national planning commission
Department:
The Presidency
REPUBLIC OF SOUTH AFRICA

2030 NDP

MEDICINE PRICING POLICIES POSITION PAPER[1]

NATIONAL PLANNING COMMISSION

APRIL 2020

1. INTRODUCTION

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 R7.2 billion on Out-Of-Pocket (OOP) payments on pharmaceutical products.

The rapidly rising cost of health services is a significant concern, as it accounts for a considerable proportion of expenditure among low-income and poverty-stricken 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, especially focusing on access to universal health care that is equitable and affordable (National Development Plan, 2012). 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 commissioned research on the drivers of medicine prices and their influence on the attainment of universal health care coverage goals. The evidence presented and recommendations made in the Research on Pharmaceutical Pricing Policies research paper and included in this document are extremely timely in the current context of the COVID-19 crisis and its multiple impacts on the lives of people, the economy and the health and social systems in South Africa and globally.

2. RESEARCH BACKGROUND

[1] This paper draws on the, Research on Pharmaceutical Pricing Policies undertaken for the National Planning Commission by DNA Economics (H Wadee, N Marawa, L Reddy, S Sherif, A Jitsing). Commissioner Bhengu led this project.

2.1 The Problem Statement

In setting the Terms of Reference for the research project, the NPC prepared the following problem statement:

There is broader contention that the cost of medicines is an important cost driver in the health sector. Price is not the only component in access to health. There are other fundamental components such as regulation, infrastructure and functioning supply chains, which are critical to effective and efficient healthcare delivery, the sustainability of the healthcare system – and the national economy. These outcomes depend significantly on the availability of affordable medicines. The pricing of medicines is an issue of great social, political and economic significance across the world.

Since 1996 South Africa has been engaged in the implementation of a National Drug Policy, with highly publicised challenges raised by the pharmaceutical industry to government's initial interventions. As part of a multi-pronged approach to address the cost and access of medicines, the Department of Health introduced a Single Exit Price (SEP) mechanism for all medicines in the private health care sector in 2004. This was aimed at regulating the sale price of products by manufacturers and importers to all their customers regardless of the size of the order and disallowed discounts to ensure transparent pricing practices for the industry. This meant that drug manufacturers could only sell their products at one price to all their customers, regardless of the nature of the customer's order size and consumption levels. The mechanism was also meant to promote the use of generics. Manufacturers' discounts and payment of incentives in the pharmaceutical industry meant pharmacies and dispensing doctors were capitalising on these incentives, while the customers/patients were not benefiting from these savings. It also implicitly promoted the use of these profitable products at the expense of generics which are much cheaper.

There is also an argument that "weak" patent applications for pharmaceutical product patents are granted and that such patents act as barriers to entry, thereby preventing competition and controlling and raising prices.

2.2 Methodology

In response to this problem statement and Terms of Reference, the researchers applied 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 interviews with 26 key stakeholders from the public and private sectors as well as civil society. Descriptive statistics were used to examine the Single Exit Price

(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 used 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.

3. SUMMARY OF FINDINGS

The researchers formulated four key research questions (RQ) which are listed below with associated findings.

RQ1: How does the policy and regulatory framework in South Africa governing medicine pricing work?

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). 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). 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 international jurisdictions. Despite regulations for an External Reference Price (ERP) methodology being published as far back as 2007, they were only finalised in 2014 but have not been promulgated yet.

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 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.

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.

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

The NPC has reviewed international strategies which include ERP, value-based pricing and patent laws for consideration by local authorities.

Three of 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 medicine prices down.

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, and alongside India, has the 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. 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.

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.

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

There are many factors that go into price determination of goods and services. For medicines supplied and consumed in SA, the NPC recognises the following as the most influential factors:

- Pricing policy and regulation;
- Market structure and competition; and
- Research and Development (R&D) and Intellectual Property laws.

Pricing Policy and Regulation

Pricing policy is distinct between the public and private sectors, reflected in the price differential. Pooled procurement can reduce the cost of medicines, as is the case in the public sector where some are purchased for less than a tenth of private sector prices. 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.

There is mixed evidence whether the SEP regime has resulted in reasonable pricing for medicine. Certainly, it seems to have had an impact on year-on-year price inflation. A recent international study found that medicine prices in South Africa are the 45th lowest in the world. Other studies suggest that private sector prices are relatively high in South Africa.[2] 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.

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

Market Structure and Competition

There are high levels of market concentration in the manufacturing of originators.[3] The manufacture of generics has lower levels of concentration, which implies greater competition. However, careful attention must be given to those companies producing originator drugs which are directly/indirectly active in the supply of generic drugs.

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

[2] (Cassar & Suleman, 2019)
[3] Helen Suzman Foundation,2017

schemes. Through their Designated Service Provider (DSP) arrangements and formularies, medical schemes can negotiate lower dispensing fees

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 South African Health Products Regulatory Authority (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.

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 are 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.

RQ4: How much Out-of-Pocket (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 expenditure, 32.9% in 2018, and appears to be increasing steadily over time.

4. NPC PLENARY COMMENTS

The EQL (Enhancing Quality of Life) Workstream of the NPC placed the presentation of the final report on the agenda of the plenary meeting of the NPC on 06 March 2020. Commissioners duly engaged with the report at length and expressed agreement with the approach and with the extent to which the report met the Terms of Reference that were drafted by the EQL Workstream. Three main issues emerged as concerns for further consideration in particular:

(i) Industry competition dynamics;

(ii) Lack of growth of domestic pharmaceutical manufacturing; and

(iii) Poor coverage of costs for fertility and oncology medicines by medical schemes.

4.1 Competition dynamics

Concerns were expressed that the pharmaceutical industry is just one more industry that is characterized by concentration and high entry barriers. There was also concern about smaller community pharmacies being crowded out by large national retailers, eg. Clicks and Dischem.

4.2 **Lack of growth of domestic pharmaceutical manufacturing**

Commissioners expressed concerns about the local pharmaceutical manufacturing industry which has not shown much growth over the years. It was acknowledged that local manufacturing would contribute positively to the SA economy by reducing unemployment, increasing tax revenues and providing some security of supply for priority medicines. There didn't seem to be satisfactory reasons why progress wasn't forthcoming.

In summary, Commissioners are concerned about excessive reliance on manufacturers from India and China for generics and Europe and USA for originator medicines.

4.3 **Coverage of medicine benefits for fertility and oncology medicines**

Commissioners expressed concern about the affordability of fertility and cancer medicines and exclusion of some of the products by medical schemes, even though prevalence is high and/or rising.

5. RECOMMENDATIONS

Taking into account the research findings and other relevant considerations, the NPC hereunder recommends that the following steps be taken urgently in order to reduce the cost of medicines to users of the public and private sectors.

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

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

5.3 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.

5.4 The National Department of Health (NDOH) consider taking steps to issue the regulations on ERP, as was always intended as the second step when the SEP regulation was set. 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.

5.5 The NDoH build capacity within government to implement the External Reference Pricing and, over the medium to long term, government should consider adopting a value-based pricing methodology.

5.6 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 across public and private sectors.

5.7 The NPC recognizes that Health Technology Assessment (HTA) is integral to the implementation of Universal Health Coverage and is referred to in the NHI Bill. The NPC recommends that this function be established on an expedited basis to reduce exposure to medicines and medical devices that are not cost-effective. Published outcomes of HTA research would have a significant influence on private sector prices as well.

5.8 The NDoH should establish a real-time medicine inventory monitoring system that provides the information it needs to better forecast demand for drugs on the Essential Medicines List.

5.9 The NPC endorses the need for a further detailed market assessment of the different segments of the value chain based on actual information about market participants and their relative market shares. [4] The NPC recommends that such further research assessment be undertaken by the Competition Commission. While the NPC is willing to collaborate with the Competition Commission it does not have the powers of subpoena necessary to extract information and value from such an exercise. Further, the Competition Commission has just completed the Health Market Inquiry which ran from 2014 to 2019, having excluded the pharmaceutical industry from its Gazetted Terms of Reference.

During this period, the Commission did launch an investigation into the pharmaceutical industry with a specific interest in oncology products. Therefore, the NPC believes the Competition Commission has a lot of data on the health sector in general and to try and duplicate that elsewhere would be counterproductive and a waste of scarce resources. There certainly is a need to study market dynamics at its various levels, and the retail pharmacy dominated by two chains while excluding local pharmacies from meaningful market participation requires a review. In the

[4] The aim of this analysis is not to duplicate the work of the Health Market Inquiry but to strengthen the policymakers understanding of the value chain.

long run, not acting on this will have dire consequences for the country given the global demand of pharmaceuticals.

5.10 South African Health Products Regulatory Authority (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).

5.11 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 relevant timelines.

5.12 The Department of Science, Technology and Innovation, in collaboration with the NDOH and the Department of Trade, Industry and Competition (DTIC), should develop a sector strategy to steer and coordinate the government's efforts to promote R&D in the pharmaceutical industry.

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

5.14 The DTIC 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 linked to South Africa's burden of disease. Until there is a deliberate effort by government to support local manufacture of strategic Active Pharmaceutical Ingredients (e.g. for anti-retrovirals), local manufacturers will not be able to compete with international manufacturers who produce API and finished ARV products. This will continue to hamper local manufacturers' capacity to grow in SA and continental markets.

5.15 Statistics SA and the Council for Medical Schemes 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 to enable a more disaggregated understanding of the impacts on the quality of life of the poorest households.

6. Conclusion

The NPC supports Government in taking 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. The findings and lessons from this independent research study are relevant to a medicine pricing policy under the NHI. The NPC further highlights the need for mental health, cancer and reproductive health therapies to be fully funded under the NHI and steps to compel private health insurers to provide benefit for these conditions be taken as a matter of urgency in the short to medium term.