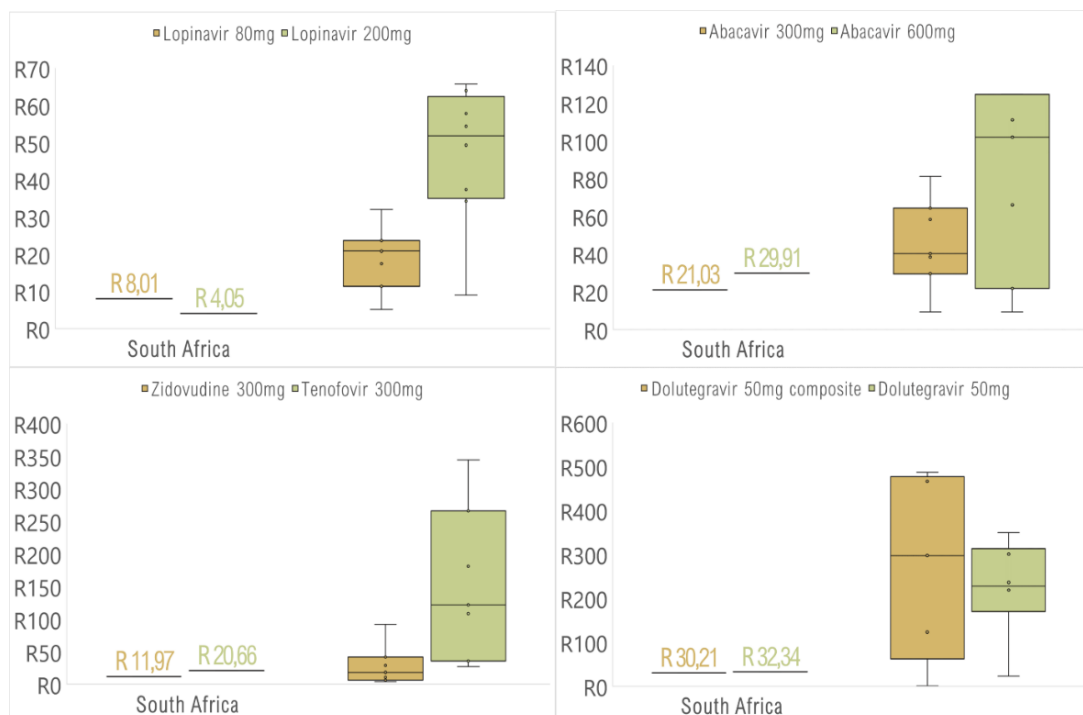
**Figure 19: Box plots of Diabetes Mellitus and antidiabetic drugs (unit prices), 2019**



Source: Medicine Price Registry, 2019. Country formularies, 2019. Own calculations.

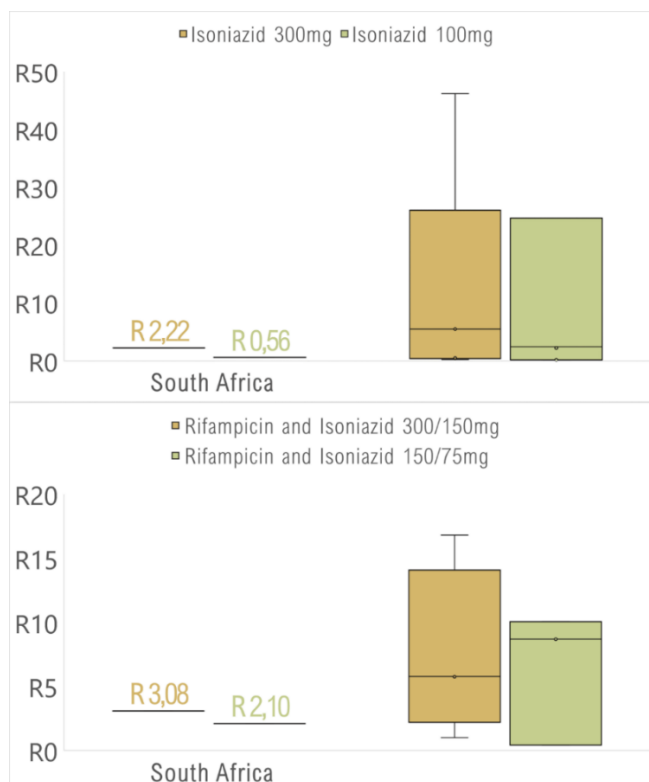
Figure 20 and Figure 21, respectively present the distributions of HIV and TB drugs. As mentioned in the above analysis on HIV and TB drugs, South Africa is among the lowest priced countries for these drugs. These findings support the notion that South Africa has managed to reduce the cost of drugs to treat public health priorities. Nevertheless, cardiac and lifestyle diabetes conditions are prevalent and growing concerns in South Africa. An important step to promoting access and controlling the cost to public health will be to manage the costs of pharmaceuticals for non-communicable diseases.

**Figure 20: Box plots of HIV drugs (unit prices), 2019**



Source: Medicine Price Registry, 2019. Country formularies, 2019. Own calculations.

**Figure 21: Box plots of TB drugs (unit prices), 2019**



Source: Medicine Price Registry, 2019. Country formularies, 2019. Own calculations.

## 6 FINDINGS

This section seeks to answer the following questions regarding key factors in the pharmaceutical sector that impact on medicine prices.

1. What are the main differences between the way medicines are **procured and priced** in the public and private sector?
2. How does South Africa's current approach to price regulation **affect the prices of medicines**?
3. How does the **market structure and competition** across the different segments of the pharmaceutical industry influence pricing?
4. How much does the pharmaceutical sector spend on **R&D** in South Africa, and how does this expenditure impact on the pricing of medicines?
5. How does access to **APIs** impact on local manufacturing?
6. How does current **IP laws and patent processes** influence medicine prices?

Section 6.1 considers price regulation (Q1 and Q2). Section 6.2 analysis the different components of the pharmaceutical value-chain and explores the market structure and competition issues (Q3). Section 6.4 examines the incentives for R&D in the industry (Q4) and section 6.3 provides an overview of issues relating to intellectual property laws (Q5).

### 6.1 Pricing policy and regulation

#### *6.1.1 A comparison of prices between the public and private sector*

The price of pharmaceutical products differs across the public and private sector. Public sector procurement – governed by the PFMA – is thought to be relatively effective, given low prices. By using its monopsonistic power, the state has negotiated lower prices with manufacturers for certain types of drugs in particular therapeutic categories. In contrast, procurement is relatively decentralised in the private sector, with each purchaser procuring medicines in the quantities they need. Private sector drug prices are governed by the SEP, as elaborated in Section 3.2.2. The SEP influences procurement in the private sector by setting price ceilings and prohibiting discounts and rebates. Differing regulations across the public and private sectors have led to significant price differentials.

There is a fair amount of research on ERP. Cassar & Suleman (2019) simulated an international benchmarking exercise using the latest methodology for ERP published by the Minister of Health in 2014. They found that private-sector drug prices tend to be higher in South Africa when compared to a basket of countries identified in the ERP.<sup>93</sup> Public sector prices, in contrast, were the lowest for 92% of sampled drugs. Cassar & Suleman's findings highlight two notable points. First, the ERP generally produces lower prices than the SEP.

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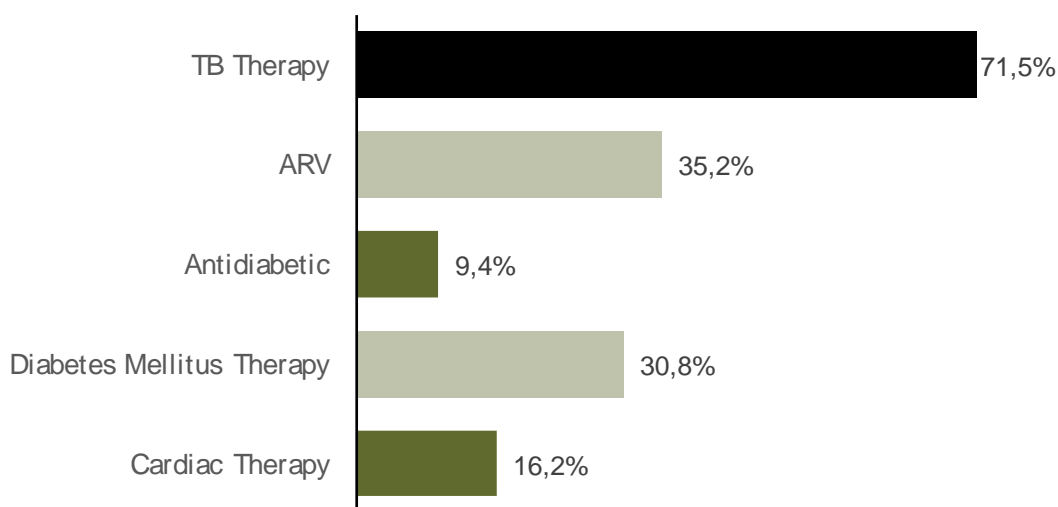
<sup>93</sup> Countries included in this study are Australia, New Zealand, Canada, Spain, India and Russia

Given that 16.08% of total benefits paid by medical schemes were for medicines, it appears that the South African consumer is still paying more for medicines in the private sector, relative to consumers in comparison countries.<sup>94</sup> Second, pooled procurement, as applied in the public sector, generally produces lower prices than ERP.<sup>95</sup> Therefore, it follows that public sector prices are significantly lower than private-sector prices in South Africa.

Figure 22 presents the average unit price paid to state suppliers of pharmaceuticals as a percentage of the average ex-manufacturer unit price of the SEP for the same suppliers and drugs, by therapeutic category. The figure shows the extent to which pooled procurement can reduce the cost of drugs. In the public sector, antidiabetic drugs, for example, are purchased for less than a tenth of private sector prices.<sup>96</sup> Likewise, for TB drugs, public sector procurement still achieves about a 30% reduction on the SEP.

In practice, though, the actual differential between public and private sector prices is likely to be even bigger. Figure 22 shows the public sector procurement prices as a percentage of the manufacturer component only but the retail price also includes a logistics fee, VAT and a dispensing fee in the private sector.

**Figure 22: Average of public prices as a percentage of SEP manufacturer component by therapeutic category, 2019**



Source : *Master Procurement Catalogue, 2019. Own calculations.*

<sup>94</sup> (Council for Medical Schemes, 2018)

<sup>95</sup> These findings cannot be extrapolated to other contexts, given that the pooled procurement model in South Africa and the exact ERP methodology applied in this study is likely to be unique to the country.

<sup>96</sup> The actual differential between public and private sector prices are even more stark given. Figure 22 presents public sector procurement prices as a percentage of the manufacturer component only. The private sector retail price also includes a logistics fee, VAT and a dispensing fee.

For non-communicable diseases, South African private sector prices tend to be higher than many comparator countries. However, the public sector prices tend to be lowest across all comparisons. Although bulk purchasing is likely the major contributor to the price differential between public and private sector prices, without information on quantities purchased in the private sector, it is not possible to assess the extent to which economies of scale lower public sector prices.

### *6.1.2 Price regulation in the private sector*

The SEP was introduced at a time when the actual price of pharmaceuticals was not clear because of the myriad of discounts, rebates and marketing incentives, given by manufacturers to ‘push’ their products. With little or no transparency on the prices of pharmaceuticals, it was difficult to determine whether South African consumers were paying a reasonable or excessive price for their medicines. This was also a time of high medicine price inflation, which fuelled rapid increases in the price of pharmaceutical products.

#### **Ex-Manufacturers price**

The SEP enhances price transparency by prohibiting discounts, rebates and any form of incentives in the sale of medicines by manufacturers. By regulating the ex-manufacturer price, the government ensures that manufacturers sell their medicines at a fixed price that is known to the public.<sup>97</sup> While the SEP fosters greater transparency, it also limits the ability of purchasers to negotiate prices down. Perhaps, the main shortcoming of the current regulatory scheme is that it fails to empower the Pricing Committee to negotiate price reductions with manufacturers. Put differently, the current approach to setting the SEP effectively makes consumers price-takers, incentivising manufacturers set their SEP price as the high as possible level from the outset. As noted in Section 3.4, the SEP effectively allows manufacturers to capture a part of the consumer surplus.

To determine whether a medicine is excessively priced, one needs to compare prices to costs. However, the current legislation does not require manufacturers to provide information on costs, and even in instances where it does give the Minister powers to request costing information, the Department cannot prohibit the registration of a product nor can the Department enforce a price reduction. The only recourse of the NDoH is to place a drug on the list of medicines that are excessively priced. In contrast, the NDoH routinely requests cost information from manufacturers during the public procurement process. This allows the NDoH to make exchange-rate adjustments to medicine prices when needed, effectively eliminating the exchange rate risks for manufacturers. Aside from the ex-manufacturer price, there is regulation for the logistics fee and dispensing fee.

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<sup>97</sup> All SEP prices are published on the Medicine Price Registry, available [here](#).

## Logistics fee

As the logistics fee is unregulated (not enforced nor monitored), it is not always clear or transparent, how the fee is determined. There are indications of firms either leveraging the logistics fee to maximise profitability or to incentivise distributors to market their products. Bangalee & Suleman (2016) found – in some instances – the manufacturer component of the SEP to increase in proportion to the decrease in logistics fees, suggesting manufacturers squeezed distributors' fees to increase revenues. In contrast, EML medicines attracted a higher logistics fee, likely due to greater demand. The authors purport that manufacturers offered distributors higher fees to gain market share.

## VAT

VAT increases the prices of medicines for even the poor, given less than complete coverage of the public healthcare system. Further, not all necessary drugs are provided by the state. For example, ARVs for third-line HIV treatment are currently under patent and only available in the private sector.<sup>98</sup> There would be notable savings if certain drugs were to be VAT exempt. Bangalee and Suleman (2017) note:

*"The potential saving for the lowest priced generic and originator 1st line antiviral regimen accrued to ZAR 693.84 and ZAR 1085.04 over a year respectively. Regarding the 3rd line antiretroviral drugs, results yielded an annual saving of ZAR 1678.68 (darunavir), ZAR 5741.04 (maraviroc) and ZAR 159.48 (rilpivirine)."*<sup>99</sup>

## Dispensing fee

The dispensing fee adds to the cost of pharmaceutical products in two ways. First, it seems that there is an incentive for pharmacists to stock higher-priced products particularly in areas where they have less competition, as the higher, the value of the medicine, the higher the dispensing fee. This implies that the regulated dispensing fee can itself limit access to affordable and low-priced drugs for patients.

Second, during interviews, a community pharmacist revealed that the dispensing fee tends to differ across medical schemes, with larger schemes pushing down the dispensing fee. This tends to disincentivise smaller pharmacies from stocking certain low margin drugs, thereby diminishing access. The dispensing fee also differs across medical scheme packages, even within the same scheme/ funder.

Therefore, in practice, it appears that consumers pay a different and potentially higher dispensing fees when from their own pockets as opposed to medical schemes that use their buying power to drive down the prices.

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<sup>98</sup> (Bangalee & Suleman, 2017)

<sup>99</sup> (Bangalee & Suleman, 2017 p. 150)

### 6.1.2.1 Has the SEP reduced prices?

When it was introduced, the objectives of the SEP was to foster greater transparency and reduce the prices of medicines. It is, therefore, worth examining the evidence on the pricing outcomes achieved under the SEP. McIntyre & Thiede (2007) estimate that the SEP led to a 22% reduction in prices in the year following its implementation. This, in combination with policy making generic substitution obligatory, led to a notable reduction in private sector pharmaceutical expenditure in the mid-2000s. Other sources suggest that the SEP led to a 19% decrease in prices, with a 25-30% reduction in generics prices and a 12% reduction in originator prices.<sup>100</sup> Findings by Moodley & Suleman (2019) confirm this decline in prices. The authors conducted a time series analysis over the period 1994-2014 to assess the change in prices post-SEP implementation.<sup>101</sup> Their findings confirm that the SEP has led to decreased prices and that the rate of increase in prices post-2004 was substantially lower than the rate of increase in prices before 2004. The lower rate of increase in medicine prices is likely attributable to the SEPA.

In interviews, it emerged that the pharmaceutical industry views it as frustrating that the SEPA is low relative to CPI. The SEPA is published annually at the discretion of the Minister and does not always follow the regulated methodology for price increases. As a result, the increase in medicines prices have been controlled, but uncertainty around the SEPA is a cause for concern for manufacturers.

While this relative price decline after the implementation of the SEP is encouraging, an important question to ask is whether private sector prices are reasonable and affordable. Medbelle (2019) shows that medicine prices in South Africa are the 45<sup>th</sup> lowest in the world.<sup>102</sup> Another international study found that private sector prices are high in South Africa.<sup>103</sup> Together with the findings from the international benchmarking exercise undertaken in Section 5.8, a fair conclusion is that prices in South Africa can be too high for some drugs and low for others.

Moreover, using primary data, Pretorius (2011) found that reduced prices did not consistently translate to lower prices for users.<sup>104</sup> The study analysed data collected from three types of pharmacies – hospital, group, and independent – which revealed different mean prices across pharmacy types. Group pharmacies displayed the highest mean medicine prices, signalling that the effects of the SEP were not uniform, and that the user did not necessarily benefit from consistently lower prices. A further finding from this study revealed that some pharmacies were charging a higher price than the SEP allowed for, taking into account the maximum dispensing fee.

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<sup>100</sup> (Moodley & Suleman, 2019)

<sup>101</sup> A sample of 50 originator drugs were used.

<sup>102</sup> (Medbelle, 2019)

<sup>103</sup> (Cassar & Suleman, 2019)

<sup>104</sup> (Pretorius, 2011)

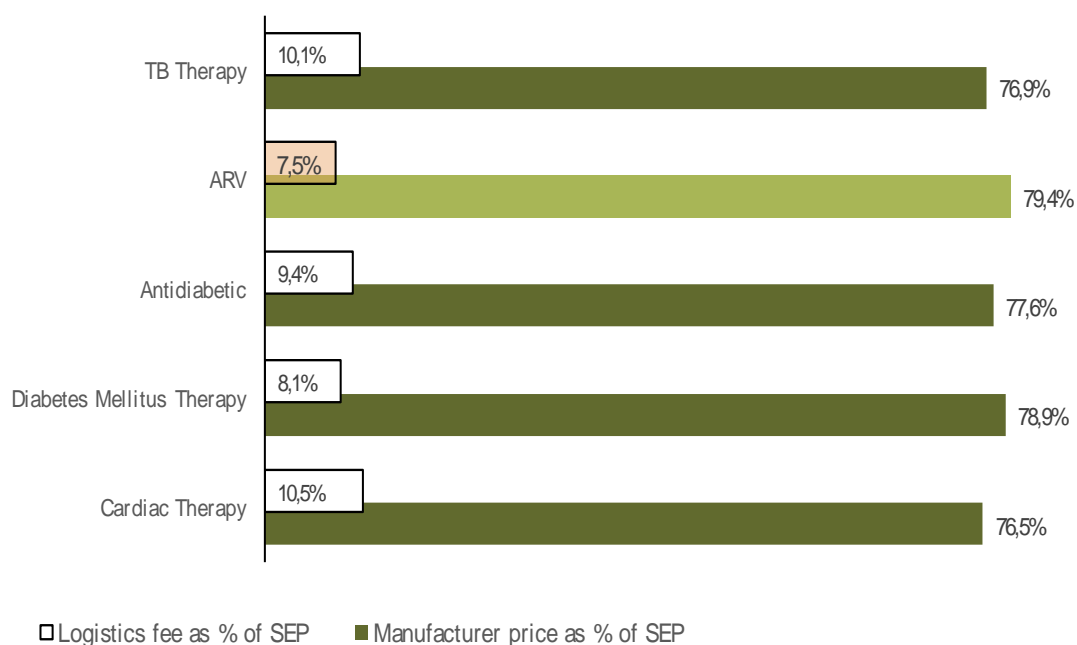


### 6.1.2.2 The relationship between the manufacturer and logistics components

The ability for manufacturers to secure a more significant share of SEP relative to distributors may be a function of their market power. If the supply of an originator drug is a proxy for market power, then it is expected that, within a therapeutic category, the manufacturer's price as a percentage of SEP will be greater for originators relative to generics.

Figure 23 presents the average manufacturer price and logistics fee as a percentage of the SEP by therapeutic category for 2019.<sup>105</sup> A higher manufacturer share of the SEP is generally associated with a lower logistics share. As Figure 23 shows, the manufacturer's share of the SEP is highest for ARVs.

**Figure 23: Average manufacturer price and logistics fee as a percentage of SEP by therapeutic category, 2019**



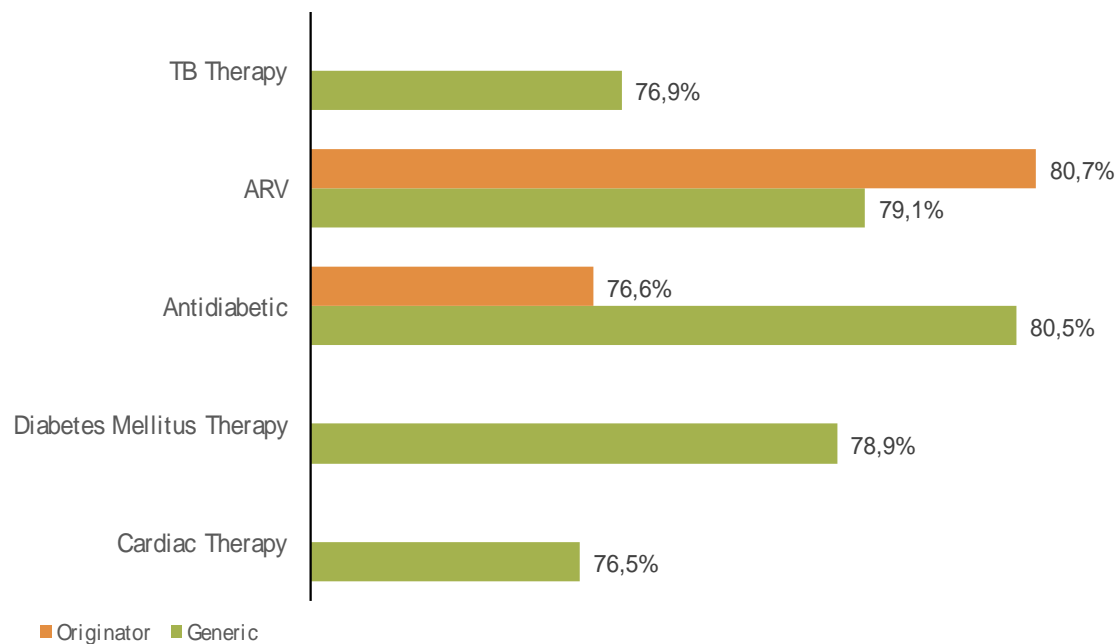
Source: Medicine Price Registry, 2019, Own calculations.

For ARVs, Figure 24 shows that the manufacturer price as a percentage of SEP is greater for originator brands relative to generic brands in four of the five therapeutic categories. However, the reverse is true for antidiabetics. This counterintuitive finding needs to be considered more carefully. There are only four antidiabetic drugs in the sample, restricting the extent to which this can be generalised to other drugs in this therapeutic category. One possible explanation is that it is more complicated and expensive to copy biologic insulin (the main ingredient in antidiabetic medicine), which has discouraged generics from pricing below originators.<sup>106</sup>

<sup>105</sup> Estimates remain similar across the period 2013-2019, hence only the latest year's estimates are presented in the descriptive analysis.

<sup>106</sup> (Healthline, 2019)

**Figure 24: Average manufacturer price as a percentage of SEP by therapeutic category and originator and generic, 2019**



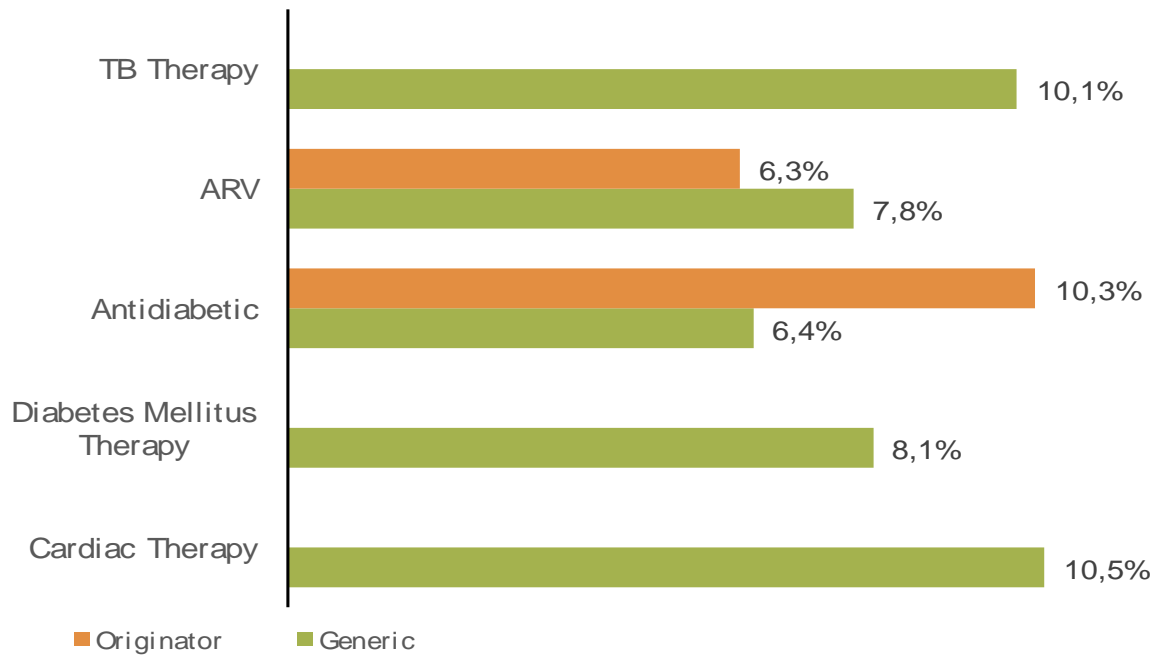
Source: Medicine Price Registry, 2019, own calculations

The analysis also tests the relationship between brand (originator versus generic), market power and the SEP. Figure 25 compares the average logistics fee as a percentage of SEP by therapeutic category and brand. Key informants have suggested that manufacturers may constrict distributors’ fees if they have market power. Conversely, if the market is competitive, manufacturers may pay greater logistics fees to incentivise distributors to market their product.

For ARVs, Figure 25 shows that logistics fees, as a percentage of SEP, are lower for originator products relative to generic products, whereas the reverse is true for antidiabetics. This may suggest that there is limited competition between originators and generics for ARVs and greater competition between originators and generics for antidiabetic drugs. This is supported when considering the analysis sample. There are four drugs in the sample for antidiabetics, one of which is generic. The generic seems to be a direct substitute for originator drugs and is about 65% of the price.

In contrast, originator ARVs – at least in the sample – do not face much generic competition. Competition may be stifled in the ARV market since an originator company also establish a generic brand.

**Figure 25: Average logistics fee as a percentage of SEP by therapeutic category and originator and generic, 2019**



Source: Medicine Price Registry, 2019, own calculations

To test the relationship between the manufacturer's price and logistics fee further, a regression analysis was conducted using SEP data across the period 2013-2019. Table 2 shows the Pooled OLS and Fixed Effects estimations of the SEP. Fixed Effects estimations are typically well suited for panel data where time-invariant characteristics are correlated with the observed independent variable.

Regressions I-IV present different functional forms testing whether a simultaneous increase in the manufacturer price (year-on-year) and decrease in the logistics fee (year-on-year) influences the SEP. Regressions V-VIII test whether a simultaneous decrease in the manufacturer price (year-on-year) and increase in the logistics fee (year-on-year) influences the SEP. A complete description of the equations and variables for these regressions can be found in Appendix 4.

**Table 2: Pooled OLS and Fixed Effects estimation of SEP**

Dependent variable = SEP	Pooled OLS		Fixed Effects		Pooled OLS		Fixed Effects	
	I	II	III	IV	V	VI	VII	VIII
Year	0.095*** (0.01)	0.095*** (0.03)	3.67*** (0.70)	3.67*** (0.91)	0.020 (0.031)	0.020*** (0.005)	3.80*** (0.70)	3.80*** (0.93)
Manufacturer increase	-50.62* (29.95)	-50.62 (45.40)	8.65** (4.36)	8.65 (5.52)				
Logistics decrease	19.59 (40.03)	19.59 (47.75)	-9.94* (5.090)	-9.94 (7.400)				
Manufacturer increase × Logistics decrease	<b>-119.10</b> <b>(74.89)</b>	<b>-119.10**</b> <b>(54.57)</b>	<b>-2.13</b> <b>(9.89)</b>	<b>-2.13</b> <b>(6.72)</b>				
Manufacturer decrease					163.50** (65.28)	163.50*** (41.00)	-2.46 (7.95)	-2.46 (4.67)
Logistics increase					98.83 (63.20)	98.83*** (25.36)	12.49 (7.99)	12.49** (4.86)
Manufacturer decrease × Logistics increase					<b>-172.80*</b> <b>(100.90)</b>	<b>-172.80**</b> <b>(84.42)</b>	<b>3.21</b> <b>(12.63)</b>	<b>3.21</b> <b>(11.11)</b>
Constant			-7244.39*** (1,418)	-7244.39*** (1,843)			-7515.41*** (1,417)	-7515.41*** (1,880)
Clustered errors	No	Yes	No	Yes	No	Yes	No	Yes
<b>N</b> (sample)	312	312	312	312	312	312	312	312
<b>N</b> (groups)	62	62	62	62	62	62	62	62
<b>R</b> <sup>2</sup>	0.419	0.419	0.160	0.160	0.420	0.420	0.157	0.157

Source: Own calculations, Medicine Price Registry 2013, 2014, 2015, 2016, 2017, 2018, 2019

Note: Standard errors are in parentheses. \*\*\*Significant at 1%, \*\*Significant at 5%, \*Significant at 10%

All regression models control for the year, which is positive and significant across all iterations, except Model V. This is expected and reflects the annual SEPA. Dummy variables are included which account for whether, relative to the previous year, the manufacturer price and logistics fee increased or decreased. Of most importance are the interaction terms, which, if statistically significant, would provide an important finding corroborating key informant views that manufacturers influence distributors' decisions on what products to stock and market through the logistics fee.

The interaction terms are only significant in Models II and VI (Pooled OLS estimator) of Table 2. When taking into account the panel structure of the data – using a Fixed Effects estimator – the interaction terms are no longer significant. This result does not support the presence of a relationship between the manufacturer's price and logistics fee. This finding on face value does not seem to support the suggestion that manufacturers increase the logistics fee to encourage distributors to push their product. While the quantitative analysis does not support this assertion, it is important to note that the actual logistics fees in contracts between manufacturers and distributors may differ from the MPR figures. The only way to test this claim would be to scrutinise manufacturers' contracts with distributors, but these are confidential. If the claim is valid, it might point to a gap in the SEP's regulatory framework.

The research team conducted an additional econometric analysis to test for a relationship between manufacturer prices and logistics fees, which might reflect some collusive behaviours. This is done by estimating the strength of the relationship between the manufacturer price and the logistics fee lagged once (see Table 3). In contrast, Table 4 estimates whether the manufacturer price in the previous period is associated with the logistics fee in the present period.

The coefficients on the logistics fee lagged are negative and significant across all regression models, even when controlling for unobserved factors (Table 3). This is also true for the coefficients on the manufacturer price lagged across all regressions in Table 4.

Collectively, these findings suggest that a greater logistics fee (manufacturer price) in the previous period is associated with a lower manufacturer price (logistics fee) in the current period. While this relationship should not be mistaken for causality<sup>107</sup>, it does suggest a price-play between the manufacturer price and logistics fee across periods.

Although the regression analysis was unable to provide conclusive empirical findings regarding the presence of collusive behaviour between manufacturers and distributors, it does provide some evidence that suggests manufacturers reduce their prices to allow for a higher logistics fee. This might point to a situation where manufacturers are using the logistics fee to push their products amongst distributors. In 2012, the Minister of Health published draft regulations for a maximum capped logistics fee: a regressive percentage (4% - 8%) of the ex-manufacturer

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<sup>107</sup> Care must be taken when interpreting these statistics as the sample size and data do not permit the application of appropriate econometric methods that are able to test for causal relationships.

price. Due to disputes from industry, the regulation did not take effect. As such, the fee is freely determined by negotiations between distributors and manufacturers.

These findings, taken together with the preceding descriptive analysis and complemented by key informant statements, support the notion that there is some leeway for manufacturers to influence the logistics fee and ‘push’ their products.

**Table 3: Pooled OLS and Fixed Effects Estimation of Manufacturer price**

Dependent variable = Manufacturer price	Pooled OLS		Fixed Effects	
	I	II	III	IV
Year	0.01 (0.01)	0.01 (0.01)	0.67 (0.45)	0.67 (0.50)
Manufacturer price lagged	0.98*** (0.01)	0.98*** (0.03)	0.51*** (0.07)	0.51*** (0.11)
Logistics fee	7.02*** (0.26)	7.02*** (1.44)	5.51*** (0.39)	5.51* (2.82)
Logistics fee lagged	<b>-6.96***</b> <b>(0.28)</b>	<b>-6.96***</b> <b>(1.42)</b>	<b>-5.01***</b> <b>(0.58)</b>	<b>-5.01***</b> <b>(1.08)</b>
Constant			-1294.33 (905.8)	-1294.33 (929.3)
Clustered errors	No	Yes	No	Yes
<b>N</b> (sample)	308	308	308	308
<b>N</b> (groups)	62	62	62	62
<b>R</b> <sup>2</sup>	0.995	0.995	0.534	0.534

Source: Own calculations, Medicine Price Registry 2013, 2014, 2015, 2016, 2017, 2018, 2019. Note: Standard errors are in parentheses. \*Significant at 1%, \*\*Significant at 5%, \*\*\*Significant at 10%

**Table 4: Pooled OLS and Fixed Effects estimation of Logistics fee**

Dependent variable = Logistics fee	Pooled OLS		Fixed Effects	
	I	II	III	IV
Year	0.01 (0.06)	.01 (.04)	0.10* (0.05)	0.12 (0.08)
Logistics fee lagged	0.98*** (0.01)	0.98*** (0.02)	0.61*** (0.07)	0.61*** (0.04)
Manufacturer price	0.10*** (0.01)	0.10*** (0.01)	0.081*** (0.01)	0.081*** (0.01)
Manufacturer price lagged	<b>-0.10***</b> <b>(0.03)</b>	<b>-0.10***</b> <b>(0.01)</b>	<b>-0.05***</b> <b>(0.01)</b>	<b>-0.05***</b> <b>(0.01)</b>
Constant			-205.30* (109.60)	-205.30 (151.50)
Clustered errors	No	Yes	No	Yes
<b>N</b> (sample)	308	308	308	308
<b>N</b> (groups)	62	62	62	62
<b>R</b> <sup>2</sup>	0.99	0.99	0.55	0.55

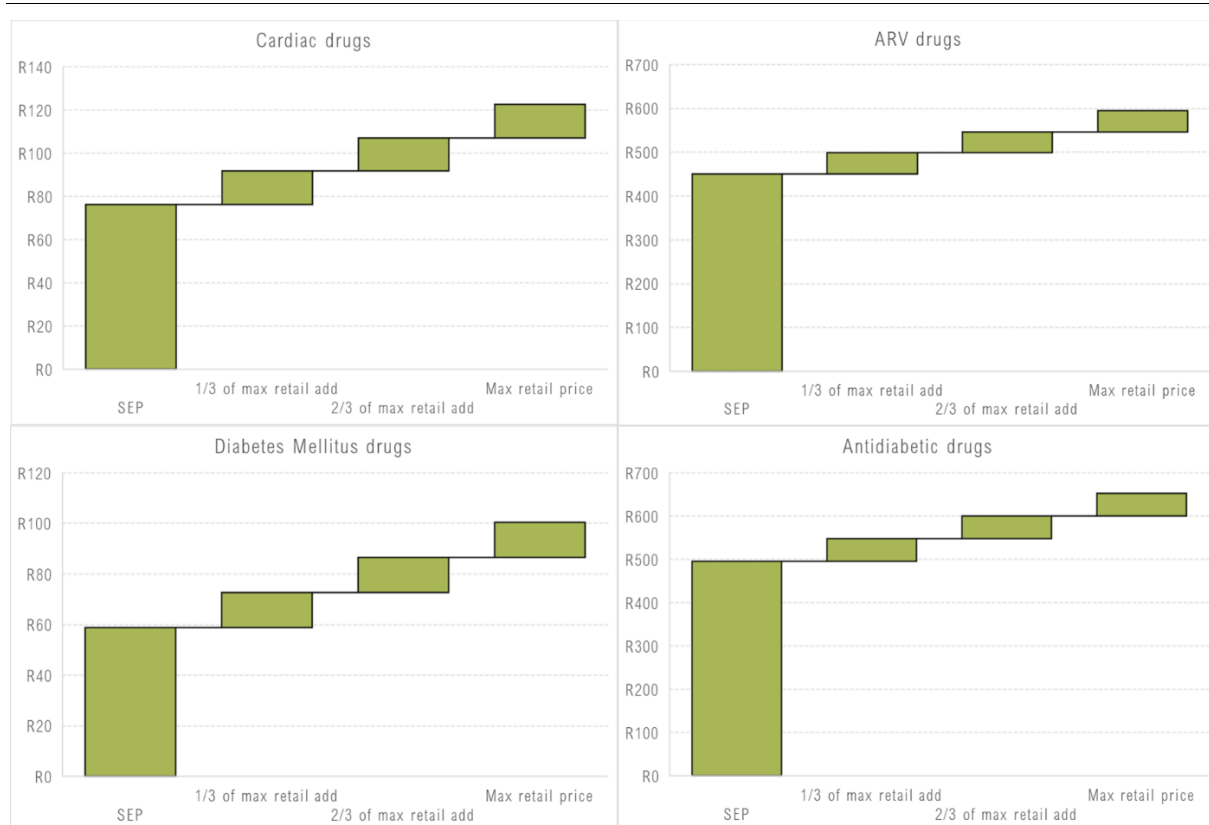
Source: Own calculations, Medicine Price Registry 2013, 2014, 2015, 2016, 2017, 2018, 2019. Note: Standard errors are in parentheses. \*Significant at 1%, \*\*Significant at 5%, \*\*\*Significant at 10%

### 6.1.2.3 Dispensing fee

Concerns around the dispensing fee tend to centre around power relations, in this case between dispensers and medical scheme funders. The quantitative analysis is unable to address these relationships mainly because data is not available.

Figure 26 models the average retail price of in-sample drugs in increments of a third of the maximum dispensing fee. The regressive pricing framework of the dispensing fee can be seen when comparing the left and right panels. For more expensive drugs, the increase in the retail price, as a proportion of the SEP price, is smaller than that for cheaper drugs.

**Figure 26: Retail fee scenarios, 2019<sup>108, 109</sup>**



Source: Medicine Price Registry, 2019, own calculations

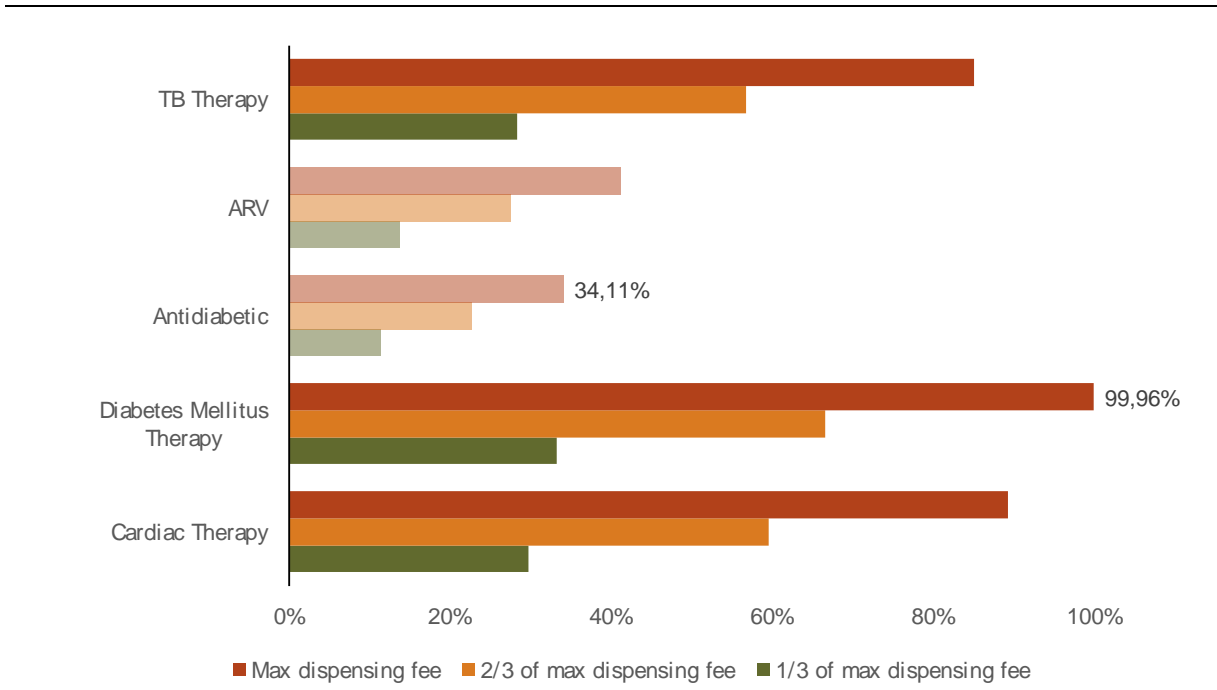
Thus, even though the regulation is seemingly effective at minimising the dispensing fee for higher-priced drugs, it still accounts for a relatively high proportion of the total cost of lower-priced drugs. This is illustrated in Figure 27, depicting the average dispensing fee as a

<sup>108</sup> Retail fee calculated using the 4-tiered pharmacy dispensing and profit bands.

<sup>109</sup> For ease of display, only four therapeutic categories are presented. TB drugs are priced similarly to Cardiac and Diabetes Mellitus drugs and therefore exhibits the same pattern.

percentage of the SEP. The maximum dispensing fee is greater than 80% of the SEP for cardiac and TB drugs, with the estimate for Diabetes Mellitus drugs being almost 100%. This percentage can be much higher for the very cheapest drugs in the sample.

**Figure 27: Dispensing fee as a percentage of SEP, 2019<sup>110</sup>**



Source: Medicine Price Registry, 2019

Effectively, this means that even if medicine prices decline and the dispensing regulation remains the same, the dispensing fee will take up an increasing share of the total cost of the medicines. That said, interviews revealed that medical schemes tend to push down the price of by listing generics on their formularies and negotiating low dispensing fees with pharmacists. However, the dispensing fee regulation may be abused for non-medical scheme patients who cannot negotiate to reduce the fee.

<sup>110</sup> Retail fee calculated using the 4-tiered pharmacy dispensing and profit bands.



### **6.1.3 Price determination in the public sector**

As the analysis shows, public sector procurement is relatively efficient in getting the lowest prices for medicines across all therapeutic categories. However, low prices in the public sector come with a unique set of issues.

#### **6.1.3.1 Uncertain demand for medicines**

There are some concerns that the government cannot estimate and plan their demand for drugs reliably. This often means that the NDoH either calls for substantially more or less of the drug quantities stated in the tender estimate. For manufacturers, the lack of reliable information on the quantities of medication needed by the public sector has two important implications for them. First, if the actual demand from the NDoH exceeds the estimates in the tender, manufacturers might not have enough stock on hand to supply the government. Second, if the actual demand from the NDoH is materially less than the tender estimate, then manufacturers will hold unsold inventory. Related to this point, since the price submitted by manufacturers is based on the specific quantity in the tender, where actual demand is less than planned demand, manufacturers have no recourse to increase their prices.

The NDoH argues that manufacturers do not understand that the tender quantity is an estimate and that deviations from this estimate are to be expected. According to the NDoH, the current tendering processes incentivise manufacturers to provide incorrect data that improves their supplier performance scorecard, which hampers the department's ability to forecast demand accurately.

#### **6.1.3.2 Length of the tender period**

Medicines in the public sector are procured through transversal contracts that typically run for three years. Indeed, manufacturers interviewed for this project advocate that the tender period should be extended beyond three years, which would give them enough time to recoup the capital expenditure. However, NDoH argues it is not practical to extend the tender period beyond three years because clinical guidelines for the treatment of diseases tend to change, and the government would become locked into the contract.

#### **6.1.3.3 Cross subsidisation between the public and private sectors.**

During interviews, some key informants have argued that manufacturers are cross subsidising the public sector by charging the private sector higher prices through the SEP. While, understandably, this argument stems in part from the price differential between the public and private sectors, there is not enough information to test the validity of this claim.

One reason for the price difference between the public and private sectors is that manufacturers might be discriminating between consumers based on their willingness to pay and the quantities ordered. The cross-subsidisation argument implies that manufacturers are making a loss in the public sector and profits in the private sector. However, as part of the tender requirements, manufacturers are required to provide a cost breakdown including their profit

margin which seems to suggest that there is a mark-up on medicines sold to the public sector.<sup>111</sup>

Despite these challenges, the preferential procurement regulations have contributed to the establishment of black empowered manufacturers and suppliers of medicines, as in the case of the Sonke Pharmaceuticals, established in 2006 as a Black Economic Empowerment joint venture between Ranbaxy and Community Investment Holdings to supply the public sector.

## 6.2 Market structure and competition

Section 4.1 of this report contains a high-level overview of the pharmaceutical value chain. This overview forms the basis for examining market structure and competition within various segments of the value chain. A key feature of a market and competition assessment is understanding the level of concentration at the various levels of the value chain. This form of analysis requires information on the actual and potential production capacities (to assess the ability) and profit margins to measure the potential incentive for the firm to engage in anticompetitive conduct. However, at present, there is not enough information available in the public domain to complete a thorough market and competition assessment. This section, therefore, relies on secondary information from the Health Market Inquiry and other documentary sources.

The pharmaceutical industry is highly fragmented with a host of different role players operating across the value chain. Firms may be active in one or more levels of the value chain, including manufacturing, distribution and/or retailing. While there is limited information in the public domain to assess concentration, empirical evidence and insights from key informant interviews do suggest that concentration levels are high at both the manufacturer and retail level.

Despite the lack of information, the research team was able to gauge market concentration by therapeutic category using 2019 quantities supplied to the public sector. Figure 28 illustrates the extent of market concentration for three of the five therapeutic categories.<sup>112</sup> This firm-level market share analysis uses the quantities purchased by the State, by therapeutic category. The size of the bubbles shows the quantities sold.

It appears that the market structure varies considerably by therapeutic category. The market for ARVs tends to be reasonably competitive with a large number of suppliers supplying both generics and originators to the state. In contrast, there is an oligopolistic market structure for Cardiac and Diabetes Mellitus drugs, that is, a few firms account for the largest share of drugs supplied.<sup>113</sup> This analysis, therefore, suggests that suppliers of Diabetes Mellitus and Cardiac medicines might be able to exercise some market power, although their ability to translate this

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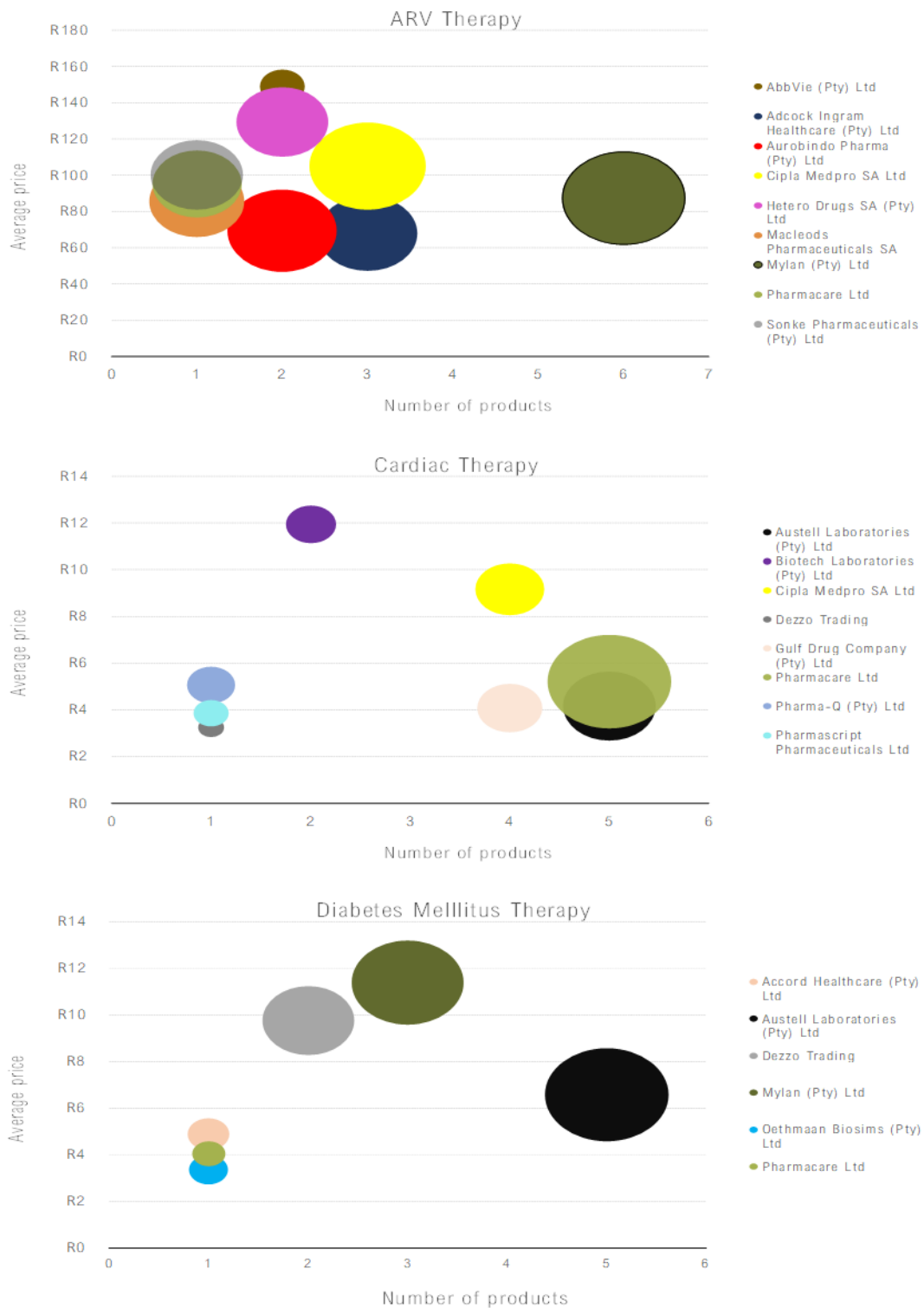
<sup>111</sup> Manufacturers reveal their costs (and margins) in exchange for NDoH taking on exchange rate risk, given that contracts span multiple years. Only originator manufacturers do not reveal their costs and therefore take on exchange rate risk. However, originators constitute a small minority of purchases in the medicines budget.

<sup>112</sup> The other two therapeutic categories have only two suppliers each given the manner in which the sample was defined.

<sup>113</sup> The extent to which this is representative of the private sector may be limited.

advantage into higher prices in the public sector is curtailed by the monopsony buying power of the state.

**Figure 28: Market concentration by therapeutic category, 2019**



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Source: *Master Procurement Catalogue, 2019*

Assessing the distribution level encounters further difficulties as there are firms which are not integrated but distribute pharmaceuticals. This emerges across a range of interviews and is present in the analysis sample

### *6.2.1 Raw materials supply*

China and India are the main global suppliers of raw materials and intermediaries. Most manufacturers rely on these two countries to supply their raw materials. In general, the production of pharmaceutical raw materials is a hazardous process but also requires the right infrastructure, skills and production capabilities. Raw material production is also seen as a dirty industry, which explains in part why many countries do not engage in production. It is therefore difficult for other countries to replicate the economies of scale and the infrastructure required to produce raw materials.

In light of the dominance of India and China in raw material production, manufacturers of pharmaceutical are essentially price takers in this segment of the value chain. Typically, API's account for 70-75% of the cost of medicines and while, arguably, on this basis there is an incentive for countries to engage in raw material production and supply, the presence of China and India present substantial barriers to entry into this global market. Specifically, China and India have developed ecosystems and incentives that encourage and promote the production of pharmaceuticals. These governments provide financial incentives to companies and have established Special Economic Zones to promote the production and export of pharmaceutical raw materials. Thus, the supply of raw materials reflects an international market, and as such, all local and international manufacturers including the larger ones, are price takers.

In principle, the DTI acknowledges that there is scope to set up capacity to produce APIs in South Africa in the long run. However, a short-to-medium term solution might be for South Africa to continue to source their APIs from India and China, while working with these countries as part of the broader BRICs partnership to transfer the capabilities and knowledge required to produce the raw materials South Africa needs to address its burden of disease.

### *6.2.2 Research and design*

Research and design activities require a substantial capital outlay. While the cost of conducting R&D will differ by the type of medication being produced, those firms with deeper pockets are best placed to engage in the development of new drugs and molecules. Nevertheless, governments play an essential role in creating incentives for R&D through their National Innovation Systems (NIS). Financial incentives (through rebates, grants or subsidies) offset the significant capital and operational costs involved in R&D. Moreover, the NIS partially offsets the cost of R&D in the private sector by encouraging the commercialisation of research conducted in universities into industrial application.

In some cases, firms may be able to get around the need for R&D by purchasing API's or waiting for patents to expire. If they choose to develop off-patent drugs, these firms may be disadvantaged by late entry into the market.

At present, there is very little information on who is undertaking R&D in the pharmaceutical industry in South Africa. It is likely that pockets of R&D are happening at universities and in companies. For instance, Pharmacen, a research unit at North-West University, is a leading role player in drug research and development.<sup>114</sup>

### *6.2.3 Regulatory approval*

No drugs can enter the market before regulatory approval. The current delays at SAPHRA have been well documented in the public domain. In effect, these delays in approval of drugs impact on pricing outcomes within the various therapeutic categories. Due to the large volume of generics which are yet to be approved, potential price competition may be delayed. However, without information from SAPHRA on the authorisation applications, approvals and rejections of drugs across therapeutic categories, it is not possible to make an assessment of the consequences of delays in regulatory approach on access to medicines and the market power of manufacturers. Nevertheless, the implication is that delays in authorising new originators and generics into the market restrict the number of products sold and entrenches the market power of existing players. This is especially worrying in therapeutic categories where a few manufacturers supply the large majority of drugs.

Finally, some interviewees alleged that originator firms are introducing generics before the expiration of their patents to weaken potential competition in the long run. A view from SAPHRA would have shed further clarity. However, the issue remains that if scope exists for manufacturers to have an originator and generic in the market while the patent is being held, this potentially reduces competition within that therapeutic category.

### *6.2.4 Production*

There appears to be different options to produce either locally, regionally or internationally. In fact, some of the larger manufacturers currently outsource a portion of their production locally to third party manufacturers. This suggests that there are limited foreclosure concerns regarding access to production capacity.

Nevertheless, policymakers are concerned about local manufacturing capacity and the ability of local manufacturers to compete. To foster local production, the DTI has designated certain types of pharmaceutical products for local production. In other words, bidders receive preferential points if they meet the minimum local content production requirements. These regulations are meant to give local manufacturers preferential access to public contracts.<sup>115</sup> Moreover, the DTI has received commitments estimated at around R10 billion from the

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<sup>114</sup> (North West University, 2020)

<sup>115</sup> (Department of Trade and Industry, 2018)

pharmaceutical industry to invest in manufacturing capacity in South Africa through the National Industrial Participation Programme.<sup>116</sup> In addition, through its Black Industrialist Programme, the DTI has provided R567 million of grant funding to support black industrialists in plastics and pharmaceutical sectors as a way of expanding local production.<sup>117</sup>

### 6.2.5 *Distribution*

This level of the value chain is strongly influenced by pricing regulations and the differences in distribution approaches between the public and private sectors. While there is not enough information in the public domain to assess the distribution market, this segment of the value chain should display lower levels of concentration because manufacturers can potentially substitute suppliers for each other as distribution services are relatively standard. It appears therefore that there are a large number of players active in distribution, and that this segment of the market is competitive. However, as shown previously in Section 6.1.2.2, manufacturers can influence the distribution market through the logistics fee.

In the distribution segment, there are also specialised forms of distribution such as those pharmaceuticals requiring pressure or temperature-controlled vessels. However, there is again not enough information on this market to determine whether there are dominant players who can influence distribution prices in this part of the market.

### 6.2.6 *Dispensing/Retail*

Medicines are purchased through competitive tendering in the public sector. The current tendering system provides an estimate of the planned demand but no guarantee of volumes for each supplier. For example, the NDoH may decide to split their total volume tendered for a specific drug through one or multiple suppliers. By doing this, the State can influence competition in the supply of pharmaceuticals.

In the private sector, there are three critical factors to consider at this level of the market and their impact on competition in drug supply. Firstly, the role that manufacturers play in influencing prescriber behaviour. While the Medicines Act makes bonusing and gifting illegal, there are suggestions that manufacturers are providing incentives to doctors to influence the medications they prescribe. However, it is difficult to collect information on these behaviours, and thus it is impossible to determine the scale of these practices in the industry, but NDoH needs to monitor compliance with the legislation, and address any transgressions.

Secondly, medical schemes formularies and Designated Service Provider (DSP) arrangements influence the drug choices open to patients. Patients are more likely to use medicines on the formularies of their medical aids even if the price is higher than the generic alternative provided that their co-payment is lower. The relationship between medical schemes and manufacturers might also influence the choice of drugs that ultimately find their way onto

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<sup>116</sup> (Department of Trade and Industry, 2018)

<sup>117</sup> (Department of Trade and Industry, 2018)

the formularies. For patients on medical aids, making use of higher-priced alternatives (unless it is for chronic medication) will invariably deplete their benefits quickly and potentially increase their OOP.

DSP arrangements can also be a form of restrictive practice by funders to influence pharmacies although consumers can benefit through being able to access a higher volume of services under the same benefit option by adhering to the DSP arrangement. A more detailed examination of medical scheme expenditure patterns on drugs is needed, taking into account the differences across medical schemes, medical scheme options and level of care. Medical schemes set a reference price for drugs that indicates to pharmacies the range of products which are reimbursed and reimbursement rates. Therefore, in the private sector, drug choices are strongly influenced by funder arrangements.

In addition, several interviewees noted that medical schemes use their market power to reduce the dispensing fees charged by pharmacists. According to interviewees, there are very few instances when the full dispensing fee is paid by funders.

Thirdly, while generic substitution is encouraged by legislation, it is unclear whether this is happening consistently in practice. If medical schemes that have the greatest influence of drug choices, followed by prescribing doctor and pharmacist recommendations, then unless each of these role players actively opts for and encourages the use of generic medicines, very little generic substitution will happen in the private sector.

### 6.3 Research and development

Investing in innovative, new generation drug development processes, health research and development (R&D) is critical to ensure that high-impact, affordable medicines and health technologies reach the people who need them most. Investments in R&D within the pharmaceutical industry maximise societal welfare by increasing access to new drugs, encouraging incremental innovation to reduce side-effects and increasing therapeutic value. South Africa has a strong policy framework supporting R&D in the health sector. The South African government has demonstrated its commitment to health R&D, by adopting several policies and strategies aimed at bolstering the country's innovation agenda broadly but also specifically in the pharmaceutical sector (see Table 5 below). Many government departments and institutions have been created and tasked with funding, regulating, and participating in health R&D<sup>118</sup>.

**Table 5: South Africa's Policies that govern Health R&D**

<p><b>1. Ten-Year Innovation Plan (2008)</b></p>	<p>This plan seeks to establish a knowledge-based economy in which discoveries in science and technology lead to economic benefits for South Africa. It establishes the "Farmer to Pharma" value chain, which aims to leverage the country's biodiversity,</p>
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<sup>118</sup> APP\_sa\_rd\_landscape\_executive summary.pdf, December 2015.

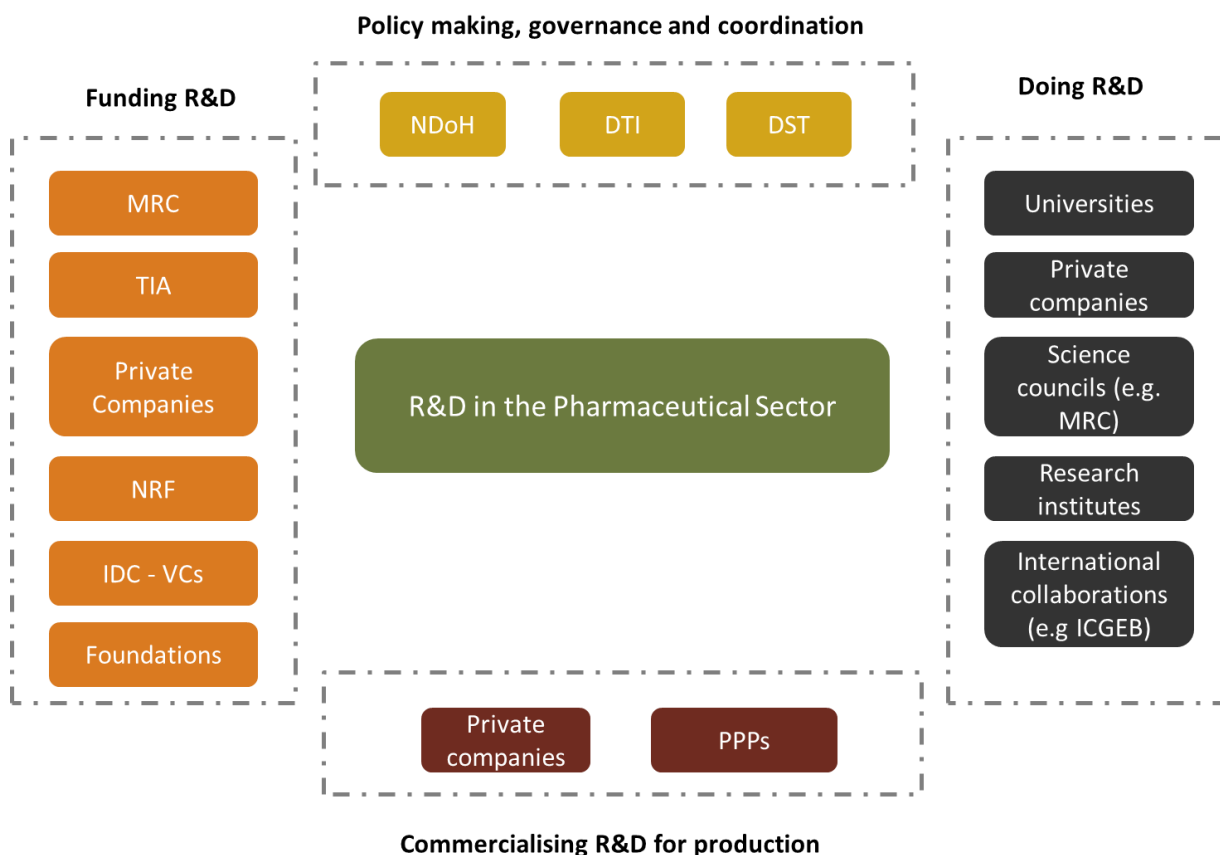
	human capital, and indigenous knowledge to spur biotechnological innovation.
<b>2. Bio-Economy Strategy (2014)</b>	The Bio-Economy Strategy is the DST roadmap for research, development, and innovation in South Africa. By bolstering the health, agriculture, and industry sectors, it aims to ensure that the bioeconomy contributes 5 percent to South Africa's GDP by 2050. It outlines key mechanisms for coordinating innovation efforts so that stakeholders can contribute—rather than compete—for opportunities, resources, and outcomes.
<b>3. Medicines and Related Substances Amendment (2015)</b>	This amendment to the Medicines and Related Substances Act of 1965 will replace the MCC with a new independent, public regulatory agency called the South African Health Products Regulatory Agency (SAHPRA). SAHPRA will regulate all medicines and clinical trials, as well as medical devices. The draft amendment was passed by Parliament in November 2015 but requires the president's signature before becoming law.
<b>4. National Health Research Policy (2001)</b>	The National Health Research Policy creates a framework for a multidisciplinary health research system to ensure that all South Africans have access to effective and efficient health services. It also seeks to build research capacity for the community, health service providers, research institutions, and decision-makers
<b>5. Draft National Policy on Intellectual Property (2013)</b>	First introduced in 2013, this draft policy would amend the 2008 IP Act. It includes a compulsory licensing provision that would allow South Africa to acquire or restrict patent rights without having to compensate IP owners.
<b>6. DTI Intellectual Property Policy of The Republic of South Africa Phase I 2018.</b>	Intellectual Property (IP) is an important policy instrument in promoting innovation, technology transfer, research and development (R&D), creative expression, consumer protection, industrial development and more broadly, economic growth.
<b>7. Industrial Policy Action Plan 2018/19-2020/21</b>	Transversal & Sector Focus Areas with key Action Programmes: Catalysing local manufacturing of critical drugs through a pharmaceuticals initiative to develop and scale-up production of active pharmaceutical ingredients (API)

By its nature, R&D is a complex process that requires the right capabilities, infrastructure and technology. Most countries develop their NSI as a mechanism to steer, deepen and promote R&D. Most NIS consists of multiple role players across the public, private, non-profit and academic sectors, all are working together to achieve the R&D objectives of the country.

In South Africa, the responsibilities for setting policy, coordinating R&D efforts and undertaking R&D are dispersed across several role-players (see Figure 29).



**Figure 29: Role-players in R&D**



Source: Adapted from (Department of Science and Technology, 2015)

This complex landscape requires strong coordination to guide the development of the pharmaceutical industry. However, as research conducted by the Council on Health Research for Development (COHRED) reveals, there are four key challenges facing health R&D in South Africa:

- Governance and commitment to R&D
- The regulatory environment
- Investment in and incentives for R&D
- Technical skills and capacity for R&D<sup>119</sup>

The key issues in each of these areas are described below.

### 6.3.1 Governance and coordination across the state

Responsibilities for coordinating and steering R&D are distributed across three national departments. Three departments have critical roles to play in health innovation: (i) the NDoH's

<sup>119</sup> (PATH, 2015)

role is to promote health research to address the burden of disease, (ii) the DST establishes and facilitates the implementation of the Health Innovation System, which is part of the National Innovation System, and (iii) the DTI supports innovation and the translation of R&D into commercially viable production.

The departments work with and oversee the following key research and funding entities:

- The **Medical Research Council (MRC)** leads health research as well as provides funding to other institutions.
- The **Strategic Health Innovation Partnership (SHIP)** is a partnership between the MRC and the DST, which funds and manages R&D projects related to the “development of new drugs, treatments, vaccines, medical devices and prevention strategies”.
- The **National Research Foundation (NRF)**, within the DST, provides research funding directly to universities and research entities.
- The **Technology Innovation Agency (TIA)**, a DST public entity that provides funding to support the development and commercialisation of technology.

Of these entities, the SHIP was established by the Bio-Economy Strategy in 2014, which outlines a roadmap for R&D and innovation in the country. One of the outcomes of the implementation of the strategy was restructured and revitalised the MRC that aims to fund and lead innovation in the medical and health sciences. The SHIP itself is a major milestone in the development of the Pharmaceutical Industry. The SHIP brings together the national and international funders, government, academia and the private sector to focus on the singular goal of encouraging innovation in the health sector.

Whereas the SHIP has successfully funded research into medicines, the TIA has been less successful in funding product development and commercialisation in the health and pharmaceutical industry. The operations of the entity have been plagued by claims of mismanagement and poor decision making. TIA also lacks the skills to fund and commercialise health R&D.

A major shortcoming in the current landscape is the lack of clarity around the specific roles and responsibilities of the NDoH, DTI and DST with regards to R&D in South Africa. This has resulted in overlapping mandates and weak coordination amongst these three government departments and their public entities. For instance, while NDoH is tasked with promoting health research, the DST provides leadership, resources, and an enabling environment for science technology, and innovation. The DTI supports firms in the pharmaceutical industry to develop local manufacturing capacity based on technologies produced by the country. However, while government identifies the production of APIs in the Industrial Policy Action Plan as far back as 2007, there is still no clear and coordinated strategy around the research, development and production of active ingredients for pharmaceuticals in the country.

A common theme emerging from interviews is the lack of coordination across government departments with regards to scientific and industrial co-operation and collaboration. For instance, BIOVAC was established as a partnership between government, academia, the non-

profit sector (through the Bill and Melinda Gates Foundation) and the private sector to produce vaccines to meet South Africa's and the region's needs.<sup>120</sup> Although the partnership produces about 25 million doses of vaccines annually, one key informant suggested that the investment into BIOVAC has not translated into cheaper vaccines nor has it spurred local manufacturing.

Contributing to some uncertainty is the Draft National Policy on Intellectual Property (2013), which raises concerns around the rights of researchers and innovators. The legislation includes a compulsory licensing provision allowing the government to acquire or restrict patent rights without compensation. From a strictly R&D perspective – not considering public health – compulsory licencing has been touted as a potential barrier to R&D.

### 6.3.2 *Regulatory capacity*

The processes involved getting authorisations for clinical trials, a critical step in R&D is complicated in South Africa. Before 2017, the Medicines Control Council (MCC) was responsible for regulating medicines and clinical trials in South Africa. However, this organisation was beset by several problems which impacted on the licensing of drugs for entry into the market. The regulator offered little guidance on application requirements. As the number of applications increased, the MCC also faced resource constraints, relying heavily on “over-committed external expertise” which could not deliver medicine evaluations timeously.<sup>121</sup>

In 2017, SAHPRA replaced the MCC through an Amendment to the Medicines and Related Substances Act (1965). At the time, the new regulator inherited a backlog of around 16 000 medicine regulatory applications for market authorisation.

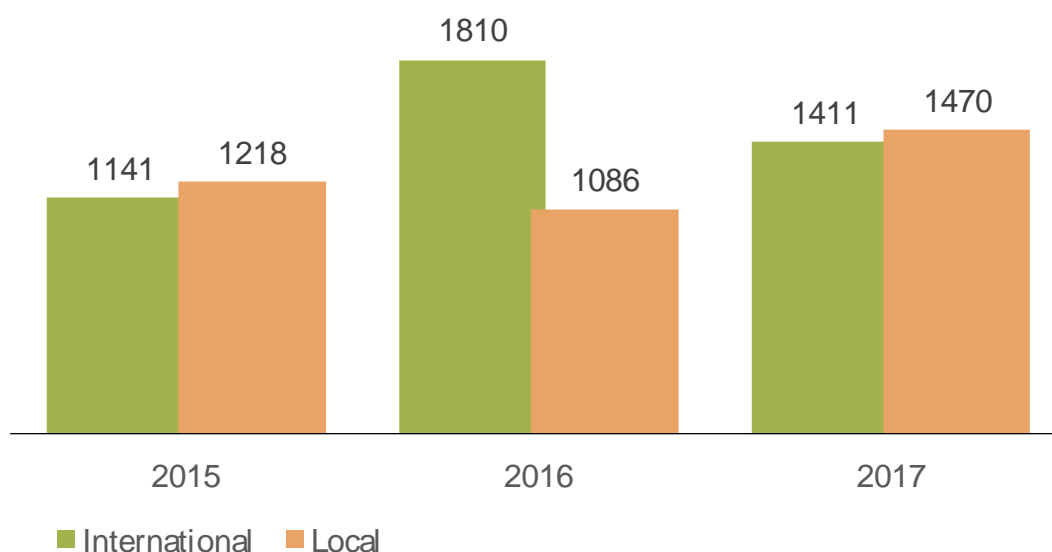
Half of these applications were over 5-years old, with some dating back to 1992. Furthermore, 90% of these applications were for generic medicines. Delays in market authorisations affect prices and access in two ways. First, it reduces the number of drugs available on the market. Of particular concern in the South African pharmaceutical industry are the slow approvals on generic medicines which limit access to affordable medicines. Second, delays in authorisations prevent new and innovative drugs that have fewer side effects or more therapeutic value from entering the market. To understand the scale of these backlogs, Figure 30 presents median approval times for applications in calendar days for the MCC between 2015 and 2017 for international and local applications. In 2017, applications took on average 6 years to be approved by SAHPRA.

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<sup>120</sup> (BIOVAC, 2020)

<sup>121</sup> (Keyter, Banoo, & Walker , 2018)

**Figure 30: MCC Median approval times in calendar days (2015-2017)**



Source: *The Regulatory Review Process in South Africa: Challenges and Opportunities for a New Improved System – DIA (2018)*

Much of these delays can be attributed to insufficient staffing and resourcing. It was estimated that the MCC received around 4 700 applications every year while it only could process 2 550 applications per year.<sup>122</sup> While SAPHRA has a more expansive mandate when compared to the MCC, it will need some time to build capacity and it is unlikely that the growing backlog will be addressed in the short term.

### 6.3.3 Investment in and incentives for R&D

Investment in health R&D has increased across the public and private sectors, rising from 13% of total R&D expenditure in 2005 to 17% in 2015. This is mostly driven by the public sector such that in 2015, South Africa was able to meet the 2008 Bamako Agreement, an international commitment to direct 2% of the national health budget to health R&D.

However, there are increasing calls from stakeholders to improve coordination across government departments to ensure that health R&D is funded across the value chain, from research to manufacturing. Funding to support commercialisation is required, given that there is limited private venture capital aimed at commercialising health innovation. Whereas the TIA has an important role to play in funding commercialisation, concerns regarding its capabilities have led to plans to establish a government backed-venture capital fund administered by TIA being put on hold.

To encourage greater private investment in R&D, the government has instituted a tax incentive that enables companies to claim a deduction of about 150% on R&D expenses incurred. While this tax incentive has been in place for a number of years, the process of applying for these

<sup>122</sup> (Keyter, Banoo, & Walker, 2018)

tax deductions is beset by administrative delays, complex processes and the inability of small and medium-sized enterprises of access this incentive. Government has taken steps to simplify the administrative processes, including developing an online platform to manage applications and clear guidance on what is required from applicants.<sup>123</sup> However, at this stage, it is unclear whether streamlined application processes will incentivise firms to increase their R&D in the pharmaceutical industry.

#### *6.3.4 Technical skills and capacity for R&D*

There are several initiatives in place to increase the technical capacity and skills to undertake R&D in South Africa. H3D is Africa's first integrated drug discovery and development centre established at the UCT in 2010 and pioneers world-class drug discovery in Africa. Likewise, the Centre of Excellence for Pharmaceutical Sciences (Pharmacem) is a research entity established within the North-West University that focuses on translational neuroscience and neurotherapeutics, drug delivery and drug discovery. Their research programme is linked to South Africa's burden of disease and national priorities. The Centre is equipped with a state-of-the-art laboratory and has several NRF-rated researchers working on drug development.<sup>124</sup> Currently, the CSIR and role players in the NIS are working on developing translational programmes to turn research into industrial applications.<sup>125</sup>

The SHIP also plays an important part in building technical capacity. So far, through a partnership between government departments (DST, DHET, DTI, NDoH and supporting public entities), academic research centres manufacturing and development partners (Global Fund, Bill & Melinda Gates Foundations, etc), the partnership programme has gained access to cutting-edge science, new technologies and funding.

### **6.4 Intellectual property laws and patents**

Patents are granted for a finite period to afford manufacturers protection from competing products, or from other manufacturers producing generic substitutes. On the one hand, in the pharmaceutical industry, where R&D accounts for a large proportion of the total cost in bringing new drugs onto the market, patents protect the manufacturers' investment and enable them to recoup some of their expenditure on research. On the other hand, granting a patent gives a manufacturer a monopoly position in the market over the supply of a drug. If no suitable alternatives are available, the manufacturer can charge high prices. Therefore, in a regulatory system, the benefits of patents in fostering innovation, research and development must be weighed against the potential harm associated with excessive pricing by manufacturers.

Interviewees raised several concerns with the current system of IP laws. It appears that manufacturers have an incentive to 'ever-green' their products. 'Ever-greening' is the process of slightly modifying the composition of the drug to lengthen the duration of patent protection.

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<sup>123</sup> (GCIS, 2018)

<sup>124</sup> (North West University, 2020)

<sup>125</sup> (Department of Trade and Industry, 2007)

In South Africa, the practice of ever-greening has led to high prices for certain essential drugs. For example, South Africans were previously unable to access linezolid, despite the high rates of tuberculosis.<sup>126</sup> Evergreening also overwhelms the regulatory system by increasing the applications for authorisations, especially for those drugs whose modifications provide little additional therapeutic benefit.

According to interviewees from civil society, weaknesses in patent laws coupled with a lack of political will to ensure compulsory licensing is applied, in line with TRIPS is one of the contributing factors. Some countries argue that India has contravened of specific WTO rules and the TRIPs in the greater public interest, which is viewed by some interviewees as the strong political will needed in South Africa. However, there are precedents for compulsory licensing. As Son and Lee (2018) report there have been 108 attempts to issue compulsory licensing for 40 pharmaceuticals in 27 countries since 1995. Most of the countries involved in compulsory licensing come from Asia, Latin America, and Africa and was initially done for HIV/AIDS medicines, although increasingly compulsory licensing is also used for medicines that are priority drugs to meet the health care needs of countries.<sup>127</sup>

## 6.5 APIs

The WHO defines APIs “as any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or another direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body”.<sup>128</sup>

Interviewees suggest that there is little capacity in South Africa to produce Active Pharmaceutical Ingredients (APIs) at scale. South African pharmaceutical companies mainly focus on reformulation or repackaging of medicines and APIs.

The DTI Industrial Policy Action Plan, 2018/2021, seeks to create the conditions to bridge the gap between research, development and industrial application. It has established several initiatives to expand local manufacturing of critical drugs and scale up production of APIs including designating the pharmaceutical sector for the National Industrial Participation Programme and funding Black Industrialists in the industry.

Another initiative is Ketlaphela, the State-Owned pharmaceutical company supplying South African Manufactured API's and final formulated medical products mainly for communicable diseases such as HIV/AIDS, Tuberculosis, and Malaria and in future non-communicable diseases. A pilot plant for the manufacture of generic APIs officially opened in Pretoria, 2017. Furthermore, CPT Pharma & IDC (R50 million joint project), supported by the Departments of

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<sup>126</sup> (Fix the Patent Laws, 2012)

<sup>127</sup> (Son & Lee, 2018)

<sup>128</sup> WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-seventh report. Geneva, World Health Organization, 2003 (WHO Technical Report Series, No. 908), Annex 4

Science and Technology, Trade and Industry and Health Departments, aims to produce Tuberculosis medicines for the local market. Going forward, lessons from the two projects need to be explored, unpacked to inform the development of best industrial, clinical and manufacturing practices between government and pharmaceutical stakeholders.

The place to start, as key informants suggest, is by developing local capacity to produce the active ingredients found in ARVs. While South Africa only makes up 1% of the global pharmaceutical market, it represents a quarter of the global ARV market in low- and middle-income countries. However, developing local production capacity for the APIs contained in ARVs requires a clear and coordinated strategy on how to incentivise R&D and local manufacturers.

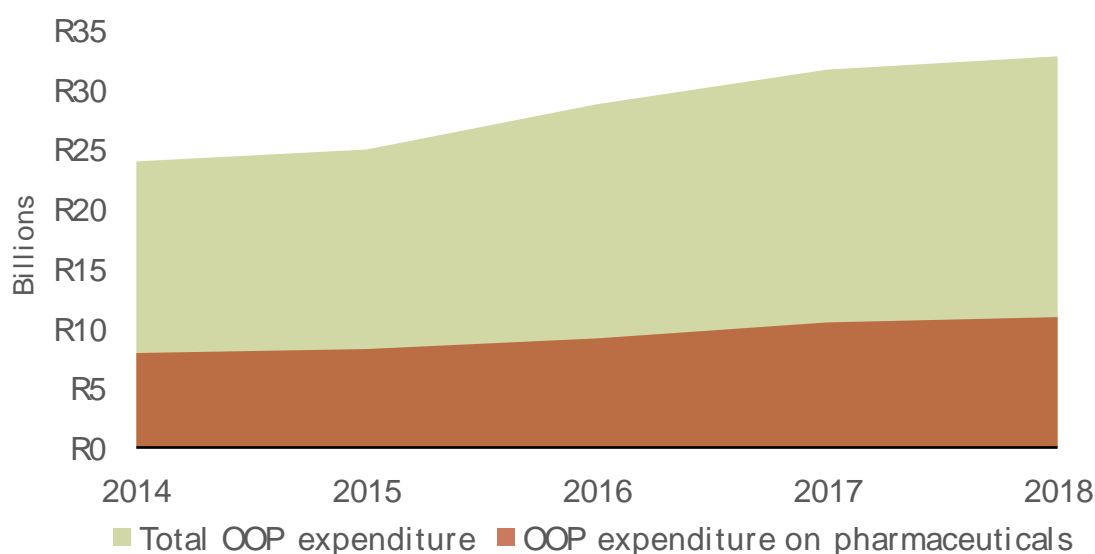
In 2019, Cabinet instructed the NDoH and DTI to develop the Master Plan on Health Economy aligned to NHI that will include identifying opportunities for localisation and economic development in the pharmaceutical industry. Perhaps, once the Master Plan is approved, it will provide the policy certainty needed by the industry to spur local production.

## 7 OUT OF POCKET EXPENDITURE

OOP expenditure can be interpreted as one of the outcomes of policy and regulation in the pharmaceutical sector. High OOPs might point to a failure within the regulatory system to protect consumers against excessive medicine prices. It also reflects gaps in public and private health coverage which forces patients to purchase medicines from their disposable income.

Based on data published by the CMS, OOP expenditure made up 19% of total healthcare expenditure for the private sector in 2019.<sup>129,130</sup> Figure 31 shows OOP expenditure data for 2014-2018. Pharmaceuticals make a significant portion of OOP – 32.9% in 2018 and appears to be increasing steadily over time.<sup>131</sup> Thus, it seems that expenditure on pharmaceuticals has financial implications across several income quintiles. That said, the OOP expenditure captured by CMS understates total expenditure as it does not capture the full range of OOP expenditure by medical-scheme users, nor does it capture OOP by public sector dependants. The estimates reported by the CMS, therefore, reflects the OOP and claims data by members of medical aid schemes. All things considered, there seems that OOP is both increasing and under-reported at the same time.

**Figure 31: Annual OOP expenditure for medical scheme users, 2014-2019<sup>132</sup>**



Source: CMS Annual report 2018/19

<sup>129</sup> (CMS, 2018)

<sup>130</sup> Total private healthcare expenditure is understated as it only reflects the amount of benefits paid out by medical schemes.

<sup>131</sup> After OOP payments are the second largest expenditure item after payments to health professionals (i.e. general practitioners, specialists, health and allied professionals).

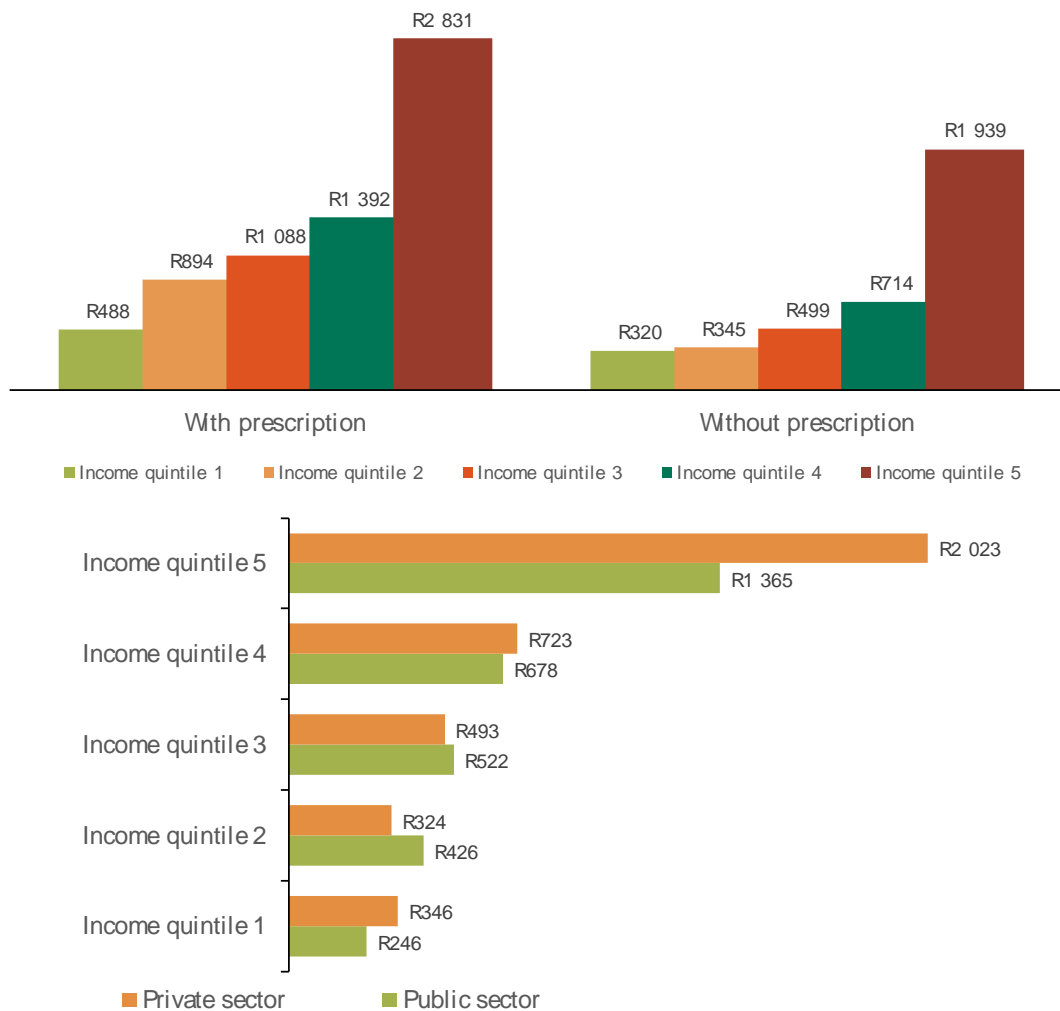
<sup>132</sup> “Out-of-pocket payments have been calculated as the difference between the claim amount billed and the amount that was paid from medical scheme risk, including the amount paid from the medical savings account. This is an understatement of the true out-of-pocket expenditure incurred by medical scheme members, since not all out-of-pocket claims are submitted to the medical scheme. In 2018, the total out-of-pocket expenditure amounted to R32.9 billion – up from the R31.8 billion in 2017. This represents 19.0% of the total benefits paid” (CMS, 2018)



Of particular concern to the NPC is the effect of OOP payments on household expenditure in lower quintiles. To gauge how much is spent by low-income households, the research team used the OOP expenditure data from Stats SA's Living Conditions Survey. The survey was conducted in 2015 and asked respondent households about the medical expenses they incurred that was not covered by their health funder (public or private).

Figure 32 presents reported OOP payments by income quintile. The upper panel considers OOP expenditure by prescription and the lower panel by sector. Care needs to be taken when analysing OOP expenditure by sector. The distinction between public and private sector, in this case, is whether the household is a user of public or private sector facilities. However, it is likely that actual expenditure happens in the private sector – community and retail pharmacies.

**Figure 32: Average annual OOP expenditure on pharmaceuticals by income quintile, 2015**



Source: Stats SA Living Conditions Survey, 2015  
Note: Estimates are weighted to be representative at a national level.

Average OOP expenditure rises across income quintiles such that households belonging to the highest income bracket spend the most OOP on pharmaceuticals. As expected, a greater

amount is spent on prescription medicines than non-prescription medication. While the data from Statistics SA is the latest estimates of OOP expenditure, there are questions around the extent to which public sector users report OOP expenditure.

The calculation of income quintiles in South Africa is influenced by the vast disparities between rich and poor. Thus, even in the income quintile 5, there will invariably be financially distressed and vulnerable households at or near the cut-off value of R186 215 (see Table 6). Thus, while these households are not defined as poor, they are still impacted by high levels of OOP expenditure.

**Table 6: Living Conditions Survey annual household income quintiles, 2015**

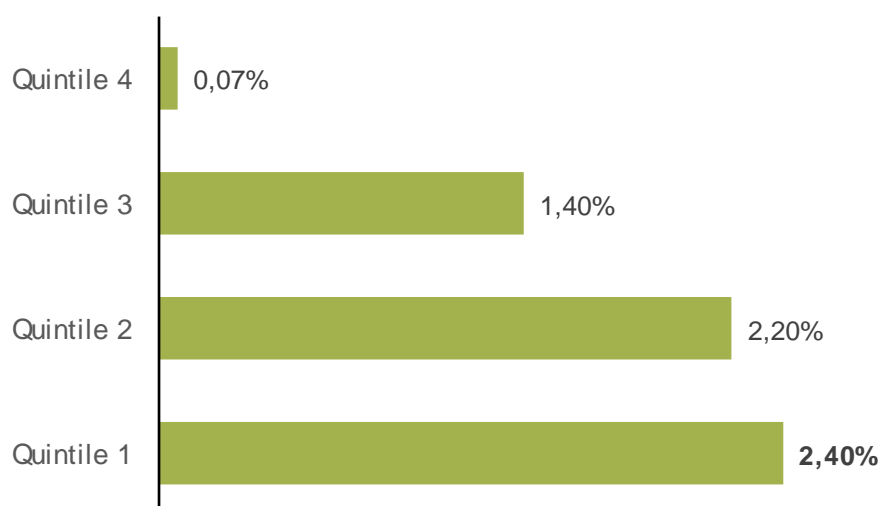
Quintile	Cut-off values
1	R 20 282
2	R 40 695
3	R 77 503
4	R 186 215
5	More than R 186 215

Source: Stats SA Living Conditions Survey, 2015

Note: April 2015 Rand values. Estimates are weighted.

Using the cut-off estimates, Figure 33 presents average OOP for prescription medication as a percentage of annual income, by quintile.

**Figure 33: OOP as a percentage of annual income by quintile, 2015**



Source: Stats SA Living Conditions Survey, 2015

Figure 33 reveals that OOP payments affect the lowest quintiles the most. For this reason, the extent to which healthcare users fall outside of their safety net, be it public or private, is concerning.

In addition, the link between OOP and the growing burden of disease vis-à-vis non-communicable diseases such as diabetes and hypertension that require long term chronic medication should be of concern to policymakers. This study shows that relative to international comparators, the costs of drugs for heart disease and diabetes medication is relatively higher in South Africa. Furthermore, the study suggests that OOP payments for lower-cost drugs and especially chronic medication tend to be higher as a share of the total cost. Thus, against the background of the rising incidence of non-communicable diseases in the general population, the prices of chronic medication and their effect on OOP payments as a percentage of total household expenditure is expected to increase over the long-term.

## 8 CONCLUSION AND RECOMMENDATIONS

All South Africans will need medicines at some point in their lives, whether it is to treat a simple cold, cure an acute illness or manage chronic disease. Making sure that South Africans have access to affordable medicines is indispensable to the proper functioning of the healthcare system. And yet, access to affordable medicines is a struggle for many South Africans. It remains a significant obstacle to the achievement of the National Development Plan's goals of extending the life expectancy of all citizens.

South Africa has a large and complex healthcare system, made up of an under-resourced public sector that serves the majority of the population and a private sector that caters to medical scheme members. With expenditure on health services increasing as a share to total household expenditure amongst the lowest income quintiles, the government is concerned with the affordability of medicines for the poorest households in South Africa. The NPC has commissioned this study to analyse prices of both originator and generic medication in South Africa and understand the effects of the regulatory regime on prices.

This study explores how historically South Africa dealt with the issues of pharmaceutical prices, affordability and availability, and makes concrete recommendations on how to improve the regulatory framework. In the rest of this section, the conclusion and recommendations are organised around each of the key research questions.

### ***RQ 1: How does the policy and regulatory framework in South Africa governing medicine pricing work?***

The pharmaceutical sector is governed by a complex set of laws, regulations and policies that influence the prices of medicines. There is no single price-setting regime in South Africa; rather, prices are determined and set differently in the public and private sectors.

In the public sector, medicines are procured through a competitive tendering process, governed the PFMA (1999). Essentially, under public procurement rules, the government must find the lowest cost product that meets their specifications. This requirement for the lowest prices drugs is however moderated by local content obligations set out in the National Industrial Participation Programme and Black Economic Empowerment obligations outlined in the PPPFA (2000).

Government has designated the pharmaceutical sector as part of the National Industrial Participation Programme. Effectively, this means that any government department that buys medicines must award manufacturers preferential points if they can demonstrate that they meet the local content requirements in the tender. Manufacturers also receive preferential points for being empowered.

In contrast, the price of pharmaceutical products in the private sector is regulated through the SEP prescribed in the Medicines and Related Substances Control Act (1967) as amended. This legislation and regulations give effect to the National Drug Policy (1996) that aimed to

ensure the availability and accessibility of drugs, lower the cost of medicines and develop a local pharmaceutical industry amongst other objectives.

The Medicines Act contains several provisions to help the government promote transparency and reduce the prices of medicines. The Act prohibits pharmaceutical companies from using financial and other incentives to market their products to pharmacists and prescribing doctors. It also outlaws discounts and rebates to distributors and retailers. The Act also includes several contested provisions such as compulsory licensing, which has been subject to legal challenge and has yet to come into effect. Some argue that Section 15(a) of the Act would effectively allow the Minister to implement the TRIPS agreement which allows countries some flexibility to license other manufacturers of drugs where it is in the public interest to do so.

While South Africa is a signatory to the TRIPS agreement, the Patent Act's (1978) conditions for a compulsory license are relatively strict. The Act only allows the intellectual property rights of the patent holder to be suspended when there is clear evidence that the right in a patent is being abused. However, while the Competition Act (1998) has mechanisms to control the abuse of dominance associated with the market power granted to patent holders, these provisions have not yet been tested in the pharmaceutical industry.

In addition to price regulation, the Act introduces a form of conduct regulation that is designed to enhance transparency and prevent rent-seeking behaviours. This includes prohibitions on the use of 'other' (non-financial) incentives by pharmaceutical manufacturers to push their products and the obligation on pharmacists to substitute the branded product for the generic alternative unless otherwise specified by the prescribing doctor.

The SEP is the regulated maximum price that patients should pay for their medicines. It is published on the MPR and was designed to enhance transparency and protect patients from excessive pricing. The SEP consists of three components: ex-manufacturers price, logistics fee and VAT. Originally, the Pricing Regulations envisaged a two-stage process to setting the price of the SEP.

In the first stage, pharmaceutical companies submit their ex-manufacturers price, logistics fee and VAT to the Pricing Committee. The ex-manufacturers price is the proposal put forward by the manufacturer for new drugs. In the second stage, the Pricing Committee was supposed to benchmark the prices proposed by manufacturers against comparable jurisdictions. Benchmarking, or ERP as it is commonly known in the pharmaceutical industry, is a widely used approach to reduce the price of medicines.

Another shortcoming in the current regulatory framework is that it does not empower the Pricing Committee to negotiate prices. Furthermore, the information disclosure provisions in the current legislation that would enable more robust negotiations are relatively weak.

However, although the government has published regulations for an ERP methodology as far back as 2007, these were only finalised in 2014. By 2019, the ERP still had not been adopted because the pharmaceutical industry had challenged the legislation in court, questioning the

basket of comparison countries, and government's choice to use the lowest instead of the average price.

The SEP and a dispensing fee determine the final price of medicines that patients pay. At present, the structure of the dispensing fee is regressive. In other words, the dispensing fee makes up a higher proportion of the total cost of lower-priced medicines.

While, South Africa has a regulatory framework in place, the uneven execution of the legislation and regulations seems to have had unintended consequences on the prices and affordability of medicines. On the one hand, the SEP has fostered greater price transparency and eliminated some of the incentives for pharmaceutical companies to 'push' their products. On the other hand, because of the stalled implementation of the ERP, South Africans might be paying more for certain drugs when assessed against comparable countries. In addition, since manufacturers' prices are strictly regulated irrespective of quantities sold, they have an incentive to price as high as would be financially viable when selling small quantities.

R1.1

- Strengthen the regulatory powers of the Pricing Committee to allow them to interrogate and negotiate prices of the originator and generic drugs with manufacturers.

R1.2

- Strengthen the disclosure obligations of manufacturers to provide information on costs, volumes and the actual (not planned) logistics fees to the Pricing Committee.

R1.3

- Conduct a regulatory impact assessment on the current regulations relating to the dispensing fee to determine how its regressive nature impacts on the affordability of medicines (especially lower-priced ones) across the income quintiles.

### ***RQ2: How does South Africa's pharmaceutical pricing regulatory regime compare to other countries?***

Three of the eight comparator countries have adopted external reference pricing to determine medicine prices. This pricing approach has, to some extent, allowed them to constrain the growth in medicine prices. In addition, there is a move in developed countries such as Sweden, the UK and France to use value-based pricing – a technique that takes the effects of the drug on health outcomes measured against its costs.

India, which has amongst the cheapest prices in the world, uses a price control mechanism where the National Pharmaceutical Pricing Authority sets the ceiling price for each drug. The regulated price is fixed at the weighted average price of brands that have more than 1% market share. Like the SEP, the price ceilings in India determine the maximum allowable price. However, a key difference between South Africa and India is that since many of the medicines

are produced locally, price competition amongst Indian manufacturers tends to drive down medicine prices.

The international comparison reveals that South Africa has done well in bringing down the price of ARVs, and alongside India, has the lowest prices in the world. However, prices for drugs treating non-communicable diseases such as diabetes and cardiac diseases remain relatively high compared to other countries. For instance, cardiac drugs are being sold locally at a higher price than many comparator countries. Lower prices are not exclusive to high- or low-income countries which indicate the potential for South Africa to bring prices closer to some of its BRICS counterparts.

Given, the growth in mortality rates from non-communicable lifestyle diseases, the higher demand for these drugs together with the higher prices, is likely to increase pharmaceutical expenditure going forward, and an issue that policymakers will face under the NHI.

R2.1

- The NDoH should take steps to issue the regulations on ERP. In the interim, the department should monitor the SEP of drugs against the basket of comparator countries, especially those used to treat non-communicable diseases.

***RQ3: What are the main factors within the pharmaceutical sector that impact on medicine prices?***

### **Pricing policy and regulation**

There are large variations in the prices of pharmaceutical products across the public and private sector. The pricing outcomes are largely influenced by the different approaches to procurement and regulation taken by the public and private sectors respectively. There is strong empirical evidence to support the notion that medicine prices in the public sector are among the lowest in the world. These low prices stem from the state's ability to leverage its bulk purchasing power through a competitive tender process. However, there are some challenges with the procurement system that leads to stock-outs and medicine shortages. The lack of capacity to forecast and plan demand and manage inventory affects patients when facilities run out of medicines. At the same time, it makes it difficult for manufacturers to plan and manage their supply.

Likewise, there is significant empirical evidence to demonstrate that the SEP has successfully reduced the prices of medicines over time while slowing the rate of increase in prices through a controlled annual adjustment. The decline in prices has contributed in part to a decrease in the share of pharmaceutical expenditure as a proportion of total expenditure after the implementation of the SEP in 2004.

While the prices of medicines have declined in absolute terms in the private sector since the introduction of the SEP, the regulation has not gone far enough. When evaluated against comparison countries, the SEP has resulted in a mix-bag of pricing outcomes. Thus, while the SEP is typically lower for ARVs and TB drugs, it is significantly higher for drugs treating non-communicable diseases such as Diabetes Mellitus and Cardiac therapy. Part of the problem is the lack of a price referencing system that would allow the Pricing Committee to determine the appropriateness of the prices submitted by manufacturers, and where warranted, negotiate for better prices. Effectively, this means that retailers, hospitals and dispensing doctors are price takers determined by supply and demand, irrespective of access and affordability considerations. The ERP provides a promising alternative to the current SEP methodology but needs to be complemented with other pricing policies. Value-based pricing can complement ERP and will give greater credence to the pricing of drugs.

Whereas the SEP has introduced transparency in the prices of drugs by removing hidden discounts and rebates, this regulatory mechanism remains open to manipulation. This analysis provides indicative evidence that a decline in the manufacturers' price in a previous period is correlated with an increase in the logistics fee in the following period. This might point to the willingness of manufacturers to reduce their prices and increase the logistics fee paid to distributors in order to stock and push their products. However, a more detailed examination of the relationship between manufacturers and distributions in the pharmaceutical value chain based on actual prices paid to logistics firms is needed to test these claims.

Like the SEP, the dispensing fee is regulated. However, the regressive nature of the dispensing fee might offset the benefits of reducing medicine prices over time. As prices decline, the dispensing fee makes up a larger percentage of the total price paid by the patient. That said, it appears that medical aid schemes can influence the dispensing fee, and in many instances negotiate lower fees with pharmacies. Therefore, the actual dispensing fee paid by funders often varies by the scheme and medical plans. This also means that it is patients who will pay the full dispensing fee from their disposable income.

R3.1

- The NDoH should build capacity within the government to implement the ERP and carry out pharmaco-economic analyses in the short-term to determine the appropriate price of medicines. Over the medium to long term, the government should consider adopting a value-based pricing methodology.

R3.2

- The NDoH should develop and implement a monitoring system that collects consistent and longitudinal data on the prices, volumes and costs of medicines across therapeutic categories, and by generic and originator.



R3.3

- The NDoH fast track setting up an independent body (similar to NICE<sup>133</sup>) or integrating the function into SAHPRA to undertake the pharmaco-economic and value-based pricing assessments.

R3.4

- The NDoH should fast track the establishment of the real-time medicine inventory monitoring system that provides the information it needs to forecast demand for drugs in the public sector.

### Market structure and competition

The pharmaceutical value chain consists of distinct yet related activities including raw material production, research and development, manufacturing, wholesaling, distribution and marketing. In South Africa, the manufacturing and retail levels exhibit high levels of concentration. This effectively means that players in these two segments of the market have enough market power to influence prices. At the manufacturing level, most manufacturers are active across the four therapeutic categories analysed in this report (i.e. Anti-Retrovirals, Diabetes Mellitus, Cardiac Therapy and TB), some possess stronger market positions within specific therapeutic categories, which implies that there may be high levels of concentration in the supply of certain drugs. Even though manufacturers have some market power, their ability to influence prices is curtailed by the buying power of the state in the public sector. In the retail segment of the market, medical schemes exert substantial influence over dispensing fees.

There is also some evidence that at the originator level, high levels of market concentration exist. While the supply of generics appears to be more competitive (lower market concentration), careful attention must also be paid to the fact that some of the companies producing originator drugs may be directly/indirectly active in the supply of generic medication. It appears that the market structure varies considerably by therapeutic category. The market for ARVs tends to be reasonably competitive with a large number of suppliers supplying both generics and originators to the state. In contrast, there is an oligopolistic market structure for Cardiac and Diabetes Mellitus drugs, that is, a few firms account for the largest share of drugs supplied.

The delays in market authorisations of new drugs and generics further entrench the power of incumbents in markets with few suppliers. The full impact of the delays by SAHPRA on the supply of medicines is difficult to gauge, as information on the types of drugs awaiting regulatory approval by therapeutic category is not publicly available. Nevertheless, it is likely that the backlog of 18 000 applications is severely constraining the supply of medicines.

More in-depth analysis of the market structure and competition is however hampered by a lack of information on the market role-players and the size of their market share.

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<sup>133</sup> The National Institute for Health and Care Excellence (NICE) in the UK provides national guidance and advice to improve health and social care. As part of its mandate, it undertakes value-based pricing and cost-effectiveness analyses.

R3.5

- The NPC should commission a detailed market assessment for the different segments of the pharmaceutical value chain based on actual information about market participants and their relative market shares.

<sup>134</sup>

R3.6

- SAHPRA must publish more granular information on the applications backlog including a detailed analysis of the backlog by therapeutic category and medicine type (generic versus originator).

R3.7

- SAHPRA should develop and publish its action plan (in response to the recommendations from the backlog eradication project) that outlines how it intends to address the backlog and by when.

## R&D

R&D in the pharmaceutical industry in South Africa is limited, although there are initiatives underway to bolster the country's capacity for research, design and development. The slow pace in building capacity for R&D is partly the result of weak intra-governmental partnership and co-operation between the Departments of Health, Trade and Industry, Science and Technology. While the SHIP was established to improve coordination of R&D efforts, it is too early to tell whether this initiative has translated into pharmaceutical innovation.

Through the NIS, the government has put in place a number of incentives from grants to tax breaks to support R&D in the country. At this point, it is unclear whether the current system of R&D and tax incentives has encouraged pharmaceutical companies to invest in research and development. TIA, the institution, responsible for supporting R&D, through grants lacks the specific skills needed to promote innovation in the pharmaceutical industry and has been plagued by allegations of mismanagement. The application process for the tax incentive offered by SARS was administratively burdensome for firms. Although, SARS has streamlined its application processes, the lack of public information on which sector the incentive benefits, makes it difficult to assess whether the pharmaceutical industry has indeed taken up this tax break.

Another factor stifling R&D in South Africa is the delays in approvals of clinical trials a by SAHPRA. While the regulator has taken steps to address this backlog, it probably will not be eradicated in the short-term.

R3.8

- The DST, in collaboration with the NDOH and DTI, should develop a sector strategy to steer and coordinate the government's efforts to promote R&D in the pharmaceutical industry.

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<sup>134</sup> The aim of this analysis is not duplicate the work of the Health Market Inquiry but to strengthen the policymakers understanding of the value chain.

## Intellectual property laws and patents

Although intellectual property laws play an essential role in fostering R&D, they also grant manufacturers market power over the supply of a particular drug. In many respects, the current patent system has created perverse incentives for pharmaceutical companies to manipulate and game the system. ‘Evergreening’ is a technique employed to extend patent protection over a drug and prevent competition. Some interviewees were concerned that drug companies had made minor modifications to the drugs to lengthen their patents. In addition, South Africa’s patent laws are much stricter than the TRIPS, and thus might be a stumbling block to the introduction of compulsory licensing in South Africa.

Combined, these two factors, the manipulation of the patent system and the strict patent laws restrict the supply of new and generic medicines into the South Africa market and further contribute to higher prices.

R3.9

- The DTI should take steps to align the current Patents Act (1978) with the TRIPS regime.

## APIs

Finally, there is little capacity in South Africa for producing active pharmaceutical ingredients (APIs) at scale. At present, South African pharmaceutical companies mainly focus on reformulation or repackaging of medicines and APIs. While it is unlikely that South Africa will develop the capacity to manufacture APIs at scale and compete with large suppliers like India and China, it does nevertheless account for a quarter of the global ARV market in low and middle-income countries. There is, therefore, an opportunity for the state to promote the local manufacturing of APIs required for ARVs.

R3.10

- The DTI should develop an industrial strategy for the pharmaceutical industry that outlines the steps it will take to develop local manufacturing capacity for high priority drugs (where appropriate) and APIs linked to South Africa’s burden of disease.

## *RQ4: How much OOP expenditure is spent on medicines by citizens and residents?*

OOP expenditure for medicines is on the increase and under-reported across income quintiles within both the insured population and the public sector dependent population. Pharmaceuticals make up the largest portion of OOP – 32.9% in 2018, and appears to be increasing steadily over time, suggesting that pharmaceuticals have financial implications across quintiles. Further, as the incidence of non-communicable diseases such as diabetes and hypertension that require long term chronic medication increases, OOP payments are expected to increase.

R4.1

- Statistics SA and the CMS should collect disaggregated data on the OOP payments by households across different quintiles. Specifically, the data should collect information on their expenditure by therapeutic category.

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## APPENDIX 1 LIST OF INTERVIEWS BY INSTITUTIONS

Interviewee	Status	Number
Academic	Completed	3
Civil Society	Completed	3
NDoH	Completed	3
the dti	Completed	1
DST	Completed	1
Expert	Completed	1
International Expert	Completed	1
Independent Pharmacist	Completed	1
Manufacturer	Completed	3
Manufacturer	No response	1
Private Funder	Completed	2
Private Hospital	Completed	1
Private Hospital	No response	1
Public Funder	Completed	1
Regulatory Authority	Completed	3
Regulatory Authority	No response	1
Retail Pharmacy	Completed	1
Retail Pharmacy	No response	1
Dispensing Doctor	Completed	1
<b>Total</b>	<b>Completed = 26</b>	<b>30</b>

## APPENDIX 2 INTERNATIONAL BENCHMARKING

### A 2.1 Unit prices for Cardiac Therapy

Country	Hydrochlorothiazid e 12,5mg	Hydrochlorothiazid e 25mg	Enalapril 5mg	Enalapril 10mg	Amlodipine 5mg	Amlodipine 10mg	Simvastatin 10mg	Nifedipine 30mg	Furosemide 40mg	Atenolol 50mg
South Africa	R1,23	R3,24	R1,24	R3,65	R1,75	R1,96	R5,59	R1,55	R5,13	R2,43
Australia	R1,10	R4,86	R2,20	R4,12	R1,32	R4,20	R6,12	R4,21	R4,35	R4,45
New Zealand	R2,82	R0,95	R3,17	R0,32	R0,12	R0,63	R2,60	R0,18	R0,36	R0,85
Canada	R0,36	R2,92	R0,17	R1,48	R0,36	R2,23	R6,81	R1,22	R2,20	R2,43
Spain	R1,89	R1,45	R1,89	R0,67	R1,21	R0,55	R1,34	R1,35	R1,35	R0,53
Bahrain	R12,65	R10,75	R24,32	R5,35	R2,31	R6,50	R6,94	R2,26	R7,91	R24,32
Argentina	R3,85	R0,76	R4,81	R12,15	R0,16	R1,14	R5,23	R0,55	R12,67	R0,63
India	R0,17	R1,22	R0,33	R1,46	R0,10	R1,68	R0,12	R0,38	R1,12	R0,40
Denmark		R0,97				R1,78		R2,75		R0,81
Brazil		R0,24			R0,12	R0,58		R0,13	R0,53	R0,14
Ghana				R0,39	R0,26	R0,72	R1,00	R0,36	R0,54	

### A 2.2 Unit prices for ARV Therapy, 2019

Country	Dolutegravir 50mg composite	Dolutegravir 50mg	Tenofovir Disoproxil Fumarate 300mg	Zidovudine 300mg	Lopinavir 200mg	Lopinavir 80mg solution	Lamivudine 10mg/ml solution	Abacavir 300mg	Abacavir 60mg	Abacavir 600mg
South Africa	R30,21	R32,34	R20,66	R11,97	R4,05	R8,01	R0,45	R21,03	R7,20	R29,91
India	R0,30	R22,69	R27,30	R3,94	R8,98	R5,16	R0,21	R9,29	R9,29	R9,29
Australia	R297,61	R218,66	R108,37	R18,12	R57,78	R1 308,89	R591,44	R40,32		R101,96
Canada	R487,34	R218,83	R121,66	R28,79	R63,96	R31,98	R3,76	R38,42		R66,04
Denmark			R344,36		R54,38	R20,85		R64,42	R4,41	
Bahrain	R466,72	R300,71		R91,59	R65,77	R21,40	R2,68	R81,16		R466,72
New Zealand		R349,67	R35,73	R6,07	R37,36	R23,63	R4,29	R29,54		R21,71
Argentina		R236,29	R266,18	R10,39	R49,30	R17,45	R1,81	R58,33		R111,08
Spain	R122,99		R181,30	R41,89	R34,22	R11,35	R22,24			R124,61

### A 2.3 Unit prices for Diabetes Mellitus Therapy, 2019

Country	Metformin 500mg tablet, 84	Metformin 500mg tablet, 56	Metformin 850mg	Glimepiride 2mg	Glimepiride 1mg	Glibenclami de 5mg
South Africa	R0,65	R0,83	R1,35	R6,45	R3,60	R1,04
Canada	R0,27	R0,27	R0,32	R5,40	R5,40	R0,63
Bahrain	R0,67	R0,67	R1,09	R2,96	R1,84	R2,66
Argentina	R0,24	R0,24	R0,50	R3,14	R3,14	R0,22
Australia	R1,42	R1,42	R2,36	R4,44	R4,15	R1,58
New Zealand	R0,13	R0,13	R0,26	R0,79		R1,05
Denmark	R0,66	R0,66	R0,67			
India	R0,22	R0,22	R0,22	R1,12	R0,71	R0,08
Spain	R0,63	R0,63	R1,00	R2,75	R1,37	
Brazil	R0,08	R0,07	R0,11	R0,27	R0,11	R0,08
Ghana	R0,21	R0,21		R1,34	R1,03	R0,10

### A 2.4 Unit prices for antidiabetic Therapy, 2019

Country	Insulin Biphasic 100ml/unit 30/70 pen	Insulin Biphasic 100ml/unit 30/70 vial	Insulin Isophane 100ml/unit pen	Insulin Isophane 100 Units/ml 3ml pen
South Africa	R54,05	R45,36	R35,77	R54,05
Canada	R520,40	R275,42		R538,48
Bahrain	R46,77	R20,44	R52,43	R52,43
Argentina	R64,01	R57,46	R64,01	R17,92
Australia	R347,68	R211,08		R347,68
New Zealand	R30,44	R65,14	R30,44	R63,55
Denmark	R33,75	R24,60		R33,42
India		R3,12		
Spain	R41,04	R250,78		

### A 2.5 Unit prices for TB Therapy, 2019

Country	Isoniazid 300mg	Rifampicin and Isoniazid 300/150mg	Isoniazid 100mg	Rifampicin and Isoniazid 150/75mg	Rifampicin and Isoniazid 150/75mg
South Africa	R2,22	R3,08	R0,56	R2,10	R2,00
India	R0,24	R1,01	R0,13	R0,41	R0,40
Denmark	R5,85	R5,85	R11,91	R10,04	R10,04
Brazil	R0,46	R5,75	R0,15		
Australia	R46,19		R2,21		
Canada	R5,49		R63,10		
New Zealand		R16,82	R2,59	R8,67	

## APPENDIX 3 ACTIVE INGREDIENTS

Therapeutic category	Description	Detailed description
Cardiac Therapy	Hydrochlorothiazide 12,5mg tablet	-
	Enalapril 10mg tablet	-
	Hydrochlorothiazide 25mg tablet	-
	Amlodipine mg tablet	-
	Furosemide 40mg tablet	-
	Simvastatin 10mg tablet	-
	Nifedipine 30mg modified release tablet	-
	Atenolol 50mg tablet	-
	Amlodipine 10mg tablet	-
	Enalapril 5mg tablet	-
Diabetes Mellitus Therapy	Metformin 500mg tablet	56 tablets
	Metformin 500mg tablet	84 tablets
	Metformin 850mg tablet	-
	Glimepiride 2mg tablet	-
	Glimepiride 1mg tablet	-
	Glibenclamide 5mg table	-
antidiabetic	Insulin Biphasic 100ml/unit 30/70 pen	Insulin, Biosynthetic, Human, Biphasic, 100units/ml, Soluble 30% And Isophane 70% 3ml Disposable Pen
	Insulin Biphasic 100ml/unit 30/70 vial	Insulin, Biosynthetic, Human, Biphasic, 100units/ml, Soluble 30% And Isophane 70% 10ml Vial
	Insulin Biphasic 100ml/unit 30/70 cartridge	Insulin, Biosynthetic, Human, Biphasic 30/70 100 units/ml, 3 ml cartridge for use in pens
	Insulin Isophane 100ml/unit pen	Insulin, Biosynthetic, Human, Isophane, 100 Units/ml, 3ml, disposable pen
ARV	Dolutegravir 50mg composite tablet	Tenofovir 300mg, lamivudine 300mg, dolutegravir 50mg tablet
	Dolutegravir 50mg tablet	Dolutegravir 50mg tablets
	Tenofovir Disoproxil Fumarate 300mg tablet	Tenofovir 300mg, emtricitabine 200mg, efavirenz 600mg tablet
	Zidovudine 300mg tablet	Zidovudine 300mg and lamivudine 150mg tablets (option 2)
	Lopinavir 200mg tablet	Lopinavir 200mg and ritonavir 50mg film coated tablet (option 2)
	Lopinavir 80mg solution	Lopinavir 80mg And Ritonavir 20mg/ml Oral Solution, 60ml Bottle with Dosage Cup Containing Graduations in Increments Up To 5ml
	Lamivudine 10mg/ml solution	Lamivudine 10mg/ml Oral Solution, 240ml Bottle with Syringe Top and A Calibrated Oral Dosage Syringe
	Abacavir 300mg tablet	Abacavir 300mg tablet
	Abacavir 60mg tablet	Abacavir 60mg crushable tablets
	Abacavir 600mg tablet	Abacavir 600mg and Lamivudine 300mg tablet (Option 2)
TB Therapy	Isoniazid 300mg tablet	-
	Rifampicin and Isoniazid 300/150mg	-
	Isoniazid 100mg tablet	-
	Rifampicin and Isoniazid 150/75mg	-

Source: National Treasury Master Procurement Catalogue 2019, Medicine Price Registry 2019

## APPENDIX 4 MODEL SPECIFICATIONS

$$SEP_{it} = \beta_1 Year_{it} + \beta_2 ManInc_{it} + \beta_3 LogDec_{it} + \beta_4 ManInc * LogDec_{it} + \varepsilon_{it} \quad (4.1)$$

- In the equation above,  $i$  represents the medicine and  $t$  represents the current time period.
- $SEP_{it}$  is the single exit price.
- $Year_{it}$  is a dummy variable that captures time trends, allowing the intercept to differ across periods.
- $ManInc_{it}$  is a dummy variable representing a year-on-year manufacturer price increase. It is equal to 1 if there was an increase in the manufacturer price and 0 if there was no year-on-year increase.
- $LogDec_{it}$  is a dummy variable representing a year-on-year logistics fee decrease. It is equal to 1 if there was a decrease in the logistics fee and 0 if there was no year-on-year decrease.
- $ManInc * LogDec_{it}$  is a dummy variable capturing the joint effect of a year-on-year manufacturer price increase and a simultaneous year-on-year decrease in the logistics fee. It is equal to 1 if there is a simultaneous year-on-year increase in the manufacture price and decrease in the logistics fee. Otherwise it is 0.
- $\varepsilon_{it}$  is the idiosyncratic error term

Equation 4.1 corresponds with Regressions I-IV in Table 2 although equations III and IV also control for the fixed effect<sup>135</sup>. The key parameter of interest is  $\beta_4$  which, if significant, would indicate that a year-on-year increase in the manufacturer price and simultaneous decrease in the logistics fee influence the SEP. If  $\beta_4$  is positive and significant, it indicates that the manufacturer price is driving the change in the SEP over and above the independent effects of the year-on-year increase in the manufacturer price and decrease in the logistics fee. If  $\beta_4$  is negative and significant, it indicates that the logistics fee is driving the change in the SEP over and above the independent effects of the year-on-year increase in the manufacturer price and decrease in the logistics fee.

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<sup>135</sup> There are factors that are medicine specific which drive prices, but those factors do not change over time. Fixed effects control for these individual characteristics. The fixed effects estimation also contains an intercept.

$$SEP_{it} = \beta_1 Year_{it} + \beta_2 ManDec_{it} + \beta_3 LogInc_{it} + \beta_4 ManDec * LogInc_{it} + \varepsilon_{it} \quad (4.2)$$

- In the equation above,  $i$  represents the medicine and  $t$  represents the current time period.
- $SEP_{it}$  is the single exit price.
- $Year_{it}$  is a dummy variable that captures time trends, allowing the intercept to differ across periods.
- $ManDec_{it}$  is a dummy variable representing a year-on-year manufacturer price decrease. It is equal to 1 if there was an decrease in the manufacturer price and 0 if there was no year-on-year increase.
- $LogInc_{it}$  is a dummy variable representing a year-on-year logistics fee increase. It is equal to 1 if there was an increase in the logistics fee and 0 if there was no year-on-year decrease.
- $ManDec * LogInc_{it}$  is a dummy variable capturing the joint effect of a year-on-year manufacturer price decrease and a simultaneous year-on-year increase in the logistics fee. It is equal to 1 if there is a simultaneous year-on-year decrease in the manufacture price and increase in the logistics fee. Otherwise it is 0.
- $\varepsilon_{it}$  is the idiosyncratic error term.

Equation 4.2 corresponds with Regressions V-VIII in Table 2 although equations VII and VIII also control for the fixed effect<sup>136</sup>. The key parameter of interest is  $\beta_4$  which, if significant, would indicate that a year-on-year decrease in the manufacturer price and simultaneous increase in the logistics fee influence the SEP. If  $\beta_4$  is negative and significant, it indicates that the manufacturer price is driving the change in the SEP over and above the independent effects of the year-on-year decrease in the manufacturer price and increase in the logistics fee. If  $\beta_4$  is positive and significant, it indicates that the logistics fee is driving the change in the SEP over and above the independent effects of the year-on-year decrease in the manufacturer price and increase in the logistics fee.

$$ManPrice_{it} = \alpha_1 ManPrice_{it-1} + \alpha_2 LogFee_{it} + \alpha_3 LogFee_{it-1} + \varepsilon_{it} \quad (4.3)$$

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<sup>136</sup> There are factors that are medicine specific which drive prices, but those factors do not change over time. Fixed effects control for these individual characteristics. The fixed effects estimation also contains an intercept.



- In the equation above,  $i$  represents the medicine and  $t$  represents the current time period.
- $ManPrice_{it}$  is the ex-manufacturer price.
- $LogFee_{it}$  is the logistics fee.
- $LogFee_{it-1}$  is the logistics fee in the previous period.
- $\varepsilon_{it}$  is the idiosyncratic error term.

Equation 4.3 corresponds with Regressions I-IV in Table 3 although equations III and IV also control for the fixed effect<sup>137</sup>. The key parameter of interest is  $\alpha_3$  which, if significant, would indicate that the logistics fee has an intertemporal relationship with the ex-manufacturer price.

$$LogFee_{it} = \delta_1 LogFee_{it-1} + \delta_2 ManPrice_{it} + \delta_3 ManPrice_{it-1} + \varepsilon_{it} \quad (4.4)$$

- In the equation above,  $i$  represents the medicine and  $t$  represents the current time period.
- $LogFee_{it}$  is the logistics fee.
- $ManPrice_{it}$  is ex-manufacturer price.
- $ManPrice_{it-1}$  is ex-manufacturer price in the previous period.
- $\varepsilon_{it}$  is the idiosyncratic error term.

Equation 4.4 corresponds with Regressions I-IV in Table 4 although equations III and IV also control for the fixed effect<sup>138</sup>. The key parameter of interest is  $\delta_3$  which, if significant, would indicate that the ex-manufacturer price has an intertemporal relationship with the logistics fee.

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<sup>137</sup> There are factors that are medicine specific which drive prices, but those factors do not change over time. Fixed effects control for these individual characteristics. The fixed effects estimation also contains an intercept.

<sup>138</sup> There are factors that are medicine specific which drive prices, but those factors do not change over time. Fixed effects control for these individual characteristics. The fixed effects estimation also contains an intercept.



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