



CROSS-COUNTRY RESEARCH STUDY

**COMPETITION IN THE GENERIC
PHARMACEUTICAL INDUSTRY**

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FOREWORD

CHAIR OF AFRICAN COMPETITION FORUM MS DORIS TSHEPE

I am pleased to write the opening words of the African Competition Forum's (ACF) cross-country research study on competition in the generic pharmaceutical industry. The ACF has produced collaborative and informative studies which assist in enhancing competition agencies' knowledge in crucial areas of the economy. This pharmaceutical industry study is one such report with contributions from Angola, Eswatini, Gambia, Kenya, South Africa, Zambia and Zimbabwe.

The pharmaceutical industry has always been critical to the development and progress of humankind and generally functions as a 'backbone industry' in many countries. However the recent Covid19 pandemic brought this sector into stark focus. It brought us all face to face with our fragility as human beings and caused us to pay attention to healthcare markets in general. The global race to develop a Covid19 vaccine exposed, at once, the best and the worst characteristics of the pharmaceutical industry. On the one hand we were comforted by the efforts of pharmaceutical firms to share knowledge and develop vaccines with unprecedented speed. On the other hand, however, we witnessed a reluctance to licence the manufacture of the vaccine, even in the face of increasing mortality the world over. Moreover we saw that wealthier countries were better able to secure adequate quantities of the vaccine for their respective populations.

This experience raised questions about the role of equity in the process of distributing pharmaceutical resources. It also raised questions about fair pricing of originator and generic pharmaceutical products and services. As competition agencies it also made us reconsider the role of competition in global pharmaceutical value chains.

This report illuminates the competitive and regulatory circumstances operating within the pharmaceutical industries of the aforementioned African countries. It explores the state of treatment and pricing for some of the most common diseases in Africa: hypertension, TB and diabetes. According to the World Health Organisation approximately 46 million adults are living with hypertension in sub-Saharan Africa alone. TB is listed amongst the

top three diseases affecting people in Africa and diabetes is a growing health challenge in Africa. According to the International Diabetes Federation, the number of people living with diabetes in Africa is expected to double from 19.8 million in 2019 to 47 million by 2045. This is due to factors such as urbanisation, unhealthy diets, physical inactivity and aging populations.

The sheer scale of these three diseases in Africa demands a reaction from competition agencies. It is imperative that competition agencies study these markets in order to determine the most appropriate response to meet the most pressing needs within each jurisdiction. The cross-country research study on competition in the generic pharmaceutical industry will assist greatly in this regard.

I would like to thank all the contributors who worked to bring this informative publication to finality. I trust that readers will find this work most useful as a tool to further the work of each competition agency within the pharmaceutical industry.



Ms Doris Tshepe
Chair of African Competition Forum

INTRODUCTION

1. A well-functioning healthcare system is a desirable objective that all nations strive towards achieving. An important component to achieving this is ensuring that medicines are accessible and affordable. The World Health Organization (“WHO”) recognises “equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness” as one of the six “building blocks” of a well-functioning national health system.¹ Given the importance of equitable access of medicines for the functioning of national healthcare systems, countries continuously endeavour to improve the affordability and accessibility of medicines for their populations.
2. Affordable and accessible medicines is particularly important for the African continent given the prevailing high rates of various infectious diseases. By way of example, in 2016 Africa accounted for a quarter of new tuberculosis (“TB”) cases worldwide and over 25% of TB deaths occur in the African Region.² Similarly, Africa accounts for almost two thirds of the global total of new HIV infections³; has the highest prevalence of hypertension at 27%;⁴ and in 2020, 95% of malaria cases occurred in Africa.⁵
3. Medicine expenditure in developing countries (and particularly out-of-pocket payments (“OOP”)) is significantly high compared to developed countries. The WHO found that medicines account for 25%–70% of overall healthcare expenditure in developing countries, compared to less than 10% in most high-income countries.⁶ Further, the WHO found that approximately, 90% of the population in developing countries purchase medicines through OOP payments, making medicines the largest family expenditure item after food.⁷ Direct OOP spending ranges from 2% (Seychelles) to 75% (Comoros). Other African countries with high direct OOP include Nigeria (74% of health funds), Equatorial Guinea (72%) and Cameroon (70%).⁸
4. The high burden of disease in Africa and the significant expenditure and OOPs spent on medicines may be linked to the high level of imported medicines on the continent. The United Nations Economic Commission for Africa (UNECA) estimated that Africa imports about 94% of its pharmaceutical and medicinal needs from outside the continent⁹ while China and India import around 5 percent and 20 percent, respectively. Africa’s reliance on imported medicines means that the medicine is susceptible to varying exchange rates and additional costs such as logistic costs thereby creating price uncertainty for medicines. These factors may be contributing to the high price of medicines making it unattainable to most people. Moreover, it has adverse implications on government fiscal budgets where in most low and middle countries the population is dependent on the public sector for their healthcare requirements.
5. Since countries are highly dependent on imports this can result in supply chain disruptions which affects the accessibility of medicines resulting in stock-outs of medicines. There have been concerns about stock-outs of medicines in African countries. In South Africa, a 2019 survey found that one in five public health facilities was unable to supply at least one ARV or tuberculosis medicine. These stock-outs may result in treatment interruptions which accentuates the importance of having local manufacturers, particularly in instances where there are supply chain distributions that adversely affects the supply of medicines in a country.
6. One of the main reasons for the substantial level of imported medicines is the lack of manufacturing capabilities on the continent. The market structure of the pharmaceutical industry in Africa is highly fragmented and undersized. The continent has roughly 375 medicine makers, most in North Africa, to serve a population of around 1.3 billion people. Those in sub-Saharan Africa are largely clustered in just nine of 46 countries, and they’re mostly small, with operations that do not meet international standards.¹⁰ For the countries that have established manufacturing capabilities such as Ghana, Kenya, Nigeria, South Africa, and Zimbabwe local production is small with production ranging between 10 and 30%.¹¹

1 WHO. Monitoring the building blocks of health systems. 2010.
2 <https://www.afro.who.int/health-topics/tuberculosis-tb>
3 <https://www.afro.who.int/health-topics/hiv-aids>
4 <https://www.who.int/news-room/fact-sheets/detail/hypertension>
5 <https://www.who.int/news-room/fact-sheets/detail/malaria>
6 <https://apps.who.int/medicinedocs/documents/s14868e/s14868e.pdf>
7 <https://apps.who.int/medicinedocs/en/m/abstract/J521016en/>
8 World Health Organisation, The state of health in the WHO African region, 2018.

9 United Nations Industrial Development Organisation. Strengthening Africa’s pharmaceutical industry: learning the lessons from COVID-19, 28 September 2021.

10 McKinsey & Company. Should sub-Saharan Africa make its own medicines, January 10, 2019. Available at: <https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-medicines>.

11 United Nations Industrial Development Organisation. Pharmaceutical industry in sub-Saharan Africa: A guide for pro-

7. African governments have committed to plans and the development of agencies to provide access to affordable essential medicines in Africa¹² through the introduction of the Pharmaceutical Manufacturing Plan for Africa (“PMPA”). The PMPA, adopted in 2012, is premised on the view that “strengthening Africa’s ability to produce high quality, affordable pharmaceuticals across all essential medicines will contribute to improved health outcomes and the realization of direct and indirect economic benefits.¹³ On 5th October 2021, the treaty for the African Medicines Agency (“AMA”) was established to regulate medical products in order to improve access to quality, safe and efficacious medical products on the continent.¹⁴ While there are cohesive plans and policies in place to improve the accessibility and affordability of medicines on the African continent, Africa is still highly reliant on imports for most of its medicine requirements.
8. The existence of a diverse and purposeful pharmaceutical industry in Africa is indispensable to improving the health status of individuals and the overall socioeconomic development of the continent.¹⁵ Instrumental to improving the accessibility and affordability of medicines on the African continent is the use of generic medicines and the development of a generic medicine market, and more importantly having a competitive generic industry.
9. There is strong evidence of the positive impact that the entry of generic has on the pricing of pharmaceutical products. For example, in the US, the first generic competitor typically enters the market at a price that is 20 to 30 percent lower than its brand name counterpart and gains market shares from the brand manufacturer. As further generic entry occurs this encourages competition resulting in savings of

up to 80 percent. In Europe, savings are estimated to be around 20 percent in the first year of generic entry, rising to 25 percent after two years. In Brazil, there is evidence that generic entry saved approximately USD 5 billion for the healthcare system between 2001 and 2007. In Canada, the prescription of generic medicines saved approximately CAD 3 billion in 2008, with estimated further savings of up to CAD 800 million per year if further generic competition could be encouraged.¹⁶

10. In the poorest countries, branded generics¹⁷ constitute about two-thirds of the market by volume and value. Unbranded generics, usually the least expensive option constitute only 5 percent of the market by volume and 3 percent by value. In a group of 10 countries in French West Africa less than 10 percent of the pharmaceutical market was comprised of on-patent products; the remainder of originator products purchased are older and off-patent, launched globally over 20 years previously. In OECD countries, by contrast, generics constitute a larger share of health product volumes and expenditure.¹⁸ In the United States and the United Kingdom, unbranded generics account for 85 percent of the pharmaceutical market by volume, but only about a third by cost.¹⁹ This means that while generic medicines have experienced relatively promising growth, they still comprise a significantly smaller share of the market in Africa.
11. Even more concerning is that in African countries²⁰ consumers in low- and middle-income countries pay as much as 20 to 30 times as much for basic generic medicines like omeprazole, used to treat heartburn, or paracetamol, a common pain reliever.²¹ This underscores the need for increased generic medicines competition to reduce

moting pharmaceutical production in Africa, 2019.

¹² African Union, Pharmaceutical Manufacturing Plan for Africa. 2012.

¹³ African Union. Pharmaceutical manufacturing plan for Africa, 2007.

¹⁴ <https://au.int/en/pressreleases/20211009/treaty-establishment-african-medicines-agency-ama-enters-force>.

¹⁵ In the pharmaceutical industry, there are two types of pharmaceutical suppliers: originator, and generic companies. The originator companies are active in research, development, management of the regulatory process for new products including the clinical trials needed for marketing authorization, manufacturing, marketing, and supply of innovative medicines. Their products are usually subject to patent protection, which, provides a compensation for them because of the high costs spent on innovation. The second category of companies, manufacturers of generic products, can enter the market with medicines that are equivalent to the original medicines, upon patent expiry of the pre-existing original products and when the data exclusivity period for the originator product expired. Their prices are typically much lower than those of the originator products. This helps in containing public health budgets and ultimately benefits consumers.

¹⁶ OECD, Generic Pharmaceuticals, 2009.

¹⁷ These are generics that are manufactured by the originator of the product.

¹⁸ Tackling the Triple Transition in Global Health Procurement, Final report of cgd’s working group on the future of global health procurement, 2019. Available at: <https://www.cgdev.org/sites/default/files/better-health-procurement-tackling-triple-transition.pdf>.

¹⁹ Tackling the Triple Transition in Global Health Procurement, Final report of cgd’s working group on the future of global health procurement, 2019. Available at: <https://www.cgdev.org/sites/default/files/better-health-procurement-tackling-triple-transition.pdf>.

²⁰ Tackling the Triple Transition in Global Health Procurement, Final report of cgd’s working group on the future of global health procurement, 2019. Available at: <https://www.cgdev.org/sites/default/files/better-health-procurement-tackling-triple-transition.pdf>.

²¹ Tackling the Triple Transition in Global Health Procurement, Final report of cgd’s working group on the future of global health procurement, 2019. Available at: <https://www.cgdev.org/sites/default/files/better-health-procurement-tackling-triple-transition.pdf>.

prices and thereby increase access. According to the WHO, many countries are unable to benefit from lower priced generics due to delays with market entry or lack of effective competition.²² The extent of generics competition depends on the number of generics companies operating in the markets and their capabilities. The generics industry is vital to ensuring competition in the medicine market and reducing the prices of medicines when the patent has expired. The speed and depth of price reductions for off-patent medicines is dependent on the extent of competition amongst generic pharmaceutical companies.

12. Africa's pharmaceutical market value is growing rapidly and was approximately \$28.56 billion in 2017. This market is predicted to be worth between \$56 billion to \$70 billion by 2030. High growth in this industry is still achievable, offering opportunity for investment in this sector. This is mainly due to the rise of major cities, a stable business climate, maturing regulatory systems and the growing African population projected to reach 1.7 billion by 2030. This makes the African continent's pharmaceutical industry an attractive investment opportunity to produce generic medicines, contributing to the socioeconomic development of the continent as well as providing affordable medicine and stable supply chains.

RESEARCH OBJECTIVES AND METHODOLOGY

13. The purpose of the study is to obtain a better understanding of the extent of competition and the barriers to entry and/or expansion in the generic medicine market in Africa. Specifically, the study focuses on the following participating countries: Angola, The Gambia, Eswatini, Kenya, South Africa, Zambia, and Zimbabwe. The study provides important insights into the factors that may promote greater levels of competition and investment in domestic capacity, including enforcement efforts by competition agencies. It also provides important insights and support for efforts to boost the continent's capabilities and the continent's generics market around communicable and non-communicable diseases prevalent on the continent.

14. The objectives of the study are as follows:

- 14.1 To assess the market structure and the levels of concentration of the pharmaceutical industry with a view to providing insights into the capabilities of local manufacturing companies and the country's reliance on imported medicines.
 - 14.2 To understand the regulatory regime governing the pharmaceutical industry in a country and how this may influence generic entry and competition in the market. The regulatory framework will identify the relevant legislation governing the supply of medicines in a country including a description of the regulatory regime for pharmaceutical products, the patent regime, registration of medicines and regulation of pricing. The study also identifies any legislative or regulatory overlaps and conflicts between the medicine regulation and other overarching regulatory frameworks.
 - 14.3 A pricing analysis is conducted for the medicines to determine the level of price competition between the originator and generic medicines. The study assesses the price difference between the originator and the generics to evaluate the impact that generic entry has on price competition in the medicine market.
 - 14.4 To understand the barriers to entry and expansion in the generic pharmaceutical industry and the extent to which this inhibits generic competition.
15. Medicines treat two categories of diseases: communicable and non-communicable diseases. Communicable diseases include illnesses caused by an infectious agent (or its toxins) that occur through the direct or indirect transmission of the infectious agent (or its products) from an infected individual or via an animal. Non-communicable diseases refer to a medical condition or disease which is non-infectious and cannot be passed from person to person. Since communicable and non-communicable diseases are highly prevalent on the African continent the study will consider both categories.

16. Given the substantial number of medicines available for the treatment of various diseases, the study relied on selected medicines to facilitate analytical ease and comparability across countries. In selecting the medicines for the study, the first step involved each country submitting the top five prevalent communicable and non-communicable diseases in their country. The country submissions were collated, and the top two common communicable and non-communicable diseases among the countries were identified for the study. The selected communicable diseases were HIV and TB, and the non-communicable diseases were Diabetes and Hypertension.²³ The medicines required to treat the identified diseases were selected using the essential medicine list.

17. The following detail findings from each of the seven countries that took part in the study.

²³ Except for Angola all the countries had non-communicable diseases that were common across the countries, but the identified diseases are prevalent in Angola.

²⁴ Zambia joined the study after the comparative medicine assessment was conducted therefore, they do not appear in Annexure 1.



A close-up, low-angle shot of a microscope's objective lenses and stage, bathed in a cool blue light. The background is softly blurred, showing more of the microscope's structure. Overlaid on the center of the image is the word 'ANGOLA' in a large, bold, blue sans-serif font. Directly beneath it, the words 'THE ANGOLA CHAPTER' are written in a smaller, bold, green sans-serif font. The text is sharp and stands out against the blurred scientific background.

ANGOLA

THE ANGOLA CHAPTER

INTRODUCTION

1. The pharmaceutical sector, in many cases, functions as an advanced health structure for local communities and one of the main gateways to the health system. The trust gained among the population and the guarantees of access to quality medicines, make it possible to promote a culture of rational use of drugs and adherence to therapy. Besides this, its permits to develop health promotion and disease prevention programs.
2. The liberalization of the market for the provision of health services, in Angola, foreshadowed by Law 21B/92, of 28 August, Basic Law of the National Health System, has boosted the Angolan pharmaceutical sector. This made it possible to structure it, according to the operational characteristics of the country's health system, aligned with a supply chain that includes importers or producers, wholesalers (Distributors) and retailers in terms of the Law 1/07, of 14 May, Commercial Activities Law, under close supervision and sectoral regulation aimed at technical compliance and the quality of services provided by operators.
3. For example, TB is already the third leading causes of death in Angola. However, the funds made available do not cover even 50% of the needs of the National Program to Combat Tuberculosis¹, which subsequently compromises the internal capacity of stock. In the case of HIV and AIDS, the situation is no different.
4. Considering the need to conveniently ensure favourable levels of availability, also for controlled drugs, and the increase in the offer of services to patients, it seems reasonable to consider a review of the current National Health Policy. On the other hand, it's necessary to work on the promotion of Policies that encourage the attraction and the implementation of factories and that conveniently integrate operators with a view to reducing barriers. Currently, Angola is not part of the group of medicine-producing countries, nor is it home to any of the major players in the pharmaceutical industry. It remains one of the countries that still faces difficulties in providing medicines for its population, especially for the poorest.

OVERVIEW OF MEDICINE EXPENDITURE

5. General Tax Administration (AGT) data shows that Angola imports generic medicines from various parts of the world, which in 2021 totalled around 75 countries, including South Africa, Brazil, China, India, Nigeria, Portugal, DRC, United States of America (USA), Belgium, Germany, UK, Singapore and the United Arab Emirates, among others. In 2020, the cost of imported medicines amounted to Kz 203 155 043 938, equivalent to about USD 326 872 947, to which other costs such as logistic cost are added.

MARKET STRUCTURE

6. According to sectoral regulation, the supply chain of medicines in Angola, is subdivided into three segments, namely: importation; wholesaler (distribution) and retail (through pharmacies). The importation and distribution of generic medicines relies on several companies and is regarded as deconcentrated, with the State being the main importer and, therefore, also a distributor. This positioning has to do with its duty as a public provider of medical and medicine assistance with national coverage, without constituting itself as a player in the competition. However, among the private operators there is acceptable competition, without an identifiable dominant player.

PHARMACEUTICAL SUPPLY CHAIN

IMPORTERS

7. Import can be defined as a commercial and fiscal process that consists of bringing a good, in the case of a product or service, from abroad to the country of reference. Therefore, an importer is an individual or legal entity that promotes the entry of foreign goods into the national market. In this segment of the chain, importers are responsible for importing raw materials and/or medicines to supply specialized clinical laboratories and/or local medicine distributors.

¹ Jornal de Angola (2018). Tuberculose é a terceira causa de morte no país. Available in: <https://www.jornaldeangola.ao/ao/noticias/details.php?id=401105>. Consulted on April 21, 2022.

WHOLESALE

8. Wholesalers are commercial entities that buy and/or supply medicine as opposed to retailers to whom they supply. The seller or wholesale distributor, as a rule, does not come into direct contact with the final consumer. Its most common role within the distribution chain is to be the intermediary between the producer or manufacturer and the retail seller.²
9. Pursuant to paragraph 7 of article 22 of the Commercial Activities Law, the activities of distributors fall under the category of Wholesalers. In terms of the pharmaceutical sector, currently in Angola, this type of sale is reserved for medicine distributors duly licensed and authorised by the Commerce and Health Sectors.

COMPANIES OPERATING IN THE ANGOLAN PHARMACEUTICAL MARKET

10. Table 1 shows the number of active pharmaceutical companies for the period 2015-2020.

Table 1 - List of Active Pharmaceutical Companies 2015 – 2020

Entities	2015	2016	2017	2018	2019	2020
Importers and/or Distributors	228	179	186	206	203	317

Source: ARMED, 2021.

11. In 2015 there were 228 importers/distributors, which increased to 317 in 2020, an increase of 89 importers/distributors over a five-year period. There are many cases in Angola in which commercial entities importing pharmaceuticals also act in the distribution segment, considering the nature and economic specificities of the national market.

12. These importers are made up of private companies (68%), public companies (30%), represented by (Central for Purchasing Medicines and Medical Means of Angola) CECOMA, NGO's and other social partners (2%), considering the total volume of imports, in values, in 2021.
13. Figure 1 shows the market shares for the top 25 importers for the year 2021.³
14. Of the total volume of imports in 2021, made by the 25 largest importers, the Ministry of Health was the largest importer with 25,76% of the quota, due to its duty as a national public provider of medical and medicine assistance. The three largest private importers were Africa Pharmacy Ltd., Prince Farma Ltd., and Aarnext Farmácia, Ltd., representing 9,38%, 8,95% and 5,89% of the import market respectively.
15. Observing the total volume of imports in 2021, in terms of values, the 25 largest operators represented 86% of the market. The data indicates that, the import and distribution chains are deconcentrated, with several operators and a considerable level of competitiveness, resulting from liberalization and the increasingly simplified process of access to the market.

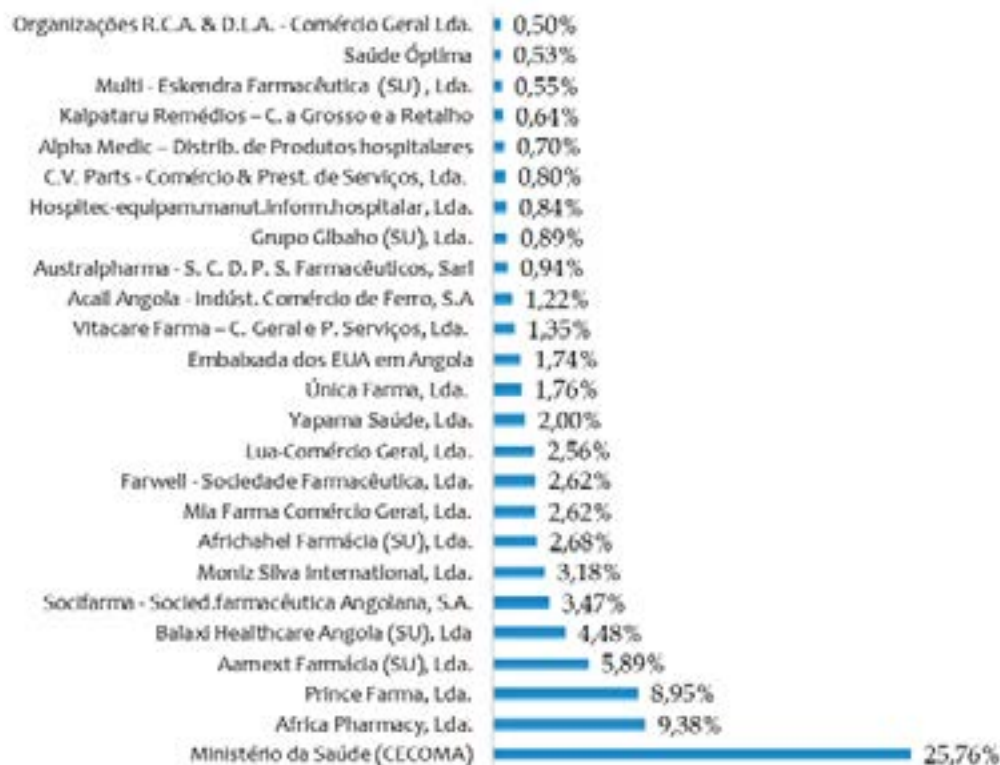
REGULATORY FRAMEWORK

16. The Pharmaceutical Sector in Angola is regulated by the Regulatory Agency for Medicines and Health Technologies (ARMED), an institution supervised by the Ministry of Health, according to Presidential Decree No. 136/21, of June 1st., which approves the Organic Statute of ARMED.

³ It should be noted that, under Angolan legislation, there is no competition for the treatment of Tuberculosis and HIV/AIDS, as their sale is prohibited, and the State is responsible for guaranteeing access to these generics in public hospitals.

² CONCEITO DE: Wholesaler Concept. Available at: <https://conceito.de/grossista>. Consulted on May 12, 2022.

Figure 1 - Import quota in 2021



Source: AGT, 2022.

17. ARMED is a public institution with legal personality and capacity, endowed with administrative, patrimonial, and financial autonomy, with the responsibility of developing actions of regulation, guidance, licensing, supervision, and control of activities in the field of medicines for human use and health technology, with a view to guaranteeing their quality, efficacy, and safety, under the terms of article 1 of its Organic Statute.

18. Accordingly, the Sector's legislation is the result of a process that, in some way, reflects a succession of political, economic, and social acts, facts and decisions with a view to improving the efficiency and effectiveness of Health Services. Thus, over the last few decades, the State has approved several legal instruments in the pharmaceutical sector, described below.

PRESIDENTIAL DECREE NO. 180/10, OF 18 AUGUST, WHICH ESTABLISHES “THE GENERAL BASIS OF THE NATIONAL PHARMACEUTICAL POLICY”

19. Pursuant to article 3 of this Decree, the National Pharmaceutical Policy is defined as the expression of the Executive's commitment and engagement in pharmaceutical assistance throughout the national territory, applicable to the public and private sectors.
20. The general objective of the national pharmaceutical policy is to guarantee the country's supply of safe, effective, and quality essential medicines and to ensure the permanent availability and accessibility of essential medicines to the entire population, at the best prices, promoting their rationale use, both by prescribers and dispensers, in accordance with article 3, referred to in the paragraph above.
21. According to article 12 of the Decree, only registered medicines in Angola, can be purchased and marketed. Thus, as a way of promoting generic medicines, they benefit from simpler registration and the relative costs are lower than those of products under commercial designation.
22. As for production, the aforementioned Decree agrees that, in order to develop national production of medicines and achieve indicators that meet the country's needs in terms of quality and quantity, the Executive, through concerted action between the Ministries of Health, Finance, Trade and Industry, must create the necessary conditions for the promotion, protection and development of the national pharmaceutical industry, according to the terms of article 19.

EXECUTIVE DECREE NO. 426/21, OF 16 SEPTEMBER, WHICH APPROVES THE “NATIONAL LIST OF ESSENTIAL MEDICINES”

23. The general objective of the national pharmaceutical policy is to guarantee the country's supply of safe, effective and quality essential medicines and to ensure the permanent availability and accessibility of those medicines, for the whole population, at the best prices, promoting their rational use, both by prescribers, dispensers and by consumers.
24. Within the framework of this legal diploma, the National List of Essential Medicines (LNME) is one of the main instruments to guarantee the supply of safe, effective, and quality essential medicines to citizens in accordance with the Recommendations of the WHO. Thus, under the terms of article 3, the LNME is intended to provide and harmonize the essential process of selection, acquisition, distribution, prescription, dispensing, local production, and donation of medicines to the different levels of the National Health System (SNS).
25. Regarding the registration process of the medicines, legislation is in progress to regulate them. Meanwhile, generic medicines marketed in Angola benefit from a simple and quick control procedure, through scrupulous compliance with the requirements of the import licensing process with ARMED.

PRICING ANALYSIS

26. Currently, there is no specific pricing policy in Angola for the pharmaceutical sector, specifically in the segment of import and distribution of generics. Therefore, prices in this sector are included in the free price regime, established by Presidential Decree no. 206/11, of 29 July, which approves the General Basis for the Organization of the National Price System. Excluded from these are medical equipment and medicines for the control, prevention, and treatment of COVID-19, under the terms of Executive Decree no. 256/20, of 30 October, which establishes the List of Goods and Services at Fixed and Monitored Prices.

27. It is important to clarify that, in accordance with article 12 of Presidential Decree No. 206/11, of 29 July, the free pricing regime means the free establishment of prices for products or services by the entities that produce or provide them, according to demand and supply in the market.

AVERAGE PRICES OF MEDICINES FOR HYPERTENSION

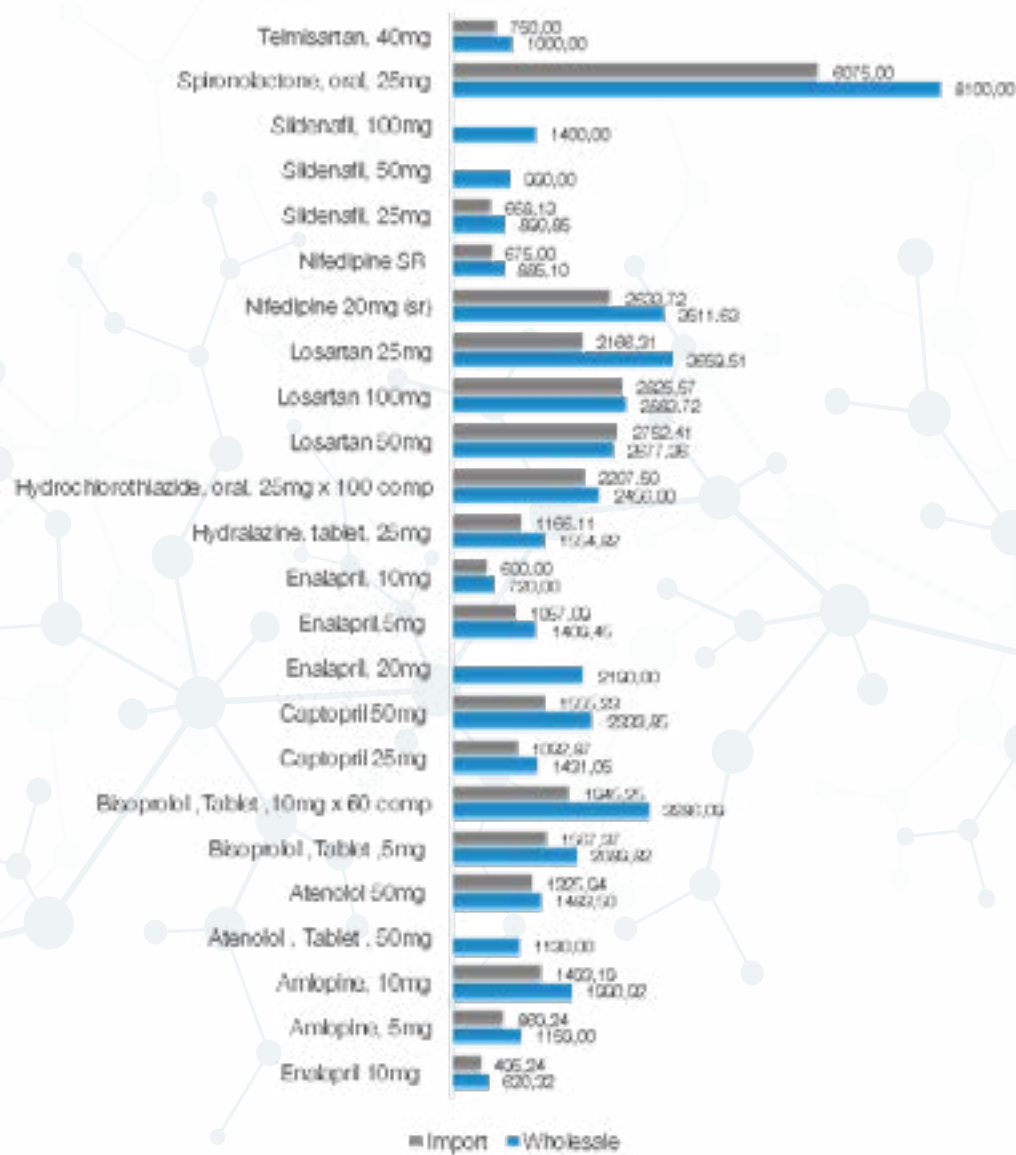
28. In Angola, according to the data collected, the import or purchase prices of medicines to treat hypertension vary, on average, between U\$D 0.79 (seventy-nine cents of dollars) and U\$D 9.69 (nine dollars and sixty-nine nine cents), which is equivalent to Kz 495.24⁴ (four hundred and ninety-five Kwanzas and twenty four cents) to Kz 6 075.00 (six thousand and seventy-five Kwanzas).
29. Of these, Enalapril 10mg stands out as the cheapest medicine and Oral Spironolactone 25mg the most expensive in this market. The unit prices of the distributors of these medicines vary between Kz 620.32 (six hundred and twenty Kwanzas and thirty-two cents) and Kz 8 100.00 (eight thousand and one hundred Kwanzas).
30. The data indicates that, despite the competitiveness between operators, resulting from the open market characteristic and, consequently, from the large number of importers/distributors, the prices of medicines used for the treatment of hypertension are relatively high, compared to the purchasing power of most Angolan families.
31. It is imperative to remember that these medicines are mostly used with high frequency, in many cases daily, to control the blood pressure of patients, affecting the monthly budget plan and management of family finances. This market context, characterized by a total dependence on imports, reinforces the need for the Angolan State to promote the production of pharmaceuticals at a national level, using public-private partnerships or internal or external investments, to guarantee the practice of more competitive prices, to the benefit of economic agents, from companies to families.

32. On the other hand, the information collected does not allow the identification of possible scenarios of restrictive competition practices. However, the existence of some operators that resort to local suppliers to distribute to pharmacies in Luanda and, mainly, in other provinces, is a factor that influences the increase in prices.

AVERAGE PRICES OF MEDICINES FOR DIABETES

33. The prices of imported generic medicines, to treat diabetes vary, on average, from USD 1.69 (one dollar and sixty-nine cents) to USD 26.94 (twenty-six Dollars and ninety-four cents), which is equivalent to on average at Kz 1 060.87 (one thousand and Sixty kwanzas and eighty-seven cents) to Kz 16 884.00 (sixteen thousand, eight hundred and eighty-four kwanzas), respectively.
34. With regard to distribution, prices range vary, on average, between USD 1.68 (one dollar and sixty-eight cents) and USD 32.63 (thirty-two dollars and sixty-three cents), which corresponds to Kz 1 051,35 (one thousand and fifty-one Kwanzas and thirty-five cents) to Kz 20 450,70 (twenty thousand, four hundred and fifty Kwanzas and seventy cents). It is crucial to note that Insolin Soluble and Humodar are the most expensive medicines at the import level, while Metformin 850mg is the cheapest.

Figure 2 - Hypertension: Prices of Import/Acquisition and Distribution of Medicines

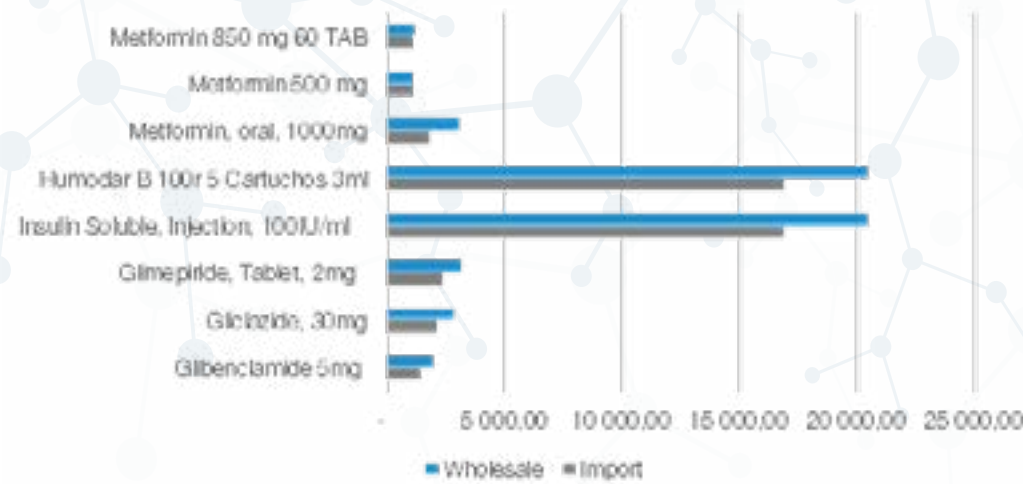


Source: Local medicine distributors (values expressed in Kwanzas).

AVERAGE PRICES OF MEDICINE FOR HIV & AIDS AS WELL AS TB

35. In Angola, contagious diseases, namely HIV & AIDS and TB, have Government Programs to combat them. This is concomitant with a wide range of responsibilities on the part of the Government, including costs and the free distribution of medicines, and subsequently generating some restrictions on their commercialization, contrary to what happens with cases of Hypertension and Diabetes. In Angola, only generics of HIV & AIDS and TB are imported.
36. This situation highlights the existence of a controlled market, where operators are subject to redoubled inspection requirements and competition is almost non-existent. In this context, the importation and distribution of these medicines, by private companies, demonstrates that, despite the market being very controlled and

Figure 3 - Diabetes: Import Prices/Acquisition and Distribution of Medicines

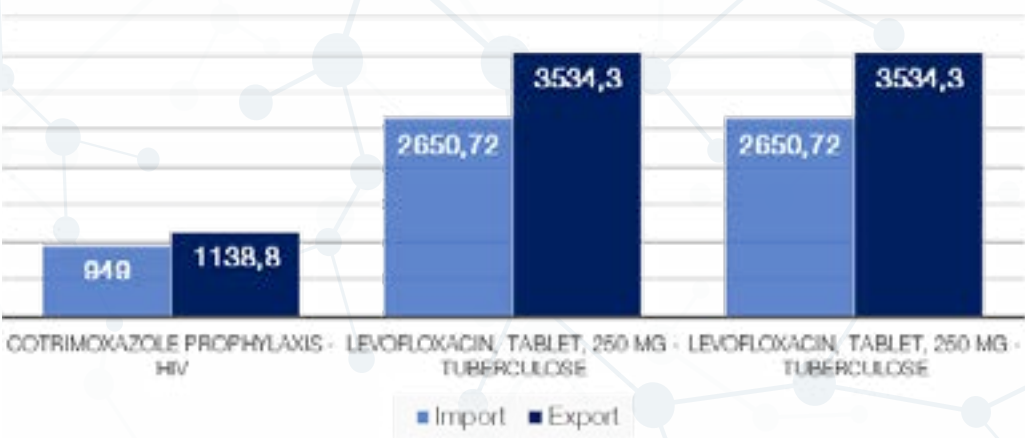


Source: Local medicine distributors (values expressed in Kwanzas).

dominated by the State, some operators do have access to them, which can raise questions of corporate persistence or illegal conduct to guarantee the sale in the market. In any case, this fact may be an indicator that the State should consider promoting competition between operators and, simultaneously, through the official circuit maximizing access to those medicines.

37. It is important to mention that, under the terms of Presidential Decree no. 54/22, of 17 February 2022, the national minimum wage is set at Kz 32,181.15. Considering this, patients affected by the diseases included in the study, may see their finances pressured, since medical prescriptions usually presuppose combinations of several medicines, and that must be consumed for a long time.

Figure 4 - Average import price of HIV-AIDS and TB Medicines



Source: Local medicine distributors (values expressed in Kwanzas).

BARRIERS TO ENTRY AND EXPANSION

38. After considering the public policies in the sector, especially those referring to the production and distribution of generic medicines, barriers to entry into the market for medicines for the treatment of Tuberculosis and HIV & AIDS were identified. However, there is no rule or measure that restricts or hinders the entry of companies in segments of the supply chain.
39. It must be emphasized that, in general, the Angolan Government has been attentive to the excesses of documentary requirements, as they end up creating a barrier in the access to markets and to the consumer. Therefore, the Project for Simplification of Procedures in Public Administration “Simplifica”, approved by Presidential Decree No. 161/21, of 21 June, is in progress.
40. Simplifica aims to reduce bureaucracy, reduce waiting time in the provision of public services, reduce levels of intervention in the chain of decision-making power, privilege the “digital principle”, remove administrative obstacles to private initiatives, as well as provide services on time and improve access to information.⁵
41. Regarding barriers to entry, they are, specifically, embodied in the process of controlling the importation of medicines, for the treatment of TB and HIV & AIDS, as it is somewhat bureaucratic and centralized in the State.
42. The intention of the State to control the importation of these medicines is understandable, considering the nature of the diseases in question, which require careful monitoring and assertive medication. On the other hand, the market shows that there is a certain scarcity of these medicines, which shows the Executive's inability to guarantee access to them.
43. Accordingly, ARMED defines these medicines, as controlled products. For this purpose, it establishes the following requirements for their importation:
- 43.1 Import request letter addressed to ARMED, signed by the Technical Director, including the Pharmaceutical Practice Authorization number assigned by ARMED;
 - 43.2 Export Authorization issued by a competent authorities of the country of origin;
 - 43.3 Opinion of the National Directorate of Public Health (DNSP) and the National Institute for the Fight Against AIDS (INLS), for the importation of Antituberculosis and Antiretrovirals;
 - 43.4 Proforma invoice of the products to be imported, in Portuguese (alternatively in English, French or Spanish);
 - 43.5 Good Manufacturing Practices (GMP) certificate;
 - 43.6 The copy of the Informative Leaflet, label that accompanies the medicine must include a Portuguese translation.
44. These procedures are reinforced by Order No. 04/ARMED/MINSA/2022, in which ARMED determines four (4) rules that interfere with the functioning of this market:
- 44.1 The manufacture, import, marketing and re-export of anti-tuberculous, anti-retroviral and anti-malarial medicines not included in the National List of Essential Medicines of the Ministry of Health is prohibited.
 - 44.2 The manufacture, import, marketing and re-export of medicinal products from the therapeutic groups not included in the list, according to point no. 1, require the prior authorization of ARMED, after consultation with the National Directorate of Public Health or the National Institute for the Fight AIDS, as appropriate.
 - 44.3 The Ministry of Health must carry out all requests for authorization to import anti-tuberculous and anti-retroviral medicines in accordance with the requirements for issuing import certificates for medicines and health products subject to control.

5 Instituto de Modernização Administrativa (IMA). Projecto Simplifica 1.0. Available in: <https://simplifica.gov.ao/>. Consulted in May 4th, 2022.

- 44.4 It is the responsibility of the importer or manufacturer to carry out the monitoring and pharmacovigilance of its products throughout the national supply chain.
45. The procedures above actually constitute a barrier to entry, as they make it difficult for private companies to gain access and, consequently, contribute to the increase and stabilization of the supply of anti-TB and anti-retroviral medicines in Angola.
46. A relevant note relates to the fact that, the responsibility for monitoring and pharmacovigilance is assigned to importers, along the chain, as it increases costs and becomes a barrier to entry and expansion.
47. Likewise, the process becomes cumbersome, since every request for authorization to import antituberculosis and antiretroviral medicines is carried out in accordance with the above-mentioned requirements, that is, for each import the company goes through the same procedures, as there is no authorization for a period in which the importer could make several imports.
48. The barriers to entry of companies in the import segment of the medicines, mentioned above, do not allow competition between companies in the supply of these medicines to hospitals and private pharmacies, despite the urgent need to increase their stock capacity.
49. The barrier imposed by the procedure for controlling the import and distribution of the medicines under analysis, causes, not only, an impact on the State's ability to respond to the needs of hospital institutions, but a competitive effect. It makes it difficult and discourages competition in this segment, which is why, there are no companies that provide these services.
50. This barrier contrasts with the information according to which there has been a lack of medicines in hospitals for the treatment of the aforementioned diseases. It reveals the inefficiency of the public sector, as well as the urgent need to promote competition so that companies can support the State in this task and give a more efficient response to this need.

CONCLUSION

51. After an overall analysis of the data collected, through documentary research, meetings and interviews with companies involved in the market and with the regulatory body, no factors were identified that greatly affect competition.
52. However, some inefficiency in communication and guidance between the sector regulator and pharmaceutical market operators has a generalized counterproductive perception about the ban on imports and marketing of pharmaceuticals under tighter control programs by the Government.
53. Furthermore, current policy can put public health at risk whenever stocks of anti-tuberculosis and anti-retroviral are low. Therefore, making it pro-competitive can prevent and reduce the impact of difficulties in this matter, including for the State to provide medicines in more remote regions.
54. With this measure, the State would continue to be responsible for the supply of anti-TB and anti-retroviral medicines in public hospitals, through CECOMA., However, it would integrate the private sector in the import and distribution network, previously authorized, through of a more streamlined process.
55. The control procedures and restrictions on the import/distribution of medicines described above, inhibit the entry of players in these business niches, simultaneously putting pressure on the State's logistical and financial apparatus, without great guarantees of effectiveness.
56. Given the national scenario presented and the recurring concerns about the capacity to supply medicines and make them available to the population, it is recommended that policies be promoted that encourage the local production of medicines. This policy aims to increase the supply and the ability to respond immediately to needs of the market, as well as the reduction, in the medium term, of the financial effort channelled to imports.

57. At the same time, it is crucial to move forward with a policy of greater integration between the National Health System and operators in the pharmaceutical sector, in a strategy of involving the players for a first-line support partnership, that they can offer to patients considering its potential for associated services.



ESWATINI

THE ESWATINI CHAPTER

INTRODUCTION

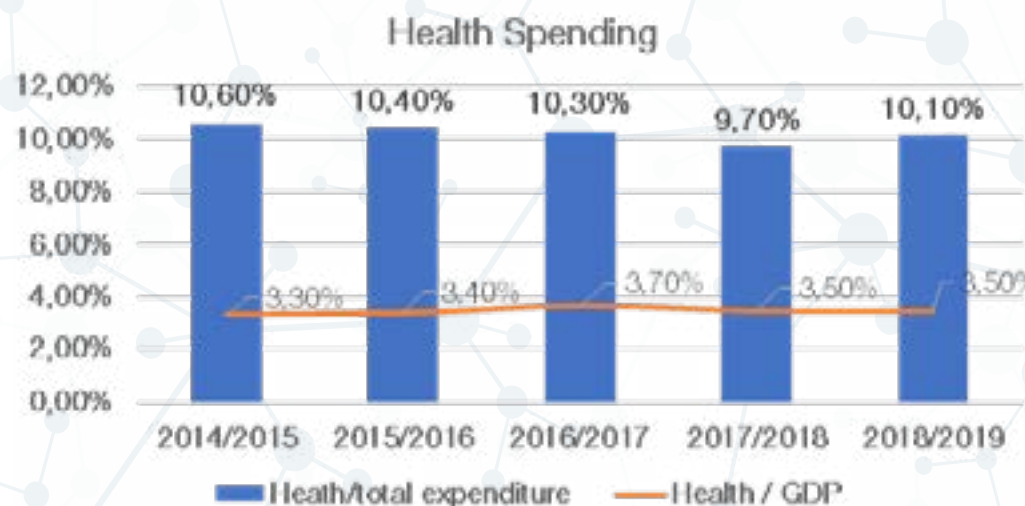
1. Section 60(8) of the Constitution of the Kingdom of Eswatini of 2005, states that the State shall take all practical measures to ensure the provision of basic health care services to the population. Eswatini faces a number of challenges when it comes to the health sector; and these include HIV and TB being the leading causes of mortality in patients, accounting for a third of deaths. For instance, more than 200,000 individuals are living with HIV, more than 24.3% of the adult population suffers from hypertension and more than 21,800 people are diagnosed with diabetes. As a result, Eswatini has a high demand for pharmaceuticals.
2. Eswatini has a universal health care system, which enables all Eswatini to access public sector health care for a fee of E10.00 (\$0.75). However, this fee, is not applicable to patients who are over the age of 60 years. Eswatini also has private health care, where patients obtain access to private health facilities including clinics, hospitals, and pharmacies. According to information sourced from the Financial Services Regulatory Authority, 27% of the country's population have access to private healthcare cover through medical aid /health insurance schemes.
3. As with most developing countries, Eswatini does not produce any pharmaceuticals. All the pharmaceuticals that are consumed in the country are imported. Despite not producing any pharmaceuticals the Kingdom of Eswatini has considered producing antiretroviral (ARVs) at the Royal Science and Technology Park (RSTP). There are discussions between the Government of Eswatini and an Indian company to establish a pharmaceutical production plant at the RSTP. The pharmaceutical production company is currently awaiting permission to operate within the special economic zone (SEZ).

OVERVIEW OF MEDICINE EXPENDITURE

THE PUBLIC HEALTHCARE SECTOR

4. According to information sourced from the Ministry of Health, between the periods 2014/2015 and 2018/2019, the Ministry of Health accounted for about 10% of the national Budget. The entire health sector spending accounted for about 3.5% of the country's gross domestic product (GDP), as indicated in Figure 5 below.

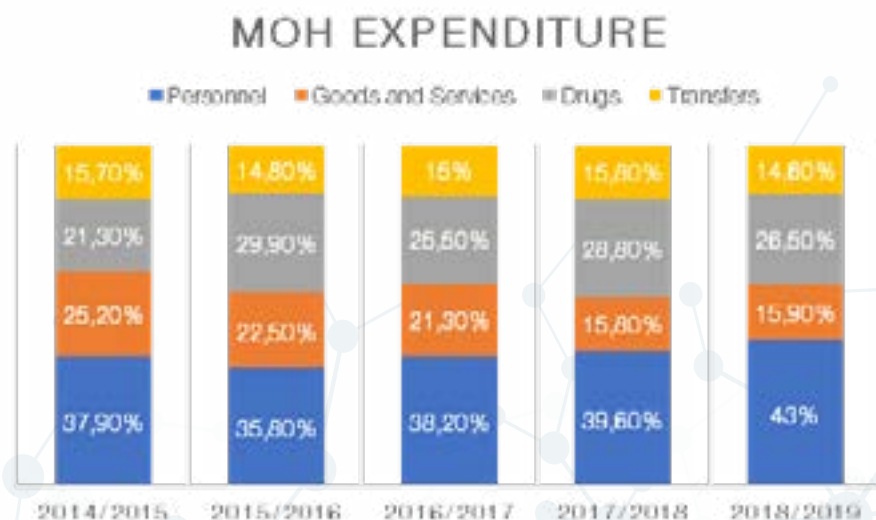
Figure 5 - Health sector's budgetary allocation, health sector spending to share of GDP



Source: Ministry of Health

5. The figure above shows that expenditure in health as a percentage of GDP and as a share of the total budget has remained relatively stagnant over the period of 2014/15 to 2018/19. Health, as a share of the total budget has declined from 10.6% to 10.1% since 2014/15 and declined to an all-time low of 9.7% in 2017/2018. Health spending as a share of GDP has averaged 3.5% and is projected to remain at this level this 2022/2023 fiscal year.
6. Figure 6 shows the breakdown of recurrent spending by economic category for the period 2014/2015 to 2018/2019.

Figure 6 - Breakdown of recurrent spending by economic category, 2014/2015-2018/2019



Source: Ministry of Health.

7. According to Figure 2, medicines are the second largest expenditure, after personnel. Secondly, pharmaceuticals expenditure has always remained between 21% and 29% of the Ministry of Health's budget. During 2014/2015, the expenditure on pharmaceuticals increased from 21.3% of the Ministry's budget to 29.9% the following year. Between 2017/2019 and 2018/2019 it decreased from 28.8% to 26.5%.
8. Notwithstanding that Eswatini has a universal health system, the country still has a large percentage of the population that purchase pharmaceuticals using their disposable income. OOP expenditure on health and medicines is a priority concern particularly for citizens living below the country poverty line (\$1.90). The OOP for medicines is costly when considering that public health facilities often do not have all the necessary medicines to treat their patients, resulting in those requiring medical treatment having to purchase their medicines from the private sector. As stated above, a large percentage of the populace in Eswatini is not under any form of medical aid or medical insurance, as such patients are forced to purchase pharmaceuticals using their disposable income, whenever there are shortages of pharmaceuticals in public centres.

PRIVATE HEALTHCARE SECTOR

9. As with most countries, private health care in Eswatini is regulated by Government. The private healthcare system is considered to provide a higher standard of healthcare services in comparison to the public healthcare system in Eswatini. Comparatively, private healthcare centres are well resourced relative to public healthcare centres.
10. A majority of patient's access private healthcare cover through medical aid or health insurance schemes. Members pay monthly contributions/premiums to their medical scheme/health insurance respectively, consequently the health care providers are responsible for financing their members' healthcare expenses. Health insurers provide numerous cover products including hospitalization plans and primary health plans (e.g., plans that cover GP visits, basic dentistry, optometry etc.).
11. Eswatini has a number of health care schemes (medical aid and insurance), some of which are risk benefit, whereby the healthcare expenditure is funded from the members' contribution. Some medical schemes also offer a Medical Saving Account (MSA) on some of the benefit options that is a fixed percentage of the total monthly contribution.

DEVELOPMENTS IN THE PRIVATE AND THE PUBLIC SECTORS

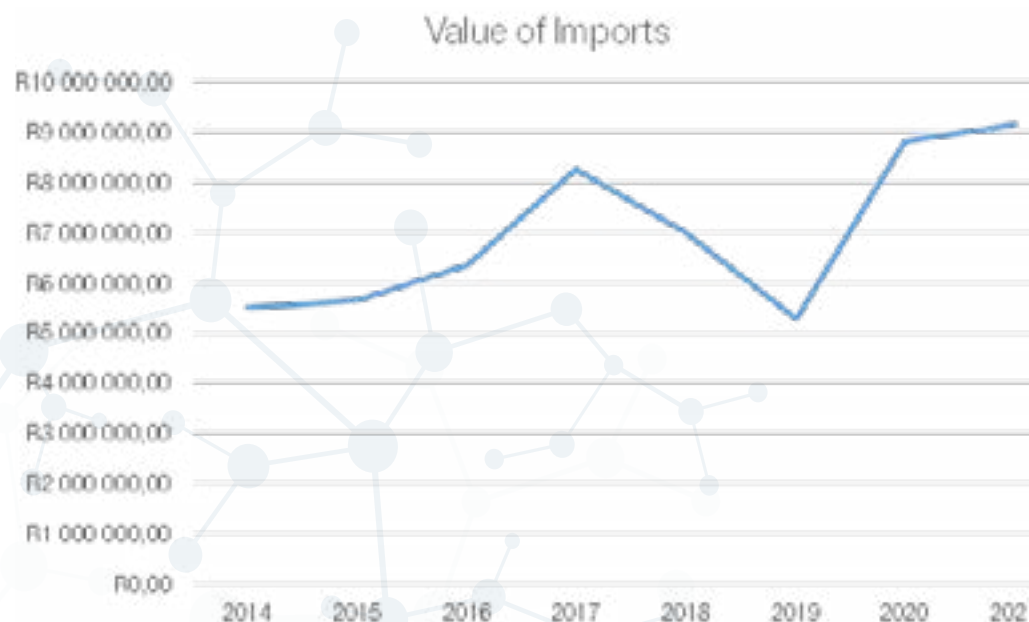
12. Eswatini is one of the many countries that faces a number of challenges when it comes to the production and distribution of pharmaceuticals. Since Eswatini relies on imported pharmaceuticals, local distribution is achieved through wholesalers who at times have contracts / long term relationships with manufacturers. This implies that Government or other procurers find themselves forced to deal with a single wholesale distributor for the specific medicine(s). In an interview with the Ministry of Health (MoH) in 2021, the Eswatini Competition Commission (“hereinafter the Commission”) was informed that due to the small size of the economy and small orders, pharmaceutical producers prefer to have exclusive supply contracts with wholesalers. According to Central Medical Stores officials as well as some of the interviewed market participants, exclusive supply contracts allow producers to better plan their production and they are a form of guarantee to the producers that they have a captive market.
13. The public and the private health sector differ in terms of the medicines that are issued out to patients. As stated above, Eswatini employs a universal health care system whereby patients receive pharmaceuticals and consultation at very low costs. The Commission found that the public sector mainly uses generic pharmaceuticals except when it comes to narcotics and psychotics. The procurement and distribution of pharmaceuticals in the public sector is the responsibility of the Central Medical Stores, within the Ministry of Health. In an interview with the Ministry of Health, the Eswatini Competition Commission was informed that the public sector prefers to buy generic pharmaceuticals.
14. The Commission was informed that the reason Government prefers to buy generics over brand name pharmaceuticals is that generics perform similar to brand name pharmaceuticals and they are likely to have the same effects. Also, since a very limited number of people in the country are likely to be able to afford brand name pharmaceuticals, generics have to be priced lower so that pharmaceutical wholesalers and pharmacies remain competitive in the market. Missionary health centres are similar to public health centres, as they mainly issue out generic pharmaceuticals. Since they are not in business for making profits, they must ensure that they save as much as possible. One of the means of cutting down expenses is by using generic pharmaceuticals.
15. On the other hand, health centres in the private sector dominantly issue out brand name pharmaceuticals. In the private sector, the pharmaceuticals are charged to the patients’ medical aid, thus the health centres themselves do not feel the pinch of paying for the pharmaceuticals. Secondly, some of the private sector health centre clients might prefer originator pharmaceuticals over generics. By the virtue of the private sector preference for brand name pharmaceuticals, it means that the private healthcare sector has a diverse selection of medicines with more active ingredients and a greater availability of medicines in each schedule than the public sector.
16. The Commission was further informed that most people that access pharmaceuticals through private health centres can afford to purchase brand name pharmaceuticals, especially since most of them use medical aid schemes. However, for customers paying cash, there is the option of prescribing generic medicines. Also, some patients are given prescriptions which they can use at a pharmacy of their choice, where they can state if they prefer brand names or generic medicines.
17. According to information sourced from the private sector, some health centres source their pharmaceuticals from wholesalers including manufacturers outside the country. On the other hand, Government sources most of its pharmaceuticals from local wholesalers, although there are instances whereby international suppliers are used.

18. The expenditure on pharmaceuticals in both the public and private sector increased during the period 2015/16 and 2018/19, accounting for about 10.5-10% of the national budget. On the other hand, the national budget for pharmaceuticals averaged 21.5% of the health sector budget between 2014/2015 and 2018/2019. Medical aid/ insurance scheme members pay a monthly contribution/ premium that is meant to fund their purchases of pharmaceuticals, yet they can still use their savings and incur OOP when purchasing medicines. The public sector uses generic pharmaceuticals except when it comes to narcotics and psychotropic medicines, whereby only brand names are used. The reasoning behind the use of generic pharmaceuticals in the public sector is that generics and brand names have similar medicinal properties although generics are relatively priced lower when compared to brand names. On the other hand, the private sector uses both generic and originators/brand names, as most patients that use private sector health centres are medical aid/ insurance holders.

TRADE IN MEDICINES

19. As stated above, Eswatini does not produce any pharmaceuticals, as such all pharmaceuticals that are consumed in the country are imported. According to information sourced from Eswatini Revenue Service ("hereinafter ERS"), most pharmaceuticals are imported from South Africa, India, China, and the European Union, amongst other countries. According to information sourced from the ERS, as shown in Figure 4 below, pharmaceuticals imported between 2014 and 2021 cost between E5.270 million and E9.145.

Figure 7 - Value of imported pharmaceuticals



Source: Eswatini Revenue Services

20. As indicated in figure 7 above, imported pharmaceuticals were valued at E8.250 million in 2017, decreasing to an all-time low of E5.270 million in 2019. In 2021 the value of imported pharmaceuticals reached an all-time high of E9.145 million, although it should be noted that this surge in the import of medicines could be attributed to COVID-19 medication.

MARKET STRUCTURE

21. With the country not having any manufacturers of generics, the major players in the generics industry are the wholesale distributors who distribute pharmaceutical products, medical supplies, and other related equipment to; i) The Government through the Central Medical Stores; ii) Humanitarian Organisations; iii) Private organisations; and iv) Others.
22. A survey carried out by the Commission revealed that there are at least 13 wholesale pharmaceutical firms operating in the Eswatini market. These include the following:
- 22.1 Swazi Pharm
 - 22.2 Pharm Industry
 - 22.3 ASD Medical
 - 22.4 Swazi Med Centre
 - 22.5 Artemis
 - 22.6 VJV Pharmaceuticals
 - 22.7 Pharm Pharm
 - 22.8 Hil Seq Distributors
 - 22.9 Centro Med
 - 22.10 Avoma
 - 22.11 VOH Surgical
 - 22.12 Elektro
 - 22.13 United Pharmaceutical Distributers (South African based)

23. According to information received from wholesalers, most of them do sell generic pharmaceuticals. Swazi Pharm stated that 72% of their sales are generic pharmaceuticals, while the rest are brand name pharmaceuticals. On the other hand, Avoma, seems to be selling the lowest percentage of generics, with only 10% and the rest being brand names, as indicated in table 2, below.

Table 2- Market share of pharmaceutical wholesalers

Name of wholesale	% Supplied to Gov.	% supplied to Private sector	% generics	% Brand names
SwaziPharm	46	54	72	28
Avoma	35	65	65	35
Pharm Industry	30	70	65	35
ASD	70	30	40	60
Hil Seq Distributors	45	55	60	40

Source: Market Players

24. According to the market players, the largest supplier in the market is SwaziPharm, which controls about 45% of the pharmaceutical industry in the country. SwaziPharm is part of the Avacare Health Group, which has a presence in several countries, including Namibia, South Africa, Lesotho, and Botswana. Furthermore, SwaziPharm was one of the first pharmaceutical wholesalers in the country, having been established in April 1985. According to the Ministry of Health, SwaziPharm, due to their presence in other jurisdictions, is one of the wholesalers that can negotiate exclusive supply agreements with wholesalers. This is also emphasized by the fact that they have the right to distribute pharmaceuticals from 24 manufacturers.

25. According to information sourced from the private sector players, some health centres source their pharmaceuticals from wholesalers including manufacturers outside the country. On the other hand, Government sources most of its pharmaceuticals from local wholesalers such as Swazi Pharm, ASD, and Swazi Med Centre. However, there are instances when international suppliers are used especially in the case of ARVs which are sourced straight from the manufacturers that are based in India to avoid market failures.
26. The pharmaceutical market in Eswatini is highly concentrated amongst a few players. The size of the economy, coupled with the fact that Government is the largest player in the market has created a conducive environment for the market to be concentrated amongst a few players. Despite the concentration of the market, the market is still experiencing an increase in the number of players. This increase could be attributed to the increase in the number of pharmacies that are in the market.
29. Sections 34-36 of the same Act provides details on how the medicines should be packaged, advertised, and sold in Eswatini. Manufacturers, wholesalers, and distributors are required to have a license to manufacture, import or export or act as a wholesaler or distributor of medicines, which are issued by the Medicines and Controlled Substances Authority, under the same Act. The Medicines and Controlled Substances Authority is responsible for regulating the supply of medicines in Eswatini, including the importation, exportation, manufacturing, packing, repacking, labelling, storing, selling, pricing and distribution.
30. As stated above, Section 23 of the Medicines and Related Substances Act states that no person shall sell medicines unless they are registered under the Act. The Act states that the registration procedure requires that the applicant register through the Ministry of Health, providing the necessary information. The Ministry of Health shall then evaluate the application, taking into consideration expected adverse effects, therapeutic efficacy, quality as measured against specific requirements, whether or not the medicine or device is banned or severely restricted by an international convention or a treaty or agreement which binds Eswatini, status of the medicine or medical device under registration schemes of other countries, and any other information that may be specified by the regulations, as specified in section 26.
31. As no pharmaceuticals are produced in the country, there is no registration required for generics; they follow the same methodology as brand name pharmaceuticals. An importer of generics has to produce a certificate of registration from the exporting country.

REGULATORY FRAMEWORK

27. 26. The pharmaceutical sector in Eswatini is regulated by the Medicines and Related Substances Control Act of 2016 and other legislations including the Patents Act of 2022, the Public Procurement Act of 2011, Central Medical Stores Technical Requirements and the Competition Act of 2007.²

THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT OF 2016

28. The Medicines and Related Substances Control Act of 2016 is the main legal framework within the pharmaceutical sector. Section 22 of this Act states that there shall be a register of medicines used in the country which shall contain any information or particulars of medicine and medical devices that are approved. Section 23 states that no person shall sell or supply any medicine or medical device unless that medicine or medical device has been registered under this Medicines and Related Substances Act.

THE COMPETITION ACT OF 2007

32. The Commission gets its powers from the Competition Act of 2007, which states that the Commission shall monitor, regulate, control and prevent acts or behaviour which are likely to adversely affect competition in the country. Some of the functions of the Commission include undertaking investigations on anti-competitive trading practices, provide information for the guidance of consumers regarding their rights under the Competition Act, undertake studies and make available to the public reports regarding the operation of the Competition Act, and advise the Minister on such matters relating to the operation of the Competition Act. The Competition Act further lists all activities that are considered anti-competitive in terms of Section 30, 31, 32 and 34.
33. The Competition Act seeks to provide all businesses and consumers in Eswatini with equal opportunity to participate fairly in the national economy and achieve a more effective and efficient economy in Eswatini, so consumers have access to quality and a variety of goods and services. Some of the trade practises that are prohibited by the Competition Act include, agreements with an objective or effect of preventing restricting or distorting competition, price fixing, bid-rigging, market or customer allocation or quota allocation,
34. Anti-competitive practices include a range of activities, such as abusive exclusionary conduct by a dominant company, refusal to provide certain goods, charging excessive prices, vertical arrangements between suppliers and distributors that may prevent, restrict or distort competition. As an economy-wide regulator, the Commission enjoys concurrent jurisdiction with other regulators insofar as it relates to the conduct of firms and the implications of such behaviour for competition in markets.

THE PATENTS UTILITIES MODELS AND INDUSTRIAL DESIGNS ACT 6 OF 1997

35. The Patents, Utilities Models, and Industrial Designs Act 6 of 1997 provides a definition of patentable inventions, and further gives the right to the inventor of the patented works. The Patents Act grants the holder of the patent 20 years from the date of application for the patent until it expires. The Patents Act further provides guidelines on the application process for a patent.

THE PUBLIC PROCUREMENT ACT AND REGULATIONS OF 2011

36. As stated above, Government is the largest customer of pharmaceuticals in the country mainly because many patients receive their medicines through public health centres, including clinics and hospitals. As such, pharmaceutical wholesalers must abide by the Public Procurement Act of 2007 - which governs public procurement. The Public Procurement Regulations further establish a system and practise that services to ensure transparency and accountability in the public procurement system, while achieving economic efficiency and maximum competition.
37. The Public Procurement Act and Regulations state all the requirements that a firm/company should meet before supplying Government.

THE CENTRAL MEDICAL STORES TECHNICAL REQUIREMENTS

38. The Central Medical Stores Regulations CMS Regulations govern how pharmaceuticals are bought, stored and distributed within the public sector. The CMS Regulations provide clear guidance on how medicines should be supplied to Government. This includes how pharmaceutical importers can acquire an import permit, the requirements that a pharmaceutical wholesaler has to meet before being granted an import permit. These include the name(s) of the pharmaceuticals, the name of the producers, composition, and registration of the pharmaceuticals. It is through this process that the Ministry of Health is able to keep a record of the pharmaceuticals that are being imported into the country.

39. The CMS Technical Requirements provide that companies that are awarded Government tenders need to provide the following documents before they can supply:

- 39.1 Manufacturers Authorization
- 39.2 Good Manufacturing Practices
- 39.3 Certificate of product registration in the country of origin
- 39.4 Experience on similar contracts in or outside the country
- 39.5 Importers registration

PRICING ANALYSIS

40. A differential pricing analysis is conducted for the medicines for the relevant diseases to determine the level of price competition between the originator and generic medicines. The study evaluated the impact of the entry of generics on price competition between originator and generic medicines and price competition between multiple generic manufacturers.³ In conducting the price analysis, the Eswatini Competition Commission compared the prices of originators and generics.

41. To ascertain the price difference of originators and generics, the Commission contacted 4 pharmaceutical wholesalers as well as Government. Table 2 below shows the pharmaceuticals used in the treatment of the different ailments, the active ingredients, the originators, the number of generics available in the market, as well as the average price difference between the originators and the generics.

³ To undertake a pricing analysis, a survey was sent to several pharmaceutical wholesalers, inquiring about prices that were charged at the end of December 2021. The basis for that was to give pharmaceutical wholesalers the comfort that they would not be sharing the same information, as well as to be able to compare during the same time of the year. A list of pharmaceuticals that was provided by the Ministry of Health, was used to get information as means of sourcing the information from the different pharmaceutical wholesalers.

Table 3 - Pricing Analysis Between Originators and the No. of Generics in the Market⁴

Ailment	Active ingredient	Originator	No of generics	Price differential range
Diabetes	Metformin (500mg)	Glucophage Xr Glucophage	2	Glucophage Xr 20% - 35% Glucophage 15% - 22%
	Metformin (850mg)	Merck (Pty) Ltd	2	22% - 34%.
	Glibenclamide		3	166% - 171%.
	Glimepiride (1mg, 2mg and 4mg)	Winthrop Pharmaceuticals	10	25% - 46% (1mg) 24% - 55% (2mg) 29%- 56%(4mg)
Hypertension	Spironolactone (25mg)	Pfizer Laboratories (Pty) Ltd	2	4%
	Furosemide (40mg)	Sanofi Aventis South Africa (Pty) Ltd	7	134% - 201%

Source: Market Players.

42. Information received from market players is that there is a price difference between originators and generics. All generics are priced lower than originators and that seems to be the case across all the different brands. The theory that the larger the number of generics in the market the lower the price of the generics seems not to hold in this market. This is more the case with Furosemide which has 7 generics in the market, and the price difference ranges between 134 and 201%. On the other hand, Glimepiride has 10 generics in the market, yet the price difference is lower ranging from 25% to 56% for the different dosages.

⁴ With respect to HIV/AIDS, the Eswatini Competition Commission could not get access to information on the number of generics there are in the market as well as the price of originators and generics.

BARRIERS TO ENTRY AND EXPANSION

43. Since Eswatini does not produce any pharmaceuticals, the Commission analysed barriers to entry and expansion based on what would restrict a producer of pharmaceuticals from entering and expanding in the local market.
44. In terms barriers to entry, the Commission is of the view that there could be natural barriers to entry into this market. The natural barriers relate to the cost of establishing and operating the manufacturing plant.
45. Another possible barrier to entry is with regards to securing local customers, given that most wholesalers in the local market are already tied to long term exclusive contracts with manufacturers outside the country.
46. Further, Eswatini is surrounded by South Africa, which is a bigger economy with a larger population. South Africa also has several pharmaceutical manufacturers, both generic and brand names, that have established production plants in the neighboring country.
47. It should be noted that Eswatini is a signatory to many trade agreements, which include the Common Market for East and South African (COMESA), the South African Development Community (SADC), the African Continental Free Trade Agreement (AfCFTA), amongst others. However, due to the size of the economy and population, and the gravity model, as mentioned above, Eswatini would find it difficult to attract investors to produce pharmaceuticals.
48. The Commission is of the view that the regulatory framework does not in any way create a barrier to entry for a company that wishes to establish a pharmaceutical production plant in the country.
49. Eswatini has natural barriers to entry into the pharmaceutical production and distribution market. These barriers to entry are mainly because of being closely located to South Africa which is a bigger economy with a larger population. Despite the natural barriers to entry, there is a company that is working towards establishing a pharmaceutical production plant within the SEZ at RSTP.

CONCLUSION

50. The overall conclusion is that patients in Eswatini consume mostly generic pharmaceuticals. Government, being the largest purchaser of pharmaceuticals prefers generics over brand names. This has increased the demand for generics in the country. The private sector on the other hand, uses both generics and brand name pharmaceuticals. Information sourced from market players indicates that more than 50% of the pharmaceuticals sold in the country are generics.
51. Public expenditure on pharmaceuticals accounts for about 3.5% of the GDP. The expenditure is mainly driven by the high percentage of the population that suffer from comorbidities, such as HIV/AIDS, hypertension and until recent years TB. The expenditure on pharmaceuticals is further driven by the fact that Eswatini depends on imports of pharmaceuticals as none are produced domestically.
52. Eswatini has a limited number of pharmaceutical wholesalers (13) who supply both the private sector and the public sector. Noteworthy is that some private health centres and pharmacies import pharmaceuticals directly from the manufacturers or international wholesalers.
53. The regulatory framework for the registration of pharmaceuticals in the country is conducive for the improvement of competition despite the fact that there are no pharmaceutical producers.
54. Due to the lack of price regulations on pharmaceuticals, the price range between brand names and generics in most cases is above 20% and in some cases can be as high as 171% . It is necessary for the country to effect the price regulation system, which is provided for in the Medicines and Related Substances Control Act, in order to regulate prices making them more affordable to consumers.





GAMBIA

THE GAMBIA CHAPTER



INTRODUCTION

1. Health financing policy and reform in The Gambia is guided by The Gambia National Health Financing Strategic Plan 2019-2024. The Gambia Government in its pursuance of universal health coverage ensures all Gambian residents have physical access to publicly managed service delivery. The Government established a uniform user fee of D25 (\$0.5) at the point of service which includes consultation and pharmaceuticals. However, low availability of pharmaceutical products at public health facilities drives consumers to private pharmacies, thereby encouraging rising OOP spending by consumers. In addition, poorly equipped and maintained primary healthcare facilities drive consumers to higher levels of care, where they face higher costs, and to private providers, who require fees for services.
2. Health insurance coverage, which like the government system, can provide a pathway to universal health coverage, is very low in The Gambia; only about 4 percent of the population is covered by a health insurance scheme (Health System Assessment Report, November 2019).

OVERVIEW OF MEDICINE EXPENDITURE

3. Health financing policy and reform in The Gambia is guided by The Gambia National Health Financing Strategic Plan 2019-2024. At the macro level, health financing indicators in The Gambia present a mixed picture. According to the WHO Global Health Expenditure database, from 2015 to 2019 (table 4, below) the current health expenditure (% of GDP) and Current Health Expenditure per capita (Current US\$) data experienced a growth between 2015 and 2018 but declined in 2019. On the other hand, OOP (% of Current Health Expenditure) increased between 2015 and 2016 before experiencing a continuous decrease from 2016 to 2018 but regained an increase in 2019.

Table 4 - The Gambia Health Expenditure on Key Indicators

Variable/Date	2014	2015	2016	2017	2018	2019
Current Health Expenditure (% of GDP)	4.45	3.18	3.68	4.14	4.89	3.82
Current Health Expenditure per capita (Current US\$)	27.04	20.99	25.44	28.17	35.81	29.73
OOP Expenditure (% of Current health expenditure)	18.39	23.42	26.46	21.58	18.53	23.19

Source: World Health Organization Global Health Expenditure database.

4. The WHO estimates that Low-Income Countries (LICs) will need to spend \$112 per capita, while Low and Middle Income Countries (LMICs) will need to spend \$146 per capita to ensure access to essential health services. Moreover, the Lancet Commission on Essential Medicines recommended countries spend a per capita budget of at least \$13 to deliver a basket of essential medicines to their public. This implies that the Gambia as a LIC with the highest per capita expenditure of \$35.81 in 2018 is far below the WHO recommended \$112.
5. According to the World Bank 's world development indicators 2019 database, in 2014, 15.3% of total government of The Gambia expenditures were spent on health, slightly higher than the 15% Abuja target. However, this indicator had declined to 7% of total government expenditure in 2015 (National Health Accounts, 2015). According to National Health Accounts, OOP expenditures on health have been trending up, rising from 17% in 2013 to 24% in 2015. In The Gambia, health care is subsidized by the government, and patients pay a flat prescription fee of D25, which covers consultations and medications prescribed by clinicians which are on the EML and available at the CMS.
6. The Gambia Government in its pursuance of universal health coverage ensures all Gambian residents have physical access to publicly managed service delivery. The Government established a uniform user fee of D25 (about \$0.5) at the point of service which includes consultation and medications. However, low availability of pharmaceutical products at public health facilities drives consumers to private pharmacies thereby encouraging rising OOP spending by consumers. In addition, poorly equipped and maintained primary healthcare facilities drive consumers to

higher levels of care, where they face higher costs, and to private providers, who require higher fees for services. Health insurance coverage, which like the government system, can provide a pathway to universal health coverage, is very low in The Gambia; only about 4 percent of the population is covered by a health insurance scheme (Health System Assessment Report, November 2019).

7. In The Gambia, according to the National Pharmaceuticals Services, GMD100 million valued at \$1.04 per capita accounted for public spending on medicines by the MOH in fiscal year 2017. The Government expenditure decreased in 2018 to D27,442,108.43 with a per capita of \$0.25 to 145 million in 2021.
8. Medicines expenditure as a percentage of total health expenditure recorded an increasing trend from 2018 to 2021. 2021 recorded a whopping increase of 45% of total health expenditure. Despite the significant reduction in total health expenditure from D1,782,441,084 in 2020 to D322,439,735.61 in 2021, the medicines expenditure increased from D100,166,034.94 to D145,209,177.20 in 2021.

Table 5 - Government expenditure on medicines and supplies

	2018	2019	2020	2021
Total healthcare expenditure (D)	840,664,629.03	927,387,887.86	1,782,441,084.00	322,439,735.61
Medicine Expenditure (D)	27,442,108.43	37,538,274.31	100,166,034.94	145,209,177.20
Population	2,214,241.86	2,287,311.84	2,362,793.13	2,440,765.31
per capita (D)	12.39345571	16.4115245	42.3930617	59.4932977
per capita (\$)	0.247869114	0.32823049	0.847861234	1.189865954
Medicine Expenditure as a % of total health expenditure	3%	4%	6%	45%

Source: Government expenditure data from Ministry of Health.

9. In 2017, \$4.9 million worth of medical products were purchased for The Gambia public health sector across the following programs: essential medicine 44%, HIV 29%, malaria 9%, TB 7%, maternal health 3% and 8% child nutrition. The main sources of public expenditure on medicines are attributed to the Ministry of Health 44%, Global Fund 45%, UNICEF 8%, and United Nations Population Fund 3%. Government funded health institutions source their medications from the Ministry of Health through the Central Medical Store (CMS) based on the Essential Medicines List (EML).

10. OOP spending by individuals and households accounts for about one fifth of total health expenditures in 2019 (Health System Assessment Report, November 2019). This flows through the system as user fees for public sector health services, direct payments to private healthcare providers and pharmacies, and to a limited degree, as premiums to private health insurance plans. The bulk of OOP spending by households occurs in response to medicine shortages in public sector health facilities, requiring them to purchase medicine from private pharmacies, and only a small proportion is spent on user fees.

MARKET STRUCTURE

MARKET SHARES

11. The market share is used to determine the power of pharmaceutical products importers within the pharmaceutical value chain which serves as an indication of dominance/monopoly situation under the competition Act 2007. The study used the importation value of importers to calculate the market shares.
12. Table 6 below illustrates the market share of importers of pharmaceutical products over the period of 2018 to 2020 with specific prominence on the pharmacies with the highest shares. It is observed that Banjul Pharmacy, City Pharmacy, Jamaa Pharmacy, Kairaba pharmaceuticals,
13. Malak Chemist and Stop Step Pharmacy retained significant parts of the market share between the period of 2018 and 2019, however, the landscape changed in 2020.

Table 6: Market Share of importers of pharmaceutical products -2018 to 2020

Importer	2018	2019	2020
Banjul Pharmacy	10%	7%	19%
City Pharmacy	15%	16%	3%
Jamaa Pharmacy	10%	7%	0%
Kairaba Pharmaceuticals	27%	16%	4%
Malack Chemist	23%	17%	2%
Stop Step Pharmacy	10%	8%	3%
Other wholesale Pharmacies	5%	29%	69%
Total	100%	100%	100%

Source: Computed from data from MCA

14. Table 6 reveals that there existed no monopoly situation for the period under review as defined by section 31 of the Competition Act 2007, which states that a firm with 30% or more market share in a particular sector is deemed to be in a monopoly situation. Kairaba pharmaceuticals enjoyed a high market share of 27%, almost approaching a monopoly situation in 2018. The highest individual market share for 2019 and 2020 were 17% and 19% registered by Malak Chemist and Banjul Pharmacy, which are less than the dominance threshold.
15. Table 6 shows a significant improvement in market share for some of the pharmacies under the others category in 2020. This resulted in Banjul pharmacy, Gam Pharma, Alhamdulillah Pharmaceuticals, Lucky Development Corporation Ltd, Kairaba Pharmaceuticals and Sino Pharmaceuticals being the top five (5)pharmacies as opposed to 2018 and 2019.
16. The table also shows that no single pharmacy enjoyed sustained leadership in terms of market shares within the period under review.

MARKET CONCENTRATION

17. The study used the Herfindahl Hirschman Index (HHI) to measure market concentration. The index indicates that highly concentrated markets are the less competitive whilst markets with low concentration index are termed not dominated by any large enterprise hence, considered competitive.
18. The index ranges between 0 and 10,000. An HHI of zero indicates perfect competition where no firm has any influence over market price and other competitive determinants, whilst an HHI of 10,000 denotes that there is only one firm in the market. An HHI of less than 1,500 represents an industry with low market concentration; an HHI ranging between 1,500 and 2,500 represents moderate concentration. HHI values of more than 2,500 represent a highly concentrated industry.
19. Figure 9 below shows the Gambia's pharmaceutical sector's HHI from 2018 to 2020. It shows that the index value for 2018 is 1792 Which indicates a moderately concentrated market. The figure also shows that the index for 2019 and 2020 were less than 1,500, hence, registered a low market concentration.
20. From the HHI values between 2018 to 2020, it reveals that the market was more competitive in 2019 and 2020 compared to 2018.

Figure 9: Market Concentration



Source: GCCPC computation

REGULATORY FRAMEWORK

THE COMPETITION AND CONSUMER PROTECTION ACTS AND THE GCCPC

21. The GCCPC is a body statutorily established to ensure that fair competition exists between and amongst enterprises where the rights of consumers will accordingly be promoted and protected. The preamble to the Competition Act 2007 clearly stipulates that the aim of the Act is "to promote competition in the supply of goods and services...and control of other types of restrictive agreements and of monopoly, by promoting understanding of the benefits of competition." This goes to show that the cradle of the Act seeks to promote and ensure that goods such as pharmaceuticals and allied medical services are adequately available to the public, enterprises and consumers for safe use. Therefore, any act or omission by importers, suppliers, distributors or retailers leading or likely to lead to the unavailability and unaffordability of pharmaceutical goods or services stalls competition and is deemed as an act contrary to sections 29, 30 and 31 of the Competition Act.
22. Similarly, sections 30 and 31 frowned at conducts where enterprises or pharmacies as the case may be, are engaged in acts of abuse of dominance or abuse of a monopolistic position. The Industrial Property (Amendment) Act 2015 and other related laws offer protection for pharmaceutical products. The Industrial Property (Amendment) Act requires products including pharmaceuticals can be subjected to patent or Intellectual Property rights protection for a period of fifteen (15) years.
23. Pharmaceutical products are accorded protection in The Gambia as a designated country by the inventor/patent agent during patent registration. It does not necessarily mean that products patented internationally or through the Patent Cooperation Treaty automatically obtain protection in The Gambia. They only obtained protection upon resignation and accepted by the Registrar General.

THE INDUSTRIAL PROPERTY (AMENDMENT) ACT, 2015 AND DRAFT INTELLECTUAL PROPERTY ACT 2020

24. The Intellectual Property Office of the Ministry of Justice of the republic of The Gambia is the office charged with the mandate to administer and enforce the Industrial Property and draft Intellectual Property Acts. The Industrial Property (Amendment) Act 2015, is completely silent on the establishment of any interface between Intellectual property and Competition regulation in the pharmaceutical sector for the past years. In fact, section 5(2) and sub-section 5 of schedule 1 of the Competition Act, expressly excludes the regulation of intellectual properties from the undertakings of the Commission. Notwithstanding, section 15(i) of the Competition Act states that the Commission has the power to 'advise government on action taken or proposed to be taken by the State or any public body that may adversely affect competition in the supply of goods and services (including matters excluded from the scope of the Act under section 5 (2)' such as Intellectual property right and the implicit exclusivities on the importation and pricing of pharmaceuticals and whether the exclusion should continue.
25. Progressively, section 33 of the draft Intellectual Act 2020, stipulates that the Intellectual Property Office of the Ministry of Justice or the Courts 'shall have power to grant compulsory license'. Per se, this provision of the draft legislation is celebrated by the competition Commission given its pursuit towards the abridgement of the imbalances observed on exclusivities or grant of intellectual property rights generally and pharmaceuticals in particular. As soon as this draft legislation comes into force it will certainly create an avenue where competitors in the pharmaceutical or the regulators such as the Commission can apply to the Registrar General or Courts for grant of compulsory license on excluded or protected pharmaceuticals to ensure that the products are affordable and available in good quantity to consumers and the public as envisaged under the objective of the CPA Consumer Protection Act.

THE TRADE RELATED ASPECT OF INTELLECTUAL PROPERTY (TRIPS) AGREEMENT OF THE WTO

26. The Trade Related Aspect of Intellectual Property Agreement of the WTO came into effect on 1st January 1995 to which the Gambia has been a member since the 23rd of October 1996. Embedded into it are relevant provisions which seek to discourage, proffer solutions and provide remedies to anti-competitive and restraints of trade conducts.
27. It is apparent that importers of pharmaceuticals into the country are given exclusive importing registration or license over the importation of certain medicines or pharmaceuticals. To some extent, it may lead to the creation of conditions where the licensed or registered importer may probably be incapable of performing, thereby creating a shortage or unavailability of medicines or pharmaceuticals to consumers and the public especially when demand becomes higher than supply. That is why Articles 8, 31 and 40 of the TRIPS clearly incorporated pro-competition friendly provisions. Purposely advocating for member States like the Gambia to make or amend its laws and regulations towards measures necessary to protect public health and prevent unreasonable restraint of trade such as exclusion contracts (Article 8), and to remedies on abuse of Intellectual Property rights or restraint of trade by the use of Compulsory license or parallels importation to combat anti-competitive behaviours (Articles 31 and 40).

MEDICINES AND RELATED PRODUCTS ACT, 2014 AND THE MEDICINES CONTROL AGENCY

28. The Medicines and Related Products Act was enacted in the year 2014 and now administered by the MCA. The object of the Act is purposely to regulate the quality, safety and efficacy of medicines and related products. The MCA regulates the advertisement, promotion and deception on pharmaceuticals to the extent that section 20 prohibits deceptive practices from dealers in the pharmaceutical sector and section 21 sub section 4 provides that 'a person shall not advertise or carry out promotional activities of a medicine or related products regulated under this Act, to

the general public as a treatment, preventive or cure for a disease, disorder or an abnormal physical state unless the advertisement has been approved by the agency.'

29. In essence, the above provision seeks to curtail deceptive practices and unsafe medicinal products in the market, making it a requirement for any medical practitioner including traditional herbalist to seek approval from the agency before engaging in any activity that may have adverse effect on consumers and the public at large. However, the challenge is with herbal medicines that still remain a problem. MCA is mandated by law to regulate the products on herbal medicines and not their services. The office responsible for herbal and traditional medicine is The Traditional Medicine unit under the Ministry of Health of the Gambia.
30. Secondly, the standard observed on pharmaceutical products sold and used in the Gambia is of major concern to the Commission. Section 6 (1)(d) of the CPA provides for consumer access to goods and services including pharmaceuticals that 'comply with any applicable standards set under the Gambia Standards Act, 2010 or any other national regulation'. Similarly, section 10(3) of the MCA Act provides for 'a person who manufactures, labels, packages, sells or advertises a medicine or a related product for which a standard has not been prescribed, or for which a standard is not contained in the publication specified in the Regulations commits an offence'.
31. There is a laboratory in The Gambia but most of the personnel are on studies. However, if the agency needs further verification of a product, samples are sent to Senegal or Ghana for testing.
32. Furthermore, most imported medicines into the country are being listed and registered with MCA in their trade or generic names. Essentially, pharmacies register various medicines or pharmaceuticals that are being traded in the country where a registration and approval number and certificate of registration for a period not more than five years is issued on each approval as contained under section 30 of the MCA Act. Registration confers on those pharmacies or enterprises an exclusive trading license to import and/or sell those registered pharmaceutical products to consumers and the public. In that way, they would have the opportunity to decide on their prices and availability of those protected or licensed pharmaceuticals. Despite the existence

of the exclusivity or monopoly as embedded in the MCA Act, in the public interest the agency can authorise parallel importation of medicines or related products as per section 36 (2) during an emergency.

REGISTRATIONS OF MEDICINES

33. Sections 25, 26 and 30 of the Medicines and Related Products Act, 2014 requires that all medicines manufactured, prepared, imported, exported, distributed, sold, supplied or exhibited for sale in The Gambia have been registered by the Medicines Control Agency. The agency in line with the Act prepares a Guideline for Registration of Medicines.

CONDITIONS FOR IMPORTATION OF PHARMACEUTICAL PRODUCT

34. Section 36 of the Medicines and Related Products Act, 2014 requires the following conditions for the importation of medicines or related products.
 - 34.1 A person who has not been issued a license or permit under this Act, shall not import a medicine or related product.
 - 34.2 Subject to sub-section (1), the Agency may in the public interest, authorise parallel importation of medicines or related products.
 - 34.3 A person shall not import medicines or related products with a shelf life of less than sixty percent unless approved by the Agency.
 - 34.4 The Agency shall grant an import license or permit to only licensed pharmaceutical companies.
 - 34.5 The Agency may grant an import license or permit to hospitals or similar health related institutions on special request only when such medicines or related products are not locally available.
 - 34.6 In this section, parallel importation means importing a medicine without authorisation of the medicine registration holder from another country where it is legitimately placed.

GENERAL REQUIREMENTS

35. A separate application is required for each product.
36. Products that differ in active pharmaceutical ingredient(s), strength, dosage forms, proprietary names though containing the same ingredients or from different manufacturers, are different products and hence require separate applications.
37. For a fixed dose combination medicine, the applicant must provide proven evidence that the product has been shown to be safe and effective and that all the active pharmaceutical ingredients contribute to the overall therapeutic effect. In addition, it should be proven that there can be real clinical benefits in the form of increased efficacy and/or a reduced incidence of adverse effects and/or improved patient adherence.
38. Registration of innovative medicines in The Gambia shall normally not be permitted within the first two years of the initial authorization and being placed on the market in the country of origin where there is prevalence of the disease condition.
43. The designation of a local agent shall not relieve the marketing authorisation holder of his/her legal responsibility.
44. The proposed marketing authorisation holder and manufacture(s) shall be clearly indicated.
45. All applications for registration shall contain the information and documents as required by the Regulations.
46. The dossier for application for registration shall be submitted in the MCA Common Technical Document (CTD) format as provided by the Agency (MCA-G-112/02) including all supporting documents, unless stated otherwise in this guideline. Other CTD formats (e.g. WAHO, WHO, ICH) would be accepted.
47. All documentation submitted shall be in English, and must be legibly printed and not handwritten.
48. The dossier shall be submitted as follows: one hard copy (CTD Module 1 (one) only) and a soft copy (all CTD Modules 1, 2, 3, 4 & 5).

PROCESS OF APPLICATION

39. The application fee shall be paid at the time of submission of an application.
40. The accompanying cover letter shall be duly signed and addressed to Executive Director, Medicines Control Agency, 54 Kairaba Avenue, K.S.M.D, The Gambia.
41. An application form (MCA-F-112/01) must be completed by the applicant for each medicine. The application form shall be dated, signed and stamped by the applicant and indicate the local agent, where applicable.
42. If the applicant is not resident in The Gambia, he/she shall appoint a contact person or company residing in The Gambia as local agent being responsible for facilitating communication with the applicant unless exempted by the Agency.
49. Copies of the proposed or marketed labels, patient information leaflet (package inserts) and professional information (Summary of Product Characteristics), conforming to the Regulations shall be included in the documentation.
50. Although clinical trial data including bioequivalence data for generic medicines derived from studies in other countries will be considered in taking a decision with any application, the Agency reserves the right to request for clinical evaluation in The Gambia, based on existing MCA guidelines for clinical trials, or bioequivalence data for generic medicines based on existing WHO guidelines for bioequivalence studies, where necessary. The cost of this trial shall be borne by the applicant.
51. The Agency may ask the applicant to provide other information as may be required to enable reaching a decision on the application.
52. All applications shall be accompanied by three (3) samples of the product in the

commercial pack(s) with batch Certificates of Analysis (CoA).

53. The CoA for the medicine shall be issued by an authorised person with expert knowledge (qualified person).
54. The Agency shall process an application for registration of a medicine within 180 days. In case of an abridged review the application should be processed within 90 days. The Agency may consider an abridged review for medicines prequalified by WHO or, on a case-by-case basis, for medicines authorised by a Regulatory Authorities (RA) recognised by MCA. However, the Agency shall decide on the timeline on a case-by-case basis for the registration of medicines in public health emergencies. Applications for major variations and renewals shall be processed by the Agency within 90 days.
55. The registration of a medicine, unless otherwise stated, shall be valid for a period of five (5) years and may be renewed for a period of not more than three (3) years.
56. The application fee for registration of medicine is \$300 per product. The fee can be paid by the manufacturer, Marketing Authorisation Holder or importers.

PRICING ANALYSIS

57. The prices in the pharmaceutical sector are unregulated. They are determined by market forces. Private pharmacies are expected to set their prices independently whilst the government, on the other hand, subsidises the cost of medicines in public health facilities.
58. Medicines for communicable diseases are mainly dispensed by public health facilities and supplied for free. There is no policy barring the private sector from participating in the supply of medicines for communicable diseases. However, all the Pharmacies interviewed claimed that they do not participate in the sale of medicines for TB and HIV and AIDs because public health facilities provide these medicines for free. The private sector mainly competes in the importation, distribution, and sales of non-communicable diseases medicines.

59. The prices of the selected medicines for non-communicable diseases were randomly collected from pharmacies within the Greater Banjul Area (urban area). The average prices of the Originator and the Generic medicines were compared. Two hypertension medicines (P/O Nifedipine 20mg and P/O Hydrochlorothiazide 25mg) have the highest average price difference of D91.00 and D125.00 with a percentage difference of 161% and 160% respectively. P/O Captopril 25mg, P/O Metformin 500mg and P/O Bendroflumethiazide 5mg also had high average price differential of D36.32, D51.74 and D24.61 with a percentage difference of 131%, 137% and 101% respectively. P/O Enalapril 10mg and Insulin mixtard 100iu has the least average price differential.
60. The pricing analysis shows that generic products are generally cheaper than the originator medicine, a percentage difference as high as 160%. According to the interviewed pharmacies, many consumers prefer the branded products but due to its high price, many go in for the generic products. However according to the pharmacies, this trend is changing as preference for branded medicine is increasing due to perceived effectiveness.

Table 7 - Comparison of Average prices Originator with Generic Medicines

Hypertension Medicine	Originator in Dalasi	Generic In Dalasi	Difference in Dalasi	Percentage difference
P/O Hydrochlorothiazide 25mg	125	13.75	111.25	160%
P/O Bendrofulmethiazide 5mg	36.61	12	24.61	101%
P/O Enalapril 10mg	50	30	20	50%

P/O Captopril 25mg	45.98	9.67	36.32	131%
P/O Amlodipine 10 mg	74.11	29.33	44.77	87%
P/O Nifedipine 10mg	150	35	115	124%
P/O Nifedipine 20mg	91.92	10	81.92	161%
P/O Atenolol 50mg	75.89	30	45.89	87%
P/O Methyldopa 250mg	59.42	35	24.42	52%
2. Diabetes Mellitus Medicines				
p/o Metformin 500mg	63.57	11.83	51.74	137%
p/o Glibenclamide 5mg	25	10.5	14.5	82%
Insulin mixtard 100iu	750	450	300	50%

Source: Commission's compilation based of on wholesalers' submission.

NB: price is per sachet of 10 tablets

BARRIERS TO ENTRY AND EXPANSION IN THE GENERIC PHARMACEUTICAL INDUSTRY

61. In the pharmaceutical sector, some of the international companies manufacturing medicines, either register their products or brands directly in The Gambia or through the local agents. Once these medicines have been registered through the MCA, the local agents have exclusive rights to import those drugs unless a competitor receives an authorization to import from the manufacturer. Although exclusivity agreements are not necessarily illegal in the Gambia as it is based on a cost-benefit analysis, it creates a barrier to entry for potential entrants. Exclusivity agreements may be prohibited if the agreement has a negative impact on public benefit and/or leads to abuse of dominance.
62. The Gambia is a small, fragile country in West Africa. Stretching 450km along the Gambia River, the country (10,689 square kilometers) is surrounded by Senegal, except for a 60-km Atlantic Ocean front. Due to The Gambia's small size and market, it sets challenges for large investments targeting short profit turnover periods. Large businesses target countries with larger populations as they provide wide domestic markets and scale economies for their products. Smaller countries such as The Gambia with a population size of 2.4 million, as at 2021 (GBoS), could hardly attract

large multinational companies such as pharmaceutical manufacturer unless its investment climate is efficient enough to penetrate into the African market.

63. Inadequate human resource capacity also impedes the growth of Gambia's pharmaceutical sector. Sections 21 and 22 of the Pharmacy Council Regulation requires wholesale pharmacies to be covered by a registered pharmacist and currently, there are only 21 registered pharmacists in the Country. This implies that the country cannot have more than 21 wholesalers/importer given the current number of licensed pharmacists. Currently, the Gambia has 23 registered wholesalers

CONCLUSION

64. The study aimed to get a better understanding of the extent of competition in the generic medicine market and to understand the barriers to entry and expansion in the generic market. This was undertaken by reviewing the underlying market structure and assessing the regulatory framework with respect to the market authorisation process, the licensing of economic operators and pricing of medicines for the selected communicable and non-communicable diseases.
65. The pharmaceutical industry consists mainly of importers, wholesale pharmacies, and retail pharmacies. Consumers are supplied by both the Government and private sector. 35% of the retail pharmacies are Government owned and located in Government health facilities whilst 65% are owned by private players. Government spending on medicines and medicines expenditure as a percentage of total health expenditure recorded a positive trend from 2018 to 2021.
66. The pricing analysis shows that the pricing of pharmaceutical products is determined by market forces. It also revealed that generic products are generally cheaper than the originator medicines with a percentage difference of as high as 160% in some instances. The study revealed that despite there being no policy barring the private sector from selling medicine for communicable diseases, the private sector shy away from the sales of TB and HIV medicines as they are provided by public health facilities for free.

67. The Herfindahl Hirschman Index (HHI) revealed a competitive market in 2019. The study revealed exclusivity agreements, small population size and inadequate human resource capacity as the main barriers to entry and expansion of the Gambia's pharmaceutical sector.







KENYA

THE KENYA CHAPTER

INTRODUCTION

1. The Kenyan health sector has experienced remarkable development in the recent years. The Kenya Health Policy (KHP 2014 - 2030) aims to support the sector to realign to emerging issues and enable the country to attain its long-term health goal as outlined in the Kenya's Vision 2030 and the Constitution of Kenya, 2010.
2. The health sector has been further identified as one of the economic development pillars under the 'Big Four' Agenda. In 2020, the country's health expenditure was estimated at 8% of Gross Domestic Product. To this end, the government sector health budget expanded from USD 940 million in FY 2012/13 to USD 2,470 million in FY 2020/21, an increase greater than two-fold, making it a priority sector for the realization of the 'Big Four' development agenda (Kenya National Bureau Statistics, 2021).
3. The achievement of the health policy is heavily dependent on the vibrancy and the level of competition in the pharmaceutical industry. As of 2020, the pharmaceutical industry in Kenya was estimated at \$8500 million, having exhibited a compounded growth rate of 11.8% during the same period. Prescription medicines account for around 78% of the market. In the coming years, the fastest sector growth is expected in the OTC product sales segment.
4. The pharmaceutical industry is growing rapidly and offers excellent opportunities for exporters and manufacturers to establish their products and services in the lucrative market for pharmaceuticals in East Africa. Currently, Kenya is the largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA) region, supplying about 50% of the regions' market (Ministry of Health, 2020).

5. The increasing Non-Communicable Diseases (NCDs) burden and continued prevalence of infectious diseases in Kenya presents opportunities for pharmaceutical manufacturers. The value of imported medicines in Kenya is estimated at \$650 million, (70%) annually, with local manufacturers covering the remainder (30%) of the domestic market. The Kenyan pharmaceutical industry is strategic in the country's development agenda to boost manufacturing and affordable healthcare.

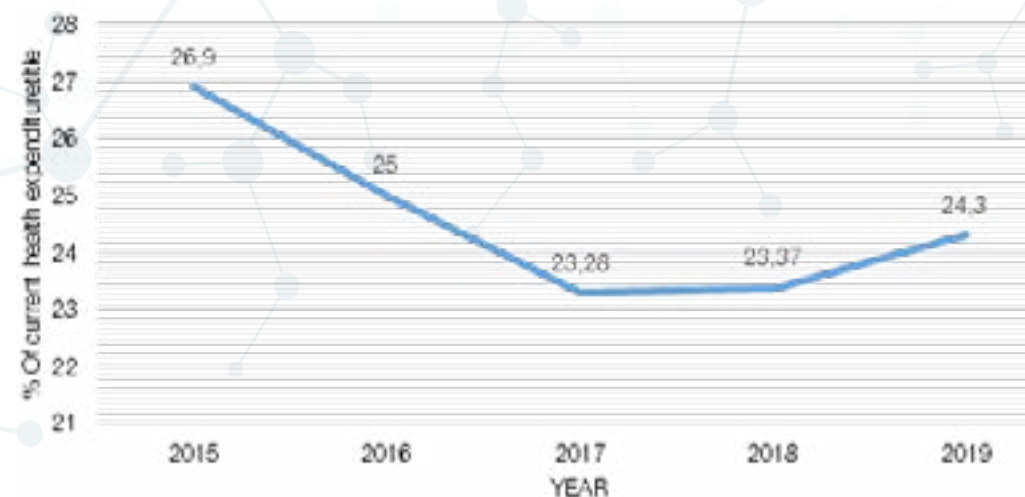
OVERVIEW OF MEDICINE EXPENDITURE

OOP PAYMENTS

6. On average, Kenyans pay USD 56.13 to cater for outpatient medical services and USD 14.92 for inpatient health care services per person per year. It is however, notable that richer Kenyans are characterized by higher OOP payments on average. Similarly, the average OOP health expenditure is higher by 30%-40% in urban areas than in rural households (Kenya Pharmaceuticals Diagnostic Report, 2020).

Figure 8 - OOP Health Expenditure as % of Current Health Expenditure, 2015 - 2019

Source: World Health Organization Global Health Expenditure database



7. OOP expenditure as a share of current health expenditure for Kenya dropped from 26.9% in 2015 to 24.3 % in 2019. This could be attributable to the increased uptake of National Hospital Insurance Fund (NHIF), which is used to pay for both inpatient and outpatient health services in the country.

PUBLIC HEALTHCARE SECTOR IN KENYA

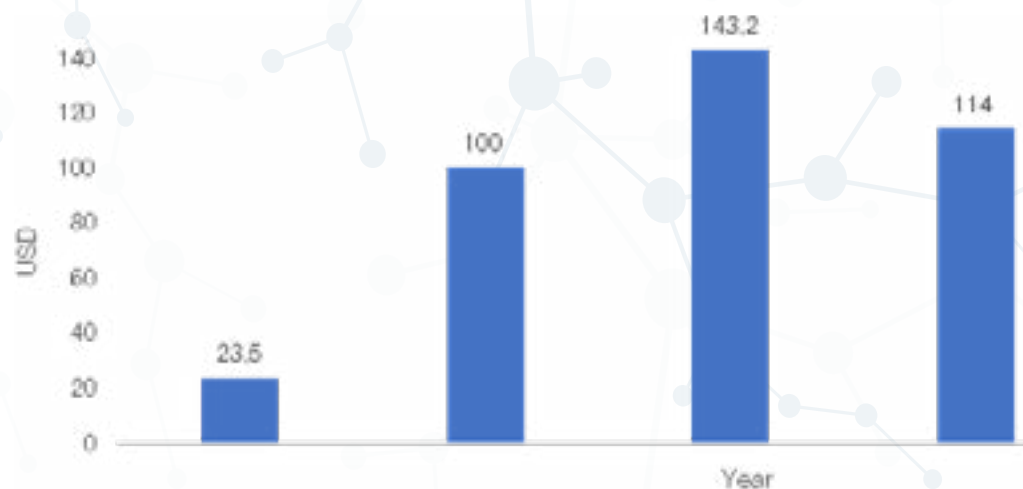
8. The Kenyan Constitution provides that every Kenyan has the right to the highest attainable health standard. Kenyan Vision 2030 main objective is to transform the country into a globally competitive and prosperous country with high quality of life by 2030. Improvements in health is a key component in the realization of the vision.
9. The government has demonstrated its commitment to providing universal health coverage (UHC) by ensuring socio-economic transformation through access to equitable, affordable and high-quality healthcare for all its citizens. (Ministry of Health, 2018). The institution of apposite health sector policies and programmes have been instrumental in achieving these. Through UHC all Kenyans have access to essential health services in the absence of financial constraints using a single unified package.
10. Efficiency in public health supply chain is critical in achieving UHC. Equally, widening the coverage of products and commodities purchased will strengthen Kenya Essential Package for Health. These will increase the coverage for additional non-communicable diseases as well as expand public health care services at large. Further, reducing costs of medicine and health care services, effective use of health resources and medicine cannot be underscored in increasing access to health care (Ministry of Health, 2018).

11. Kenya increased its National Government health expenditure by 34.5% to USD. 1,031 million in the financial year 2019/20. Out of this, development expenditure accounted for 41.0%. On the other hand, County governments' expenditure on health services rose by 16% to USD 1060 million during the same period. Health sector expenditure rose by 6.5% to USD 2,470 million in the 2020/2021 budget period (Kenya Economic Survey, 2021). The significant increase in budgetary allocations to the sector are yet to meet the government's target of 15% of total national budget as enshrined in the 2001 Abuja Declaration.¹.

12. Membership to National Hospital Insurance Fund (NHIF) took an upward trajectory, rising by 6% to 22 million by June 2020. Contribution to the Fund, therefore, rose by 5.7% to USD 595 million by June 2020. Benefits payout summed to USD 544, representing an increase of 1.8% from the previous year 2018/2019. As at 2020, Kenya had 14,600 health facilities with 82,091 hospital beds. Nevertheless, hospital costs rose to USD 89.46; an increase of 7.7% from 2019. In terms of disease incidences, a total of sixty (60) million cases of disease were reported in health facilities, in 2020, a decrease of 31.6% in cases reported in 2019. Respiratory diseases and malaria account for 27.6% and 19.1% of the total disease load respectively (Kenya Economic Survey, 2021).

¹ Members of African Union (AU) states in 2001 ratified the commitment to increase their budgetary allocations towards healthcare provision to a minimum of 15% healthcare systems. The commitment was referred to as Abuja Declaration.

Figure 9 - Public Expenditure of Medicine, health products and technologies



13. Medicine, health products and technologies expenditure increased from USD 31.7 million to USD 48.7 million in 2018/2019 and 2019/2020 respectively. However, in 2021/2022, there was marginal decrease from USD 41.3 million to USD 39.9 million. The Kenyan government expenditure on medicine, health commodities and technologies were none the less marginal at 16.5% of the total health expenditure in the year 2020/2021.

PRIVATE HEALTHCARE SECTOR

14. The government policies aimed at increasing the participation of private healthcare coupled with declining investment in public health care resulting in poor quality services and medicine stock-outs are among the factors which incentivize expansion of profit-oriented players who are viewed to have neglected public healthcare concerns.
15. Privatization of healthcare provision has had distressing effects on access and affordability in Kenya, making the public health sector unable to meet the demands of the patients. Provision of private healthcare in Kenya tends to be more focused on cherry picking on high profit earning services while paying little attention to areas, patients and services that do not generate more revenue.
16. This has retarded the country's efforts towards realization of UHC. An increasing number of Kenyans are being priced out of health services due to their inability to pay or access private healthcare. Even though quality healthcare is available in the private sector, a majority cannot afford to pay, which predisposes the poor to below standard health services provided by select private players. A situation is therefore, presented where privileged and disadvantaged are served by completely divergent private healthcare providers.

17. According to Kenyan Master Health Facility List 2021², there are 9,696 health facilities. 4,616 of which are public sector owned, while 3,696 are commercial private sector owned. 1,384 facilities are run by Faith Based Organizations (FBOs), Non-Governmental Organizations (NGOs) and Community Based Organizations (CBOs) (Ministry of Health, 2022).

18. Health insurance coverage in Kenya is estimated at 25%, entailing cover by public, private or community-based health insurance schemes. The implication, therefore, is that over three quarters (75%) of Kenyans pay OOP to access health services.

19. The National Hospital Insurance Fund (NHIF) has contracts with the private health providers, subsidizes cost of private healthcare and reimburses them for services provided. Most claims submitted to NHIF are from the private sector. The fund works with international private hospitals on public private partnership framework to enable members access high expense specialized healthcare in their facilities. NHIF is viewed as a springboard to achieving universal health coverage.

20. The public sector's position to provide universal healthcare needs to be underscored. However, NHIF is more centered on the private healthcare provision, growth of the fund shall definitely channel more public funds to private players devoid of eradicating high-cost concerns and increasing inclusivity in healthcare access. Strengthening regulatory framework in private health sector could significantly address the above challenges.

MARKET STRUCTURE

² An application with all health facilities and community units in Kenya. Each health facility and community unit is identified with unique code and their details describing the geographical location, administrative location, ownership, type and the services offered.

21. In 2019, Kenya's pharmaceutical market was estimated to be worth \$1 billion and projected to grow at 6.6% annually until the end of 2021. However, this value could be understated due to lack of data on parallel imports. Kenya is currently the largest producer of pharmaceutical products in the COMESA region, supplying approximately 50% of the regions pharmaceuticals demands (Ministry of Health, 2020, UNIDO, 2019). Out of the fifty (50) recognized pharmaceutical manufacturers in the region, thirty (30) are in Kenya.
22. According to the Ministry of Industrialization, Trade and Enterprise Development (2018), the target markets for exports of Kenya's pharmaceutical products are COMESA, the EAC, and the rest of Africa. The total value of this market is estimated at \$13 billion. Currently, Kenya is only able to export, on average, \$63 million to this market each year (Ministry of Health, 2015). Due to increased demand and inadequate supplies, the Kenyan market extends to the other parts of the continent.
23. Pharmaceuticals industry in Kenya is characterized by stiff competition for markets where most local firms compete on the same market segments with identical product portfolios in addition to aggressive pricing strategies. This is motivated by the high return on investment, estimated at more than 20% (Karenje and Murigi, 2020).
24. Notably, Kenya remains a marketing hub of Indian produced pharmaceutical products. This is attributed to its low pricing of generics which India pioneered (Mukuria, 2020). Demand for pharmaceutical products in Kenya has been increasing significantly over the years. This is because of population growth, national health-care-related initiatives (especially the program to expand universal health coverage), increasing health-seeking behavior by citizens on account of better access to information with rising literacy and greater use of the internet services, and the increased purchasing power of citizens as a consequence of the country's strong economic growth and performance.
25. Further, the government's rollout of a universal health coverage program has improved citizens' access to health services, increased demand for medicines, and spurred growth in the local pharmaceutical industry. The domestic market is heavily reliant on imported products for innovator medicines and brands. Local manufacturers, however, focus on the production and provision of generic medicines. The market is also slowly transitioning from branded innovator products to lower-priced generics mainly in response to the price sensitivity of the medical insurance industry.
26. The drivers of the pharmaceuticals industry growth include: local economic growth; rising population; increase in government contribution to health care, increase in NHIF coverage, and universal health coverage; expanded urbanization, growing communicable and non-communicable disease burden and increased awareness of preventative healthcare.
27. Key issues on the use of generics in Kenya include;
- 27.1 Absence of policy guidance on use of generic medicines and generic substitution,
 - 27.2 Low prescribing by generic name in all sectors,
 - 27.3 Unethical promotion of branded products, eroding the confidence of prescribers and consumers in the use of generics,
 - 27.4 Lack of authoritative information on the quality of medicines in the market,
 - 27.5 Information asymmetry and perverse incentives within the pharmaceutical market,
 - 27.6 Conflicting legislation on counterfeits which focuses on patent protection, and creates the risk of generics being erroneously classified as counterfeits,
 - 27.7 Limited public resource allocation for promoting appropriate medicines use, including use of generics.
28. Multinational companies (MNCs) dominate the pharmaceutical market in Kenya

by value, while local manufacturers dominate by volume. Most of the multinational companies import products from their production facilities located in Africa or other parts of the world. The local manufactures have focused on production and supply of off-patent generic products. The number of companies engaged in manufacturing and distribution of pharmaceutical products in Kenya continue to expand, driven by the Government's efforts to promote local and foreign investment in the sector. The country has an estimated 700 registered wholesalers.

29.
- Table 8 shows the top 15 pharmaceuticals players in Kenya by sales and market share. The pharmaceutical market space is dominated by MNCs in terms of market share and sales value. Out of the top fifteen pharmaceuticals in the country, only three are local; Dawa (5.1%), Cosmos (3.7%) and Medisel Kenya (2.6%). In as much as MNCs dominate the private sector retail market, local manufactures have been increasing their reach, with three local companies among the top 15 pharmaceutical players by sales value as well.
30.
- GlaxoSmithKline Pharmaceuticals is the largest MNC in the industry in terms of market share and sales volume at 10.8% and 32.4%, respectively. In the second place is Pfizer with a 5.2% market share and 15.7% of sales volume. The industry has a larger number of players, which is healthy for competition. However, the pharmaceutical manufacturers specialize in different categories of medicine (Table 1).

Table 8 - Top 15 Pharmaceuticals Players in Kenya by Sales and Market Share

Rank	Corporation Name	Local/ MNC	Market Share 2019 (%)	Sales 2019 (%)	2017-19 CAGR ³ (%)
1	GlaxoSmithKline (Pharma)	MNC	10.8	32.4	-0.6
2	Pfizer	MNC	5.2	15.7	5.9
3	Dawa	Local	5.1	15.4	-4.2
4	GlaxoSmithKline (Consumer Health)	MNC	4.2	12.6	13.5
5	Glenmark	MNC	3.9	11.7	20.8
6	Sanofi	MNC	3.9	11.7	4.0
7	Cosmos	Local	3.7	11.2	27.7
8	Novartis	MNC	3.7	11.1	-0.6
9	Roche MNC	MNC	3.3	9.9	8.4
10	Getz Pharma	MNC	3.2	9.5	17.6
11	AstraZeneca	MNC	3.0	8.9	-4.7
12	Medisel Kenya	Local	2.6	7.9	12.2
13	Merck Sharp and Dohme	MNC	2.5	7.5	-7.2
14	Cipla	MNC	2.4	7.1	-16.8
15	Bayer	MNC	2.3	6.8	3.8

Source: Ministry of Health, 2020

31.
- There are other pharmaceutical manufacturers with less than 2% market share. A comprehensive analysis of the top fifteen molecules by sales value indicates that MNCs have 87% of the market share, dominating in most formulation categories, excluding the penicillin-type antibiotics Amoxicillin and Flucloxacillin, and the diabetes treatment Metformin, in which local manufacturers also have a significant market share at 47%, 68%, and 45% respectively. Other molecules in which local players have significant market share are the analgesic Paracetamol and the antibiotic Ceftriaxone, with corresponding 23% and 13% market share. GlaxoSmithKline’s market share of Kenya’s pharmaceutical industry has grown largely due to the popularity of its anti-infectives, which account for approximately 42% of all revenues generated in the prescription sector.

3

Compound annual growth rate

GENERIC MEDICINE MARKET IN KENYA

32. The expansion in the generic medicines industry in Kenya has majorly been propelled by the rising population, increased demand, and initiatives to realize universal health coverage in the country. The increased use of social health insurance schemes is one of the factors that has encouraged the use of generics as they are less costly. The pharmaceuticals industry is changing rapidly due to enhanced political support for local pharmaceutical producers and the shift in healthcare policies and practices which support the development of generics as opposed to patented medicines.
33. As of 2017, the market for generic medicines was valued at \$610 million, accounting for over 64% of the entire market. This was estimated to expand by 10% annually. Expansion of Kenyan generics market is attributed to increased urbanization and improved health facilities. Further, the promotion of “Buy Kenya Build Kenya” strategy has propelled the uptake of domestically manufactured generic medicines. The market, however, was not spared from the adverse effects of COVID-19.
34. Local producers of generics experience competition not only from among themselves but also from imports. Ease of registration of foreign medicines, reduction of import tariffs on pharmaceutical products to zero, inadequate capability of the Pharmacy and Poisons Board (PPB) to ascertain Good Manufacturing Practices rating of foreign pharmaceutical manufacturers that import medicines into the country, non-uniformity and asymmetrical testing of generic medicines being imported into the country are some of the factors contributing to increased importation of substandard generics in Kenya (Warier & Mehta, 2016).
35. On the other hand, local pharmaceutical manufacturers are underprivileged in terms of not possessing the OOP pre-qualification, hence fail to benefit from donor funding purchases and lack capacity to participate in high value procurements and experience stiff price competition from imported generic medicines. Lastly, local pharmaceutical producers may face liquidity constraints associated with late VAT and duties refunds by the government (Warier & Mehta, 2016).
36. Multinational pharmaceutical manufacturers in Kenya have widened their medicine production lines to include branded generics. This has been motivated by the increased demand for generics and voluminous purchase by donors. Family run pharmaceuticals dominate the production of unbranded generic medicine in Kenya. Nearly 80% of local medicines are produced by up to ten medicine manufacturers, producing unbranded generics. More than 50% of firms in Kenya concentrate on producing anti-infectives and have not ventured into more profitable immunological and cardiovascular medicine segments.
37. The firms have focused on production of simple forms including tablets and capsules. Whereas some firms have expanded into manufacture of syrups, creams and suspensions, those who produce injectables and ophthalmic formulations which demand complicated procedures and strict quality controls standards, including sterile environments, are not more than three firms (Ministry of Health, 2020).
38. Kenya has laws, which support function and practice in the health sector and the pharmaceutical value chain. The local laws and those of other countries are essential for companies and individuals who target regional export markets for their health products and services. The country has consistently advocated the review of laws in the East African Community (EAC) and the Common Market for Eastern and Southern Africa (COMESA) regions to allow increased trade in goods and services and to support the export of its expanding range of locally manufactured pharmaceutical products. Several laws have been enacted to support pharmaceutical manufacturers in Kenya. The following laws are of particular relevance to the pharmaceutical sector:

REGULATORY FRAMEWORK

THE PHARMACY AND POISONS ACT NO.39 OF 1956

39. This Act provides for the regulation, 39 functioning and practice of pharmacy in Kenya. It was amended in 2014 to clarify the governance and structure of the PPB, the pharmacy workforce, and practice. The amendments outlawed the production, storage, and distribution of counterfeit and unregistered pharmaceutical substances and medical devices. In addition, the amended act introduced guidance on clinical trials of pharmaceutical products and medical devices.
40. The Board regulates the manufacture of pharmaceuticals in the country by putting in place appropriate regulatory remedies. It further implements the regulations through continuous inspections of domestic and international manufacturers with the object of ensuring compliance with Good Manufacturing Practices (GMP). Additionally, the PPB monitors adherence to Good Distribution Practices (GDP) and provides authority for manufacturers to market medicines after undertaking product registration with the board. In efforts to ensure that all medicines in the country meets the stipulated quality standards, the PPB conducts post registration compliance checks (Vugigi, 2020).
41. Moreover, PPB provides the guiding principles that oversee advertising of medicines and medical devices in Kenya. All medicine advertising and promotional schemes must therefore be approved by PPB prior to launching. Bestowed upon PPB are also the powers to impound and eliminate materials it cogitates to be in contradiction to advertising rules.

THE ANTI-COUNTERFEIT ACT NO. 13 OF 2008

42. This Act created the foundation for the establishment of the Anti-Counterfeit Agency in 2010, outlawed the production of counterfeits, and enhanced protection of intellectual property rights. Despite this, illicit trade (including of pharmaceuticals) remains a major concern for business, government, and development partners. Anti-Counterfeit Agency, in collaboration with PPB, continues to intervene in the industry to minimize the presence of counterfeit medicines in the market.

THE INDUSTRIAL PROPERTY ACT NO. 3 OF 2001

43. This Act has been amended to strengthen the intellectual rights of individuals, communities, and organizations. However, knowledge of Intellectual Property (IP) rights remains limited, and there are very few IP experts in Kenya. The country has aligned the Act to exceed the minimum requirements under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
44. Countries that are party to the TRIPS Agreement are implementing TRIPS II, which will see increased protection for patented medicines and medical devices, as well as allow products to be used for more purposes without needing permission from the patent holders. TRIPS II aims at provide an enabling environment for local pharmaceutical manufacturers in Kenya to innovate in product formulation and product processes. In addition, TRIPS provides flexibility for countries to use compulsory licenses to manufacture biosimilar and a window to undertake parallel importation of certain products whose patents are still in force to respond to the needs of national public health.

LAWS THAT PROTECT AGAINST ANTI-COMPETITION PRACTICES THROUGH INTELLECTUAL PROPERTY

45. The Competition Act No. 12 of 2010 preoscribes restrictive trade arrangements or agreements that amount to the use of IP rights beyond the limits of legal protection. The Constitution of Kenya, 2010, and the Consumer Protection Act No. 46 of 2012, also make special protection reference to consumers by giving them the right to goods and services of reasonable quality. The main objective of IP rights is to allow manufacturers to distinguish their products and services from others, thus empowering consumers to choose.

THE HEALTH ACT NO. 21 OF 2017

46. This Act aims at consolidating actions, institutions, and regulation of health, but it has not been fully implemented. Based on information provided by the PPB, the Pharmacy and Poisons Act was amended through the Health Laws Act, 2019 in order to increase the market share for generic medicines. The regulatory framework however needs to be strengthened to encourage a departure from expensive branded medicines.

PRICE ANALYSIS

47. Cross sectional survey design was employed to collect data on prices, opinions, and perceptions of players in the generics and pharmaceuticals industry in Kenya. The survey focused on Nairobi, which is the economic hub and hosts all major pharmaceutical manufacturing industries in Kenya, as well as industry regulators and associations. The study utilized both quantitative and qualitative approaches. Secondary data on generic medicines was gathered from government publications, pharmaceutical industry statistics and journals among others. Data obtained includes the generic medicines used to treat TB, HIV, Hypertension in both children and adults.
48. Selection of the diseases is based on their prevalence and mortality rates. TB was the fourth highest cause of death (21,000) among communicable, maternal neonatal and nutritional diseases in the country in 2021. Kenyans who developed TB in 2020 were about 139,000, with 17,000 being children. Additionally, HIV prevalence in Kenya stood at 4.2% in 2020 with 19,486 deaths recorded in 2021.
49. Purposive sampling was employed where Kenya Medical Supplies Authority (KEMSA) and Mission for Essential Medicines and Supplies (MEDS) provided primary data on the prices of generic medicines used to treat TB, HIV and hypertension and diabetes. Additionally, literature has been reviewed from reports on manufacturing and pharmaceuticals industry, government legislations, policy briefs and journals. Desk research was undertaken using keyword searches on search engines existing

in the public domain. Data analysis was mainly descriptive, and results presented in tables, bar graphs and pie-charts and interpretations provided for the same.

50. Kenya pharmaceuticals industry and the market are liberalized, characterized by the absence of a distinct price control policy. Pricing is based on supply chain networks and the consumers' willingness and ability to pay. Numerous mark-ups exist at each level of the distribution chain, increasing as the products moves closer to consumers. Producers supply to distributors in addition to direct sales to select strategic buyers such as hospitals and big institutional clinics (Ministry of Health 2020). This is aimed at lowering the cost barrier and ensuring that their products do not get substituted in the market as a result of cost or due to unresponsive distributor supply.
51. Stiff competition in Kenyan Pharmaceutical landscape coupled with aggressive scramble for market shares has compelled select players to heavily discount their products with some offering up to 30% discounts. Additionally, medicines that are approaching the expiry date are discounted at a higher percentage with the object of attracting more consumers. Consumers in Kenya therefore have developed an attitude where low priced medicines are associated with poor quality and viewed manufacturers as using short cuts to improve on their profit margins (Ministry of Health, 2020).
52. Factors that determine medicine prices and availability include location of business, rent charges, regulatory and business licenses, business size and type; whether distributor or retail pharmacy, product type, that is innovator or generic, therapeutic class of the product, formulation type; liquid or tablet and source of product; locally produced or imported. Medicine price transparency challenges are identified as one of the issues impacting negatively on retail pharmacies, in which retail pharmacies are faced with information asymmetry in regards to the how many intermediaries are involved in the supply chain.

53. Consumer prices of medicines in Kenya is influenced to a greater extent by how many distributors exist in the supply chain and retailer prices. Distributors in the country continue to feel the heat from competition from parallel imports and contra-band medicines (Ministry of Health, 2020). This could be attributed to poor laidback regulations and poor enforcement of guidelines at the national level.
54. KEMSA and MEDS lead in the supply of medicines to public and non-profit health facilities and clinics in Kenya. An estimated 40% of all the medicines used in public and non-profit health facilities are supplied by MEDS, which has presence in nearly thirty-three (33) counties out of forty-seven (47) counties in Kenya (Ashigbie et al., 2020, Rockers, et al., 2019).
55. KEMSA and MEDS purchase more domestically manufactured medicines than imported medicines. According to Health Action International (2018), locally produced medicines were on average 30% (KEMSA) and 25% (MEDS) less priced in comparison to imported products. Additionally, median prices for domestically manufactured and imported medicines were priced below reference prices in the international markets.
56. Medicines produced in Kenya had a higher mean availability (48%) than imported medicines (23%), an indication that local generic medicines are more available in the Kenyan market in comparison to imported medicines. In instances where patients paid for the medicines, the median prices for locally produced medicines were more or less similar to imported medicines. However, a number of medicines were three times above the international reference prices. To use imported branded medicines, one had to pay more by 45% than when using Kenyan manufactured generics (Health Action International, 2018).
57. Haque et al. (2021) indicate that insulin glargine originator drug in Kenya is 3.4 times higher in comparison to soluble insulin and insulin Mixtard. As one would expect, affordability of the medicines therefore constrains its access and usage. Overall, prescription of long-acting insulin glargine originator in Kenya is low due to affordability challenges. To boost utilization insulin glargine in Kenya, its prices will have to be lowered to a greater extent in as much long-acting insulin had been incorporated in Essential Medicines List in the country (Haque et al., 2021).

MEDICINE PRICES AND AVAILABILITY IN THE PRIVATE SECTOR

58. Generally, the private sector patients pay more by 48% for imported generic medicines compared to medicines manufactured in Kenya. Branded generics produced in the country were more available (36%) in comparison to imported generics (28%). Imported branded generics were more expensive by 34% compared to generics manufactured within the country. Innovator medicines are few in the market but more expensive for all imported medicines.
59. There was a marginal variation in the availability of locally produced generics and imported medicines in the private sector. The mean availability were 37% and 34% for locally manufactured and imported medicines respectively.
60. Innovator medicines being sold in Kenya were more expensive than the corresponding generics by between 1.5 to 76.5 times. Originator medicines were on average 13.8 times more expensive than the lowest priced generics in Kenya as at 2019. In terms of median price ratio (MPR), Kenyans are paying more for generic medicines than the international reference prices for 68.6% of generic medicines in the country. Analysis of hypertensive medicines shows that Furosemide dosage for thirty days was the cheapest while Etenolol and Enalapril were the most costly. With respect to diabetes medicines, a thirty-day dosage of Metformin 500mg was a third more costly than thirty-day dosage of Glibenclamide (Ongarora, et al., 2019).

MEDICINE PRICES AND AVAILABILITY IN MISSION SECTOR

61. Similarly, Kenyans pay more for imported medicines than locally manufactured medicines in the mission sector. Imported medicines were more costly by 33% than those produced locally. There were variations in the median mark-up between patient price and MEDS purchase price. This was larger for domestically manufactured medicines (343%) compared to imported medicines (257%). These were way beyond the provided mark-up ranges. In terms of availability, locally manufactured branded generics are more available than branded generic imports. By and large, patients

were charged more by 63% for imported branded generic medicines than Kenyan made generics (Ashigbie et al., 2020).

62. For instance, the high cost of insulin in Kenya could be a reflection of the absence of competition in its global manufacturing market, where its three main manufacturers account for up to 96% of the global market by volume and 99% in terms of value (Beran et al., 2019; 2021).
63. Notably, MEDS does not sell medicine for treatment of TB, HIV & AIDS Anti-Retroviral Medicines. However, it provides warehousing services and supplies the medicines to facilities on behalf of USAID under a donor programme. Medicine prices were relatively stable between 2018 and 2020, but this was not the case in 2021 when a number of the medicines experienced an increase in prices.
64. Comparison of select medicine prices for treatment of NCDs in Kenya indicates that medicines supplied by MEDS to the private sector are more expensive than those supplied by KEMSA to the public health sector. For instance, Metformin Tablets 500mg, 30 Pack costs 0.25 US dollars at KEMSA, while the same costs 0.62 US dollars, which is 148% higher than the public wholesale price. Equally, Hydrochlorthiazide Tablets 25mg, 100 Pack costs 0.35 US dollars in the public supply system while it costs 0.54 US dollars in the private supply system, a fifty-four percent (54%) price difference.
65. Medicine prices were relatively stable in the public sector supply and where increase were witnessed, the changes were almost negligible. However, in the private supply chain, prices were stable between 2018 and 2020 but in 2021, prices went up by increasing margins of 12.9% on average.

CONCLUSION

66. Medicine prices are higher in the private sector in comparison to the public sector medicine value chains. Prices of medicines are not regulated in Kenya and are determined by a number of factors including supply chain networks and customers' willingness and ability to pay. Additionally, the country does not have a policy to guide

the use of generics and generic substitution.

67. Generally, originator medicines used in the treatment of Diabetes, TB, Hypertension, Malaria and HIV retail at higher prices compared to generic medicines. However, certain generic medicines Methyldopa Tablets 250mg, 100 Pack are priced higher than originator medicines in the country.
68. Medicine price analysis indicates that there is no predetermined strategy for medicine pricing in Kenya. Profit margins vary per region, within and among medicine categories, size and by business type, the manufacturer of the medicine, where the medicine is produced. Further, pricing decisions are not only based on traditional parameters such as input costs, marketing and advertising expenditure, transport but also more importantly on information asymmetry and market intelligence.

BARRIERS TO ENTRY AND EXIT

69. At the policy level, limited national funding due to competing health priorities, slows incorporation of generic medicines into the essential medicines list (EML) and structural and financial barriers are responsible for limited access to generic medicines (Kishore et al., 2015).

NON-TARIFF BARRIERS

70. Kenyan based pharmaceutical manufacturing industries that focus on the EAC and COMESA as the major market for their products face the challenges associated with Non-Tariff Barrier (NTBs). Exports to these regions have been on the decline because of the NTBs particularly to Uganda and Tanzania. The barriers entail red tap documentation processes, not recognizing certificates of origin, inconsistency in standards and punitive application of sanitary and phyto-sanitary requirements, longer border crossing procedures, attendant costs, non-uniformity in transit charges and procedures.

71. Equally, the Common External Tariff is obsolete given that the three-band tariff structure lacks flexibility to permit value addition at various stages of manufacturing. Opportunities for manufactured goods including generic pharmaceuticals products are projected to expand under the ambit of the Tripartite Free Trade Area, comprising the EAC, COMESA and Southern African Development Community (SADC). Further, as Kenya is a signatory to the African Continental Free Trade Area (AfCFTA), this will provide an expanded market for generic medicines manufactured in Kenya (Kenya Pharma Industry Diagnostic Report, 2020).
72. In addressing this constraint, and in the spirit of regional integration, EAC partner states are putting efforts to ensure harmonization of pharmaceutical policies and standards including regulation of generics medicines sub-sector. This will not only strengthen access to generic medicines but also broaden the market regionally and smoothen cross-border regulation of pharmaceuticals.
74. Kenya's capacity to locally manufacture and distribute generic medicine is significant. The country, nevertheless, imports significant quantities of originator medicines and generics to offset demand shortfalls and for export to its neighboring and regional markets. The government has, over the years, levied no import duty or VAT on imported medicines and raw materials meant to support the manufacturing of medicines. VAT of 16% is, nonetheless, imposed on packaging materials imported by suppliers. This can be claimed back if proof can be provided on their sale, delivery to the client, and use in the pharmaceutical manufacturing industry.
75. The absence of import duty on medicines has promoted an import-driven market and has, over the years, undermined local manufacturing of pharmaceutical products in the country. The government has sought to reduce the proportion (in volume and value) of imported medical products to support the local manufacturing industry. The fees levied on imported pharmaceutical products include the PPB levy: 0.75%, import declaration fees: 3.5% (increased from 2%), railway development levy: 2% (recently increased from 1.5 %), port charges: fixed fees, insurance of goods: 0.5%, and clearing agent: fixed fees.

DIFFICULTY IN MEETING GOOD MANUFACTURING PRACTICE (GMP)

73. A number of local pharmaceutical manufacturers in Kenya experience difficulties in meeting GMP requirements. Some of the challenges they face relate to the physical site and the quality management system (QMS). For example, if the entity is renting space, it is difficult to modify the space without going against the lease agreement or destabilising the structural integrity of the building. Additionally, manufacturers face constraints in accessing finance from local lenders to purchase more equipment to expand and upgrade their infrastructure. It is opined that the limited access to financing could be due to banks' reluctance to provide loans to an industry mostly dependent on apparent uncertain business, especially those dependent on public sector tenders with uncertain payment periods.

INCENTIVES, IMPORT LEVIES AND TARIFFS

REGULATORY BARRIERS

76. PPB, established under Chapter 244 of the Pharmacy and Poisons Act (2002), is responsible for the registration of pharmaceuticals and medical devices in Kenya. The National Quality Control Laboratory undertakes pharmaceutical testing for regulatory purposes. Importers are expected to meet legal requirements such as the provision of medicine samples to the Kenya Bureau of Standards (KEBS) for quality checks and registration and complying with national policy regulations adopted by the Ministry of Health. This includes an essential medicines list, using WHO guidelines, the objective of which is to promote the availability of quality pharmaceutical products at affordable prices. Kenya is viewed as having an overtly complicated regulatory environment,

despite the fact that the initial approval is relatively straightforward.

77. The difficulties are mostly present in the procurement and supply sectors, due to the overlapping work of government agencies, aid agencies and NGOs. For example, the semi-autonomous KEMSA is mandated to supply essential medicines to public facilities. KEMSA, however, contests the supply with MEDS as well as private merchants. The supply chain is further convoluted by the lower prices offered to developing countries by some patented medicine manufacturers, resulting in a situation where procurement of branded generics is more costly than the originator brands. Additionally, getting all necessary regulatory authorizations prior to selling or distribution of a new medicine involves red tape and is exceptionally costly for new entrants. This usually take between six(6) months to one year

78. The Requirements for Registration Entrant Pharmaceutical Manufacturers in Kenya are;

78.1 Each foreign manufacturer shall have one local agent with blanket power of attorney. The local agent must be a registered whole seller of medicines in Kenya.

78.2 Provision of a free sale certificate from the country of origin or a certificate of a pharmaceutical product.

78.3 A separate application for each product.

78.4 Dossier to be submitted as one original hard-copy and one electronic copy (in a Portable Document Format, PDF, on a CD-Rom) and should include MS-Word document for Modules 1 and 2, cross-referenced to the dossier by clearly indicating the title and section number of all the supporting documents.

78.5 The manufacturer must comply with GMP. The Board reserves the right to verify the Good Manufacturing Practices Compliance of the manufacturer at the applicant's expense.

78.6 Three (3) samples of the smallest commercial pack(s) from one batch with batch certificates of analysis.

78.7 An original Certificate of Pharmaceutical Product (WHO Format) on official papers of the issuing competent medicine regulatory authority.

78.8 A site master file in case the product is manufactured at a plant(s) not inspected and approved by PPB.

78.9 Nonrefundable application fee for registration of medicines in Kenya (USD 1000) and GMP inspection fees (USD 6000) for facilities not yet inspected by PPB. This applies to both generic and originator medicine.

79. The medicine approval process for new pharmaceutical products, including biotechnology-derived products follows the following steps:

79.1 Receipt of applications

79.2 Market agency authorization

79.3 Manufacturers and manufacturing sites inspection for current Good Manufacturing Practices

79.4 National Quality Control Laboratory analysis

79.5 Committee on Medicine Registration Recommendation

79.6 Practice Committee review

79.7 Full board approval

79.8 Gazetted

80. Medicine application is considered withdrawn if requests are not satisfactorily answered in a period of six months period of the request. In a case a medicine is not approved, the applicant may appeal that decision within two months from the date of notification. Nevertheless, approval takes at least six months and a maximum of twelve months.

ANTI-COUNTERFEIT RULES

81. No clear distinction exists between generic and counterfeit terms in the Kenya Anti-Counterfeit Act. Sometimes regulations may be drafted in such a way that they fail to draw a clear-cut distinction between counterfeit and generic medicines, thereby impeding access to affordable generic medicines. For instance, in 2012, a high court ruling determined that the Kenya Anti-counterfeit Act 2008 was not clear and had the potential to debilitate access to affordable generic medicines in Kenya. This was based on the position that the Act failed to distinguish between generic and counterfeit medicines. To this effect, regulations should be drafted with clarity to ensure access to generic medicines is not hampered courtesy of any regulation or policy (Maleche & Day, 2014).

RESEARCH AND DEVELOPMENT (R&D) COSTS

82. The pharmaceutical manufacturing industry is one of the top ten costly industry to invest in with respect to research and development. Starting a pharmaceutical manufacturing company requires large investments in infrastructure and R&D, with the possibility of not earning revenue for over a decade. It takes over a decade before one can recover the investments put in conducting research and development of pharmaceutical originator medicine. Additionally a firm may not recover its costs within twenty (20) years of patenting an originator medicine. This may make it progressively challenging for new firms to enter this competitive market as they are not guaranteed recovery of costs incurred.
83. Investors who do not have sufficient financial footing may find this an entry barrier. In as much as commercial banks are always ready to finance such investments, significant high value of collateral is required in comparison to the funding request. Additionally, the cost of the loans in terms of interest is higher in Kenya (12.08%) compared to other countries such as India (8.7%) and China(4.35%), which continue to be pharmaceutical manufacturing hubs. The financial demand to set up a pharmaceutical plant in Kenya may be an entry barrier for new entrants.

INTELLECTUAL PROPERTY RIGHTS AND PATENTS

84. Patents function as legal frameworks and security to existing firms and facilitate the prevention of entry of medicine manufacturers into a market in the absence of an entirely innovator medicine (Bagheri, 2003; Idris, 2003). Patents for the pharmaceutical industry in the developed countries always last up to twenty (20) years coupled with a shorter window of sales of less than ten years, given that the manufacturing firm has to patent the medicine before its first launch.
85. The firm, therefore, has to recover its cost of research and development in the shortened sales period of ten years, including the cost of failed medicine tests and costs of marketing. After expiry of the patent, competition from generics emerges, leading to drastic a reduction in price of the medicine as well as its market share. Given patent life is a key determinant of the earnings which are generated from a new medical product, innovator pharmaceutical firms always attempt to lengthen the patent period as much as practicable, known as patent ever greening (Anon, 2009).
86. Patent ever greening in certain instances can be undertaken through patenting of the manufacturing process including formulating the medicine and its delivery process. On the contrary, generic firms advocate for doing away with patents in an attempt to invent ways of by-passing the patents (Boehm, et al., 2013). In certain instances, the patent holder decides to pay a generic medicine manufacturer to delay the manufacture and sale of its innovator medicine in which case both firms benefit. However, the medicines become costly after patent expiry than they should be. This practice is nevertheless legally questioned (Silverman, 2014). Patent ever-greening is not a common practice in the Kenyan market.
87. Patent and marketing exclusivities for instance on insulin affect medicine access and affordability not only from a global perspective but with severe effects on prices in third world countries like Kenya (Luo & Kesselheim, 2016). The cost of medicines for treating diabetes and related co-morbidities accounts for nearly 52.4% of the overall costs of seeking health services (Oyando et al.2020). This is estimated to have adverse effects on access and affordability of diabetes treating medicines and other medicines used to treat NCD in the country (Opanga, et al., 2021).

88. The generic medicines market has been pointed for over regulation, creating competition barriers in certain jurisdictions. The extent to which generic medicines can compete with originator brands is dependent on the Kenyan domestic patent laws. A variety of alternatives, however, exists in Kenya towards improving access to generic medicines. The options comprise encouraging the use of generics, procuring more generic medicines which would ensure price competition, prescription of and dispensing generics, fully implementing TRIPS flexibilities and enhanced financing of generics by government (Kenya National Pharmaceutical Policy 2012).

ECONOMIES OF SCALE

89. This has the potential to be a key barrier, particularly where generic medicine manufacturers produce large volumes of small generic medicines. It is potentially challenging for new entrants to manufacture similar medicines in bigger volumes as compared to existing firms. The existing firms have well-established infrastructure coupled with established distribution network as well as enhanced marginal economies. Product differentiation and marketing are at the core of competition in the pharmaceutical industry.

90. Brand name recognition is however, important in supplements market given that most consumers may be cagey in regards to medicines they are not familiar with or even pharmaceutical companies they are not sure about. This presents a significant barrier to address for new entrants.

CONCLUSION

91. Kenya is predisposed to competing health priorities, red tapes in incorporating generic medicines into essential medicine list and exertion in meeting Good Manufacturing Practice by pharmaceutical manufacturers. These challenges coupled with limited access to finance, regulatory barriers and low prescription of generic medicines at health facilities presents entry barriers for potential generic medicine manufacturers in the Kenya Market.





SOUTH AFRICA

THE SOUTH AFRICA CHAPTER

OVERVIEW OF THE PHARMACEUTICAL SECTOR

1. The pharmaceutical sector in South Africa is governed by policies that set out the framework to achieving affordable and accessible medicines to all South Africans. One of the preliminary policies was the National Medicine Policy of 1996 that sets out specific health, economic and national development objectives to inform medicine policy and regulation. Recent developments include the National Health Insurance White Paper (2017) and National Health Insurance Bill (2019) that aim to improve the overall functioning of the healthcare system, including increasing the affordability and accessibility of medicines in SA.
2. The South African Government has also recognised the importance of developing the local pharmaceutical manufacturing industry and the benefits that can be derived to the local economy such as access to affordable medicines and security of supply, as well as additional benefits such as increasing employment and growth of the economy. However, the South African government has also noted that there are some key weaknesses to developing the local manufacturing sector. These include the high capital costs required to invest and gain a competitive position within the market (which the government argues limited new entry in the market) and the significant dependence on imported APIs and finished pharmaceutical products, as well as the skills shortage (and the cost of specialised skills).¹
3. In South Africa there is strong support from government and the private sector to increase the use of generics. The Medicines and Related Substances Act 101 of 1965 (as amended) (Medicines Act) contains provisions requiring pharmacists to inform private patients about generic alternatives when they purchase prescription medicines. The private healthcare sector also recognises the importance of using generics. Discovery Health (medical scheme administrator) finds that the use of cheaper, good-quality generic medicines can reduce healthcare inflation, saving as much as R1.5 billion per annum for medical scheme members, while a major hospital group had begun promoting use of these medicines through its hospital pharmacies.²

¹ <https://pmg.org.za/committee-meeting/24697/>.

² Chris Bateman, *Promote cheaper generic medicines to patients – and help contain medical inflation*, September 2014, SAMJ. S.Afr.med Vol. 104, No. 9.

4. South Africa has a high demand for pharmaceutical products and is one of the few countries on the African continent with API manufacturing capabilities.³ In 2017, total pharmaceutical expenditure was equivalent to 0.9% of GDP and 11.1% of total healthcare expenditure. South Africa's pharmaceutical market is dominated by prescription medicine spending, including patented and generic medicine expenditure, which accounts for approximately 88.3% of the total market and over the counter (“OTC”) medicine spending representing the remainder of 11.5%.⁴ Total pharmaceutical sales in South Africa were estimated at \$3.428 billion in 2018 with generic medicine sales constituting \$1.251 billion.⁵

OVERVIEW OF MEDICINE EXPENDITURE

5. The South African healthcare system is comprised of two parallel sectors, a public healthcare sector and private healthcare sector that operate alongside each other. The public healthcare sector serves the majority of South Africans (83%), while the private sector serves less than 17% of the population that have access to medical scheme membership (health insurance). While the public sector serves the majority of South Africans its pharmaceutical expenditure is significantly less compared to the private sector.⁶ In 2019, the South African pharmaceutical market generated total revenue of around R56.4bn, with the private sector contributing R45.2bn and the public sector R11.2bn. Notably, the public sector accounts for around 80% of total pharmaceutical sales by volume, but only 20% of sales in value-terms.⁷ The lower medicine expenditure in the public sector can be attributed to the tender procurement process undertaken by the Department of Health (“DOH”) that results in government purchasing medicines at a lower price than the private sector.

³ <https://pmg.org.za/committee-meeting/24697/>.

⁴ Africa Health, *Industry insights: South Africa healthcare market overview*. https://www.africahealthexhibition.com/content/dam/Informa/africahealthexhibition/en/2020/pdf/AFH19_Industry_Insights-SA_MARKET_REPORT.pdf

⁵ Roy Horner, *Global value chains, imports orientation, and the state: South Africa's pharmaceutical industry*. *Journal of International Business Policy* (2022) 5, 68–87.

⁶ WOW. *The Pharmaceutical industry in South Africa*, December 2020.

⁷ WOW. *The Pharmaceutical industry in South Africa*, December 2020.

PUBLIC HEALTHCARE SECTOR

6. Table 9 shows total public healthcare expenditure and medicine expenditure for the period 2015/16 to 2019/20. Total public healthcare expenditure increased over the relevant period from R 154 074 million in 2015/16 to R210 750 million in 2019/20, an increase of 36,78%. From 2015/16 to 2019/20 the public sector expenditure on medicines increased from R11 388 million to R17 699 million an increase of 55,42%. During the relevant period the public sector expenditure on medicines represented between 7% - 9% of total public healthcare expenditure.

Table 9 - Public sector medicine expenditure (R/ million), 2015/16 – 2019/20

	2015/16	2016/17	2017/18	2018/19	2019/20
Total public healthcare expenditure	154 074	166 062	180 836	195 477	210 750
Public sector expenditure on medicines	11 388	13 394	15 552	16 583	17 699
Percentage of medicine expenditure relative to total public sector health expenditure	7,39%	8,07%	8,60%	8,48%	8,40%

Source: National Treasury, Publications-Intergovernmental Fiscal review (IGFR)- 2021 – Provincial Budget and Expenditure Review: 2015/16 – 2022/23, Chapter 4- Health. Available at: <http://www.treasury.gov.za/publications/igfr/2021/prov/Chapter%204%20-%20Health.pdf>.

7. The National Treasury, in its Provincial Budget and Expenditure Review: 2015/16–2022/23, noted that “although centralised procurement of medicine has resulted in sizable savings over the years, these savings have been partly offset by the weaker rand which has driven up the cost of imported medicines”.⁹ While the DoH has made significant strides in procuring medicines at a lower price and passing on the savings to the public, the prices are susceptible to varying inflation and exchange rates that creates price uncertainty for imported medicines. This partial erosion of the savings realized from procurement scale efficiencies provides the impetus for increased local manufacturing capabilities to counteract the reliance on imported medicines and the associated exchange rate risks that arise.

8. In South Africa, individuals can purchase private healthcare cover through medical schemes or health insurers. Members pay monthly contributions to their medical scheme who are responsible for financing their members’ healthcare expenses.⁹ Health insurers provide gap cover products, hospital cash plans and primary health plans (e.g., plans that cover GP visits, basic dentistry, optometry etc.).¹⁰ Table 10 shows the medical scheme medicine expenditure for the period 2015/16 to 2018/19 which consists of medicines paid from the risk benefit, savings benefit, and OOP. With the risk benefit, healthcare expenditure is funded from the members’ contribution. Medical schemes also offer a Medical Saving Account (“MSA”) on some of the benefit options that is a fixed percentage of the total monthly contribution. The MSA allows a member to pay for day-to-day medical expenses or to cover shortfalls in healthcare payments. The OOP¹¹ is calculated as the difference between the total amount claimed less the total risk benefits paid by medical schemes with the shortfall being paid from the member’s own pocket.
9. Table 10 shows the medical scheme medicine expenditure for the period 2015/16–2018/19.

Table 10 - Medical scheme medicine expenditure (R/million) by category, 2015/16 – 2018/19

Expenditure categories	2015/16	2016/17	2017/18	2018/19
Medicines expenditure paid from the risk benefit	17 252	18 386	19 856	20 624
% of total medical scheme healthcare expenditure	12,44%	12,16%	12,37%	11,90%

PRIVATE HEALTHCARE SECTOR

Medicines expenditure paid from the savings benefit	5 069	5 571	5 956	6 340
% of total medical scheme healthcare expenditure	3,65%	3,68%	3,71%	3,66%
Medicines expenditure paid for OOP	891	950	104	110
% of total medical scheme healthcare expenditure	0,64%	0,63%	0,06%	0,06%
Total medical scheme healthcare expenditure	138 696	151 214	160 557	173 275

Source: CMS Annual Report Annexures, 2015/16-2018/19.

Available at: <https://www.medicalschemes.co.za/publications/#2009-2010-wpfd-annual-reports>.

10. The above table shows that total medical scheme healthcare expenditure increased from R138 696 million to R173 275 in the period 2015/16 to 2018/19, an increase of 24,93%. Medicine expenditure paid from the risk benefit represents between 11%-12% of total medical scheme healthcare expenditure with the savings and OOP representing a smaller percentage at around 3% and 1% respectively. The highest expenditure on medicines is paid from the risk benefit (approximately 12%), followed by member payments through the savings accounts as well as OOP. Collectively, total medicine expenditure represented approximately 16% of total medical scheme healthcare expenditure for the relevant period.

11. The table below shows the percentage that medicines paid from savings and OOP represented of total medicine expenditure (risk, savings, and OOP) for medical scheme members for the period 2015/16-2018/19.

Table 11 - Total medical scheme medicine expenditure, (R/ million), 2015/16 – 2018/19

	2015/16	2016/17	2017/18	2018/19
Total medicines dispensed (savings plus risk benefit plus OOP)	23 212	24 907	25 916	27 074

Medicines dispensed (Total benefits paid from savings)	5 069	5 571	5 956	6 340
Percentage of savings paid for medicines relative to total medicine expenditure	21,95%	22,36%	22,98%	23,41%
OOP for medicines	891	950	1 040	1 100
Percentage of OOP medicine expenditure relative to total medicine expenditure	3.83%	3.81%	4.01%	4.06%

Source: CMS Annual Report Annexures, 2015/16-2018/19.

Available at: <https://www.medicalschemes.co.za/publications/#2009-2010-wpfd-annual-reports>.

12. During the relevant period the amount paid from medical savings for medicines represented between 22% and 24% of total medicine expenditure while OOP represented approximately 4% of total medicine expenditure. While the OOP medicine expenditure represented a minimal percentage of total medicine expenditure, the medical savings used to purchase medicines represented a much higher percentage of medicine expenditure. Collectively, the medical savings and OOP, which represents the member's own expenditure for medicines rather than the medical schemes payments (risk benefit), constituted approximately between 25% and 28% of total medicine expenditure.

PRIVATE SECTOR UTILISATION OF GENERIC MEDICINE IN SOUTH AFRICA AND OTHER COUNTRIES

13. There is a growing demand for the use of generics in the private healthcare sector in South Africa, with both the value and volumes of generics increasing over time. The

Mediscor¹² Medicine Review (2019) report indicated that the average item cost for generic equivalents was R123 compared to R154 for originals with expired patents and R303 for originals with valid patents. Originals with expired patents were, on average, 25% more expensive than generic equivalents while originals with valid patents were 147% more expensive. The pricing difference between the generics and originals with expired patents accentuates the importance of having generic entry as generics generates significant savings to consumers.

14. The report also assessed the trends for expenditure and volumes for generics in South Africa. The demand for generics has been steadily increasing with the generic utilisation¹³ rate or percentage of generic equivalents claimed increasing from 59.9% in 2017 to 62.4% in 2018 and increased slightly to 62.7% in 2019. A similar trend was also observed for generic uptake¹⁴ which increased from 77.8% in 2017 to 80.4% in 2018 and 80.8% in 2019. The data shows that the demand for generic medicines has been increasing, representing more than half of medicine claims and there has been a significant uptake of generics.

15. Figure 9 shows the expenditure and volume distribution for 2019 for the three medicine classifications namely: generic equivalents, original with expired patents and original with valid patent.

16. In 2019, generic equivalents accounted for 45.9% of overall expenditure, while originals with expired patents made up 13.6% and originals with valid patents 40.5%. Generics equivalents represented the highest volumes in the market with just over 62%, with the original with valid patent and original with expired patent accounting for a much smaller percentage at approximately 22% and 16% respectively.

17. To determine if South Africa's share of generics is on par with other countries the study compared South Africa share of generics with the OECD countries. Figure 10 shows the shares of generics in the total pharmaceutical market for the OECD countries for the year 2019.

¹² Mediscor is a South African pharmaceutical benefits management (PBM) organisation that specialises in electronic claims processing and the management of medicine benefits for medical schemes.

¹³ The number of generic equivalent products expressed as a percentage of the total number of items.

¹⁴ The percentage of instances where a generic equivalent was available and used.

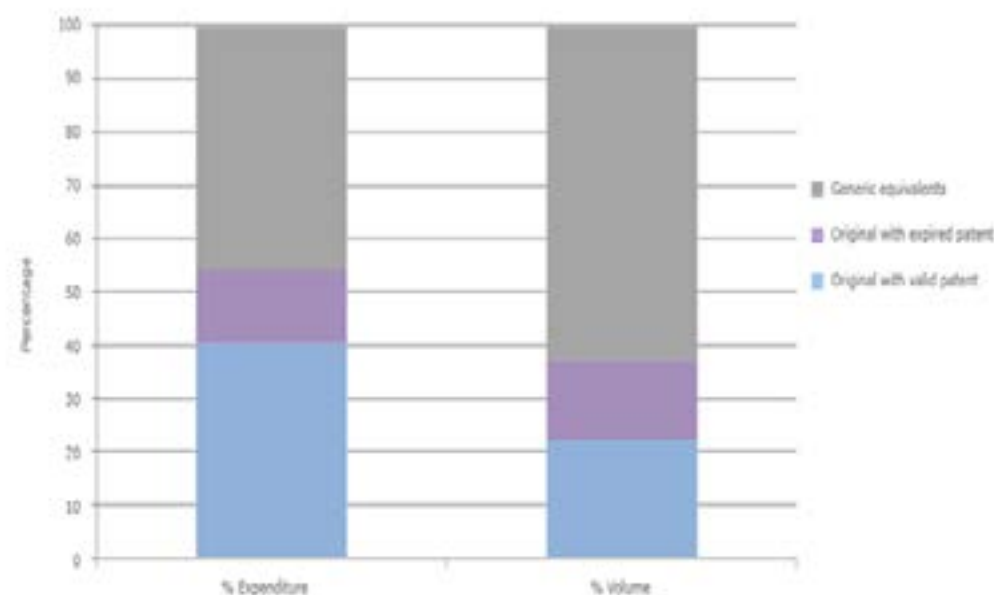
18. The figure above presents a diverse range in the value and volume of the share of generics across the OECD countries with some countries having both a higher value and volume of generics (Chile, United Kingdom and Germany) compared to others (Italy, Switzerland and Luxembourg.¹⁵ Of the 26 countries, South Africa's total volume of generics (62%) used is lower than 10 of the countries, with these countries' volumes ranging from 85%-63% and higher than 16 of the OECD countries. While South Africa may have a higher generic utilization than most of the OECD countries, there is still potential for South Africa to achieve a higher use of generics. In relation to the value of generics, except for Chile, South Africa has a higher value of generics compared to the OECD countries in the graph above.

SELECTION AND SUPPLY OF MEDICINES IN THE PUBLIC AND PRIVATE SECTOR

19. While the public sector procures medicines at a lower price than the private sector it still faces its own challenge which is the persistent stockout of medicines. The

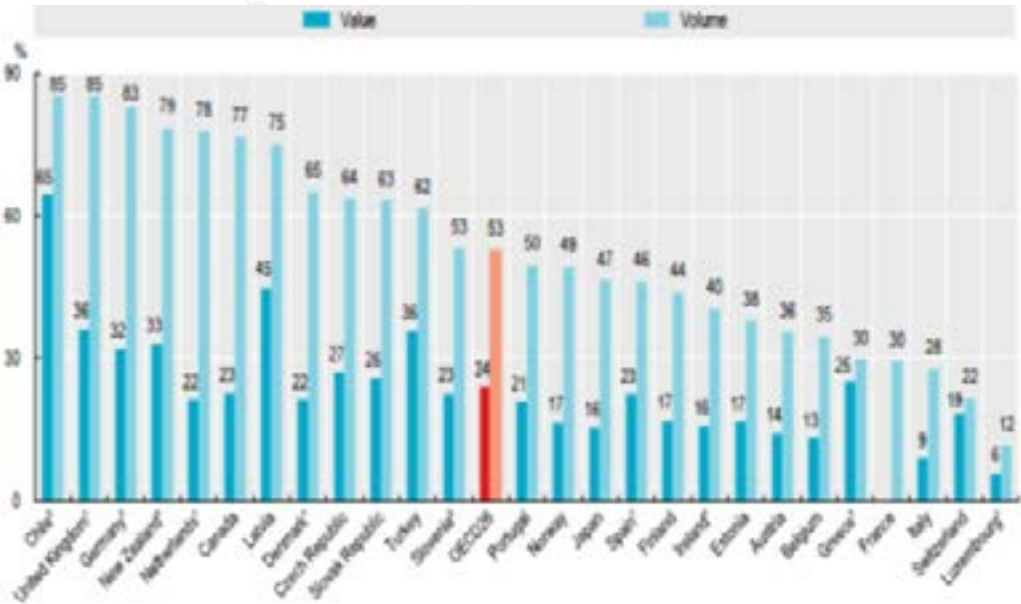
¹⁵ Differences in market structures (notably the number of off-patent medicines) and prescribing practices explain some cross-country differences, but generic uptake also depends on policies. In Austria, for example, generic substitution by pharmacists is not permitted. In Luxembourg, generic substitution by pharmacists is limited to selected medicines.

Figure 9 - Expenditure and volume distribution by product type, 2019



Source: Mediscor medicine review 2019.

Figure 10 - Shares of generics in the total pharmaceutical market, 2019



Source: OECD indicators, Health at a glance 2021.

stockout of medicines may result in individuals forgoing or delaying their treatment which adversely affects their health outcome and may set back the progress of their treatment. In 2017 the Stop Stockouts Project (“SSP”) in South Africa assessed the proportion of public facilities impacted by stockouts. Notably, the SSP noted that measures should be implemented to mitigate the impact of global supply chain disruptions.¹⁶ This further emphasises the need for domestic generic manufacturing capabilities.

20. The SSP found that the in most severely impacted province (Northern Cape), a third of all facilities experienced a current or recent stockout of an antiretroviral or anti-tuberculosis medicine. In the worst impacted districts (located in Eastern Cape and Gauteng), half of the facilities reported current or recent stockouts. Also, concerning was the time taken to resolve stockouts, with facilities in Mpumalanga all reporting a resolution of stockouts within a week and 42% of facilities in Limpopo reported a wait

of more than a month for their stockouts to end.¹⁷

21. In 2019, a study was conducted for 2 370 public facilities to assess the prevalence of stockouts in South Africa. The finding from the study revealed that 20% of public facilities (485) reported a stock-out for at least 1 ARV and/ or TB-related medicine and 36% (864) experienced a stock out three months prior, ranging from 74% (163/220) of health facilities in Mpumalanga to 12% (32/261) in the Western Cape provinces. Of the stock-outs, 25% (366) resulted in a high impact outcome, where patients left the facility without medicine or were provided with an incomplete regimen. Of the 757 stock-outs that were resolved, 70% (527) lasted longer than one month.¹⁸

22. The public and private healthcare sector also differ in terms of the number of active ingredients, number of suppliers and array of medicines available in these sectors. In the 2018 the Helen Suzman Foundation (“HSF”) report on the pharmaceutical industry¹⁹ found that the private sector had 1228 active ingredients while the public sector had a significantly lower number of active ingredients at 486.²⁰ In 2021 the private sector has a greater number of suppliers and medicines with 189 suppliers supplying 9404 products while the public health sector had 80 suppliers supplying 1123 products.²¹

23. Table 12 shows the number of medicines available in the public and private delineated by schedule²² in 2018.

Table 12 - Number of medicines available in the public and private by schedule (2018)

Schedule	Private	Public
1	500	27

17 Stop Stockouts 4th National Survey Report (2017).
18 Hwang B, Shroufi A, Gils T, Steele SJ, Grimsrud A, Boule A, et al. (2019) Stock-outs of antiretroviral and tuberculosis medicines in South Africa: A national cross-sectional survey. PLoS ONE 14(3): e0212405
19 The analysis was based on the Anatomical Therapeutic Chemical Classification (ATC) system 3 categories. In the ATC classification system, medicines are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties.
20 HSF, The supply of pharmaceutical in South Africa, 2018. Available at: <https://hsf.org.za/publications/special-publications/pharmaceuticals-in-south-africa/pharma-report-2018.pdf>.
21 Department of Health, South African medicine price registry, database of medicine prices 24 December 2021. Available at: <http://www.mpr.gov.za/PublishedDocuments.aspx#DocCatId=21>. Department of Health, Master health product list, 01 October 2021. Available at: <https://www.health.gov.za/tenders/>.
22 Medicines are classified by schedule. In deciding the scheduling status of a medicine or substance, the primary emphasis is on evidence of safety in use and the requirements for professional advice and/or supervision of its use.

2	900	35
3	4	190
4	4042	280
5	931	79
6	147	10
Not stated/ascribed	3	455
Total	3 921	1076

Source: HSF, The supply of pharmaceutical in South Africa, 2018. Available at: <https://hsf.org.za/publications/special-publications/pharmaceuticals-in-south-africa/pharma-report-2018.pdf>.

24. For schedule 1-6 medicines the private sector had considerably more medicines for each schedule compared to the public sector, particularly for schedule 3 and 4 medicines. Overall, the private healthcare sector in South Africa has a diverse selection of medicines with more active ingredients and a greater availability of medicines in each schedule than the public sector.

TRADE IN MEDICINE

25. According to Who Owns Whom ("WOW"), while almost 70% of pharmaceutical products consumed in South Africa are locally produced, various active pharmaceutical ingredients and finished products are imported.²³ The report also noted that in South Africa there is a reliance on the importing of active ingredients and final pharmaceutical products as local manufactures cannot compete on price. This has contributed significantly to South Africa's trade deficit in pharmaceuticals.
26. According to the Industrial Development Corporation ("IDC"), South Africa's pharmaceutical exports increased from R4 540,12 million in 2018 to R4 700,00 in 2019 while imports increased from R32 048,99 million in 2018 to R33 852,60 million in 2019. In 2018 and 2019 the number of pharmaceutical imports into South Africa was quite significant with pharmaceutical imports representing almost 90% of South Africa's trade in medicine. Since South Africa is highly reliant on imports and most of the APIs are predominately imported from China and India this had on certain

occasions led to import and distribution challenges.²⁴

27. Because South Africa imports most of its medicines this implies that the medicines are subject to varying exchange rates which creates price uncertainty for the medicines. Also, because the medicines are imported, they are incurring additional costs such as logistic and freight costs which further increases the price for the medicines. When the medicines are imported into the country there may also be supply and distribution challenges that adversely affects the accessibility of medicines in South Africa. To mitigate the price uncertainty and supply challenges it is imperative to develop the generic pharmaceutical manufacturing sector to improve the affordability and accessibility of medicines in South Africa. This may also facilitate a reduction in the medicine expenditure for both the public and private sector.

CONCLUSION

28. The medicine expenditure in both the public and private sector has been increasing during the relevant period. In the public sector, medicine expenditure represents between 7%-9% of total public expenditure while in the private sector, medicine expenditure represents a higher percentage (16%) of total medical scheme expenditure. While the public sector procures medicines at a lower price (due to scale economies) it still experiences its own challenge of persistent stockout of medicines.²⁵ The SSP has pointed that to reduce the level of stockouts there should measures in place to alleviate the impact of the global supply chain disruptions which points to the need for security of supply, among others, the development of domestic manufacturing capabilities. Furthermore, the public healthcare sector appears to have limited supply of active ingredients, medicines, and supplies, while the private sector can access a much wider variety of these.
29. In the private sector, medicine expenditure (savings and OOP) by members represents approximately 25%-28% of total medicine expenditure. The private sector

²⁴ IDC, Sector trends, Performance of the primary and secondary sectors of the South African economy, March 2018, March 2019, April 2020. Available at: <https://www.idc.co.za/research-reports/sectoral-trends/>.

²⁵ Stop Stockouts 4th National Survey Report (2017) The Fragile System.

also experiences its own challenges as medical scheme members pay a monthly contribution that is meant to fund their medicine purchases, yet they still use their savings and incur OOP when purchasing medicines. This may be indicative of the high price of medicines in South Africa and emphasises the need for a competitive generic market as generics are usually priced substantially lower than the originators.

30. The demand for generics in South Africa has been encouraging with generics representing more than half of medicine claims and there has been a significant uptake of generics. While South Africa compares favourably in the utilisation of generic medicines when compared to other OECD countries, there is still a potential to achieve a higher generic utilisation than is currently the case. The development of this opportunity would yield significant gains for both the public and private healthcare sectors in terms of the savings that could be realised from the introduction of competing generic medicines in South Africa as well as ensuring security of supply. More importantly, the introduction of competing generic medicines would also lead to greater consumer choice and ultimately increase access to competitively priced medicines.

MARKET STRUCTURE

MARKET SHARE

31. In South Africa the medicine supply chain consists of four distinct levels: manufacturing, distribution, wholesale, and retail. The manufacturer is involved in the manufacturing of the medicine which entails the research, design, and production of the medicine. The medicines can be completely manufactured locally, or the active ingredient or other ingredients can be imported and blended in South Africa to produce a final product. The distributor supplies a medicine or Scheduled Substance to a retailer or wholesaler on behalf of the manufacturer (typically on imported products). A wholesaler is a dealer who purchases medicines or scheduled substances from a manufacturer or distributor and sells them to a retailer and includes a wholesale pharmacy. Wholesalers are responsible for the effective, efficient, and safe handling,

storage and distribution of products ensuring the quality and identity of these during all aspects of the wholesaling and distribution process.²⁶ There are over 200 manufacturers, wholesalers, and distributors in South Africa.

32. The markets consist of large multinationals, established local multinationals, emerging companies, and many small vendors. Table 13 shows the market shares for the top five pharmaceutical companies in 2021.

Table 13 - Market shares for top five pharmaceutical companies, 2021

Company	Market share
Aspen	10.8%
Adcock Ingram	9.5%
Cipla	7,1%
Novartis	5.9%
Sanofi	5.3
Other	61.4%

Source: Adcock 2021 Integrated report.

33. The table above shows that in 2021 the top five companies were Aspen (10.8%), Adcock Ingram (9.5%), Cipla (7,1%), Novartis (5.9.%) and Sanofi (5.3%). The top five firms represent 38.6% of the market, with the top 10 corporations representing 53% of the total private market value and the top 20 companies contributing 71.4% to the total market value.²⁷

34. Table 14 lists the five largest players in the market as a whole and the market leaders in prescription medicines, over-the-counter medication and non-schedule products and the largest suppliers of pharmaceuticals to the public health sector.²⁸

Table 14 - Pharmaceutical market leaders

Rank	Overall	Rx	OTC	Non-schedule	State
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26 SAHPRA, South African good wholesaling practice for wholesalers, July 2016.
27 Adcock 2021 Integrated report.
28 WOW. The Pharmaceutical industry in South Africa, December 2020.

	All schedules	Schedule 3 and above	Schedule 1 & 2 only	Scheduling not applicable	All schedules
1	Aspen*	Aspen*	Adcock* Ingram	Adcock* Ingram	Mylan
2	Adcock* Ingram	Sanofi	Aspen*	Ascendis*	Sanofi
3	Cipla	Novartis	Cipla	Cipla	Aspen*
4	Sanofi	Cipla	Johnson & Johnson (Customer)	Aspen*	Adcock* Ingram
5	Novartis	Adcock* Ingram	Inova Pharma	Abbott	Pfizer
Total	722	144	95	647	371

Source: WOW. The Pharmaceutical industry in South Africa, December 2020.

Note:

*Denotes local companies

Rx- Prescription medicines

OTC- Over-the-counter medicines

35. In terms of schedule 3 and above medicines, two local companies, Aspen and Adcock Ingram represent the top five companies with Aspen being the leading company. Similarly, for schedule 1 and 2 medicines, Adcock Ingram and Aspen are the only two local companies in the top 5 with Adcock Ingram being the market leader. For non-schedule medicines there are three local companies Adcock Ingram, Ascendis and Aspen representing the top five companies. For the medicines supplied to the public sector, the top two suppliers are Mylan and Sanofi with the local manufacturers Aspen and Adcock Ingram comprising the top five suppliers to the public sector.

36. There are several international pharmaceutical corporations that operate in South Africa. They include Chemical, Industrial & Pharmaceutical Laboratories (“Cipla”), headquartered in Mumbai, India, Sanofi (France), Novartis (Switzerland), Johnson & Johnson (US), Mylan (US), Bayer (Germany), Fresenius Kabi (Germany), Pfizer Laboratories (US), GlaxoSmithKline (UK), AstraZeneca Pharmaceuticals (UK and Sweden), Abbott Laboratories (US), Roche Products (Switzerland), Merck (US) and Bristol-Myers Squibb (US).

37. Major South African players include the following:²⁹

37.1 Johannesburg Stock Exchange (JSE) listed Aspen, the largest pharmaceutical manufacturer in Africa. In South Africa, it is the market leader in the prescription medicines segment. It has a global network of operations supplying more than 150 countries. It is emerging market-focused and is one of the world's largest producers of sterile products.

37.2 Adcock Ingram (part of the Bidvest Group), the second largest manufacturer and the largest supplier of critical care products to the South African public sector and a primary supplier of antiretroviral medicines (“ARVs”)a). The JSE-listed company is the market leader in schedule 1 and schedule 2 over-the-counter medicines in the retail pharmacy segment, with a market share of 18% by value and 27% by volume. It is the probiotics segment leader and it ranks second in consumer analgesics (pain relief) with its Panado brand being the consumer pain tablets market leader.

37.3 JSE-listed Ascendis Health, the second largest supplier of non-schedule health products and nutraceuticals in South Africa. It supplies locally and exports to Australia and the European Union (“EU”). It manufactures in South Africa, Spain, Cyprus, and Hungary.

38. Table 15 shows the pharmaceutical manufacturers in South Africa, indicating the nature of the company's business.

29

WOW. The Pharmaceutical industry in South Africa, December 2020.

Table 15 - Pharmaceutical manufacturers in South Africa, 2022/23

Company	Nature of business
Aspen Healthcare Holdings Ltd	Aspen Pharmacare Holdings Ltd, operating through its subsidiaries, is involved in the manufacture, marketing, import and distribution of branded and generic pharmaceutical products, consumer healthcare, as well as treatment of acute and chronic conditions, covering both hospital and consumer markets through its key business segments.
Afriplex (Pty) Ltd	Afriplex (Pty) Ltd manufactures products for the pharmaceutical, nutraceutical, veterinary and cosmetic industries. Their products include syrups, drops, sprays, tablets, capsules, effervescent tablets, powders, and granules.
Adcock Ingram Holdings Ltd	Adcock Ingram Holdings Ltd is a South African importer, exporter, manufacturer, researcher, marketer, and distributor of healthcare and pharmaceutical products.
Ascendis Health (Pty) Ltd	Ascendis Health (Pty) Ltd has manufacturing capabilities and owns a portfolio of branded pharmaceutical, medical, wellness, cosmetic, and nutrition products.
Bioclones (Pty) Ltd	Bioclones (Pty) Ltd t/a Genius Biotherapeutics has two production units which focuses on manufacture and product development.
Cipla Medpro South Africa (Pty) Ltd	Cipla Medpro South Africa (Pty) Ltd is involved in the manufacture, distribution and packaging of tablets and other pharmaceutical and nutraceutical products.
Columbia Pharmaceuticals (Pty) Ltd	Columbia Pharmaceuticals (Pty) Ltd operates as a third-party manufacturer and operates locally, manufacturing pharmaceutical products such as vitamins and antibiotics for various pharmaceutical companies.
Fresenius Kabi Manufacturing SA (Pty) Ltd	Fresenius Kabi Manufacturing SA (Pty) Ltd operates as the manufacturing plant for South Africa, undertaking the manufacturer of pharmaceutical products.
Glaxosmithkline South Africa (Pty) Ltd	Glaxosmithkline South Africa (Pty) Ltd manufactures, imports, exports and distributes pharmaceuticals and medicines, including antibiotics, anti-virals and asthma sprays, as well as consumer health care products such as skin care products, supplying to wholesalers and pharmacies countrywide.

Company	Nature of business
Nkunzi Pharmaceuticals (Pty) Ltd	Pharmaceuticals firm Merck South Africa sold its Merck Pharmaceutical Manufacturing operations to a company controlled by Nkunzi Investment Holdings, a black-owned investment firm. Nkunzi Investment acquired the company, creating Nkunzi Pharmaceuticals, which started trading on May 3, 2011. Nkunzi incorporates the operations of Merck Pharmaceutical Manufacturing (Pty) Ltd and is a contract manufacturer of pharmaceutical products for pharmaceutical companies.
PharmaForce (Pty) Ltd	PharmaForce (Pty) Ltd undertakes the import, export, distribution, warehousing, and manufacturing of pharmaceuticals.
Sandoz South Africa (Pty) Ltd	Sandoz South Africa (Pty) Ltd specialises in manufacturing, marketing, and retailing of generic medicines.
Sanofi Industries South Africa (Pty) Ltd	Sanofi Industries South Africa (Pty) Ltd manufactures a wide range of pharmaceutical products which is distributed by the holding company, Sanofi-Aventis South Africa (Pty) Ltd.
Specpharm Holdings (Pty) Ltd	Specpharm Holdings (Pty) Ltd operates as a manufacturer of pharmaceutical products. The company also has several exclusive and non-exclusive marketing and sales agreements with international pharmaceutical manufacturers to distribute products in southern Africa.

Source: WOW. The Pharmaceutical industry in South Africa, December 2020.

39. Table 15 shows that the South African pharmaceutical manufacturers market is consist of 14 manufacturers. Notably, a common feature across the manufacturers is that manufacturers are involved in different levels of the supply chain, have a portfolio of products and are active in different market segments such as wellness, cosmetic, vitamins etc. This may suggest that a firm may have to be active at different levels of the supply chain and/or operational in complementary markets to generate sufficient economic of scale and/or scope to be sustainable in the pharmaceutical sector.

40. Table 16 shows the market shares for the top five wholesale distributors in the market for the year 2021.

Table 16 - Market shares for the top five wholesale distributors in the market, 2021

Company	Market share
DSV	30%-35%
UPD	20%-25%
Dischem	10%-15%
Adcock	5%-10%
Alphapharm	5%-10%

Source: Competition Commission of South Africa, 2021Jul0018 Click and PnP merger report.

41. Table 16 shows that DSV is the largest player in the wholesale distribution market with a market share of 30%-35%, followed by UPD and Dischem with a share of 20%-25% and 10%-15% respectively. Adcock and Alphapharm have a similar market share in the range of 5%-10%. Notably, Adcock is the only manufacturer that constitutes the top five distributors in the market.

ORIGINATOR AND GENERIC MARKET STRUCTURE

42. In 2018, the HSF report analysed the market structure for originator and generic medicines as shown in table 17.

Table 17 - Identical medicines in the private healthcare sector, by composition

Type of medicine	Number
Originators only	2064
Mixed	545
Generics only	1312
Total	3921

Source: HSF, The supply of pharmaceutical in South Africa, 2018. Available at: <https://hsf.org.za/publications/special-publications/pharmaceuticals-in-south-africa/pharma-report-2018.pdf>.

43. The study segmented the companies for the ATC 3* category of medicines by originators medicines, a combination of originators and generic medicines and only generic medicines. Table 17 shows that in 2018 the ATC 3 category consisted of 2064 originators, 545 mixed and 1312 generics. The originators constituted 52,63 percent of the identical medicines.

Table 18 - Pharmaceutical product markets by number of participants in the private healthcare sector

Number of participants	Number of markets
1	3038
2	388
3	184
4	83
5	52
6-10	126
11+	50
Total	3921

Source: HSF, The supply of pharmaceutical in South Africa, 2018. Available at: <https://hsf.org.za/publications/special-publications/pharmaceuticals-in-south-africa/pharma-report-2018.pdf>.

44. The HSF report also noted that the markets are concentrated with 77,5% of pharmaceutical products having no substitutes, 9,9% have only one substitute and

4,7% have only two substitutes and 2,1% have three substitutes as shown in table 10.

45. The HSF report provided a list of the manufacturers in South Africa that supplied both the public and private sector in 2018. The list also shows whether the manufacturer supplies generic, originator, or a mixture of both. The private sector had 5115 generic products and 4137 originator products, a total of 9252 products whereas the public sector had 1175 products. The list shows that private sector had 95 suppliers, the public sector 16 suppliers and 64 suppliers operated in both the public and private sector. Of the 159 manufacturers which supply to the private sector:

- 45.1 48 supply only originator medicines
- 45.2 19 supply mostly originator medicines (more than 80% originators)
- 45.3 15 have a mixed output (the supplies of originators and generics are both at least 20%)
- 45.4 19 supply mostly generic medicines (more than 80% generics)
- 45.5 58 supply only generic medicines.

46. In South Africa there are more wholly generic manufacturers than originator medicines and an equal number of companies supplying either generic or originator medicines. While South Africa does have some generic manufacturing production the generic market is still undeveloped and small and more importantly most of the API's are imported into South Africa.

47. The delineation of the pharmaceutical sector by prescription, OTC, and non-scheduled shows that most of the top five companies in the market feature across the segments, with typically two local companies constituting the top five. Notably, a common feature across the manufacturers is that most of them have a wide portfolio of products and are active in different levels of the supply chain and market segments

48. The market is concentrated by originators medicines with limited generic options available for consumers in the South African market with a minimal percentage of the

pharmaceutical products having substitutes.

49. Therefore, it is important to ensure that generic companies can enter and expand in the market to increase the number of generic suppliers and generic products in the product. An increase in local generic manufacturing may encourage further entry and competition, ultimately benefiting consumers by increasing the affordability, supply, and variety of medicines in South Africa.

REGULATORY FRAMEWORK

50. The South African pharmaceutical sector is highly regulated and governed by various legislative and regulatory policies. The main legislation governing the medicine market is the Medicines and Related Substances Act 101 of 1965. Other pieces of legislation interrelated to the pharmaceutical manufacturing sector are the Patent Act of 1978, the Public Finance Management Act (1999) and the Competition Act of 1998. Collectively these Acts influence key outcomes in the pharmaceutical sector such as the affordability and access of medicines, generic entry, and the growth of the local manufacturing pharmaceutical sector. A description of the different act is provided below.

THE MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965

51. The Medicines and Related Substances Act 101 of 1965, as amended ("Medicines Act") is the main legal framework and came into effect in 1967 and provided for the registration of medicines and related substances for human use.
52. The Medicine Act seeks to, among others, increase the access to affordable medicines in South Africa. The Medicine Act strongly advocates for the use of generic medicine in South Africa (see section 22F). The Medicine Act requires a pharmacist or person licensed to dispense medicine to inform customers of the benefits of the generic medicine unless expressly forbidden by the patient to do so or if the person prescribing the product has requested no substitution of the product. It also permits for the parallel importation of medicines into the country (section 15C) which

essentially allows the Minister to waive the patent rights to a medicine and procure less expensive medicine than the one already registered in South Africa. The Minister may authorise, through a permit, the importation of the same medicine manufactured by, or on behalf of, the approved manufacturer from any other country. The provision empowers the Minister of Health to prescribe the conditions on which the patent may be waived regardless of the patent status of the medicine. While section 15C can facilitate the access of affordable medicine, the conditions under which the provision can be invoked remains unclear and to date has not been used in South Africa.

53. To supply medicines in South Africa, manufacturers, wholesalers, and distributors are required to have a license to manufacture, import or export or act as a wholesaler or distributor of medicines which are issued by and regulated by the South African Health Products Regulatory Authority (“SAHPRA”), previously the Medicines Control Council (“MCC”). SAHPRA is an entity of the DoH and is tasked with regulating (monitoring, evaluating, investigating, inspecting, and registering) all health products. This includes clinical trials, complementary medicines, medical devices, and in vitro diagnostics (“IVDs”). Obtaining a license for the manufacture, import or export of medicines in South Africa requires the payment of an application fee which is dependent on the license that is required such as new chemical entity (“NCE”), generic or biological. The Medicine Act also sets out a provision (Section 15) that expedites the registration of essential medicines.
54. Table 19 sets out the target timelines for SAHRPA’s review process for the business-as-usual (“BAU”) and Backlogs (“BL”) medicines. The BAS timelines for the review process for fast track, NCE, and generics are 350, 590 and 250 calendar days respectively. For BL the timelines remain the same as the BAU expect for NCE which has a quicker turnaround time of 250 calendar days.

Table 19 - Target timelines for SAHRPA review process

Process	SAHPRA	SAHPRA BL
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Overall review time (fast track)	350 calendar days	350 calendar days
Overall review time (NCEs)	590 calendar days	250 calendar days
Overall review time (generics)	250 calendar days	250 calendar days

Source: Keyter A, Salek S, Danks L, Nkambule P, Semete-Makokotlela B and Walker S (2021) South African Regulatory Authority: The Impact of Reliance on the Review Process Leading to Improved Patient Access. *Front. Pharmacol.* 12:699063. doi: 10.3389/fphar.2021.699063.

55. The Medicines Act also contains provisions for a pricing committee to provide a framework that ensures a transparent pricing system by wholesalers or distributors to prevent rent seeking behaviour that is detrimental to consumers. The transparent pricing system includes a single exit price (“SEP”) which set the prescribed maximum price that manufacturers can sell prescription medicines in the private sector. Over the counter medicines have been exempt (schedule 0) from the SEP. The SEP is composed of the ex-manufacturer price (as determined by the manufacturer), the logistic fee (as determined by the manufacturer) and the value added tax component (15%) for these medicines sold to all purchasers other than the State.
56. The ex-manufacturer price is determined by the manufacturer and is the price to produce a medicine or scheduled substance for consumption and includes costs incurred in releasing a final pack of a medicine or scheduled substance. The logistic fee is determined through a negotiation process between the manufacturer or importer and the logistic services provider. It is the fee paid by the manufacturer to the logistic service provider for the distribution of the medicine from the manufacturer or importers premises to end dispensers. The logistics fee is regulated, and a maximum fee is set. The Minister of Health determines the extent to which the medicine prices may be adjusted on an annual basis considering the following factors:
 - 56.1 The average CPI for the preceding year;
 - 56.2 The average PPI for the preceding year;
 - 56.3 Changes in the rates of foreign exchange and purchasing power parity;
 - 56.4 International pricing information relating to medicines and scheduled substances;
 - 56.5 Comments received from interested persons in terms of regulation 8(2); and

- 56.6 The need to ensure the availability, affordability, and quality of medicines and scheduled substances in the Republic.

THE COMPETITION ACT

57. The Competition Commission of South Africa is governed by the Competition Act no 89 of 1998 (as amended) and is empowered to investigate, control, and evaluate restrictive business practises, abuse of dominant positions and mergers to achieve equity and efficiency in the South African economy. It seeks to provide all South Africans with an equal opportunity to participate fairly in the national economy and achieve a more effective and efficient economy in South Africa, so consumers have access to quality and a variety of goods and services. The objective of competition policy is to ensure a fair functioning of the market and, that entry and expansion into the market is likely and encouraged. Anti-competitive practices include a range of activities, such as abusive exclusionary conduct by a dominant company, refusal to provide certain goods, charging excessive prices, vertical arrangements between suppliers and distributors that may prevent, restrict, or distort competition. As an economy-wide regulator, the Commission enjoys concurrent jurisdiction with other regulators insofar as it relates to the conduct of firms and the implications of such behaviour for competition in markets.

THE PATENT ACT

58. The Patent Act 57 of 1978 provides for the registration and granting of letters patent for inventions. The Patent Act grants an applicant a patent term of 20 years from date of application. The Patent Act also allows for the issue of compulsory licences. The use of compulsory licensing in terms of section 56 of the Act empowers the commissioner of patents to grant a compulsory licence to an “interested party”, including a government agency, without the consent of the patentee in instances where there is an abuse of patent rights. A compulsory licence seeks to counter the following abuses by a patentee:³¹

- 58.1 The patented invention does not meet the demand of the republic on reasonable terms.
- 58.2 The refusal of the patentee to grant a license on reasonable terms prejudices the trade, industry and agriculture of the Republic of South Africa, such that it is in the interest of the public that a compulsory license be granted; or
- 58.3 The patented product is imported, and the price charged by the patentee is excessive compared to prices of the same product in other countries.
59. The onus is on the applicant seeking a compulsory licence to prove that at least one of the above abuses has occurred. To date there has been only one compulsory licence case in South Africa in respect of a dependent patent in the matter between Atomic Energy Corporation of SA Ltd v The Du Pont Merck Pharmaceutical Co 1997 BIP 90 (CP) at 93H. The Patent Act also allows for a voluntary license where the patent holder may surrender the patent allowing the product to be produced by other manufacturers. While the Patent Act provides the patent holder with protection for a period of 20 years, to reward the inventor for their investment, it does however conflict with the Competition Act which seeks to ensure that markets are open and free, ultimately providing consumers with choice and products at competitive prices.

PUBLIC FINANCE MANAGEMENT ACT

60. The Public Finance Management Act (“PFMA”) governs the procurement process for all goods and services purchased by government. With regards to medicines, the PFMA requires a competitive tendering process to ensure the government gets the best price and value for money for its 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 DoH in collaboration with the National Treasury, through a transversal contract, although provinces can issue their tenders for medicines not on the EML. In the National Planning Commission report it was noted that 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

³¹ <http://patentblog.kluweriplaw.com/2021/05/17/south-africa-compulsory-licensing/>.

giving empowered firms preferential access to public sector markets, possibly at a premium price.³²

61. The manufacture and supply of medicines in South Africa is regulated by several legislations which are aimed at ensuring access to safe medicines at competitive prices. The regulatory compliance brought about by these do not appear to be onerous.

PRICING ANALYSIS FOR MEDICINES

62. A pricing analysis³³, is conducted for the medicines for the relevant diseases to determine the level of price competition between the originator and generic medicines. The study evaluates the impact of the entry of generics on price competition between the originator and generic medicines and price competition between multiple generic manufacturers. To conduct the assessment, the study used publicly available price data for both the public and private healthcare sectors for the year 2020. The medicines for the private sector were obtained from the Medicine Price Registry (“MPR:). The MPR is published by the DoH. The MPR sets out the medicines licensed for sale, and it contains information on, inter alia:

- 62.1 The identity of the manufacturer;
- 62.2 The active ingredient in each medicine;
- 62.3 The dosage form that each medicine takes, for instance, whether the medicine is contained in a tablet, capsule, or a solution; and
- 62.4 Whether the medicine is an originator medicine or a generic.

63. The medicines for the public sector were obtained from The Master Procurement List (“MPL”). The MPL of medicines is published by the DoH. This sets out information on current government procurement contracts, and it contains information on, inter alia:

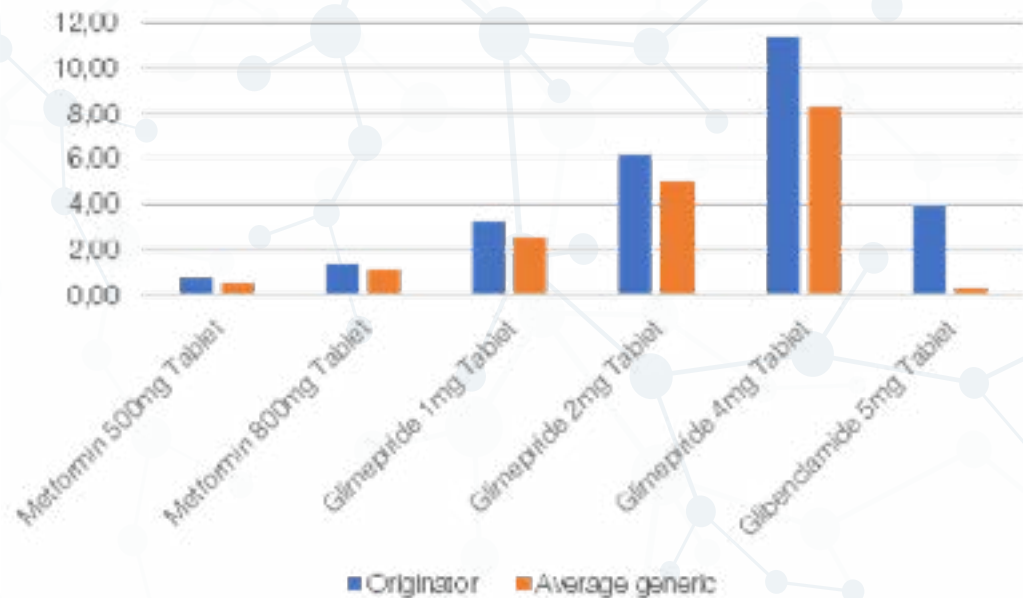
- 63.1 The identity of the manufacturer;
- 63.2 The active ingredient in each medicine;
- 63.3 The strength, unit of measurement and dosage form of the medicine; and
- 63.4 The price of a unit of medicine and the quantity to be provided in terms of the contract.

COMPARISON OF AVERAGE PRICE OF GENERICS TO ORIGINATORS³⁵

64. There are usually several generics for an originator product, therefore the study compared the average price of the generics to the originator for the relevant diseases to assess the price difference between generics and originators³⁶.

³⁵ In instances where there was more than one originator the average price was calculated to obtain a price for the originator.
³⁶ There were no originators for TB.

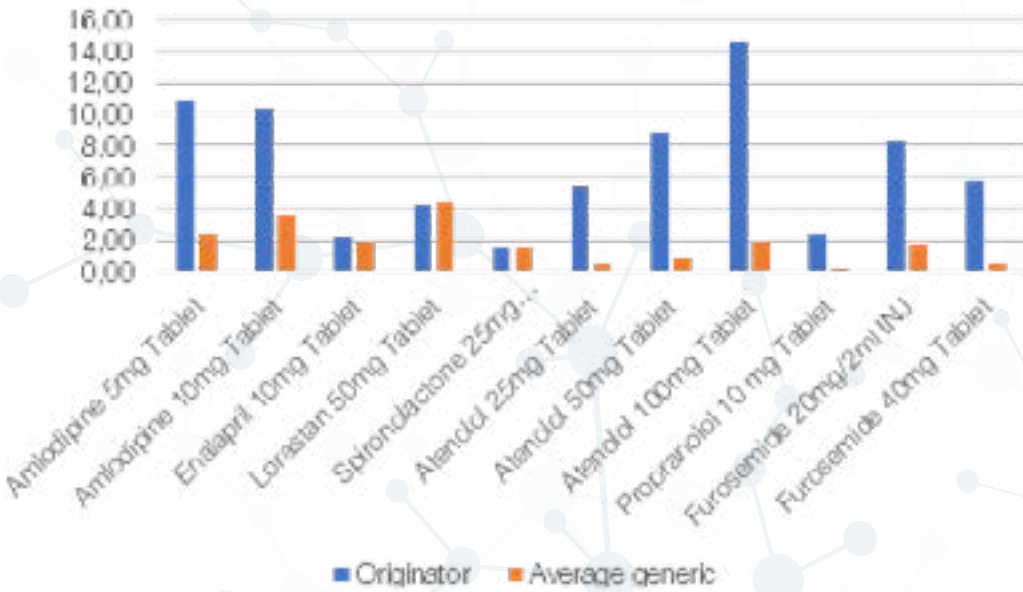
Figure 11 - Average price of generics to originators for diabetes



Source: Commission's own compilation based on MHPL.

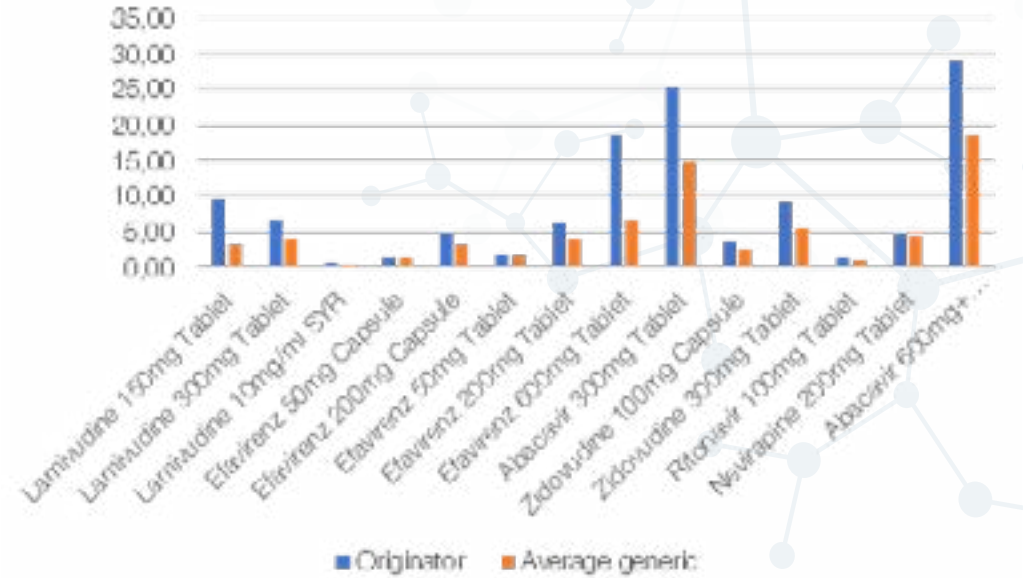
³² National Planning Commission, Research on Pharmaceutical Pricing Policies, February 2020.
³³ Medicines that had missing data were excluded from the analysis.
³⁴ The unit prices were used for all the medicines.

Figure 12 - Average price of generics to originators for hypertension



Source: Commission's own compilation based on MHPL.

Figure 13 - Average price of generics to originators for HIV/AIDS



Source: Commission's own compilation based on MHPL.

65. The figures above show that for most of the medicines the generic is cheaper than the originator expect for two hypertension medicines, Losartan (50mg) tablet, Spironolactone (25mg) tablet and the HIV/AIDS medicine Efavirenz (50mg) capsule where the originator was priced lower than the generic, however the price difference for these medicines was minimal. The figures above also show that the level of the price difference between the generic and originator differs among the various medicine which is assessed further in the table below.
66. The study assessed the level of price competition between the originator and generic/s.³⁷ In this regard, the study assessed the price differences between these various products (see Table 20 below³⁸).

Table 20 - Price difference between originator and generics

	Active ingredient	Originator	Number of generics	% price difference range ³⁹ (originator vs generics)	No. of generics priced higher than originator
Diabetes	Metformin (500mg) Tablet	Glucophage Xr	2	25%-26%	0
		Glucophage		30%-31%	0
	Metformin (800mg) Tablet	Glucophage	2	19%-29%	0
	Glibenclamide (5mg) Tablet	Euglucon	6	91%-92%	0
	Glimepiride (1mg) Tablet	Glamaryl 2	10	(33%)-43%	1
	Glimepiride (2mg) Tablet	Glamaryl 2	10	(29%)-52%	1
	Glimepiride (4mg) Tablet	Glamaryl 4	10	(33%)-50%	1

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Percentage differences have been computed using the formula: Percentage Difference = (Originator-Generic)/Originator.

There was only one originators for TB, but it did not have a generic.

The range specifies the price difference between the lowest priced generic and originator and the highest priced generic and originator.

	Active ingredient	Originator	Number of generics	% price difference range ⁴⁰ (originator vs generics)	No. of generics priced higher than originator
Hypertension	Amlodipine (5mg) Tablet	Norvasc Tablets 5mg	11	44%-70%	0
		Caduet 5mg/20mg		76%-89%	
	Amlodipine (10mg) Tablet	Norvasc Tablets 10mg	10	49%-72%	0
	Enalapril (10mg) Tablet	Renitec	2	11%	0
	Losartan (50mg) Tablet	Cozaar	1	(1%)	1
	Spironolactone (25mg) Tablet	Aldactone 25	3	(3%)- 1%	1
	Atenolol (25mg) Tablet	Tenormin 25	1	91%	0
	Atenolol (50mg) Tablet	Tenormin 50	8	81%-94%	0
		Tenoret 50		81%-94%	
	Atenolol (100mg) Tablet	Tenormin 100	9	68%-94%	0
	Propranolol (10 mg) Tablet	Inderal	2	94-%95%	0
	Furosemide (20mg/2ml) INJ	Lasix 20 mg/ 2 ml	4	71%-84%%	0
	Furosemide (40mg) Tablet	Lasix 40 mg	9	84%-97%%	0

	Active ingredient	Originator	Number of generics	% price difference range ⁴¹ (originator vs generics)	No. of generics priced higher than originator
HIV/AIDS	Lamivudine (150mg) Tablet	Combivir	9	77%-83%	0
	Lamivudine (300mg) Tablet	Mivuten	3	19%-60%	0
	Lamivudine (10mg/mL) syrup	3TC Oral Solution	1	18%	0
	Efavirenz (50mg) Capsule	Stocrin 50	3	(33%)-33%	2
	Efavirenz (50mg) Tablet	Stocrin 50	1	27%	0
	Efavirenz (200mg) Capsule	Stocrin 200	4	20%-49%	0
	Efavirenz (200mg) Tablet	Stocrin 200	1	35%	0
	Efavirenz (600mg) Tablet	Stocrin	10	10%-67%	0
		ATRIPLA		61%-86%	
		Atreslawin		51%-82%	
	Abacavir (300mg) Tablet	Ziagen Tablets	2	26%-85%	0
	Zidovudine (100mg) Capsule	Retrovir	3	34%%-35%	0
	Zidovudine (300mg) Tablet	Retrovir	10	20%-86%	0
	Ritonavir (100mg) Tablet	Norvir (100mg) Tablet	1	99%	0
	Nevirapine (200mg) Tablet	Viramune 200 mg	10	(8%)-46%	6
	Abacavir (600mg) + Lamivudine (300mg) Tablet	Kivexa	3	20%-35%	0

Source: Commission's own compilation based on MHPL.

67. The analysis above shows that generic medicines bring about substantial price gains

for consumers given the relatively high price differences between these and originator products. By way of example, for the active ingredient metformin 500mg (diabetes), Merck (Pty) Ltd produces two originator medicines, Glucophage Xr and Glucophage, the unit price is R0,71 and R0,75 respectively. Both these medicines have the same active ingredient with the same strength. There are two generic medicines available in the market for this active ingredient produced by the same manufacturer. Notably, the generic medicines that are alternatives to Glucophage Xr are cheaper by up to 26% whilst for Glucophage, they are 31% cheaper. This demonstrates that even in instances where there may be a single generic manufacturer in the market, the presence of same is able to introduce substantial price gains for consumers and the fiscus.

68. There are also instances where there may be multiple generics available for a single active ingredient. By way of example, for Amlodipine (10mg) tablet there are about 10 generic medicines. The price difference between the originator and the generics ranges between 44%- 72% with the generics being up to 72% cheaper than the originator. Similarly, Lamivudine (150mg) tablet has nine generics with the price difference between the generics and the originator ranging between 77%-83% with the generic being cheaper by up to 83% of the originator. This is a good example which demonstrates that the higher the number of generics present, the more price gains there are given the intensity of competition introduced by generic medicines in the market. The table shows that the presence of multiple generic medicines brings about much needed price competition as evidenced by the variation in the unit prices charged for the various generics. This indicates that price competition is enhanced when there are multiple generic manufacturers in the market.
69. The trend observed in the preceding paragraph (i.e., the presence of multiple generic products gives rise to significant price differences between the originator products and generics) is found in respect of most of the generic medicines considered. However, there are some instances where the generic is more expensive than the originators although this appears to be the exception rather than the norm.
70. The analysis confirms the earlier observation that the introduction of generics brings about price competition as these products are typically priced lower than the

originators. Second, this analysis also shows that multiple generic entry stimulates price competition in the market with significant price gains realizable for consumers.

GENERIC COMPETITION

71. The study found that there are medicines where there are only generics and no originators in the market. The study assessed the price difference between the generics to determine the level of price competition among the generics. Figures 14 to 16 shows the price differences between the generics for the relevant diseases.⁴²

42 Diabetes does not have medicines that only consist of generic medicines.

Figure 14 - Comparison for generic medicine prices for hypertension

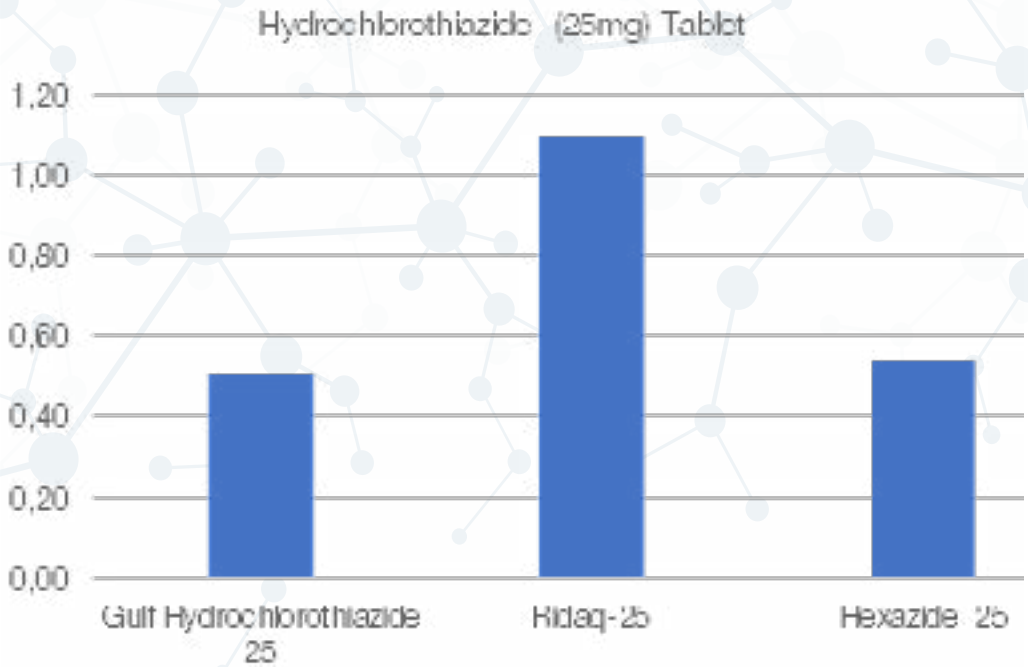
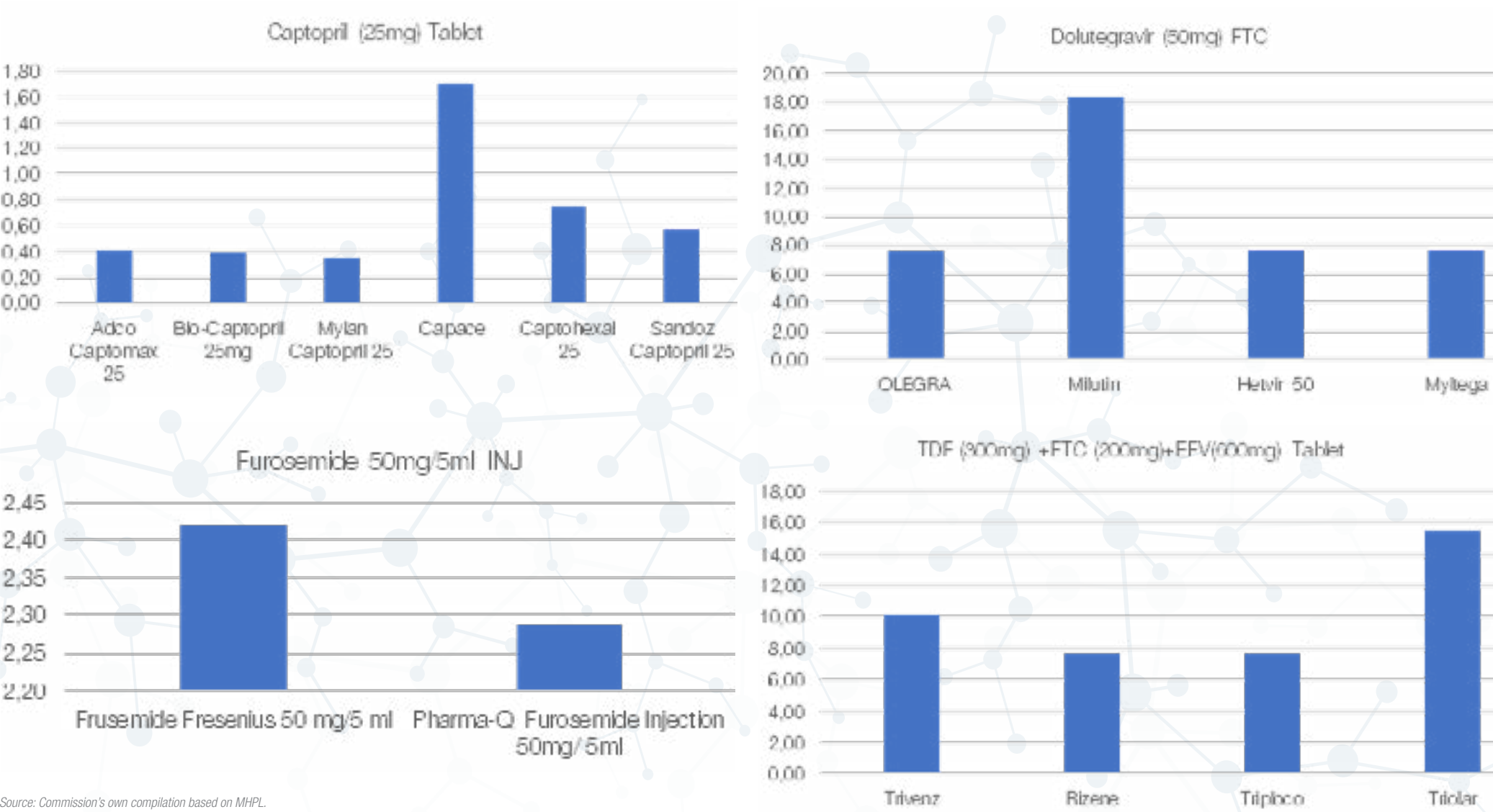


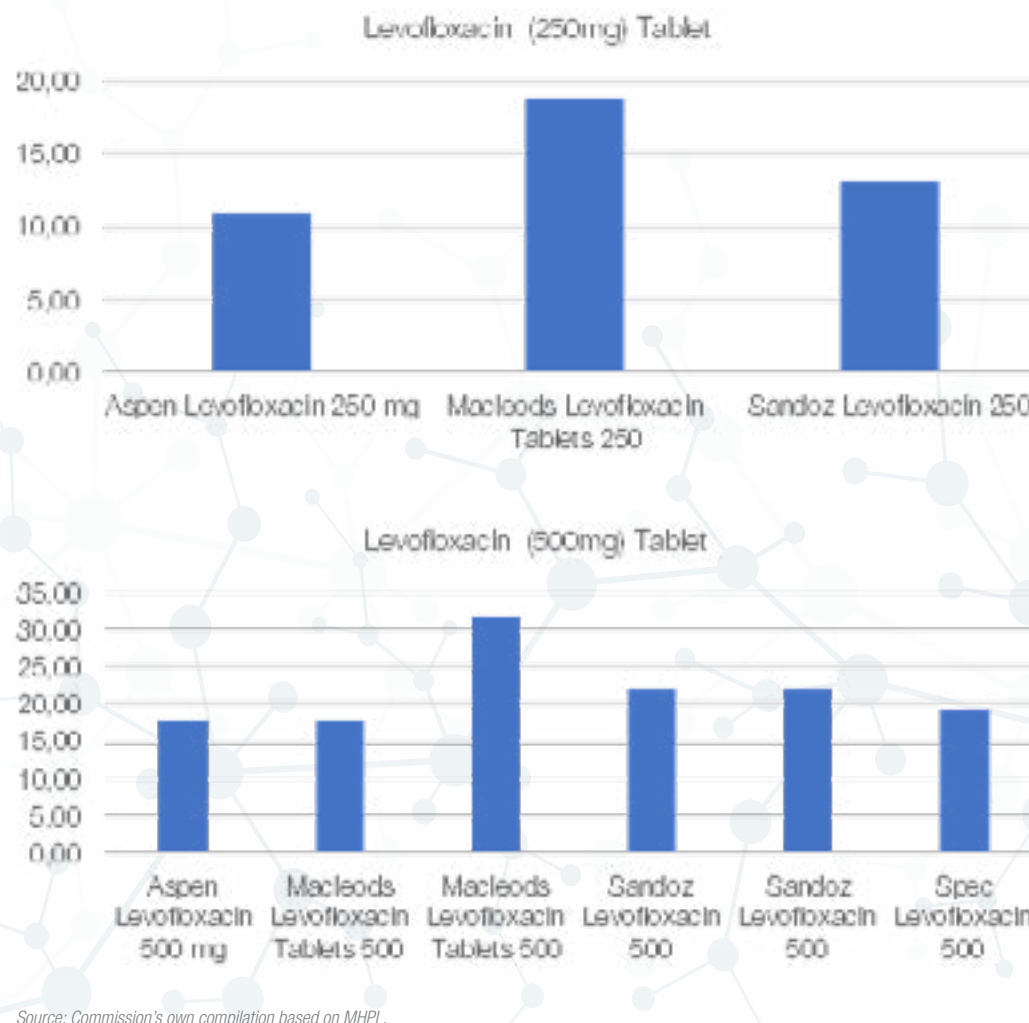
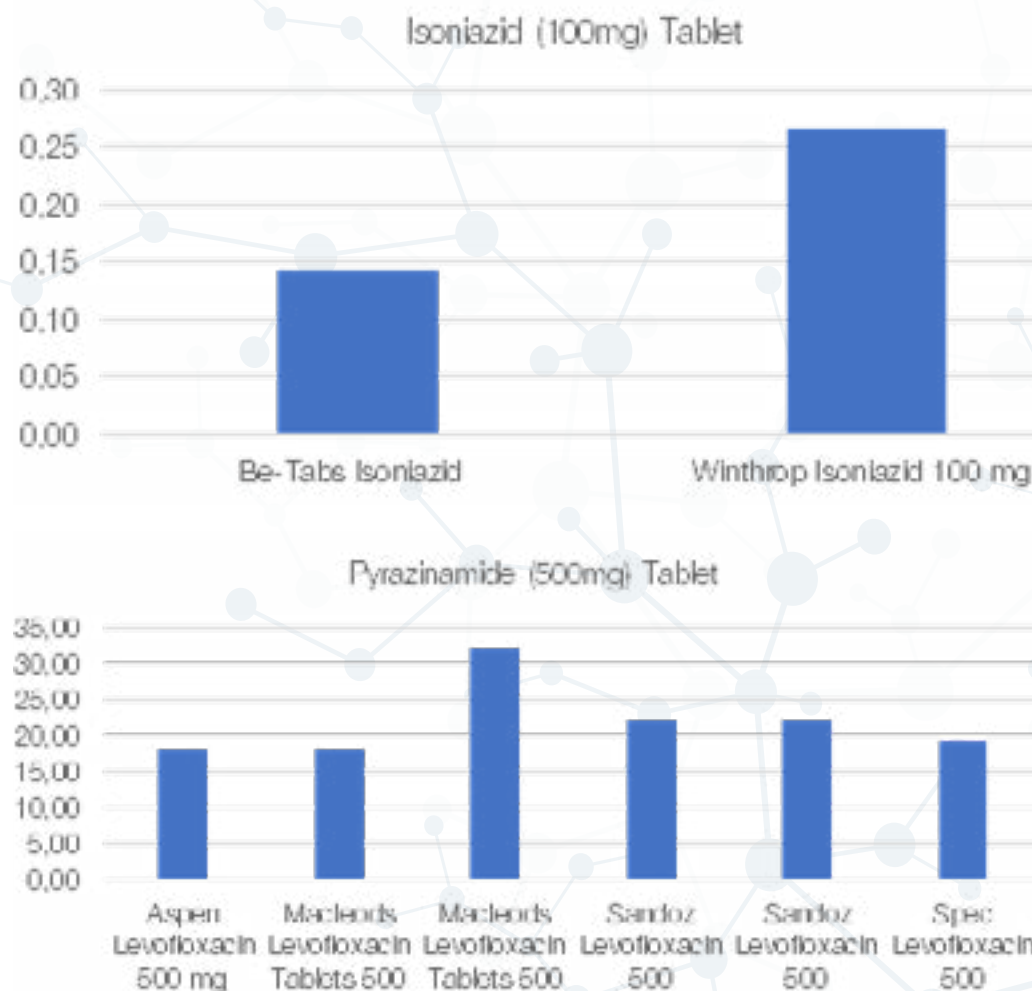
Figure 15 - Comparison for generic medicine prices for HIV/AIDS



Source: Commission's own compilation based on MHPL.

Source: Commission's own compilation based on MHPL.

Figure 16 - Comparison for generic medicine prices for TB



Source: Commission's own compilation based on MHPL.

72. For hypertension, HIV/AIDS, and TB, the number of generic medicines available varies for each active ingredient. The figures above show that the presence of multiple generic medicines for each active ingredient brings about much needed price competition as evidenced by the variation in the unit prices charged for the various generics. Notably, even in instances where there are few generics available, such as is the case for the Isoniazid (100mg) tablet which is used to treat TB, there are only two generics, but price competition exists as evidenced by the price range of R0,14–R0,26. Similarly for the hypertension medicine Furosemide (50/5ml) Injection, there are two generics with Frusemide Fresenius 50 mg/5 ml and Pharma-Q Furosemide Injection 50mg/ 5ml priced at R2,42 and Triolar priced at R2.28.

73. Also notable are the price differences that even when there is a single generics manufacturer that produces more than one generic with the same strength and active ingredients. For example, Sandoz SA Pty Ltd manufactures Captopril (25mg) tablet under the name Captohexal 25 and Sandoz Captopril 25 which are priced at R0,75 and R057 respectively. The pricing variation also applies to Hetero Medicines South Africa (Pty) LTD HIV/AIDS medicine that produces two generics with the active ingredient dolutegravir the unit price being R7,67 for Hetvir 50 and Milutin is R18,43. This indicates that there is price competition even within a company's products.

74. The figures above show that there is typically price competition among the generics as evidenced by the variation in the unit prices charged for the various generics, even in instances where there are a few generics. This accentuates the importance of having a generic enter the market when a product comes off patent.

ORIGINATOR WITH BRANDED GENERIC ENTRY

75. There are also instances where a manufacturer of an originator product may also, upon the expiry of their patent, introduce their own branded generic product. The table below assesses the price differences when a manufacturer has both an originator and generic product (branded generic) in the market. The analysis includes both the price difference to the branded generic and other generics where relevant.

Table 21 - Originator with branded generic entry

	Active ingredient	Originators	Generics	Company with originator and generic	Price difference originator and branded generic	% unit price difference range (originator vs generics)
Hypertension	Amlodipine (5mg)	Caduet 5mg/20mg	11	Pfizer Laboratories (Pty) Ltd (1 originator and 1 generic)	73%	54%-73%
		Norvasc Tablet 5mg	11	Pfizer Laboratories (Pty) Ltd (1 originator and 1 generic)	86%	76%-89%
	Amlodipine (10mg)	Norvasc Tablet 5mg	10	Pfizer Laboratories (Pty) Ltd (1 originator and 1 generic)	71%	49%-71%

Source: Commission's own compilation based on MHPL and MPR, 2020.

76. For the active ingredient amlodipine (5mg) there were two originators produced by Pfizer and a branded generic and ten additional generics. For amlodipine (5mg) the branded generic was priced cheaper by 73% and 86% than the originator. The price difference between the originator and generics ranged between 54% to 73%, and 76% to 89% with all the generics priced lower than the originator. Similarly for amlodipine (10 mg) the branded generic was cheaper by 71% than the originator and all the generics were cheaper than the originator.

77. When the originator introduces a generic in the market it is usually priced lower than the originator. This may allow the manufacturer to retain its dominant position in the market in relation the specific medicine through its originator and lower priced branded generic. The entry of the branded generic, especially if it entered the market before the patent expired, may deter generic entry or hinder expansion into the market which may prevent competition in the market.

PRICE DIFFERENCES FOR MEDICINES IN THE PUBLIC AND PRIVATE SECTORS

78. The table below shows the price difference for medicines in the public^o and private sector.

Table 22 - Price difference between the public and private sector

Disease	Active ingredient	Company	Private price	Public price	% Difference
Diabetes	Glimepiride 1mg Tablet	Austell Laboratories (Pty) Ltd	R2,20	R0,11	95%
	Glimepiride 2mg Tablet	Austell Laboratories (Pty) Ltd	R4,31	R0,20	95%
		Accord Healthcare (Pty) Ltd	R3,64	R0,17	95%
	Glimepiride 4mg Tablet	Austell Laboratories (Pty) Ltd	R6,70	R0,26	96%
		Accord Healthcare (Pty) Ltd	R5,75	R0,17	97%
	Glibenclamide 5mg Tablet	Oethmaan Biosims (Pty) Ltd	R0,34	R0,12	64%
		Pharmacare Limited, Woodmead	R0,32	R0,12	63%

Disease	Active ingredient	Company	Private price	Public price	% Difference
Hypertension	Hydrochlorothiazide 25mg Tablet	Gulf Drug Company (Pty) Ltd	R0,50	R0,13	75%
		Pharmacare Limited, Woodmead	R1,09	R0,15	86%
	Captopril 25mg Tablet	Biotech Laboratories (Pty) Ltd	R0,39	R0,17	57%
	Lorastan 50mg Tablet	Cipla Medpro (Pty) Ltd	R4,32	R0,33	92%
	Spironolactone 25mg Tablet	Pharmacare Limited, Woodmead	R1,51	R0,40	74%
		Sandoz SA (Pty) Ltd	R1,54	R0,45	71%
	Atenolol 25mg Tablet	Austell Laboratories (Pty) Ltd	R0,47	R0,56	-19%
	Atenolol 50mg Tablet	Biotech Laboratories (Pty) Ltd	R0,70	R0,12	82%
		Dezzo Trading 392 (Pty) Limited T/A Indo Pharma	R0,72	R0,13	82%
		Pharmacare Limited, Woodmead	R1,75	R0,27	84%
	Atenolol 100mg Tablet	Biotech Laboratories (Pty) Ltd	R1,22	R0,17	86%
	Propranolol 10 mg Tablet	Gulf Drug Company (Pty) Ltd	R0,11	R0,19	-65%
	Furosemide 40mg Tablet	Pharmacare Limited, Woodmead	R0,87	R0,24	72%
		Innovata Pharmaceuticals cc	R0,26	R0,16	37%
		Ranbaxy Pharmaceuticals (Pty) Ltd	R0,22	R0,12	46%
	Minoxidil 10mg Tablet	Pfizer Laboratories (Pty) Ltd	R10,46	R6,17	41%

Disease	Active ingredient	Company	Private price	Public price	% Difference
HIV/AIDS	Lamivudine 150mg Tablet	Adcock Ingram Limited	R0,77	R0,68	11%
		Pharmacare Limited, Woodmead	R2,54	R0,68	73%
	Dolutegravir 50mg Tablet	Hetero Drugs South Africa (Pty) LTD	R13,05	R1,67	87%
		Aurobindo Pharma (Pty) Ltd	R7,63	R2,03	73%
	Efavirenz 50mg Capsule	Adcock Ingram Limited	R0,81	R0,64	21%
	Efavirenz 200mg Capsule	Adcock Ingram Limited	R2,41	R0,73	70%
		Sonke Pharmaceuticals (Pty) Ltd	R3,76	R0,73	81%
	Abacavir	Mylan (Pty) Ltd	R5,29	R2,11	60%
	Zidovudine 300mg Tablet	Adcock Ingram Limited	R2,88	R1,51	48%
	Stavudine 200mg Capsule	Pharmacare Limited, Woodmead	R0,98	R0,49	50%
	Nevirapine 200mg Tablet	Pharmacare Limited, Woodmead	R4,88	R0,71	86%
	Tenofovir + Efavirenz + Emtricitabine 300mg + 600mg + 200mg Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	R15,53	R3,92	75%
	Abacavir + Lamivudine 600mg + 300mg Tablet	Cipla Medpro (Pty) Ltd	R18,71	R2,91	84%
Disease	Active ingredient	Company	Private price	Public price	% Difference

TB	Rifampicin 150mg Tablet	Sandoz SA Pty Ltd	R2,32	R1,77	24%
	Pyrazinamide 500mg Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	R1,01	R0,64	37%
	Levofloxacin 500mg Tablet	Macleods Pharmaceuticals SA (Pty) Ltd	R24,93	R3,15	87%

Source: Commission's own compilation based on MHPL and MPR, 2020.

79. Table 22 shows that for most of the medicines for the relevant diseases, the private sector price is significantly higher than that charged for the public sector. This is expected since the medicines in the public sector are purchased through a competitive tender process in which the manufacturers compete on offering the lowest price to secure the government tender.

EXPIRED AND LAPSED PATENTS

80. The study has also identified several instances where a patent has expired or lapsed and there has been no generic entry in the market. An expired patent refers to a patent that is no longer enforceable. A lapsed patent refers to a patent that expired because the renewal fee was not paid in due time.^{44 45} The European Commission provides a possible explanation for why a firm may allow its patent to lapse. They note that some countries have renewal fees that sharply increases at the end of patent life which can be considered as an incentive to maintain only highly valuable patents (for the patent holder perspective) and, up to a certain point, a way to promote innovation by unlocking the use of IP that may not be valuable for the inventor but can be put in to

⁴⁴ The renewal fee must be paid every year starting from the end of the 3rd year from the filing date for the duration of the patent. The renewal fee plus fine must be paid within 6 months after the due date. Thereafter the patent will lapse due to non-payment of the renewal fee. To restore it, firms will have to follow a restoration procedure in terms of the Patent Act and the Regulations.

⁴⁵ https://www.cipc.co.za/?page_id=4333.

use for a third party. The progressive increase of renewal fees encourages patentees to drop patents which are not valuable enough while obtaining a reasonable income from the most valuable ones.⁴⁶

81. South Africa also employs a progressive renewal fee payment structure which may explain why some firms have allowed their patents to lapse⁴⁷ and also explain why there has been no generic entry in the market. If the patent holder could not derive value from the patent, this may disincentivise generic companies from investing in that product due to the limited demand for the product. In addition, the administration around renewing a patent may discourage those patent holders with invaluable patents.
82. Considering the above, the assessment confirms that the presence of generics (whether branded generics owned by the originator manufacturer or made by a generic manufacturer) leads to price competition in the supply of medicines. This is in line with the findings by Mediscor which indicated that generics are significantly cheaper than original brands. Moreover, the assessment shows that a higher number of generics is associated with higher price differences in favour of the generics since they are priced significantly lower than the originator products. Therefore, multiple generic entry simulates price competition which benefits consumers in the form of lower priced medicines. This is even more pertinent for the consumers in the private healthcare sector who do not enjoy the benefit of the procurement scale efficiencies realised in the public sector. The analysis also demonstrates that there are significant price differences between the private and public sector, with the public sector enjoying more favourable pricing. The above accentuates the importance of ensuring generic manufactures can enter the market once a product has come off patent and is able to expand in the market to offer consumers competitive prices.

BARRIERS TO ENTRY AND EXPANSION

83. The production of medicines in South Africa has been declining since the 1990's

with several pharmaceutical manufacturing plants closing resulting in significant job losses. The declining industry can be attributed to various reasons such as the MNEs preferring to concentrate production at “centres of excellence” elsewhere, involving large, lower-cost units benefiting from economies of scale and serving global markets.⁴⁸ The barriers to entry and expansion in the South African pharmaceutical manufacturing may be deterring firms from setting up manufacturing facilities in South Africa. The section below identifies some of the main barriers to entry and expansion in the South African pharmaceutical manufacturing sector.

LACK OF LOCAL API PRODUCTION

84. There is limited API production in South Africa which can be attributed to the small size of the South African market which will not generate the economics of scale needed to produce high volumes at low cost.⁴⁹ Effectively, South Africa does not offer the volumes for greater investment to justify the expense of establishing an API plant as the volumes produced would have to be larger than the local demand to make such a facility economically viable. More importantly, APIs can be purchased cheaper in the international market therefore manufacturers rather import the API then produce it locally.⁵⁰
85. API production is quite limited in South Africa. Currently South Africa only has four API manufacturers, BBI Enzymes SA (Pty) Limited, Chemical Process Technologies Pharma (Pty) Ltd, Fine Chemical Corporation (FCC) and LACSA (Pty) Ltd. South African CPT Pharma, a recent entrant was granted a licence by the SAHPRA to manufacture APIs for human medicine on 28 August 2020. BBI Enzymes SA is a

⁴⁸ C Roy Horner, *Global value chains, import orientation, and the state: South Africa's pharmaceutical industry*, *Journal of International Business Policy* (2022) 5, 68–87.

⁴⁹ Roy Horner, *Global value chains, import orientation, and the state: South Africa's pharmaceutical industry*, *Journal of International Business Policy* (2022) 5, 68–87.

⁵⁰ Roy Horner, *Global value chains, import orientation, and the state: South Africa's pharmaceutical industry*, *Journal of International Business Policy* (2022) 5, 68–87.

⁴⁶ European Commission, *Patent costs and impact on innovation*, December 2014.

⁴⁷ https://www.cipc.co.za/?page_id=4080.

UK company that converts raw materials from animal and plant sources to produce high-quality diagnostic and pharmaceutical enzymes. FCC is a subsidiary of Aspen that is supplier of narcotic APIs in South Africa, which include codeine phosphate, codeine hydrochloride, morphine sulphate, morphine hydrochloride, pholcodine and fentanyl, which are used as inputs in the manufacturing of pharmaceutical products. Fine Chemicals also supplies non-narcotic APIs which include paracetamol powder, scopolamine N butyl bromide and azathioprine. LACSA produces Lactulose which is a synthetic non-calorific disaccharide which is used as a laxative and in the treatment of hepatic encephalopathy. Of the four API manufacturers, there are two local firms and CPT is yet to produce API's. Notably, there is no API production for the most prevalent diseases in South Africa.

86. With limited API production in South Africa, manufacturers are reliant on imports to produce the medicines. There are various concerns when importing an API into the country, for example, the imported APIs are subject to varying exchange rates which creates price uncertainty for the medicines. Also, since the APIs are imported, they are incurring additional costs such as logistic and freight costs which further increases the price for the API. Lastly, there may be supply and distribution issues when importing APIs into the country which may negatively impact the supply of the medicine. Considering the above, this may adversely affect the ability of local generic manufactures to effectively compete due to the increase costs of importing the API and the potential supply disruptions.

HIGH COST OF PRODUCTION

87. There are high various costs associated with producing medicines in South Africa. A significant amount of capital is required to set up a manufacturing facility to produce the medicines.⁵¹ The cost of the equipment in the pharmaceutical manufacturing is also high (glass lined vessels, valves, instruments, purification units, etc) due to the lack of local engineering and manufacturing capabilities.⁵² Foreign companies have pointed out that the costs of producing in South Africa is high due to the high input

costs such as water, electricity, and labour so they rather make the product abroad and import into South Africa which is more cost effective.⁵³ Since medicines can be imported at a cheaper price than produced locally this may discourage firms from setting up local production facilities to manufacture medicines in South Africa.

LACK OF RELEVANT SKILLS

88. The South African Government has identified that the skills shortage and the costs of specialised skills creates a barrier to entry in the pharmaceutical manufacturing market. The pharmaceutical manufacturing industry requires a unique and specific set of skills for the formulation of the medicine and the production of APIs. Currently, the local universities do not have the capacity to produce the pharmacist with the necessary skills to operate at a manufacturing level. Therefore, due to the lack of local skills and the high cost of labour in South Africa, the local manufacturers tend to import the skills from India to train the South African pharmacists.⁵⁴
89. There is also a shortage of process and project engineers & construction companies experienced in building an API plant.⁵⁵ If South Africa plans to build more API plants it would need to import the skills of chemical engineers from China and India.⁵⁶ The lack of relevant skills in the pharmaceutical manufacturing industry adversely affects the ability of local generic firm to compete effectively since without the specific set of skills required to operate in a pharmaceutical production environment, it would be extremely challenging to produce medicines locally.

⁵³ S.C. te W. Naude and J.M. Luiz, *An industry analysis of pharmaceutical production in South Africa* S.Afr.J.Bus.Manage.2013,44(1). Afr.J.Bus.Manage.2013,44(1).

⁵⁴ Parliamentary Monitoring Group. *Pharmaceutical Industry: Department of Health & DTI briefing*. 28 June 2017.

⁵⁵ Roy Horner, *Global value chains, import orientation, and the state: South Africa's pharmaceutical industry*, *Journal of International Business Policy* (2022) 5, 68–87.

⁵⁶ Parliamentary Monitoring Group. *Pharmaceutical Industry: Department of Health & DTI briefing*. 28 June 2017.

⁵¹ Parliamentary Monitoring Group. *Pharmaceutical Industry: Department of Health & DTI briefing*. 28 June 2017.

⁵² Roy Horner, *Global value chains, import orientation, and the state: South Africa's pharmaceutical industry*, *Journal of International Business Policy* (2022) 5, 68–87.

REGISTRATION PROCESS

90. The current timeframe for the registration of medicines in South Africa is 350 calendar days for fast track, 590 calendar days for NCEs and 250 calendar days for generics. This is higher than the United Kingdom's ("UK") registration process for new active substances and biosimilar products and existing active substances which takes a total of 150 days with an intervening clock-off period between phase I and phase II. The assessment of phase I is completed 80 days after the clock starts and issues arising or requiring clarification from the initial assessment will be raised with the applicant and should be addressed within the clock off period of 60 days.⁵⁷ Similarly, in the United States ("US"), the Food Drug Administration ("FDA") has a shorter timeframe for the registration of medicines. The goal for a standard review is 10 months and six months for a Priority Review. Priority Review is for drugs that offer major advances in treatment or provide a treatment where none existed.⁵⁸ Compared to the US and UK, South Africa's registration process is longer which implies that the current registration timeframes could potentially cause manufacturers to lose market share to other suppliers in the market that have registered their product in the market.
91. Considering the above, the South African pharmaceutical manufacturing sector faces various significant barriers to entry and expansion that hinder the development and growth of the domestic market.

INSIGHTS AND CONCLUSION

92. In South Africa there is a strong emphasis on providing affordable and accessible medicines to all citizens. The South African legislative and regulatory framework encourages the increased use of generics to increase access and affordability of medicines in South Africa. Furthermore, the South African Government has recognized the importance of developing the local pharmaceutical manufacturing industry to provide all citizens with affordable medicines as well as improve the security of supply of medicines.

93. The South African pharmaceutical sector is highly regulated and governed by various legislative and regulatory policies including the Medicines and Related Substances Act 101 of 1965, Patent Act of 1978, the Public Finance Management Act (1999) and the Competition Act of 1998. The regulatory compliance brought about by the various legislation do not appear to be onerous. Notably, a significant change to the regulation is the timeframe to register the medicines that are in backlog. The purpose of this change was to improve on the timeline for the registration process and reduce the backlog of the registration of medicines. However, this has only been applied to new chemical entity (new product) registrations and not generics or the fast-track registration process.
94. To gain a better understanding of the level of medicine expenditure in South Africa, the study assessed the medicine expenditure in both the public and private sector over time and compared the expenditure between the public and private sector. While the public sector serves the majority of South Africans its pharmaceutical expenditure is significantly less compared to the private sector. In the public sector, medicine expenditure represents between 7%-9% of total public expenditure while in the private sector, medicine expenditure represents a higher percentage (16%) of total private healthcare expenditure.
95. It has been well documented that generics are usually priced lower than branded medicines providing consumers with affordable medicines. The results from this study confirm this view, demonstrating that the presence of generics (whether branded generics owned by the originator manufacturer or made by generic manufacturer) leads to price competition in the supply of medicines. This observation holds even in instances where there is only a limited number of generics. Moreover, the assessment showed that a higher number of generics suppliers is associated with higher price differences where generics are cheaper compared to originator products. Therefore, multiple generic entry simulates price competition which benefits consumers in the form of lower priced medicines. This is even more pertinent for the consumers in the private healthcare sector who do not enjoy the benefit of the procurement scale efficiencies realised in the public sector. Lastly, the analysis demonstrated that there

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<https://www.gov.uk/guidance/guidance-on-150-day-assessment-for-national-applications-for-medicines#assessment>.

58

<https://www.fda.gov/drugs/special-features/frequently-asked-questions-about-fda-drug-approval-process#2>.

are significant price differences between the private and public sector, with the public sector enjoying more favourable pricing.

96. Given the importance of generic entry to consumers it is imperative to develop the local manufacturing sector. Overall, the South African pharmaceutical market consists of large multinationals, established local multinationals, emerging companies, and many small vendors. The delineation of the pharmaceutical sector by prescription, OTC, and non-scheduled shows that most of the top five companies in the market feature across the segments, with two local companies constituting the top five (Adcock and Aspen). Further, the sector faces various significant barriers to entry and expansion that hinder its development locally. Even if a firm can set up a manufacturing facility, there are various production costs that are quite significant which may prevent a firm from expanding in the market.
97. South Africa is one of the few countries on the African continent that manufacturers medicines with about 14 manufacturers active locally. Notably, a common feature across these manufacturers is that they are involved at different levels of the supply chain, have a portfolio of products including complementary segments such as wellness, cosmetic, vitamins etc. This may suggest that a firm may have to be active at different levels of the supply chain and/or operational in complementary markets to generate sufficient economies of scale and/or scope to be sustainable in the pharmaceutical sector.
98. The foregoing notwithstanding, South Africa imports most of the medicine ingredients including APIs. Currently South Africa only has four API manufacturers although one is still yet to produce API's. It is noteworthy that there is no local API production for the most prevalent diseases in South Africa. The importation of medicine ingredients, particularly APIs, has significant implication for the affordability and accessibility of medicines. This is because imported products are subject to varying exchange rates which creates price uncertainty for the medicines. This is particularly concerning for APIs given that they represent one of the highest cost components for medicines. Also, since the medicines ingredients are imported, they are incurring additional costs such as logistic and freight costs which further increases the price for the medicines. Lastly, imported medicine ingredients are also prone to global supply and distribution

challenges and this adversely affects the accessibility of medicines in South Africa. As a result of the challenges, the South African public sector has been known to experience persistent stock shortages of medicines.

99. Considering the above, it is evident that there are significant price benefits derived from the use of generics. An increase in the number of generic entrants simulates price competition which benefits consumers in the form of lower priced medicines. This accentuates the need to support, invest and develop the local API and generic manufacturing sector to improve the affordability, supply, and variety of medicines in South Africa. The development of the local generic manufacturing sector will also mitigate the price uncertainty and stockouts associated with the substantial number of medicines ingredients that are imported into the country. This may result in a reduction in the medicine expenditure for both the public and private sector, which is imperative given the high burden of disease in South Africa. Therefore, the development of a diverse and purposeful generic pharmaceutical manufacturing industry in South Africa is crucial to improving the health status of individuals as well as the overall socioeconomic development of the country.



A hand wearing a white nitrile glove holds a rectangular microarray chip. The chip features a grid of 10 numbered wells (1-10) arranged in two columns of five. Each well contains a small, dark, rectangular sample. The background is a blurred laboratory setting with a person in a white lab coat and mask visible on the right. A network diagram with interconnected circles is overlaid on the left side of the image.

ZAMBIA

THE ZAMBIA CHAPTER

OVERVIEW OF THE HEALTH SECTOR

1. Zambia has a well-developed private and public health care system which provides specialized medical services including diagnostic and curative services¹. The healthcare system in Zambia is run by state and non-state actors, which include Non-Governmental Organizations (NGOs) and Faith Based Organizations (FBO)². Although the government is responsible for setting policy and provision of care, non- governmental and faith-based organizations play a major role in the provision of healthcare in Zambia³. Church-affiliated facilities are common and are well integrated into the government system in terms of service delivery practices and reporting⁴.
2. Medical care in Zambia was largely made free or heavily subsidized at primary level, though the country introduced the Universal Health Insurance scheme through the National Health Insurance Act, 2018⁵ to improve quality of care. Zambia continues to suffer from malaria and the HIV & AIDS epidemic, as well as a significant growth in non-communicable diseases.

REGULATORY FRAMEWORK

3. Regulation is the management of complex systems according to a set of rules and trends used by the state to coerce change in both individual and organizational behaviors in the health delivery system⁶. The Zambian generic medicine regulatory system includes institutions and legislation as follows:

1 Health Sector Profile; Zambia Development Agency (ZDA), June 2013. Retrieved 29th December 2021.
2 COUNTRY PROFILE: ZAMBIA - The Center for Health Market <https://healthmarketinnovations.org/default/files>
3 National Health in All Policies Strategic Framework 2017-2021, 2018 MoH, Zambia. <https://www.afro.who.int/sites/default/files/201905/NATION-AL%20HEALTH%20IN%20ALL%20POLICIES%20%20STRATEGIC%20FRAMEWORK%20%20%283%29.pdf>. Retrieved 4th January 2022
4 2014 Zambia Malaria Concept Note (link is external) (link is external) for the Global Fund
5 <https://www.nhima.co.zm>
6 McGivern, Gerry; Fischer, Michael Daniel (1 February 2012). "Reactivity and reactions to regulatory transparency in medicine, psychotherapy and counselling" (PDF). *Social Science & Medicine*. 74 (3): 289–296. doi:10.1016/j.socscimed.2011.09.035. PMID 22104085.

MINISTRY OF HEALTH (MOH)

4. The Ministry of Health (MoH) is the superintendent of the health system in Zambia and provides information about health and delivery of health services⁷. The MoH has the ultimate responsibility for delivery of health care services within Zambia⁸. Leadership within the health system includes setting priorities and an overall vision and direction for the health system⁹. The MoH is additionally responsible for health policy formulation and oversees referral of health services from Level 2 provincial hospitals up to Level 3 tertiary hospitals, health training institutions and health statutory boards¹⁰.

ZAMBIA MEDICINES REGULATORY AUTHORITY (ZAMRA)

5. The Zambia Medicines Regulatory Authority is the Statutory Body established under an Act of Parliament; the Medicines and Allied Substances Act No. 3 of 2013 to regulate and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances¹¹. The Authority is mandated to ensure that pharmaceutical products being made available to the Zambian people consistently meet the required standards of quality, safety and efficacy throughout the manufacturing, importation/exportation, distribution, storage and supply and that only qualified persons carry out relevant pharmaceutical practices¹².

7 "Ministry of Health". moh.gov.zm. Retrieved 5th January 2022.
8 "Ministry of Health". www.moh.zm. Archived from the original on 28 July 2015. Retrieved 5th January 2022.
9 <https://ab-network.jp/wp-content/uploads/2014/07/Health-Sector-Profile.pdf>
10 World Health Organization (WHO). (2014, August 03). Country Corporation Strategy: Zambia. Retrieved from World Health Organization: http://www.who.int/countryfocus/cooperation_strategy
11 <https://ab-network.jp/wp-content/uploads/2014/07/Health-Sector-Profile.pdf>
12 Zambia Medicines Regulatory Authority (ZAMRA). <https://www.zamra.co.zm>

ZAMBIA MEDICINES AND MEDICAL SUPPLIES AGENCY (ZAMMSA)

6. Zambia Medicine and Medical Supplies Agency (ZAMMSA) formerly known as Medical Stores Limited (MSL) is another autonomous government agency established by an act of Parliament with the express objective of making available good quality drugs and medical equipment at accessible prices¹³. ZAMMSA is responsible for ensuring continuous distribution of pharmaceutical products in a financially viable and sustainable manner. In addition, ZAMMSA distributes drugs to various public and private institutions around the country¹⁴. ZAMMSA was established under the Companies Act (current 1999)¹⁵. The Company's original mandate was to carry out procurement, storage and distribution of all essential drugs for Zambia's public health sector¹⁶.

THE PATENT AND COMPANY REGISTRATION AGENCY (PACRA)

7. The Patent and Company Registration Agency (PACRA) is an agency of the Government under the Ministry of Commerce, Trade, and Industry. The Agency is responsible, among other things, for the registration and enforcement of patent rights. Zambia recently reviewed its patent law to align with international best practice and provides for a patent period of 20 years, exhaustion of rights and compulsory licensing.

COMPETITION AND CONSUMER PROTECTION COMMISSION

8. Competition and Consumer Protection Commission (Commission) is responsible for the enforcement of the Competition and Consumer Protection Act No. 24 of 2010. The Commission is an agency of the Ministry of Commerce, Trade and Industry and is responsible for ensuring fair competition in the market including the pharmaceuticals as well as consumer protection.

¹³ https://www.parliament.gov.zm/sites/default/files/documents/committee_reports/REPORT%20ON%20HEALTH%20-%202021_0.pdf

¹⁴ <https://www.zamra.co.zm/wp-content/uploads/2021/02/ZAMBIA-PHARMACOVIGILANCE-Handbook-March-2020.pdf>

¹⁵ *Ibid* 39

¹⁶ *Ibid* 40

ZAMBIA PUBLIC PROCUREMENT AUTHORITY

9. Zambia Public Procurement Authority (ZPPA) is responsible for policy regulation, standard setting, compliance and performance monitoring, professional development and information management and dissemination in the field of public procurement¹⁷. The ZPPA has recently through the deployment of monthly price indices (MPIs) based on the revised Zambia Public Procurement Act 2021 sought to provide benchmarks for prices of various goods and services to protect Government from over pricing¹⁸.

PROCUREMENT OF MEDICINES IN ZAMBIA

10. Before the 1970s, the procurement and supply of essential medicines and medical supplies in Zambia had been a key concern within the health sector. Several substantial changes over the years have been made to improve the availability and supply of essential medicines and medical supplies. These interventions include reforms at the central level related to the management of the procurement, storage and distribution functions, the development and adoption of new commodity management systems and service delivery sites¹⁹.

¹⁷

<https://www.zppa.org.zm/public-procurement-act>

¹⁸ *Ibid* 31

¹⁹ <https://www.devex.com/organizations/medical-stores-ltd-98363>

11. Effective procurement and distribution of essential medicines and medical supplies is critical for maintaining the health of Zambia's citizens²⁰. Zambia has a three-tier public sector procurement and distribution system of essential drugs. Before the reforms, procurement was done by the Ministry of Health (MOH), while primary distribution of drugs and other health commodities was managed by a parastatal agency called Medical Stores Limited (MSL)²¹. Secondary distribution fell under the responsibility of District Health Management Teams (DHMTs) reporting to the MOH²². The MSL hubs functioned as 'cross docking' hubs where orders from facilities across Zambia were assembled from the central MSL and transported to regional hubs and then transported to respective facilities²³.
12. In 2012, the Ministry of Health delegated the provision and management of procurement and supply chain services for essential medicines and medical supplies to MSL. Among the key developments was the assumption of procurement services by MSL and the provision of supply services directly to the health facilities, rather than up to the district stores. This new mandate is underpinned in the National Supply Chain Strategic Plan (2015-2017)²⁴.
13. Further reforms included the enactment of the Zambia Medicines and Medical Supplies Agency Act No. 9 of 2019 meant to provide for an efficient and cost-effective system for the procurement, storage and distribution of medicines and medical supplies and to transform the Medical Stores Limited to Zambia Medicines and Medical Supplies Agency²⁵. Effectively, all procurement, management and distribution of essential medicines and medical supplies are now the preserve of the Zambia Medicines and Medical Supplies Agency.

20 <https://www.usaid.gov/zambia/fact-sheets/usaidzambia-health-office-global-health-supply-chain-procurement-and>

21 Medical Stores Limited (MSL) is an autonomous government agency established by an act of Parliament with the express objective of furnishing to the nation good quality drugs and medical equipment at accessible prices, made available through approved government and non-government agencies throughout Zambia.

22 Monique Vledder, Jed Friedman, Mirja Sjöblom, Thomas Brown & Prashant Yadav (2019) Improving Supply Chain for Essential Drugs in Low-Income Countries: Results from a Large Scale Randomized Experiment in Zambia, *Health Systems & Reform*, 5:2, 158-177, DOI: 10.1080/23288604.2019.1596050

23 <https://www.medstore.co.zm/services-4/distribution/>

24 <https://www.idc.co.zm/industry-sectors/health-care-2/medical-stores-limited/>

25 <https://www.parliament.gov.zm/node/8205>

GOVERNMENT EXPENDITURE

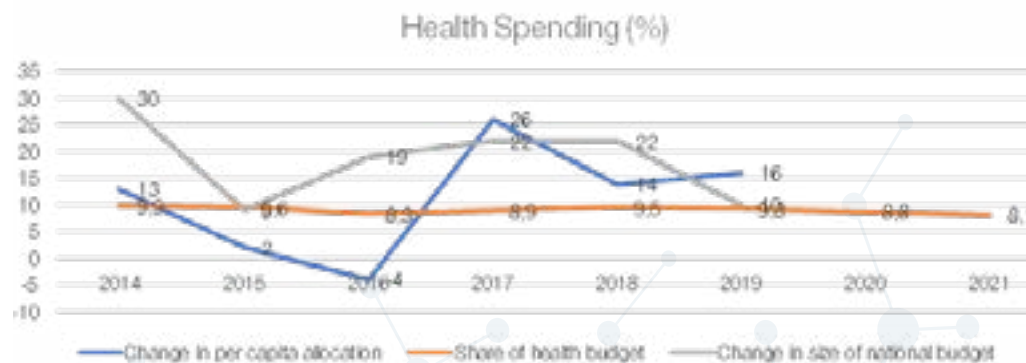
14. Zambia's Public Budget system has undergone substantial changes. Most notable, from the period 1991 to the 2000's. Before 2004, the 'incremental' line budgeting system was implemented. After 2004, the country shifted from the first-generation budget reforms to Activity Based Budgeting (ABB) which focused on activities and programmes in government departments. In 2021, the country further shifted to Output Based Budgeting (OBB) which is more results oriented²⁶.
15. Over the past 8 years, government expenditure on essential medicines has been dependent on the budgetary allocations. Budgetary allocations as a percentage of the total budget have been around 9.5%. In 2019, Zambia was reported to be spending less than its regional peers on a per capita basis. For example, the 2019 expenditure at \$57 was lower compared to \$86 for Lesotho and \$221 for Swaziland. Household expenditure accounted for 31% of overall expenditure, while government expenditure was 69 % of overall spending. While changes in the national budget have been around 19% from 2014 to 2021, changes in the health budget have only been around 9.5% with an average change in per capita allocation of 11%²⁷.
16. The MoH buys essential medicines and medical supplies through framework contracting, with the goal of ensuring a guaranteed and uninterrupted supply of the commodities. Through a competitive bidding process, suppliers receive two-year procurement contracts. During this period, contracts lock in prices of essential drugs and medicines. Adjustments can occur only after an extension of the initial contract. Although nominal budgetary allocations for essential drugs increased from an average of 8% between 2010-2012 to an average of 14% between 2013 and 2015, the depreciation of the Kwacha against the US dollar by more than 40% reduced the real value of the allocation. This decrease in real value reduced the quantity of imported drugs and medical supplies from a given budget allocation while the debt service on purchased products increases²⁸.

26 <https://transectscience.org/the-zambian-public-budget-system-has-under-gone-significant-transformations/>

27 <https://www.pwc.com/zm/en/assets/pdf/zambia-budget-2018.pdf>

28 Source: Republic of Zambia Ministry of Health - Health Financing Strategy: 2017 – 2027

Figure 18 - Health Spending

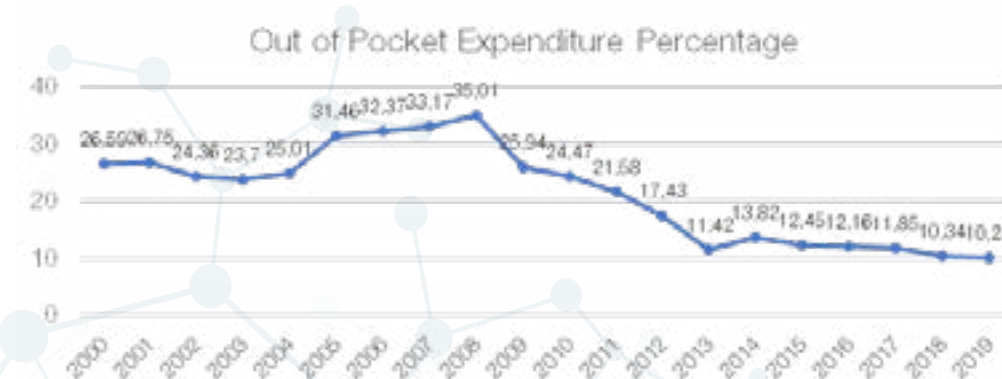


OOP EXPENDITURE ON HEALTH

17. OOP expenditure on health is considered as an inequitable source of health spending. It has remained a significant source of health expenditure in Zambia. Evidence shows that 20% of households pay using OOP to access public health services. However, the burden of paying OOP is still great for secondary health services, mostly at hospital level. The largest expenditure items for OOP spending are drugs at 42%, consultations at 26%, other costs at 17%, and transport/food at 7%. In addition, OOP payments are significantly higher for individuals in urban areas, who spend twice the amount spent in the rural areas. Nearly 70% of OOP spending is on non-communicable diseases (NCDs)³⁰.

29 Ibid77

Figure 19 - OOP Expenditure Percentage

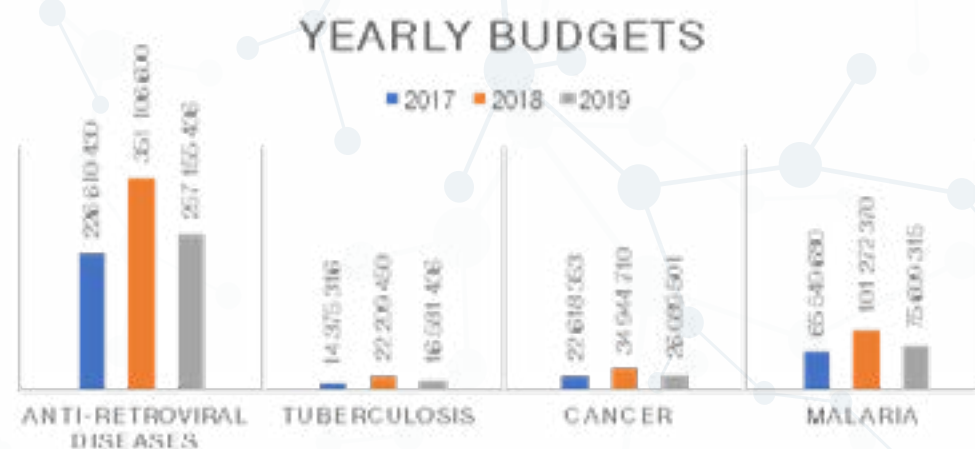


PROCUREMENT OF DRUGS

18. Procurement towards anti-retroviral drugs increased by 35.5% from 2017 to 2018 before seeing a decline of 36.5% in 2018 to 2019. Medicines for TB, Cancer and Malaria equally saw an increase from 2017 to 2018 before a decline in 2018 to 2019³¹. In 2022 the annual budget towards essential drugs and medical supplies procurement was K1.1 billion, a 36.2% increment from K718 million for 2021³¹.

30 2017 to 2019 yellow books
31 <https://www.parliament.gov.zm/node/9885>

Figure 20 - Procurement of drugs



19. Procurement of medicines and medical supplies has equally seen a fair share of support from co-operating partners such as the USAID, Swedish International Development Cooperation Agency (SIDA), European Union (EU), WHO, United Nations International Children's Emergency Fund (UNICEF), World Bank (WB), Global Fund, Japan International Cooperation Agency (JICA), Irish government, United Nations Development Programme (UNDP), United Nations Capital Development Fund (UNCDF) and Department for International Development (DFID). In 2022 Zambia received grants amounting K 640 million, 66.4% increase from the K215, million received in 2021 for the procurement of medicines and medical supplies³².

ZAMBIA DISEASE BURDEN

20. The Government of the Republic of Zambia has placed priority on ensuring that Zambians are healthy and productive as a catalyst to the attainment of socioeconomic development. However, this aspiration is threatened by the double burden of Communicable and Non-Communicable Diseases. Zambia has been recording an increase in morbidity and mortality due to Non-Communicable Diseases (NCDs) such as cancers, diabetes, chronic respiratory and cardiovascular diseases.
21. The disease burden in Zambia varies according to region with the most prevailing diseases being Malaria, HIV & AIDS, TB, Diarrhoea and Lower Respiratory tract infections³³. Recently, Zambia has seen a sudden increase in non-communicable disease (NCDs) such as Hypertension, Diabetes, Chronic respiratory disease, cardiovascular disease, and Cancer (cervical)³⁴.
22. Data indicate that 29%³⁵ of all deaths in Zambia are attributed to NCDs. This is high,

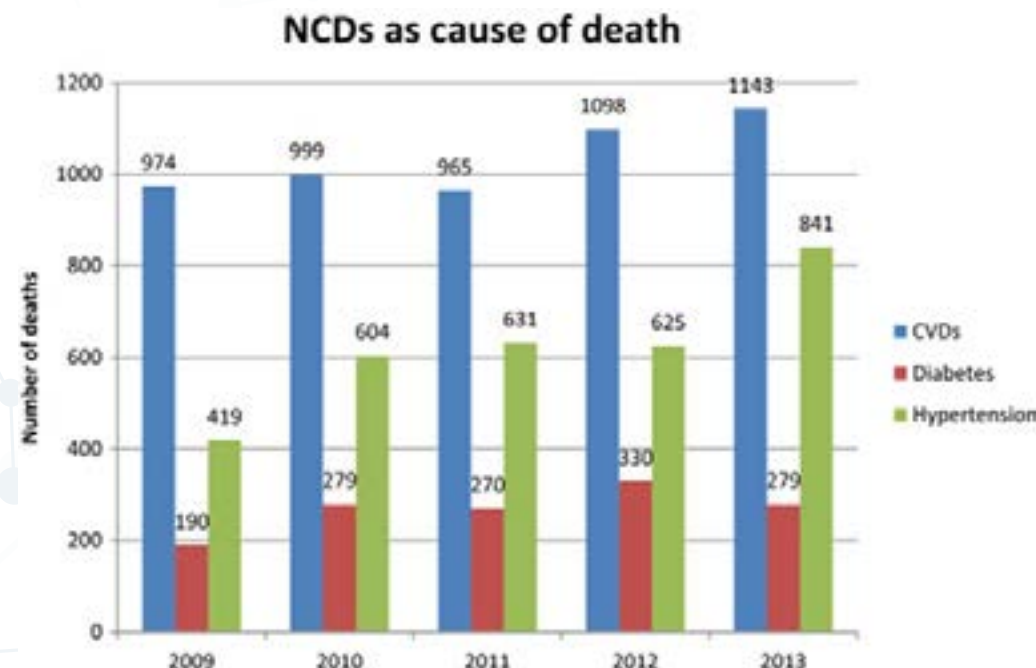
³² Ibid70

³³ *Zambian Strategic Plan 2013-2016, Non – Communicable Diseases and their risk factors, version 1. Page 10.* https://www.iccp-portal.org/system/files/plans/ZMB_B3_NCDs%20Strategic%20plan.pdf. Retrieved 5th January 2022

³⁴ *Health Sector Profile; Zambia Development Agency (ZDA), June 2013. Retrieved 29th December 2021.*

³⁵ 2016 WHO NCD country profiles,

Figure 21 - NCDs as cause of death



considering that most of these diseases can be reduced by modifying four main behavioural risk factors for NCDs which are tobacco use, harmful use of alcohol, unhealthy diets and physical inactivity³⁶.

COMMUNICABLE DISEASES (CDS)

23. A communicable disease is defined as an illness that arises from transmission of an infectious agent or its toxic product from an infected person, animal, or reservoir to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector or environment³⁷. Communicable diseases can cause epidemics and pandemics which have the potential to overwhelm the capacity of communities; with serious health and socio- economic consequences³⁸. There are five main

³⁶ <https://www.afro.who.int/publications/prevention-and-control-non-communicable-diseases-zambia-case-investment>

³⁷ *Fighting the Top Diseases in Zambia Through Collaboration:* <https://borgenproject.org/fighting-top-diseases-in-zambia/> Retrieved 5th January 2022

³⁸ *Health Emergency and Disaster Risk Management Communicable diseases: Health Emergency and Disaster Risk Management Fact Sheets: Decem-*

Communicable diseases of public health interest in Zambia: malaria, HIV and AIDS, Diarrhoea, Lower Respiratory disease and TB³⁹.

NON-COMMUNICABLE DISEASES

24. Non-communicable diseases (NCDs) have been traditionally defined as chronic diseases that were non-infectious by nature⁴⁰. Non-Communicable diseases (NCDs) are diseases of long duration and generally slow in progression. The main types of non-communicable diseases are cardiovascular diseases (CVDs) (heart attacks, Hypertension and stroke), cancer, chronic respiratory diseases (such as chronic obstructive pulmonary disease and asthma) and diabetes⁴¹. There has been growing concern over NCDs particularly in low and middle-income countries like Zambia as they contributed significantly to mortality and morbidity⁴². These diseases were prevalent in the productive age group of thirty to sixty years and contributed significantly to premature deaths in Zambia. This meant that an adult person in Zambia was, more than ever before, likely to die from an NCD⁴³. Figure 21 below illustrates the NCDs cause of death.
25. Non-Communicable Diseases, or NCDs, cost the Zambian economy an estimated 6 percent of its GDP every year. More than 90 percent of that economic burden stems from economic productivity losses as workers get sick and die prematurely of the four main NCDs – cardiovascular disease (CVD), cancers, diabetes, and Chronic Obstructive Pulmonary Disease (COPD). This NCD Investment Case report identifies 11 key evidence-based interventions that would deliver an economic Return on Investment (ROI) of 4:1 over 15 years, leading to significant economic growth, generate additional revenue and most importantly, reduce the morbidity and premature mortalities from these illnesses⁴⁴.

ber 2017. <https://www.who.int/nac/techguidance/preparedness/risk-management-communicable-diseases-december2017>. 4th January 2022

39 *Zambian strategic plan 2013-2016 non-communicable diseases and their risk factors. strategic plan 2013 to 2016 period prepared by the ministry of health: directorate of disease surveillance, control, and research non-communicable diseases unit, Ndeke house, Lusaka Zambia.*

40 *Zambia National Health Strategic Plan 2017-2021*

41 <https://www.afro.who.int/sites/default/files/2020-10/Zambia%20Investment%20Case.pdf>. Prevention and Control of Non-Communicable Disease in Zambia. The Case for Investment: 2019 Report by the Ministry of health. Page 3.

42 *Responding to Non-communicable Diseases in Zambia: a Policy Analysis: Mulenga M. Mukanu, Joseph Mumba Zulu, Chrispin Mweemba and Wilbrod Mutale* <https://health-policy-systems.biomedcentral.com/articles>

43 *WHO Country Profile: Zambia. (2016, June 9). Retrieved from World Health Organization: <http://www.who.int>*

44 *Ministry of Health Zambia - Prevention and control of non-communicable diseases in Zambia - The case for investment*

PHARMACEUTICAL PROFILE

26. Zambia has a total of sixty-seven (167) registered wholesalers of pharmaceutical products and ten (10) registered pharmaceutical manufacturers. The ten include Baxy Pharmaceuticals Manufacturing Company Limited, International Drug Company Limited, International Drug Company Limited Sterile Products Division, Kingphar Company Zambia Limited, NRB Pharma Zambia Limited, Pharmanova (Zambia) Limited, Yash Life Sciences Limited, Mylan Laboratories Limited, Missionpharma Zambia Limited and Yash Pharmaceuticals Limited⁴⁵.
27. It is estimated that the local production represents between 10-15% of the demand for pharmaceuticals in Zambia. There are no multinational pharmaceutical companies in the country. The current operating pharmaceutical companies can be categorized as Uni-national pharmaceutical companies⁴⁶. These companies mostly do the secondary production which is the formulation of bulk pharmaceuticals into various pharmaceutical dosage forms.
28. The local manufacturing of essential medicines in Zambia meets with manifold challenges related to internal dimensions of manufacturing and, the operating environment⁴⁷. The country's manufacturers of pharmaceutical products do not meet the WHO pre-qualification standards, which then limits their production and excludes them from participating in international public tenders⁴⁸. Also, because most developing countries do not have the capacity to invest in research and development (R&D), they therefore cannot innovate and produce lifesaving medication as shown in the recent case of the COVID-19 pandemic.

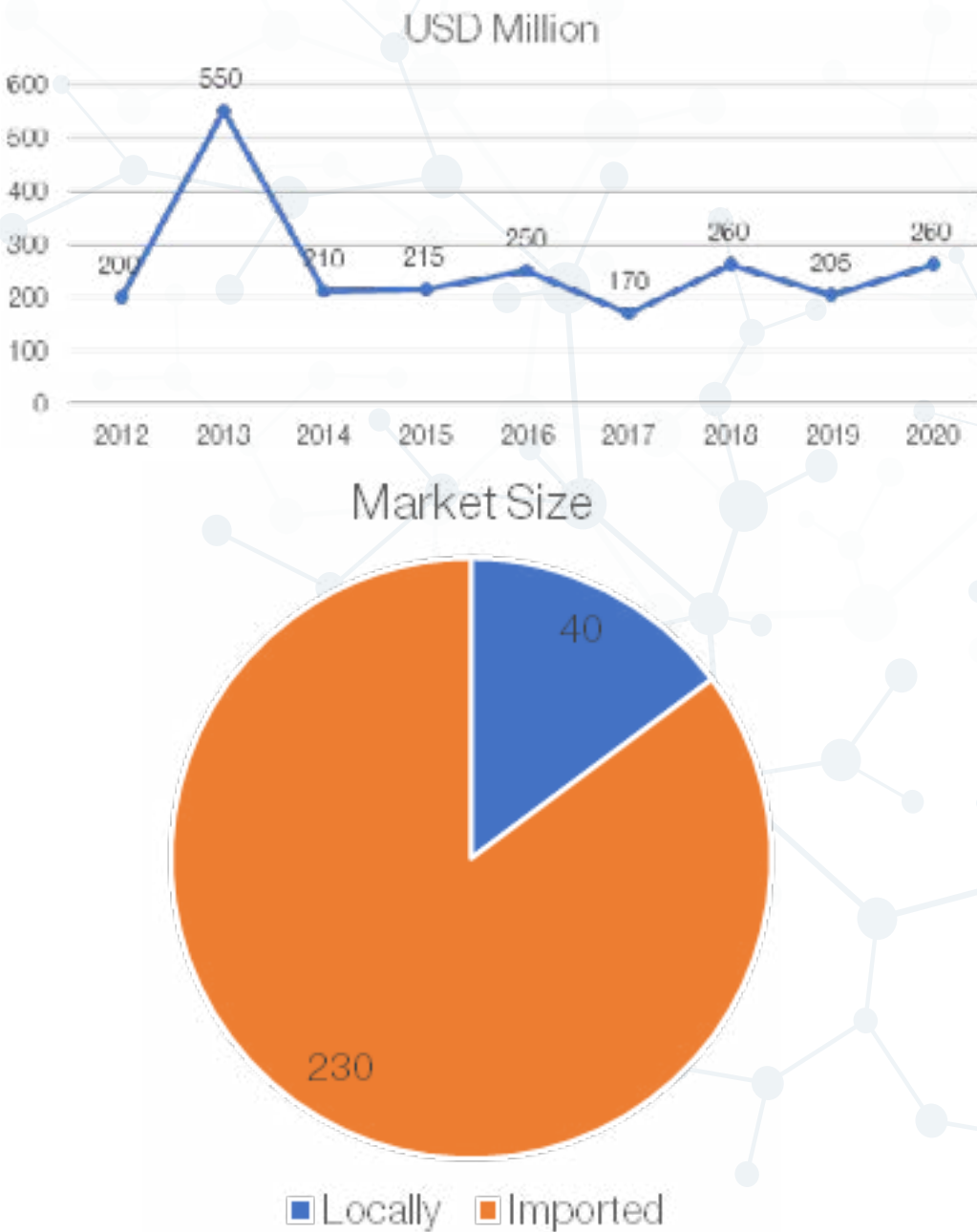
45 ZAMRA submission

46 <https://zambiatrade.work/top-7-importers-of-pharmaceutical-products-in-zambia/>

47 <https://www.cgdev.org/sites/default/files/Procurement-factsheet-generics-competition.pdf>

48 <https://joppp.biomedcentral.com/articles/10.1186/s40545-021-00337-4>

Figure 22 - Zambia's imports of pharmaceutical products 2012-2020 and percentages of Zambia's locally produced and imports pharmaceuticals.



29. Zambia's imports of pharmaceutical products were around US\$260.07 million during 2020⁴⁹ and averaged USD 258 million from 2012 to 2020. As of 2018, Zambia pharmaceuticals sector was approximately USD270 million with locally produced pharmaceuticals at USD40 million and imports at USD230 million at representing 85% of the market as shown below. Donor expenditure for public pharmaceuticals accounted for USD75 million with Non-Donor expenditure at USD105 million and private expenditure at USD90 million⁵⁰.

BARRIERS TO ENTRY AND EXPANSION

30. Zambia, like several other developing African countries is not able to produce most medications to supply its population and is largely dependent on medical imports. Several reasons exist as to why the manufacturing of pharmaceutical products poses a challenge. Zambia has limited capacity to invest in research and development (R&D) which affects the rate of innovation to produce lifesaving medication. Investment into state-of-the-art laboratories, research facilities and research personnel in Zambia's health sector has lagged and affected the level of patented innovations.
31. Zambia has remained one of the worst performers in innovation and ranked 122 out of 131 countries in terms of innovation⁵¹. The low levels of R&D therefore inhibit any level of collaboration with the pharmaceutical industry, whose role is to scale up and commercialize pharmaceutical products. Only 27 patent applications were lodged in 2020, out of which 9 were ultimately granted.⁵²
32. Another major challenge for manufacturing growth in the sector is the excise duty charged on raw materials and products in the pharmaceutical sector. There are no import duties on final pharmaceutical products that are imported into Zambia, disincentivizing local manufacturing. Therefore, trading and distribution become easier for Zambian pharmaceutical companies as they would rather import and

49 United Nations COMTRADE database on international trade <https://tradingeconomics.com/zambia/imports/pharmaceutical-products>
50 NRB Pharma Zambia Ltd., Zambia Company Presentation_01032018 Bonn.pdf. https://www.unido.org/sites/default/files/files/2018-03/NRB%20Pharma%20Zambia%20Ltd.%2C%20Zambia_Company%20Presentation_01032018%20Bonn.pdf
51 Global Innovative Index by the World Intellectual Property Organisation (WIPO),
52 Patents and Companies Registration Agency (PACRA) 2020 annual report,

distribute rather than manufacture locally⁵³.

33. Moreover, the lack of pharmaceutical product intellectual property registration in developing countries which increases production costs drastically and the concurrent huge capital, entails that in developing countries with small populations such as Zambia, recouping the investment from the domestic market alone may take time. A country like India, which has a huge population, has taken an advantage of this large market to establish a big pharmaceutical industry, whilst having strong export markets in several developing nations⁵⁴.

ZAMBIAN PATENT SYSTEM

34. Pharmaceuticals are much a product of invention which often requires extensive investment in research and development. The protection and promotion of such inventions and their use is largely a function of the intellectual property laws. The Zambian legislation is an Act of Parliament No.40 of 2016 which in part was enacted to conform to the TRIPS Agreement.
35. Despite Zambia having a law in place, there are no known local patent holders of pharmaceuticals including licensed manufacturers nor manufacturers who hold patents over pharmaceutical manufacturing in Zambia through the ARIPO mechanism as recognized by Section 63 of the Act.
36. Indications are that Zambia is largely an importer to a large extent of generic drugs. Section 76 of the Act recognize the exhaustion of right which in part explains the proliferation of players at wholesale and retail levels who specialize in import and distribution.

⁵³ http://zam.co.zm/propelling-big-pharmaceuticals-in-zambia/?utm_source=rss&utm_medium=rss&utm_campaign=propelling-big-pharmaceuticals-in-zambia

⁵⁴ http://zam.co.zm/propelling-big-pharmaceuticals-in-zambia/?utm_source=rss&utm_medium=rss&utm_campaign=propelling-big-pharmaceuticals-in-zambia

37. While instances of compulsory licensing have been limited with selected instances such as the compulsory licensing for the manufacture of antiretroviral drugs under the names Norvavir 30 and Norvarvir 40 patented drugs, Zambia has not exercised these measures. Nevertheless, Zambian law retains provisions for compulsory licensing specifically Sections 96-104 and the exploitation of patented inventions by Government under Section 105-108. These remain essential instruments in (i) promotion of local utilization of inventions to increase drug availability and increase competition and (ii) as a source of bargaining power during negotiations by Government.

WTO TRIPS AND HOW THEY HAVE MADE GENERIC DRUGS AVAILABLE

38. Drug availability and its alternatives determine the levels of competition for that drug. Zambia like many other African countries have intellectual laws that allow for compulsory licensing and exhaustion of rights. Under the World Trade Organization (WTO), the amendments to the intellectual property (TRIPS) agreement is meant to allow for compulsory licensing as part of the overall balance between promoting access to existing drugs and promoting research and development into new drugs⁵⁵. The Zambian Government, using this provision, granted a compulsory license No. CL 01/2001 to Parco Limited a company incorporated in Zambia to manufacture antiretroviral drugs under the names Norvavir 30 and Norvarvir 40 patented drugs. The Thailand and Brazil experience over the Efavirenz, an HIV drug owned by Merck⁵⁶ shows that while the use of compulsory licensing can make cheap drugs available to the public in competition to originator drugs, the same has the potential in the long run to deny such a country future new drug⁵⁷.
39. Besides compulsory licensing, parallel imports are applicable to a WTO member under the exhaustion of rights.

⁵⁵ https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm

⁵⁶ *Journal of International Business and Law*, Vol. 8, Iss. 1 [2009], Art. 9

⁵⁷ For example, Abbott Laboratories reacted to Thailand's actions by stating, "Thailand has revoked the patent on our medicine, ignoring the patent system. Under these circumstances we have elected not to introduce new medicines there."

PROMOTION OF PHARMACEUTICALS

40. While the use of compulsory licensing may serve to make available drugs in the short run, it has a potential to affect an innovation ecosystem. Expropriation of intellectual property rights leaves little incentive to invest in the risky, complex, difficult, and expensive process of innovating new products such as pharmaceuticals. A study of 642 new drug launches in 76 countries from 1983 to 2002 found that the speed and extent of drug diffusion was strongly associated with a countrys’ patent regimes. Countries moving to long product-patent terms reduced drug launch lag times by 55 percent⁵⁸.

COMPETITION ASSESSMENT

41. Zambia is among the 152 developing countries in the world⁵⁹. Developing countries account for a very small fraction of the global pharmaceutical market and the generation of income to fund more research and development is not dependent on profit from these markets⁶⁰. For a country where payment of pharmaceuticals is mainly “OOP” and health insurance is rare, escalating and unrealistic prices play a central role in denying access to patients of life-saving medicines⁶¹. Entry by generic pharmaceuticals can enhance competition in the drug market by offering more choice and by lowering drug prices to the benefit of health customers⁶².

42. Generic medicines have played an important role in curbing rising pharmaceutical costs and their cost-saving potential is significant as generic medicines provide both; a lower-priced option for patients and a tool to drive down prices of originator drugs⁶³. Price competition from generic medicines leads to price reductions. High generic market share countries have seen a larger decrease in medicine prices than low

market share countries⁶⁴. At the same time, innovation should be sustained, notably by allowing innovators to obtain intellectual property rights on their originator drugs. Competition concerns however, have been seen to arise when originator companies use their intellectual property rights to delay or to prevent the entry of generics into the market⁶⁵.

ZAMBIAN PHARMACEUTICAL MARKET

43. Zambia has 167 registered wholesalers as well as ten (10) manufacturers of pharmaceutical products with no multinational pharmaceutical companies. The ten currently operate as Uni-national pharmaceutical companies⁶⁶. These companies mostly do secondary production which is the formulation of bulk pharmaceuticals into various pharmaceutical dosage forms⁶⁷. Table 1 below shows the registered manufacturers and their product range.

Table 23 - Range of products made in Zambia

Name of Manufacturer	Product Range
Baxy Pharmaceuticals Manufacturing Company Limited	Antibiotics, Anti-malaria’s, inti-hypertensives, analgesics/ antipyretics, sedatives
International Drug Company Limited	Antibiotics, Anti-protozoals, analgesics/antipyretics including NSAIDS, Antihistamines, Expectorants, cough syrups
International Drug Company Limited Sterile Products Division	Parenterals: Fluid volume replacement and nutrition component products, electrolyte replenishment products.
Kingphar Company Zambia Limited	Antibiotics, Oral rehydration Therapy (Fluid, electrolyte and Acid- Base correction products), antipyretics/ analgesics, anti-protozoals
NRB Pharma Zambia Limited	Antipneumocytosis and antitoxphasmosis, antibiotics, anti-protozoals, antacids, anti-malarial, ovulation inducers, antihistamines, anti-asthmatic, anti-tuberculosis

58 <https://itif.org/publications/2018/08/24/spread-compulsory-licenses-threatens-undermine-latin-americas-innovation>
59 <https://www.worlddata.info/developing-countries.php>
60 <https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf>
61 <https://www.who.int/medicines/areas/policy/AccessToMedicinesIPP.pdf>
62 <https://pubmed.ncbi.nlm.nih.gov/21797288/>
63 <https://www.oecd.org/competition/generic-pharmaceuticals-competition.htm>

64 <https://pharmaceutical-journal.com/article/news/market-competition-a-predictor-of-changes-in-generic-drug-prices-concludes-us-study>
65 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7540181/>
66 Cardino Shaping Future Report (2011:11)
67 Management Science for Health (1997:47)

Name of Manufacturer	Product Range
Pharmanova (Zambia) Limited	Analgesics including NSAIDS, antipyretics, laxatives, cough syrups, anyacids, antibiotics, antifungals, anti-malarials, cough expectorants, oral rehydration therapy (Fluid, Electrolyte and Acid-Base Correction products), Anthelmintics, Antihistamines, Dietary Supplements.
Yash Life Sciences Limited	Antibiotics, Antiprotozoals, analgesics/antipyretics including NSAIDS, Vitamins (B-Complex, Folic Acid, Pyridoxine, Ascorbic Acid) Anti-asthmatic (Salbutamol), Anti-malaria's, Antacids, Anti-diarrhoeal, Cough medication, Antiseptics
Mylan Laboratories Limited	Anti-retroviral, Anti-malaria's
Missionpharma Zambia Limited	Health Kits (Psychotropics, Beta-Lactams, Cephalosporins, Anti-Cancer, Anti-Malarials, Anti-TB, Anti-Retroviral)
Yash Pharmaceuticals Limited	Oral Contraceptives (safe plan), contraceptives (Male latex condoms)

Source: ZAMRA's submission

EFFECTS OF PRICE ON GENERIC DRUGS

44. A generic drug is created to be the same as an existing approved brand-name drug in dosage form, safety, strength, method of administration, quality, and performance characteristics⁶⁸. Generic medications, like branded drugs, require generic market competition before costs decline; two to three years after losing exclusivity protection. Generic drug prices typically fall by 60–70 percent relative to their branded counterparts⁶⁹. Even for very old unpatented pharmaceuticals, sustained market competition is required to keep prices down.
45. Data collected from various pharmacies and dispensing shops showed that about 83% of the drugs on the market were generic with 17% being originator drugs.

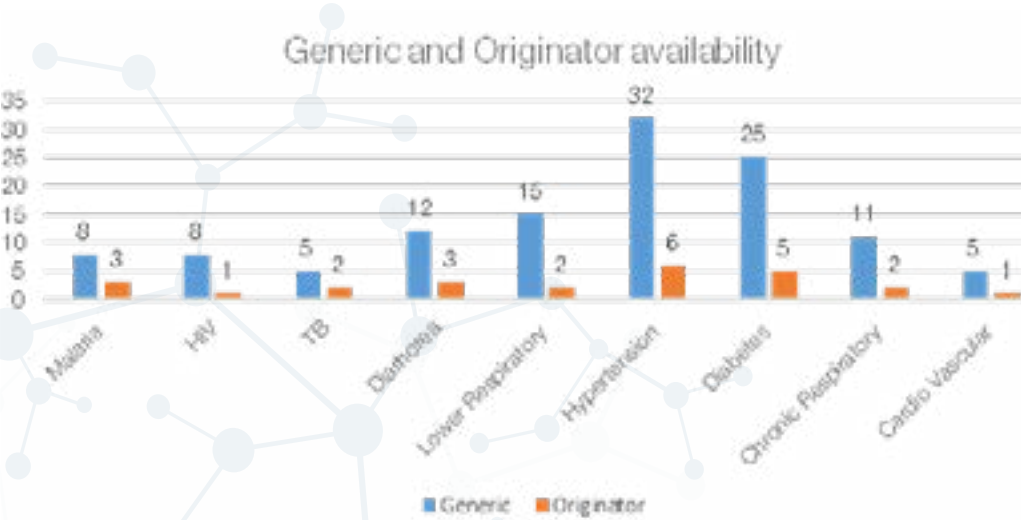
68

US Food and Drug Administration (FDA)

69

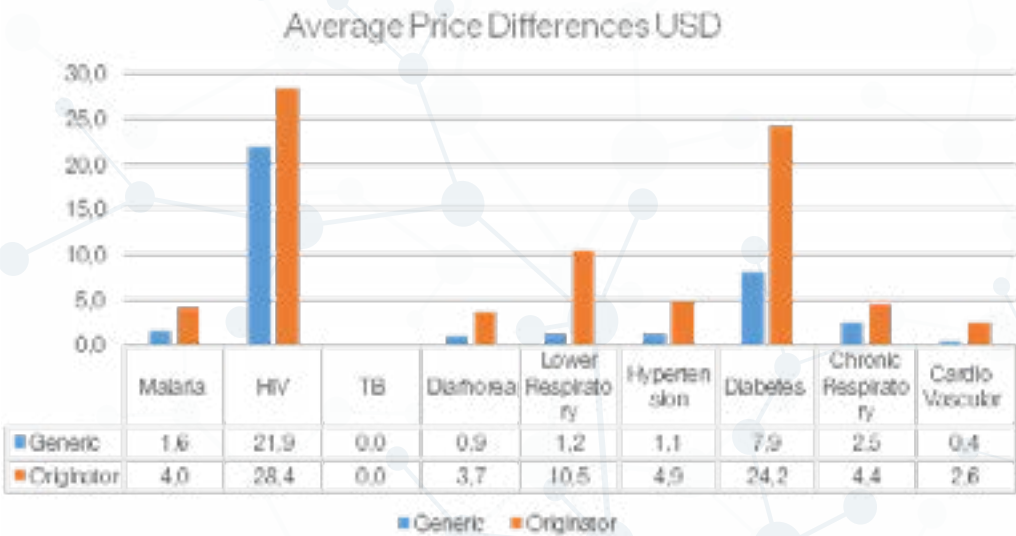
<https://www.europeanpharmaceuticalreview.com/article/166397/generic-drug-market-growth-insights-to-2030/>

Figure 23 - Generic and Originator drugs available



46. Despite a significant number of generics on the market in competition with originators, lower respiratory disease medicines had a somewhat high difference between generics and originators. On average, prices for originators were USD10.5 while those for generics were USD1.2 dollars. The onset of the COVID 19 pandemic may partly explain the high price differences and the existence of the large varieties on the market. The Figure 24 below shows the price difference in USD per disease class.
47. Hypertension 301%, followed by Diabetes with 205% and Malaria with 148%. HIV was at the least end with 77% and 30% respectively.

Figure 24 - Price difference per disease class



HIV

48. HIV drugs on the Zambian market are a preserve of the government as they are distributed at government hospitals. The drugs are highly controlled and stocked by very limited pharmacies across the country. The study looked at 8 generic brands and 1 originator drug whose price difference was 30%. HIV is treated with active ingredients that include Atazanavir, Ritonavir, Tenofovir and Nevirapine. Generic brands include Atazanavir, Ritonavir, Emtricitabine Tenovir, Efavirenz, Tenofovir, Lamivudine and Nevirapine. Originator drugs include Norvir, Viread, Viraday, Truvada, Epivir and Viramune.

TB

49. TB drugs are highly controlled in Zambia and are a 100% preserve of the government. When abused, the TB drugs can become resistant, resulting in failure to control the disease. Thus, there are no available drugs in pharmacies and chemists. The study, therefore, did not compare the prices on the market. However, 5 active ingredients were recorded which included Rifampicin 150mg + Isoniazid 100mg TB: Isoniazid

(H), Rifampicin +Isoniazine + Pyrazinamide + Ethambutol + Hydrovhloride, Rifa 300 Capsules (Rifampicin 300mg), Anacox Plus LD (Isoniazid BP 75mg + Rifampicin BP 150mg) and Ethambutol (Ethambutol, Hydrochloride 100mg). Two originator prices were recorded which included Q-TIB and Rimstar-4-FDC.

HYPERTENSION

50. Hypertension, also known as high blood pressure, is a non-communicable disease which can lead to severe health complications and increases the risk of heart disease, stroke and can cause death. The study considers 36 hypertension generic drugs and 6 originator drugs. The generic drugs considered included Atenolol, Ateleb, Atenelol Denk, Nifedipine Procardia, Calnif Retard, Nifen, Umedica, Ziflodip, Amlodenk, Amlodipine, Amlodipine Twinestar, Amlodipine Midamor, Kamtopril, Klodip, Enalapril, Vaseletic, Losa, Losakind, Envas, Nusar, Onapril, Enzipril, Captopril, Amizide, Carvedilol, Enatopril, Amlowin, Preloten, Primodil and Losartan Potassium. The originator drug considered included Tenormin, Calcigard Retard, Teva, Norvasc, Moduretic, Amiloride and Carvetrend. The price difference between the generic drug and the originator was 338%.

DIABETES

51. Diabetes is a disease that occurs when blood glucose/sugar is too high. The Diabetes drug market is characterized by a variety of medications, both generic and originator. The study sampled 25 generic brands and 5 originator brands. The price difference between the generic brands and the originator drugs was 205% which indicated that the price of the originator drugs was 205% higher than the average price of the generic medicines. The generic brands sampled included Soluble insulin, Insuline Lente, Insuline Actraphan, Wosulin, Metformin, BG Met, Ketformin, Metsafe, Metcheck, Sulfonylureas (Amaryl), Glucophage, Glimepride, Glimepride-Denk 2, Gliclazide, Glucozid, Pervial, Ilet B2, Sitagliptin phosphate, Glibenclimide, Meglitinides, Insulin Asphart, Ranophage, Insulin, Lispro, Insulin glargine and Insulin Determir. The originator drugs sampled included, Actrapid, Amaryl, Januvia, Novolog

and Levemir.

52. Generic drugs for diabetes had a wide variety giving consumers a wider choice while the originator brands were relatively few. Generally, the generic brands with soluble insulin, like Insulin Aspart, Insulin, Lispro, Insulin Glargine, Insuline Determer, Insuline Actraphan, Insulin Lente recorded higher prices than the insulin pills like Metformin, Glimepiride and Glipizide. The originator drugs were priced highly regardless of the state (soluble or pills).

CONCLUSION

53. Zambia has a well-developed private and public health care system which provides specialized medical services such as diagnostic and curative among other diseases and remains the dominant health care facility provider. The Ministry of Health (MoH) is the superintendent of the health system in Zambia while several other government agencies are responsible for regulating and controlling manufacture, importation, storage distribution, supply, sale and use of medicines and allied substances.
54. Effective procurement and distribution of essential medicines and medical supplies is critical for maintaining the health of Zambia's citizens. Procurement towards anti-retroviral drugs increased by 35.5% from 2017 to 2018 before seeing a decline of 36.5% in 2018 to 2019. The increase in budgetary allocation and roll out of the universal health coverage has seen a decline in OOP expenditure.
55. There are five main Communicable diseases of public health interest in Zambia: malaria, HIV & AIDS, Diarrhea, Lower Respiratory disease, and TB. In addition, Zambia has been recording an increase in morbidity and mortality due to Non-Communicable

Diseases (NCDs) such as; cancers, diabetes, chronic respiratory and cardiovascular.

56. Zambia has a total of sixty-seven (167) registered wholesalers of pharmaceutical products and ten (10) registered pharmaceutical manufacturers. Despite the relatively large presence of manufacturers, Zambia's imports most of its pharmaceutical products. Several factors contribute to this situation, among them being Zambia's limited capacity to invest in R&D, Zambia fiscal regime which makes local manufacturing expensive and Zambia's lack of pharmaceutical product intellectual property registrations.
57. Generic medicines play an important role in curbing rising pharmaceutical costs and their cost-saving potential is significant as generic medicines provide both; a lower-priced option for patients and a tool to drive down prices of originator drugs. Data collected from various pharmacies and dispensing shops showed that about 83% of the drugs on the market were generic with 17% being originator drugs. With a significant presence of generics on the market, some class of diseases like diabetes had large price difference between the generics and originators.
58. Competition promotion in the pharmaceutical sector remains paramount as it benefits consumers. There is however a need to strike a balance between making available affordable generics and growing the country's potential and capacity to produce its own generics and or patented drugs.



A row of seven test tubes, each containing a different amount of blue liquid. The tubes are arranged in a slightly staggered fashion, with the liquid levels varying from about one-third full to nearly full. The background is a soft, out-of-focus blue and white.

ZIMBABWE

THE ZIMBABWE CHAPTER

INTRODUCTION

1. Zimbabwe's national development plan – the NDS1(2021-2025) recognises health as an important pillar of economic development leading to the attainment of its national vision of “an upper middle-income economy by 2030”. NDS1 aspires to improve access to essential medicines in-country through supporting local drug manufacturing. Furthermore, ZNIDP sets out government's plans to develop domestic industry, including the pharmaceutical value chain, amongst other targeted sectors. The local pharmaceutical sector is perceived to have a comparative advantage due to the availability of local raw materials (flora and fauna) which can be extracted to produce medicines (MOIC, 2019). ZINDP also prioritizes operationalization of a local content policy to support local industry development. Government also promulgated Statutory Instrument (SI) 18 of 2016 with the purpose of boosting local production through government procurement of drugs manufactured locally.
2. The National Health Strategy (2021-2025) seeks to improve the health and wellness of the population and eventually ensure universal access to health services for all by recognising the importance of local drug manufacturing. According to the strategy, the local manufacturing industry is experiencing low levels of capacity utilization estimated to be less than 30% and currently supplies about 2% of medicines in the public sector down from 40% in the year 2000 (MOHCC, 2021). The strategy thus seeks to promote local manufacturing of medicines and medical products through a series of interventions, including developing a local manufacturing strategy; resuscitating hospital pharmacy manufacturing units for simple hospital formulations; strategic procurements by manufacturers and wholesalers of raw materials through category management (classifying and managing commodity categories as strategic business units rather than as a collection of individual products) and introducing specialised undergraduate and postgraduate programs at tertiary institutions in regulation and manufacturing of medicines.

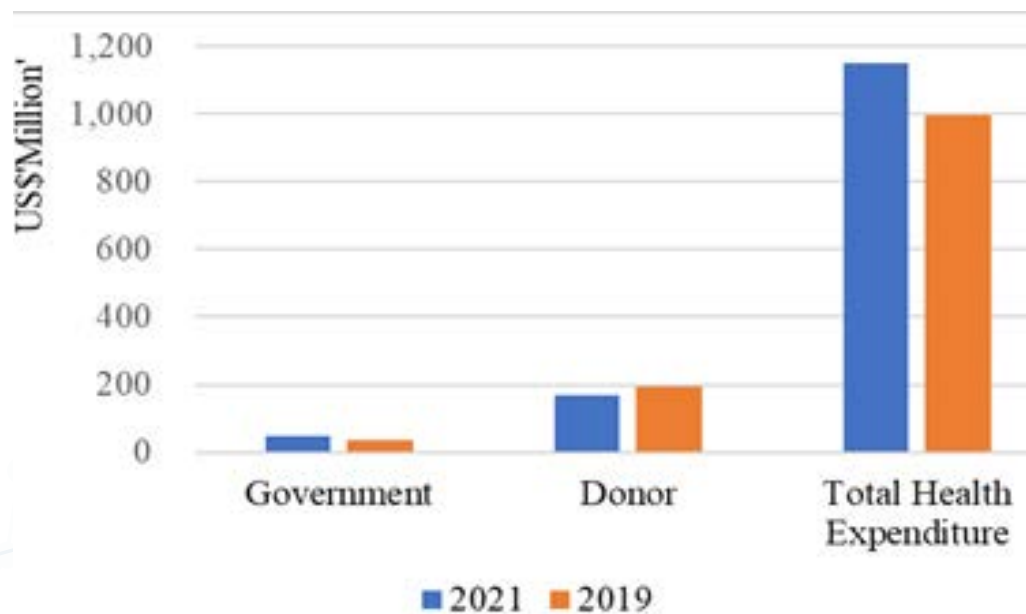
3. From the above, government policies identify local medicines manufacturing as essential in achieving broader national objectives. Notwithstanding this, there is conflict on the implementation of the programs, as both the ZNIDP (MOIC) and National Health Strategy (MOHCC) all seek to develop the drug manufacturing industry. There is currently no separation of authority on paper since the two policy documents belong to two different ministries with different goals. Ideally, all manufacturing must rest with the MOIC while the MOHCC provides support in identifying key drugs to be manufactured based on the essential drugs list, amongst others.
4. Notwithstanding this, local generics manufacturers have raised concerns with Government's lack of implementation of SI 18 of 2016 promulgated to boost local production of pharmaceuticals, including obligations for government purchase of drugs locally manufactured. Local manufacturers bemoan lack of enforcement of the SI as Government is not buying from local manufacturers given that it is a major player in the procurement of drugs. For instance, the NAC imported ARVs, maximising access to drugs but failed to buy from local manufacturers with capacity but high prices (UNIDO, 2011).

ZIMBABWE COUNTRY OVERVIEW

MEDICAL EXPENDITURE

5. Zimbabwe has been experiencing challenges over the past two decades, characterised by an unstable macroeconomic environment, as reflected in Government's medicine expenditure. (Figure 26 below). Medical spending constituted 7% of total government spending in the health sector in 2021 translating to 4% of total health expenditure, with donor funding being by far the largest contributor to medical expenditure in Zimbabwe. In 2021, medicine donations accounted for 35% of total donor funding in the health sector or 14% of total health care spending. Thus, drug supply in Zimbabwe is largely supported by donor funding, contributing more than thrice of what government contributes towards purchase of medicines. A similar trend was observed in 2019.

Figure 26 - Medicine Expenditure in Zimbabwe by Funder/Source



Source: MOHCC (2021)

- Overall, medicine purchases expenditure in Zimbabwe declined from US\$229 million in 2019 to US\$215 million in 2021, because of a decline in donor support towards medicine purchases from US\$194 million in 2019 to US\$168 million in 2021. Important to note is that government spending over the same period increased from US\$35 million to US\$49 million, on the back of increased spending for coronavirus vaccines purchase. According to the MOHCC (2021), 90% of health services in Zimbabwe are accessed through the public health system with the remaining 10% accessed through the private sector. Latest data from the Price Income and Consumption and Expenditure survey showed that households contributed 13% to the total health expenditure in 2018, with OOP spending amounting to 9% of the total health expenditure. While available data does not disaggregate the data further to show how much of the 9% was spent on medicine, it can be deduced that OOP spending constitutes a small share.

MARKET STRUCTURE

PHARMACEUTICAL MANUFACTURERS & DISTRIBUTORS IN ZIMBABWE

- The Zimbabwe pharmaceutical industry consists of eight pharmaceutical manufacturers namely CAPS Pharmaceuticals, Graniteside, Gulf Drug, Pharmanova, Varichem, Datlabs, Plus Five and Zimpharm. According to UNIDO classifications, all of them are SMEs as their annual turnover is less than US\$15 million. Most locally produced products are in oral solid and liquid dosage forms as there is no parenteral production in the country. Five of the companies (CAPS Pharmaceuticals, Graniteside, Gulf Drug, Pharmanova, and Varichem) are located in Harare, while factories for 3 companies (Datlabs, Plus Five, and Zimpharm) are based in Bulawayo.
- Distribution of pharmaceutical products takes place at two levels, namely wholesale and retail. The wholesale links manufacturers and retailers ensuring continuous supply of medicines, regardless of the geographical location and portfolio of medicines required. These serve many pharmacies with products sourced from many manufacturers. In Zimbabwe, there are 22 active wholesalers. The local pharmaceutical retail market has approximately 1 200 retail pharmacies since entry requirements are very low.

ORIGINATOR AND GENERIC MANUFACTURERS IN ZIMBABWE

- There are no originator pharmaceutical manufacturers investing in research and development (R&D) to discover and bring new medicines to the market. Originator manufacturers rely on patents and other forms of intellectual property rights (IPR) to justify investment required to bring a product to market. However, Zimbabwe has eight (8) generic manufacturers, producing copies of originator pharmaceuticals containing the same active ingredients and identical in strength, dosage form and route of administration.

10. R&D - a vital cog of originator manufacturers, is lowly funded and not all companies have approved R&D units. Local pharmaceutical manufacturers are generally unable to meet the GMP requirements such as WHO prequalification and Pharmaceutical Inspection Co-operation Scheme, as set out by the international funders and other global agencies because of the required investment. Donors such as UNICEF have been reluctant to purchase registered locally manufactured products as they are pricy. In 2014, 40% of essential medicines were donated, 50% were imported while local manufacturers supplied only 10%. Table 25, below shows the value of contributions of each market component to the total consumption of medicines in the domestic market.

Table 25 - Market Contributions (value) by Market Component

	2014 (US \$, millions)
Imported Medicines	123.6
Donated Medicines	96.8
Medicines produced by Local Industry	24.1
Total	244.5

Source: UNIDO (2011)

11. From Table 25, it can be deduced that local manufacturers have approximately 10% market share in the medicines market in Zimbabwe, showing that they are less competitive.

ORIGINATOR VS GENERIC MEDICINES IN ZIMBABWE

12. Given that the Government of Zimbabwe is the biggest funder of health expenditure, the number of generics compared to originator medicines can be estimated from this perspective. As already highlighted above, 90% of health services in Zimbabwe are accessed through the public health system and only about 10% of the population seek services in the private sector. Government is also the main contributor of capital and recurrent expenditure implying that generic medicines are a larger proportion of medicines in Zimbabwe.

CONCENTRATION LEVELS IN ZIMBABWE PHARMACEUTICAL MANUFACTURING SECTOR

MARKET SHARES

13. Larger players in pharmaceutical manufacturing are Datlabs, CAPS Pharmaceuticals and Varichem. Value wise, they are almost at them same level. The market share for Zimbabwean pharmaceutical manufacturing business is very low at 10% while 90% is for foreign suppliers, according to a UNIDO (2011) study on the “Pharmaceutical Sector Profile Zimbabwe”. The market has evolved ever since that time. These three major manufacturing players have 7% of the 10% market for local producers. Zimbabwean manufacturers produce off patent medicines as they lack capacity and resources to produce patented medicines.

Table 26 - Market Shares of local producers

Manufacturers	Market Share
Varichem	2.4
CAPS	2.3
Datlabs	2.3
Other local manufacturers	3%

Source: Author's compilation from stakeholder consultation, date

14. It is vital to highlight challenges in accessing market data for market shares. What is presented here are approximates from stakeholder consultations, with Varichem estimated to be the biggest player. Varichem has more active product lines on the market compared to companies such as CAPS. Each of the 130 products registered by Varichem is available on the market. In terms of speciality, Varichem is an all-rounder and produces drugs for chronic diseases, diabetes, BP, pain killers and over the counter (OTC) medicines. Other players have different market segments which they focus on. Datlabs mainly produces OTC medicines while CAPS focuses on OTC and non-OTC medicines. Zimbabwe has a total of 1 600 products registered for sale in the local market and the biggest player produces 130 lines (CTC, 2009).

15. In relation to local pharmaceutical distribution, the wholesale business is dominated by Pharmaceutical and Chemical Distributors (PCD), New Avakash International, Sky Pharmaceuticals, Pulse Pharmaceuticals and Greenwood Wholesalers.
16. Competition in the manufacturing of drugs in Zimbabwe is currently intense given that local drug production has been constrained by import competition and donated drugs. As shown earlier, local manufacturers only account for 10% of the market share which has led to more competition among manufacturers as they strive to increase market share.

REGULATORY FRAMEWORK

17. The local pharmaceutical industry is amongst the well-regulated industries in the country given its importance to the wellbeing of the general citizenry. The principal legislation regulating production of pharmaceutical products is the Medicines and Allied Substances Control Amendment Act (MASCA) (No. 1 of 2006) [Chapter 15:03], enforced by the MCAZ. MCAZ also enforces the Dangerous Drugs Act [Chapter 15:02] and is a successor to the DCC and the ZRDCL, established in 1969 and 1989 respectively.

MEDICINES AND ALLIED SUBSTANCES CONTROL AMENDMENT ACT

18. The MASCA Act regulates clinical trials, Zimbabwe regional medicines laboratory, registration of medicines and licensing and control of pharmaceutical premises and persons.

REGISTRATION OF MEDICINES

19. Consistent with the MASCA Act, all medicines used in Zimbabwe for the treatment of both people and animals must be registered by MCAZ. MCAZ is empowered by the Act to keep a register of all approved medicines used for clinical purposes. MCAZ's medicines registration considers safety, quality and therapeutic efficacy and its effect on the health of man. The Act also empowers MCAZ to deregister any

medicines if there is failure to comply with the conditions subject to which a medicine has been registered; or non-payment of the annual fee payable for the retention of the registration of a registered medicine; or a registered medicine does not comply with any prescribed requirements; or a registered medicine has been advertised in Zimbabwe in an advertisement which is false or misleading or does not comply with the Act; or it is not in the public interest that a registered medicine should be made or continue to be made available to the public; or it is in the public interest to vary the conditions of registration of a registered medicine.

20. MCAZ also regulates medicines manufactured in Zimbabwe by ensuring that premises at which medicines are manufactured and manufacturing processes meet required set standards. For imported medicines, MCAZ only registers these upon receipt of a valid registration certificate issued by an appropriate authority for the registration of medicines in the country of origin. In light of the above, the Act criminalises selling of unregistered medicine in Zimbabwe, whether produced locally or imported. Selling of unregistered drugs attracts a fine or imprisonment not exceeding two years or both.

LICENSING AND CONTROL OF PHARMACEUTICAL PREMISES AND PERSONS

21. MCAZ also licenses and controls pharmaceutical premises and persons. It is therefore the custodian of the register for all licensed premises and medicines in the country. According to the MASCA Act, no unlicensed premises and individuals are allowed to dispense any medicine, whether for human or animal treatment. In line with licensing requirements, no person or company is allowed to manufacture any medicine unless the premises are licensed and under continuous supervision of a person licensed by MCAZ. Failure to comply with the requirement attracts a fine or/and a jail term not exceeding 2 years.

CLINICAL TRIALS

22. MASCA Act also provides for the regulation of clinical trials on medicines. The Act prohibits any person or company to conduct clinical trials without approval from MCAZ. It empowers MCAZ to supervise and discontinue clinical trials if they are not to the general interest of the public. A person or firm conducting clinical trials on any medicine is also obliged to report the findings to MCAZ. Failure to comply with this provision leads to a fine and imprisonment not exceeding two years.

ZIMBABWE REGIONAL MEDICINES LABORATORY

23. Through the Act, MCAZ is empowered to operate the ZRML. ZRML is state owned and is responsible for verifying the quality, safety and efficacy of any medicines and allied substances referred to it by any person in or outside Zimbabwe; verifying standards of specifications of any medicines and allied substances referred to it by any person in Zimbabwe or elsewhere; training persons in the analysis of medicines and allied substances; and performing any other function relating to the analysis of medicines and other substances which the Minister, with the approval of the Authority, may direct or authorize the Laboratory to perform.

DANGEROUS DRUGS ACT [CHAPTER 15:02]

24. The Dangerous Drugs Act [Chapter 15:02] which came into effect in 1956's primary focus is to regulate importation, exportation, production, possession, sale, distribution and use of dangerous drugs. In general, the Act identifies some of the dangerous drugs as medicinal opium, cocaine, morphine and other drugs. Section 14 provides a comprehensive list/schedule of dangerous drugs which the Act controls. It empowers the responsible Minister to either control or prohibit the production of dangerous drugs. The same powers also apply in the importation, exportation, possession, sale and distribution of dangerous drugs.

PATENTS REGIME

25. The protection of IPR has a bearing on the level and nature of competition in the pharmaceutical industry. The two main pieces of legislation and agreements framing Zimbabwe's pharmaceutical industry patent system are the Patents Act of 1996, as amended in 2002, and the accompanying regulations, and the TRIPS Agreement. The TRIPS Agreement addresses, inter alia, patents and establishes that all WTO member states should grant patents for inventions in all technological fields, including pharmaceutical products and processes.
26. According to UNIDO (2011), the Patent Act of 1996 does not have sufficient provisions to prevent evergreening and patenting of frivolous inventions. This has been an obstacle for Zimbabwean manufacturers in introducing essential generic medicines at a pace similar to other developing nations. Other challenges emanating from the Patent Act of 1996 include lack of legal requirements for applicants to disclose all patents other than those relating to processing covering any new drug application as in other countries (UNIDO, 2011). This makes it very difficult for local manufacturers to verify the validity and enforceability of patents when preparing generic drug product development activities (UNIDO, 2011).

PROCUREMENT OF MEDICINES IN ZIMBABWE

PUBLIC HEALTH SECTOR

27. Procurement of medicines for public hospitals is regulated by the NatPharm - a government owned company responsible for procuring all medicines and medical supplies required by government hospitals and clinics. Natpharm is the successor to the former Government Medical Stores privatised in 2002. Purchase of medicines and medical supplies have to conform to the provisions set out in the Public Procurement and Disposal of Public Assets Act [Chap 22:23]. In addition, all medicines and medical supplies purchased have to be registered in accordance with the MASCA requirements.
28. Natpharm uses both the open and closed tendering system when sourcing medicines and medical supplies. Open tenders invite international bidders to ensure price competitiveness is achieved. Due to challenges faced by Zimbabwe, it has become impossible for government to fully fund Natpharm. As a result, international organisations and the donor community such as the World Bank, European Union, UK's Department for International Development (DFID) among others, also provide medicines through Natpharm. Despite the existence of a clearly spelt out procurement framework from the private sector, in practice, manufacturers have supplied government hospitals directly through a public competitive bidding process.

PRIVATE HEALTH SECTOR

29. Procurement of medicines in the private health sector follows company specific procurement systems. There is currently no obligation for private health care providers to follow any laid down procurement method. In general, the majority of private hospitals use suppliers lists open to any manufacturer to register as long as registration requirements are met. However, just like the public health sector, all medicines procured by the private health sector have to be from registered premises and institutions and in compliance with the MASCA Act.

30. Despite the existence of the regulatory framework for procurement of medicines by government as highlighted earlier, the government contributes the smallest share of financial resources towards medicines purchase. This, therefore makes the use of public procurement ineffective to support development of local industry. Given that donor agencies are currently the largest funder of medicine purchases, it implies that procurement of medicines in Zimbabwe is subjected to donor agencies' procurement regulations, which prefer international competitive bidding subjecting the local manufacturing industry to intense competition from competitive international companies.

LEGISLATIVE OR REGULATORY OVERLAPS AND CONFLICTS

31. As highlighted earlier, MCAZ is the apex regulator of the sector, registering all manufacturing premises and drugs produced and imported into Zimbabwe and persons involved in the production of pharmaceuticals. On premises, MCAZ assesses whether the premises meet the widely accepted Current Good Manufacturing Practices (CGMP) set by the WHO. However, two other institutions namely the HPA and PCZ also regulate production of pharmaceuticals directly. HPA is the apex health regulatory body mandated to coordinate the functions and operations of the health profession. To fulfil its mandate, HPA is empowered by the Health Profession Authority Act, requiring that all pharmaceutical manufacturing premises must be registered by the Authority. HPA issues a premises and person license for pharmaceutical manufacturing companies.

32. As in the case above, the PCZ derives its mandate from the HPA. In accordance with the provisions of the Act, the PCZ is mandated to regulate the practice of the regulating pharmacists, pharmacy technicians, optometrists, dispensing opticians and hearing aid specialists. Its functions include the promotion of the health of the population; the practice of the professionals or callings and to foster research into and develop knowledge of the profession and regulating and supervising all matters affecting training of persons in the pharmacist profession. Besides these two institutions, municipalities also issue registration of all manufacturing enterprises in their areas of jurisdiction. They inspect premises and then issue a certificate of operation.
33. Regulatory overlap exists on the registrations of premises and persons. MCAZ, HPA and Municipalities all regulate production facilities while, MCAZ, HPA and the PCZ regulate persons engaged in the production of pharmaceutical products. Manufacturers have raised concerns about the duplication of registration processes in the sector especially on the registration of premises, where all the three institutions perform the same inspection. There is therefore, need to streamline the registration processes to make it easier for companies to register their manufacturing facilities. Registrations by different institutions are a cost to manufacturers who have to pay registration fees to each regulatory institution.

ESSENTIAL MEDICINES LIST AND STANDARD TREATMENT GUIDELINES FOR ZIMBABWE (EDLIZ)

34. Just like many other countries globally, Zimbabwe has a national Essential Medicines List and Standard Treatment Guidelines (EDLIZ), constructed factoring in the local context i.e., prevalent diseases and experiences resulting from evidence-based therapeutics, among others. The list applies to all medical institutions in Zimbabwe - both private and public. All medicines on EDLIZ are categorised firstly, by level of availability in the health care system and secondly, according to priority. For example, amoxicillin is available at primary health care facility (C) level and is ranked vital (V) (EDLIZ, 2015). In relation to level of availability: medicines are categorised into C, B, A and S medicines³. These are medicines that require special expertise and / or diagnostic tests before being prescribed. Medicines are also classified according to priority, namely V, E and N⁴. This too prioritizes medicines based on economic considerations.

PRICING ANALYSIS

35. Zimbabwe does not have any legislation or regulatory provisions controlling the pricing of medicines in the country. Unlike other countries like South Africa which regulates the price through the Single Exit Price, Zimbabwe does not have such regulations in the selling of medicines. Medicine pricing in Zimbabwe is determined through the operation of market forces of supply and demand. Given the low level of local production by domestic manufacturers as discussed earlier, local industry faces competition from imported and donated drugs. Therefore, prices for drugs in Zimbabwe where there is local production, are subject to a combination of local and import competition. When there is no local production then the price is the import price.

³ C are those required at primary health care level and should be available at all levels of care. B medicines are found at district hospital level or secondary and higher levels of care. Some B medicines may be held at primary health care facilities on a named patient basis .e.g., in the management and follow up of chronic illnesses. A medicines are prescribed at provincial or central hospital levels. S medicines (specialist only) have been brought back into this edition.

⁴ V medicines are vital and considered lifesaving and their unavailability cause serious harm and efforts should always be aimed at making them 100% available; E medicines are essential and second priority. Without E medicines there would be major discomfort or irreversible harm. N medicines are still necessary but are lower in priority than V and E medicines.

36. Local manufacturers depend on producing off-patented drugs as they do not have the necessary financial resources and capacity to make patented drugs. They also do not produce drugs supplied by donors such as drugs for treating HIV & AIDS, Malaria and TB. Further, given the low incomes of the general citizenry, the country relies on generic drugs. Originator drugs are very rare to obtain in the market as they are expensive and beyond the reach of the general citizenry.

37. Table 4 below shows prices of generic medicines in Zimbabwe charged to the private sector. Manufacturing firms indicated that they do not charge the same prices when supplying government hospital. Government normally purchases drugs in large quantities and is given bulk purchases discounts. The wholesale price represents the price charged by local manufacturers when selling the product to Retail Pharmacies, and the price charged by importing wholesalers to Retail Pharmacies in cases where there is no local production.

38. As reflected in the table for the identified prevalent disease (Hypertension, HIV/AIDS, TB, Diabetes, Malaria and Covid-19) in Zimbabwe, local manufacturing is only in hypertension and diabetes drugs. Medicines for the remainder of the disease (HIV/AIDS, TB, Malaria and majority of drugs to manage coronavirus) are all imported by wholesalers and the donor community. It is also important to highlight that treatment of TB is only accessed via the public hospitals therefore retail pharmacies do not sale TB drugs to private customers.

Table 27 - Locally produced Medicine Prices in Zimbabwe vs Imported

Disease	Active ingredient	Number of Manufacturers	Local Wholesale Price	Imported Wholesale Price
Hypertension	Amlodipine Besilate (5mg + 10mg)	2	10mg - \$8.3/100 tablets	
			5mg - \$6.52/100 tablets	\$6.67/100
	Hydrochlorothiazide (25mg)	2	\$16.75/1000 tablets	None
	Losartan	1	50mg -\$7.55/100 tablets	\$6.67/100
			100mg – \$10.9/100 tablets	\$11.67/100
Diabetes	Glibenclamide 5mg	1	\$13.18/1000 tablets	\$11/1000
	Metformin, oral, 500mg – discovered in 1957	2	\$35.96-1000 tablets	
Covid	Zinc Sulphate	1	\$8.3/100 tablets	\$7/100

Source: Authors using information gathered from interviews

39. Retail pharmacies are charging supernormal profits for all locally manufactured drugs. For instance, the lowest margin is 83% on Losartan 100mg, while the highest margin is 165% again on Losartan 50mg. Importantly, these drugs used to manage chronic diseases, are bought regularly including monthly. Worth noting is that the high markup is also prevalent on OTC medicines .e.g., paracetamol with a 156% markup, zinc tablets with a 141% markup.

40. Mark-up on imported drugs is slightly lower than on locally manufactured drugs albeit still high. These range from 43% on all HIV/AIDS drugs to 66% on malaria drugs. The lower mark-up on imported drugs in comparison with locally produced might be a result of competition from donated drugs. As already highlighted, HIV/AIDS and Malaria treatment drugs are normally freely donated to government's public hospitals. It therefore means that retail pharmacies will only be targeting a small population of private customers that access healthcare services from the private sector.
41. There is a marginal price differential between locally produced drugs and imported equivalent as shown in table 27.
42. Imported drugs for hypertension and diabetes namely, Losartan (50mg) and glibenclamide are cheaper than those produced locally. It is also worth noting that for all the three drugs there is a single local producer, implying that there is no competition from other domestic producers. Amlodipine Besilate is the only locally produced drug that is cheaper than the imported equivalent. Importantly, there are two domestic manufacturers implying that there is more competition and thus possibly explaining the lower domestic price in comparison with the import equivalent. In conclusion, the price analysis above indicates that imported drugs are cheaper than locally produced drugs.

BARRIERS TO ENTRY INTO PHARMACEUTICAL MANUFACTURING

43. There are a number of barriers to entry into pharmaceutical production cited by firms, key among them being regulatory, capital and skills shortage.

API

44. Local producers also depend on imported Active Pharmaceutical Ingredients (API) since these are not locally produced. Absence of API manufacturers is largely due to the lack of expertise and the economies of scale needed to be competitive on the world market.

PACKAGING

45. Some of the packaging like plastics is available locally while the bulk of their requirements are imported. From the information gathered from interviews, imported packing materials attract between 40-45% customs duty which increases the cost of production for local manufacture.

REGULATORY

46. Pharmaceutical manufacturing is a highly regulated industry in Zimbabwe. The multiplicity of regulatory bodies is a barrier to entry for any new entrants as they must comply with regulatory requirements of five institutions namely MCAZ, HPA, PCZ, EMA and local authorities before commencing production. Further, fragmentation of these institutions makes it hard for new entrants that would need to engage each of these five institutions. In relation to the above, MCAZ requires that the production facility be fully resourced with a full complement of staff before inspection. The implication of this is that, new entrants must employ staff and pay salaries and wages, adding to their cost even before they even start producing.
47. The time taken to register new drugs is another regulatory barrier to entry. Information gathered from interviews shows that registering a drug in Zimbabwe takes between 6 months to 60 months in certain instances. However, firms confirmed that there are discussions with the key regulator MCAZ to reduce the time to 3 months. Lengthy time frames discourages small companies since the payback and return on

investment periods becomes long. Reduction of the time taken to register drugs will not only incentivise new entrants but also incumbents to introduce new drugs and improve competition in the sector.

CAPITAL

48. Huge capital requirements to set up a production facility is another barrier to entry into pharmaceutical production. Production of drugs requires specialised equipment for the drugs produced to meet minimum set standards. The amount of capital required to set up a factory obviously depends on the scale; type of product being produced and size. For instance, a small plant producing syrups would require about US\$200 000. A small-scale plant that produces more variety of drugs requires a minimum of US\$2 million, while a medium to large scale plant requires between US\$40-45million.
49. Pharmaceutical manufacturing companies must also continuously adhere to GMP which are constantly improving and thus requiring firms to continuously upgrade their factories to maintain international standards. Continuous capital investment is thus critical in the sector for the production facility to comply with set standards. The burden to continuously look for capital to meet GMP standards has become a barrier to entry for new entrants into the sector.

SKILLS SHORTAGE

50. In addition to the above, the other challenge is accessing requisite skills to produce medicinal drugs. A new entrant into the sector bemoaned the shortage of specialised critical skills such as specialised welders, experienced scientists, microbiologists, pharmacists and engineers in the pharma industry. The firm indicated that despite local universities and technical colleges producing these skills, they do not specialise in the pharma industry and cadres must be re-trained or head hunt for experienced professionals which comes at a huge cost.

WHO PRE-QUALIFICATION STANDARDS

51. Local companies also highlighted the challenge of meeting WHO's pre-qualification standards, especially for HIV & AIDS drugs. This is of particular importance to Zimbabwe since the supply of HIV & AIDS, TB and Malaria drugs is dominated by donors such as Global Fund (HIV) which requires suppliers to meet these standards. One of the first manufacturers of HIV drugs in Zimbabwe which managed to meet this standard in 2010-2011 has since exited the manufacturing of HIV drugs due to the cost of maintaining standards and continuous changes in the regiment of the drug (which requires registration with MCAZ as discussed earlier). One manufacturer indicated that the regiment changes after 3-4 years and in 2017 they invested about US\$140 000 in studies to register the product which was changed only after manufacturing two batches and failed to recoup the cost. This forced local manufacturers to focus on producing drugs not in the international donors' space. Thus meeting these WHO prequalification requirements becomes a barrier to entry for new players and also for incumbents in the production of drugs for the treatment of HIV, TB and Malaria.

TECHNICAL BARRIERS

52. Further to the above, manufacturers in Zimbabwe raised concerns about technical barriers to trade (TBT) at the regional level despite progress in the harmonization of pharmaceutical manufacturing regulations in the SADC region. While there is a working relationship under the auspice of ZAZIBONA which has enabled standardized regulations and factory inspections, in practice manufacturers still have to register their products in every country and some countries use TBT and thereby inhibiting competition. Some manufacturers raised concerns over South Africa's policy of only allowing drugs into the country via OR Tambo International Airport which is expensive as a barrier to exporting to other countries like Swaziland and Lesotho.

EXCLUSIVE AGREEMENTS BY WHOLESALERS

53. Information gathered also indicates that despite the existence of competition among pharmaceutical wholesalers in Zimbabwe, there are also allegations of some of them signing exclusive agreements with foreign manufacturers. Due to the lack of sufficient competition from local producers on a number of drugs, some local wholesalers have taken this opportunity to sign exclusive agreements with manufacturers in India. For instance, one of the manufacturers alleged that one local wholesaler holds exclusive distribution agreements with three different drug manufacturers used to treat the same disease. It means that this wholesaler has a monopoly over the distribution of these drugs in Zimbabwe.
54. However, wholesalers often argue that they enter into exclusive distribution agreements for purposes of managing the distribution. In instances where the foreign manufacturer is forced to recall the product, it will be easy to administer since there will be a single distributor in the country. This argument needs to be evaluated empirically and establish whether the public interest outweighs the competition benefit.

CONCLUSION

55. The Zimbabwean pharmaceutical manufacturing sector faces a number of challenges stemming from the unstable macroeconomic environment. While competition amongst the eight manufacturers is stiff, local players only account for 10% of the market with the remaining 90% accounted for by imports. Donors are currently the largest procurer of drugs as government faces financial constraints to support drug purchases. This scenario makes public procurement less effective as the largest share of medicines are procured using donor procurement systems. It also ushers in enhanced competition for local manufacturers as a result of international competitive bidding applied by donor agencies.

56. Despite the existence of supportive policies for the sector, government has not been meeting its obligations of supporting local production. There is also conflict between the MOIC and MOHCC on who should be responsible for developing the local pharmaceutical industry. Current policy documents show that both ministries are targeting to develop the local pharmaceutical sector. However, from information gathered from interviews there is a working relationship between the two ministries.
57. Overlap also exists on the regulation of the pharmaceutical sector, with three institutions regulating premises namely MCAZ, HPA and Municipalities. The same also applies to regulations of persons where the PCZ also comes in. This overlap does not only burden manufacturers with bureaucracy but also comes with high compliance costs since each institution charges registration fees. Regulation in the sector also stands as a barrier, stifling both new entry and expansion of incumbents in the sector. Other barriers include high capital and failure to meet WHO prequalification requirements.
58. Lastly, competition in the production of medicines is high due to the presence of imports and donated drugs in the market accounting for over 90% of the market share.

A laboratory setting with a scientist in the background and various glassware in the foreground. The scientist is wearing a white lab coat and is working with a piece of equipment. In the foreground, there is a round-bottom flask containing a blue liquid, a test tube rack with several test tubes, and a beaker. The text "KEY INSIGHTS AND OBSERVATIONS" is overlaid in the center of the image.

KEY INSIGHTS AND OBSERVATIONS

INTRODUCTION

1. The pharmaceutical sector generally functions as one of the main gateways to the health system for local communities. In some instances, medicines may be a first point of reference to access healthcare services. It is on this premise, that medicines ought to be easily accessible and affordable to all individuals in a country. Generic medicines play an important role in this regard. It is generally well accepted that generic medicines curb rising pharmaceutical costs and their cost-saving potential is significant in that they provide both a lower-priced option for patients and a tool to drive down the prices of originator medicines. This is particularly important for African countries that are typically confronted by a high burden of disease. Some of the common diseases noted in the study include HIV, TB, diabetes, and hypertension.
2. The countries participating in the study have recognised the positive impact that the entry of generic medicines has on the pricing of pharmaceutical products and have strived towards increasing the demand and supply of generics through various healthcare policies and regulations. Notably, the achievement of affordable generic medicine is heavily dependent on the vibrancy and the level of competition in the generic pharmaceutical industry.

MEDICINE EXPENDITURE

3. The participating countries in the study all have a parallel healthcare system, consisting of a public and private sector that operate in tandem with each other. In all the participating countries, a significant percentage of the population is serviced by the public sector with the reminder serviced by the private sector. For example, Eswatini and Kenya have a similar percentage of the population covered by private healthcare at 27% and 25% respectively, while this figure is lower in South Africa at 18% and significantly less in Zimbabwe and The Gambia at 10% and 4% respectively. With the population of these countries being highly reliant on the public sector for their

medicine needs, it is imperative that medicines are affordable to ease the burden on the fiscus, as well as ensure that medicines are accessible to address the healthcare needs of the population.

4. The level of medicine expenditure varies across the participating countries. Of the participating countries in the study, Zimbabwe had one of the lowest medicine expenditure relative to total healthcare expenditure at 4%. In South Africa and Kenya, medicine expenditure was higher representing 12% and 16.5% of the total health expenditure while in Eswatini, medicines were the second largest expenditure, accounting for between 21% and about 29% of the total healthcare budget. Notably, The Gambia had one of the highest medicines expenditures at 45% of total health expenditure. The pharmaceutical spending varies across the countries ranging from 4% to 45% with large variations across the countries.
5. One of the findings from the study showed that the medicine expenditure incurred by the countries was not sufficient to cover the medicine needs of the population. For example, in Angola, TB and HIV/AIDs are the leading cause of death, but funds made available do not cover even 50% of the needs of the National Program to Combat Tuberculosis, which subsequently compromises the internal capacity of stock. Some of the participating countries in the study are also highly reliant on donor funding. For example, in Zambia and Zimbabwe donor funding is a significant contributor to medical expenditure. However, donor funding is not a guaranteed form of support and therefore, a sudden decline in donor sponsorships can adversely affect the supply of medicines in a country. This has been the experience of Zimbabwe, where medicine purchases expenditure declined because of a decrease in donor support towards medicine purchases from US\$194 million in 2019 to US\$168 million in 2021.
6. In some countries (such as Eswatini, The Gambia and South Africa) it was also observed that the public healthcare sector faces consistent stock out of medicines for diseases that are highly prevalent. The low availability of pharmaceutical products at public health facilities drives consumers to private pharmacies thereby encouraging rising OOP spending by consumers. In South Africa in the private sector, members savings and OOP represents approximately 16% of total healthcare expenditure even

though individuals are covered by private healthcare, while in The Gambia OOPs represent between 18%-26% of healthcare expenditure and 20% in Zambia. In Kenya, the average OOP differs between the urban and rural areas with the OOPs being 30% - 40% higher in urban areas than in rural households. Notably, the study finds that the OOPs in Zimbabwe are minimal.

7. The substantial number of medicines imported is also concerning as it creates price uncertainty and increases the price of the medicine due to the additional logistic costs. This adversely impacts the fiscal healthcare budget therefore countries must either increase their medicine expenditure or reduce the level of medicines purchased. This was Zambia's experience when the nominal budgetary allocations for essential medicines increased. However, the depreciation of the Kwacha against the US dollar by more than 40% had reduced the real value of the allocation. Therefore, the decrease in real value reduced the quantity of imported medicines and medical supplies from a given budget allocation.
8. The combination of the relatively high levels of medicine expenditure (as a percentage of total healthcare expenditure) and persistent stock-out of medicines in the public sector provide a compelling business case for the development of a competitive generics regional supply chain. The observed increases in medicine expenditure are in part driven by the increasing costs of medicines. A notable observation is also the increasing trend towards OOP by consumers in both the public and private sector. This has significant implications for, particularly low-income households who are faced with increasing cost of living challenges given the persistent high level of inflation experienced globally. This has severe consequences for the health outcomes of individuals as they do not receive the full treatment or there is a delay in the treatment with may impede the health progress of patients. This is especially concerning in countries with a high burden of disease. Therefore, the development of a competitive generic regional supply chain can assist to ensure that medicines are affordable and assessable to all individuals in Africa.

MARKET STRUCTURE

9. The study observed that the pharmaceutical supply chain typically consists of manufacturers, importers, wholesalers/distributors, and retailers. For instance, in Kenya, South Africa, Zambia and Zimbabwe, the supply chain includes the manufacturing sector which may consist of large multinationals, established local multinationals and emerging companies as well as several wholesalers and distributors. On the other hand, Angola, Eswatini and The Gambia do not have manufacturing capabilities, but largely rely on wholesalers/ distributors and importers active in these markets.
10. For those countries with manufacturing capabilities, market concentration information was only provided for Kenya and South Africa. In Kenya the pharmaceutical market space is concentrated and dominated by large multinationals in terms of market share and sales value. Though in the generic market, the local firms dominate with nearly 80% of local medicines produced by up to ten medicine manufacturers. South Africa, on the other hand, has a less concentrated market as the top five firms constitute approximately 40% of the market.
11. Although some of these countries have manufacturing capabilities, they are still heavily dependent on imports. The value of imported medicines in Kenya is estimated at 70%, with this figure being much higher in South Africa, Zimbabwe, and Zambia at approximately 90%. In relation to the import level of the supply chain, the levels of concentration vary among these countries. The Eswatini market is highly concentrated while The Gambia's import market had experienced varying levels of concentration from being highly concentrated to less concentrated in a short period of time. Angola, on the other hand, has a deconcentrated industry, although some markets for specific medicines such as for the treatment of hypertension, appear to be relatively high.

12. The findings from the study indicate that these markets exhibit a tendency towards concentration at varying degrees. From a concentration perspective, concentrated markets typically serve as an indicator of potential competition concerns that may exist such as high prices, low levels of innovation and reduced quality.

REGULATORY ENVIRONMENT

13. A feature that is common across the countries is that the pharmaceutical sector is highly regulated and governed by various legislative and regulatory policies including the applicable competition laws. The pharmaceutical sector across the countries appears to be well-regulated aimed at ensuring the supply of safe, and quality essential medicines. All the countries have a National Medicine List (commonly referred to as Essential Medicine List) which provides medicines for the treatment of highly prevalent diseases in a country. These lists are constructed factoring in the local context, prevalent diseases and experiences based on evidence-based therapeutics, among others. The regulation of medicines has also been fluid over the years with countries making amendments to improve the functioning of the sector. All the countries are members of TRIPS with The Gambia, South Africa and Zambia regulations also containing a compulsory licence provision.
14. All countries require the medicines to be registered before they can be sold in a country to guarantee the country's supply of safe, effective, and quality medicines. To increase the supply of generics in a country, some countries have simplified the registration process to ensure that generics can quickly enter the market. For example, in Angola as a way of promoting generic medicines, generics benefit from a simpler and quick registration process and the relative costs are lower than those of products under commercial designation.
15. In some countries, there are concerns about the time taken to register a medicine. In South Africa the time registration for generics is 250 days. In Zimbabwe it takes between 6 months to 60 months in certain instances, however, there are discussions with the key regulator MCAZ to reduce the time to 3 months. . Kenya, on the other hand has a quicker registration time that can take between six months to a year.

Similarly, in The Gambia, the registration of a medicine also takes 6 months. The registration times in South Africa and Zimbabwe are higher than those in applicable in developed countries. In the United Kingdom's ("UK") the registration process for new active substances and biosimilar products and existing active substances takes a total of 150 days with an intervening clock-off period between phase I and phase II. The assessment of phase I is completed 80 days after the clock starts and issues arising or requiring clarification from the initial assessment will be raised with the applicant and should be addressed within the clock off period of 60 days. Similarly, in the United States ("US"), the Food Drug Administration ("FDA") has a shorter timeframe for the registration of medicines. The goal for a standard review is 10 months and six months for a Priority Review.

16. The study observed that for most countries there is no price regulation in place, except for South Africa which regulates the price of medicines through its SEP regulation.
17. A review of the prevailing regulatory framework in the participating countries indicates that the regulations in place are aimed at safeguarding the well-being of communities by seeking to ensure that there is security of supply and safe medicines. From a competition perspective, the study notes the concerns associated with the timelines for the registration of medicines which appear to raise barriers to entry and may require a reconsideration to facilitate generic entry and improve competition.

BARRIERS TO ENTRY

18. Although some of the participating countries have manufacturing capabilities, they still import most of the medicine ingredients or medicines. This is due to the various barriers to entry and expansion that hinder the development and growth of their domestic market. The pharmaceutical manufacturing industry is one of the top ten costly industries to invest in, due to the high research and development costs, among others. Notably, even if countries can secure the necessary investment, concerns have been raised regarding the ability of local pharmaceutical manufacturers to attain the WHO pre-qualification standards as is the case in countries like Kenya, Zambia, and Zimbabwe. The inability to qualify for these standards puts the local manufacturers

- at a disadvantage, relative to their international counterparts, and therefore, they fail to benefit from donor funding purchases and lack capacity to participate in high value procurements. As such, domestic manufacturers fail to establish the requisite economies of scale that would enable them to compete effectively with imported generic medicines.
19. Other challenges to establishing manufacturing capabilities include the excise duty charged on raw materials and other related inputs such as packing materials which further disincentivizes local manufacturing. As a result, pharmaceutical companies would rather import and distribute medicines than manufacture these locally. For example, in Zimbabwe imported packing materials attract between 40-45% customs duty which increases the cost of production for local manufacturers. Similarly, in Kenya a VAT of 16% is imposed on packaging materials imported by suppliers.
 20. Furthermore, local producers depend on imported APIs since these are not locally produced. The absence of API manufacturers is largely due to the lack of expertise and the economies of scale needed to be competitive in this market. The skills shortage and the costs of specialised skills for API manufacturing therefore create a significant barrier to entry in the sector.
 21. Non-tariff barriers also create a barrier to entry and expansion. Kenya noted that it consistently advocates for the review of laws in the East African Community (EAC) and the Common Market for Eastern and Southern Africa (COMESA) regions to allow increased trade in goods and services and to support the export of its expanding range of locally manufactured pharmaceutical products. The barriers entail red tape documentation processes, not recognizing certificates of origin, inconsistency in standards and punitive application of sanitary and phyto-sanitary requirements, longer border crossing procedures, attendant costs, non-uniformity in transit charges and procedures. Zimbabwe has also indicated that while there is a working relationship under the auspice of ZAZIBONA which has enabled standardized regulations and factory inspections, in practice manufacturers must register their product in every country. Furthermore, there are concerns about the time taken to register generic medicines which may inhibit entry thereby restricting and preventing competition in the generic market.
 22. Another barrier to entry and expansion relates to the relatively small size of the domestic economies of the participating countries which does not generate sufficient economics of scale needed to produce high volumes at low cost. Essentially, the countries do not offer the volumes for greater investment to justify establishing a manufacturing plant as the volumes produced would have to be larger than the local demand to make such a facility economically viable. While a single country's medicine demand may not be large enough to generate the production volumes needed to realise sufficient economics of scale, the demand from multiple countries can mitigate this issue by facilitating large scale production. Accordingly, a regional generic supply chain approach would be beneficial as countries can participate at different levels of the pharmaceutical supply chain based on their comparative and competitive advantage.
- ## PRICING OF MEDICINES
23. It is well documented that generics are usually priced lower than branded medicines providing consumers with affordable medicines. The results from this study confirm this view, demonstrating that the presence of generics (whether branded generics owned by the originator manufacturer or made by a generic manufacturer) leads to price competition in the supply of medicines. For all the participating countries, the study established that generic medicines were consistently priced lower than branded medicines. The assessment confirms that the presence of generics (whether branded generics owned by the originator manufacturer or made by a generic manufacturer) leads to price competition in the supply of medicines.
 24. Moreover, the study shows that a higher number of generics is associated with higher price differences in favor of the generics since they are priced significantly lower than the originator products. Therefore, multiple generic entry simulates price competition which benefits consumers in the form of lower priced medicines. Effectively, the study shows the importance of ensuring that generic manufacturers can enter a market once a product has come off patent. Importantly, the study established that the depth of price reductions for off-patent medicines is closely related to the extent of competition amongst generic pharmaceutical companies.

OTHER POTENTIAL COMPETITION CONCERNS

25. Other potential competition concerns identified in the study relate to the use of long-term exclusive supply agreements (for example, in Eswatini, The Gambia and Zimbabwe) between wholesale distributors and manufacturers. This limits the choice available to customers such as Governments or other procurers as they find themselves forced to deal with a single wholesale distributor for specific medicine(s). Pharmaceutical manufacturers have indicated that the exclusive contracts are due to the small size of the respective economies (and the associated demand thereof). As a result, it is more commercially viable for these manufacturers to deal with a single wholesaler on an exclusive basis. However, this may potentially raise competition concerns as the lack of competition may incentive wholesalers to charge a higher price than what would normally prevail in a competitive market.

CONCLUSION

26. Africa's reliance on imported medicines means that the supplies are susceptible to varying exchange rates and additional costs such as logistic costs thereby creating price uncertainty for medicines. These factors may be contributing to the high price of medicines making it unreachable to most people. This has adverse implications on the fiscus where in most low and middle countries the population is dependent on the public sector for their healthcare requirements. Furthermore, imported medicines are subject to global supply chain disruptions, resulting in countries encountering persistent stock-out of medicines. Therefore, it is important to develop the regional value chain for generic medicines to ensure security of supply and access to affordable medicines.

27. It is also imperative that there is sufficient competition in the generic market, as an increase in the number of generic entrants stimulates price competition which benefits consumers in the form of lower priced medicines. This accentuates the need to support, invest and develop the local API and generic manufacturing sector to improve the affordability, supply, and variety of medicines in Africa.

28. The development of the local generic manufacturing sector will also mitigate the price uncertainty and stockouts associated with the substantial number of medicines ingredients that are imported into the countries. This may result in a reduction in the medicine expenditure for both the public and private sector, which is imperative given the high burden of disease in Africa. Furthermore, the pharmaceutical sector is concentrated so generic entry may facilitate a decrease in the concentration levels, creating a more competitive market. Therefore, the development of a diverse and purposeful generic pharmaceutical regional supply chain in Africa is crucial to improving the health status of individuals as well as the overall socioeconomic development of the country.

A scientist wearing a white lab coat, a blue surgical mask, and blue gloves is holding a test tube containing a blue liquid. The scientist is looking down at the test tube. In the background, there is a microscope and other laboratory equipment. The scene is brightly lit, with a warm, golden light source in the upper right corner.

BIOGRAPHIES

GENERIC PHARMACEUTICAL STUDY BIOGRAPHIES



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4. Penelas holds an Executive Diploma in Banking, Corporate Finance and Law from the ZHAW School of Management and Law, Switzerland, an MBA from the American InterContinental University, USA, and a BSc in Economics from the Lusíada University in Angola.

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5. Hugo Nguina Fuema is a Public Aid Control senior technician at the Competition Regulatory Authority. He holds a Master's Degree in European Cooperation & Human Rights from the Pontifical University of Salamanca – Spain, Post-Graduate in Finance and Business from the BBS Institute. He has experience of teaching and working in the Private Sector.

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10. Nontobeko holds a Master of Commerce degree in Economics, obtained in 2021, from the North West University, South Africa.
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BASIRU NJIE

15. is the Director of Consumer Protection, also overseeing investigations at the Gambia Competition and Consumer Protection Commission. He is in charge of all consumer protection issues and investigations at the Commission, also involved in conducting market studies and developing policy notes to advise Government on Competition and

Consumer Protection related issues. He has over ten years' experience in conducting market research and investigations in sectors like aviation, tourism, banking, cement, public procurement, real estate, liquefied petroleum gas (LPG) and pharmaceutical etc. Basiru holds an undergraduate degree in Business Management (honors) from Kentucky State University and a postgraduate degree in International Trade and Investment (distinction) from the British University in Egypt / Baden International Business School. His main interests are with regards to competition and consumer protection policy, MSME development and entrepreneurship.

AMADOU NJIE ESQ

16. has graduated from the University of the Gambia in 2015 with LLB in law; in 2019, upon completion of the Bar Program from the Gambia Law School was called to the Gambia Bar Association. In 2021, Mr. Njie was enrolled in the Gambia to practise at the Superior Courts of the Gambia. He is currently at the Gambia Competition and Consumer Protection as Legal and Enforcement Officer. Amadou's work at the Commission is overseeing the Gambia Consumer Protection Tribunal, issuing legal analysis on competition and consumer related issues, conducting research and contributing in enriching the legal jurisprudence of the Gambia particularly in Anti-trust and Competition law.

FABAKARY TOURAY

17. successfully completed a law degree (LLB Honours) at the University of West of England (UWE), Bristol in 2008. He also did his Postgraduate Diploma in International Human Rights Law at the same university. In 2021 he successfully acquired his LLM at the University of South Wales with merits. Fabakary started working at the Commission in 2013 and he is currently the Acting Consumer Protection Manager.

MARIAMA DIBBA

18. is an investigator at The Gambia Competition and Consumer Protection Commission. She holds an undergraduate degree in Business Management (Honours) from the University of Northampton.

MUSTAPHA JOBARTEH

19. is a Regulatory officer at the Pharmacy Council, The Gambia, the regulatory body for pharmacy in The Gambia. A Pharmacy Technician and have work at the Pharmacy Council since 2019. Before that, I had worked at several public and private health facilities in The Gambia. His role and responsibilities at the council are to Conduct inspections on personnel and premises, to prepare necessary inspections reports, to undertake trekking visits by Inspectorate Unit, to Collating, evaluating, organizing and managing inspectorate information and data, to participate in performance audits and reviews related to functions of the Inspectorate Unit and to assist in the prosecution of alleged offenders of the Pharmacy Council Act and Regulations



KENYA

NINETTE K. MWARANIA

20. Provides leadership in Research, strategic planning and policy development, which are critical to advance the Authority's mandate. She is also in charge of advocacy and International Relations functions responsible for supporting in maintaining effective partnerships. In addition, she oversees knowledge management, resource mobilization and performance monitoring and evaluation for the Authority.

ARTHUR ODIMA – SENIOR ANALYST

21. Mr. Odima is a Senior Analyst in Planning, Policy and Research Division at Competition Authority of Kenya (CAK). He is a Competition and Economic Regulatory Policy Expert and carries out policy engaged research and policy analysis and advisory into economics and public policy issues relating to competition policy and economics of regulation. Mr. Odima is a seasoned and published Economic Researcher with over thirteen (13) years of experience in researching on economics, competition policy and consumer protection regulations, public policy, development economics and management of complex economics and competition policy research projects both nationally and regionally. He has led high impact research projects on topical issues of

high interest to policy makers in sectoral and emerging markets. His research interest are on (but not limited to) competition policy and law, economics of regulation, trade policy, financial inclusion, industrial economics and development economics.

22. Mr. Odima is a final year PhD candidate in Public Policy specializing on Economic Regulatory Policy at the University of Nairobi, Kenya and holds Master's degree in Economics and Bachelor of Education (Arts) degree in Economics and Mathematics both from the University of Nairobi. Additionally, he has specialist training on Public Policy Analysis, Research Methods, Econometrics and Macroeconomic Modeling from Kenya Institute for Public Policy Research and Analysis (KIPPR) and a member of International Public Policy Association (IPPA).



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YONGAMA NJISANE

23. Yongama Njisane is a Principal Economist within the Economic Research Bureau of the Competition Commission South Africa. His career in competition regulation spans over fourteen years, straddling both public and private practice. He is a published author on various competition economics topics, with particular interest in the intersection between public interest and competition law. He holds a Master of Commerce (Economics) degree from the University of KwaZulu Natal and a Master of Business Management and Administration from the University of Stellenbosch Business School.

MELISSA NAIDOO

24. Melissa Naidoo is an Economist in the Economic Research Bureau ("ERB") at the Competition Commission of South Africa ("Commission"). She has experience in strategic research projects across various industries and had worked on merger and acquisitions and abuse of dominance cases at the Commission. She holds a MCom in Economics and a BCom (Hons) in Economics from the University of KwaZulu-Natal.



AFRICAN COMPETITION FORUM

PRECIOUS MATHIBE

25. Precious Mathibe is an International Relations Specialist within the Competition Commission South Africa and serves as the African Competition Forum (ACF) Secretariat. Previously employed by the Department of Trade and Industry in the International Trade and Economic Development with the focus in Africa. She holds a Master's degree in International Business from Gordon Institute of Business Science (GIBS) and Btech Honours Level in International Communications majoring in International Relations from Tshwane University of Technology (TUT).



COMPETITION AND CONSUMER PROTECTION COMMISSION – ZAMBIA

26. The report on the ACF Cross-Country International Roaming and Pharmaceutical Study – Zambia Chapter was prepared by a team of Researchers namely Mr. Peterson Mumbuluma – Research Analyst, Ms. Thelma Simfukwe – Research Analyst, Ms. Mweete Chiluba - Research Analyst, Ms. Inonge Mulozi – Senior Research Analyst in the Competition and Consumer Protection Commission’s Research and Education Unit. The collection of data, analysis and the overall drafting of the report was coordinated by the Chief Analyst – Mr. Parret Muteto and approved by the Executive Director Mr. Chilufya Sampa of the Competition and Consumer Protection Commission. The team of Researchers that worked on the report has knowledge and a wide understanding of Competition Law and Policy, Industrial Economics, Finance and Investment Appraisal.



ZIMBABWE

TATENDA ZENGENI

27. Tatenda is a Senior Researcher at the Competition and Tariff Commission, Zimbabwe. Tatenda is responsible for heading the Commission’s Research and Public Relations Unit. Prior to joining the Commission, He worked as a Researcher at the University of Johannesburg’s Centre for Competition Regulation and Economic Development (CCRED). He has over ten years of work experience in the field of competition economics and international trade. This included representing the Zimbabwean government in trade negotiations under Common Market for Eastern and Southern Africa (COMESA), Southern Africa Development Community (SADC), and WTO. Tatenda has authored and co-authored book chapters on competition economics and presented papers at regional competition conferences. Tatenda holds a Master of Commerce in Development Economics from the University of the Witwatersrand Johannesburg, South Africa. He also hold a Bsc Hons in Economics from the University of Zimbabwe.

TATENDA MAPURANGA

28. Tatenda Mapuranga is a Research Officer at the Competition and Tariff Commission in Zimbabwe where he has gained experience in competition and international trade related research with an end goal of supporting industrial development. Prior to joining the Commission in 2018, he worked at the University of Zimbabwe as a Graduate Teaching Assistant and had exposure to industrial economics matters. Mr Mapuranga holds an MSc in Economics from the University of Zimbabwe where he participated at the Joint Faculty of Electives sponsored by the African Economic Research Consortium in Kenya. He also holds a BSc in Economics from the University of Zimbabwe.

