COMPETITION AND CONSUMER PROTECTION COMMISSION

STUDY ON COMPETITION IN THE GENERIC PHARMACEUTICAL INDUSTRY IN ZAMBIA

May 2022

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ABSTRACT

Zambia has a well-developed private and public health care system superintended by the Ministry of Health. These provide specialized medical services such as diagnostic and curative among other diseases and remains the dominant health care facility provider. The countries noted communicable diseases of public health interest are Malaria, HIV/AIDS, Diarrhea, Lower Respiratory disease, and TB while the non-communicable diseases are cervical cancer, diabetes, chronic respiratory and cardiovascular. Zambia has 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 markets. Zambia has a total of sixty-seven registered wholesalers and ten registered pharmaceutical manufacturers as of 2019. Further, payment of pharmaceuticals is mainly "out-of-pocket" and health insurance is rare.

Medicine prices in Zambia have revealed high prices for originator medicines in the large majority of settings, often 2 to 5 times higher than lowest priced generic products. Data collected during the study revealed that various pharmacies and dispensing shops showed that about 83% of the drugs on the Zambian market were generic with 17% being originator drugs. In terms of competition, 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-price option for patients and a tool to drive down prices of originator drugs. High generic market share countries have seen a larger decrease in medicine prices than low market share countries. 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 generic entry into the market. With these notable observations, the study made appropriate recommendations for the enhancement of the Generic Pharmaceutical industry in Zambia.

ACROYMNS

ABB	Activity Based budgeting
AfCFTA	African Continental Free Trade Area (AfCFTA)
CDs	Communicable Disease
CDs	Cardiovascular Diseases
DHMT	District Health Management Teams (DHMTs)
EML	Essential medicines list (EML
MoH	Ministry of Health
NCDs	Non-communicable disease
NGO	Non-Governmental Organizations
FBO	Faith Based Organizations (FBO)
MSL	Medical Stores Limited
IG	Irish Government
OECD	Organization for Economic Co-operation and Development
OBB	Output Based Budgeting
OOP	Out of Pocket expenditure
R&D	Research and Development
PACRA	Patents and Companies Registration Agency
WHO	World Health Organisation
TRIPS	Trade-Related Aspects of Intellectual Property Rights
ZAMRA	Zambia Zambia Medicines Regulatory Authority
ZAMMSA	Zambia Medicines and medical Supplies Agency

INTRODUCTION

BACKGROUND TO THE STUDY

1. The use of generic medicines has been steadily increasing internationally as a result of economic pressure on pharmaceutical budgets and the expiry of patents on widely used medicines[1]. For high-income countries, use of generic medicines has been generally supported by a series of policies promoting their utilization and these policies have been subject to continuous monitoring and evaluation[2]. The World Health Organisation (WHO) found that medicines account for 20% – 60% of overall healthcare expenditure in low- and middle-income countries, compared to less than 18% in countries belonging to the Organization for Economic Co-operation and Development (OECD), which triggered growing concerns about the affordability of medicines on the African continent[3]. The WHO also found that 90% of the population in low and middle-income countries purchase medicines through out-of-pocket payments, making medicines the largest family expenditure item after food[4].

2. Out-of-pocket spending in 2018 ranged from 9.98% (Zambia) to 23.54% (Seychelles). Other countries with high out-of-pocket payments include Nigeria (76.60% of health expenditure) and Bangladesh (73.87%)[5].The generics industry is critical to introducing competition and reducing medicine prices when a patent has expired[6]. Low and middle-income countries (LMICs) have had better availability and lower medicine prices than others showing that access to quality assured, affordable essential medicines can be improved through stronger partnerships among governments, pharmaceutical companies and civil societies[7].

3. The WHO concept of essential medicines developed over 30 years ago, and its associated Model Essential medicines list (EML), assists countries to select safe and effective medicines that are relevant to their populations' needs. Many medicines on the Model EML are produced as 'generic' versions of medicines originally made by the so-called "originator" company (a manufacturer that was first on the relevant market with the particular medicine and that conducted research and development (R&D) that lead to the product)[8]. Typically, the originator company gives the medicine a unique name as a 'brand' to identify it in the minds of the providers and consumers[9].

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5594322/
[2] https://haiweb.org/wp-content/uploads/2017/02/HAI_Review_generics_policies_final.pdf
[3] https://www.oecd.org/health/Health-Brochure.pdf
[4] https://www.who.int/publications/10-year-review/chapter-medicines.pdf
[5]https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS?end=2018&locations=ZM&name_desc=false&start=2
[6] https://repository.uchastings.edu/cgi/viewcontent.cgi?article=3898&context=hastings_law_journal
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7159295/
[8] https://apps.who.int/iris/rest/bitstreams/65092/retrieve
[9] https://pubs.rsc.org/en/content/chapterhtml/2015/bk9781782621898-00001?isbn=978-1-78262-189-8

Medicine prices in LMICs have revealed high prices for originator medicines in the large majority of settings, often 2 to 5 times higher than lowest priced generic products[10].

4. The generics industry is vital to ensuring competition in the medicine market and reducing the prices of medicines when the patent has expired[11]. The speed and depth of price reductions for off-patent medicines is dependent on the extent of competition amongst generic pharmaceutical companies[12]. Competition in the generics industry is influenced by the number of companies operating in the market, their capabilities, and their pipeline of medicines[13]. The pipeline, in turn, is likely to be impacted by the market size for medicines at generic prices, the investment required to develop and market the generic medicines, and the market share that generic companies can secure[14].

PURPOSE OF THE STUDY

5. The purpose of the study was to get a better understanding of the extent of competition in the generic medicine market of Zambia and to understand the barriers to entry and expansion in the generic market. This provided important insights into the factors that promote greater levels of competition and investment in domestic capacity. The study also provided important insights and support for efforts to boost continental capabilities in generics around vaccines, communicable and non-communicable diseases prevalent on the continent.

OBJECTIVES

6. The study objectives were as follows;

- To understand the extent of competition in the generic medicines market of Zambia.
- To understand the barriers to entry and expansion in the generic medicines market.
- To assess market trends in prices of generic medicines and branded medicines.

[10] https://haiweb.org/wp-content/uploads/2017/02/HAI_Review_generics_policies_final.pdf
[11] https://www.oecd.org/competition/generic-pharmaceuticals-competition.htm
[12] https://www.oecd.org/competition/generic-pharmaceuticals-competition.htm
[13] https://unctad.org/system/files/official-document/tdrbpconf8d3_en.pdf
[14] https://www.nber.org/digest/nov17/competition-generic-drug-markets

METHODOLOGY

7. The methodology used in the study involved collecting information in phases. A combination of primary data was collected using survey instruments along with review of secondary data. Primarily, the Commission collected information on generic and originator prices of medicines randomly from local pharmacies across the country. The prices collected provided essential information on the generic pharmaceutical. The Commission also engaged the Zambia medicines Regulatory Authority (ZAMRA) on the legal framework of the sector. The study also used secondary information gathered from several credible sources that included published studies, articles, journals, and websites.

LIMITATIONS OF STUDY

8. The major limitation of the study was failure to receive responses from key stakeholders identified at the inception of the study which limited the scope of analysis conducted.

STUDY FINDINGS

OVERVIEW OF THE HEALTH SECTOR IN ZAMBIA

9. Zambia has a well-developed private and public health care system which provides specialized medical services such as diagnostic, curative among others[15]. The healthcare system in Zambia is run by state and non-state actors, which include Non-Governmental Organizations (NGOs) and Faith Based Organizations (FBO)[16]. 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 Zambia[17]. Church-affiliated facilities are common and are well integrated into the government system in terms of service delivery practices and reporting[18].

10. Over the years, Government increased the investment in the health sector with the construction of new health facilities at provincial and district levels. Government has remained the dominant health care facility provider with approximately 81% of the health facilities across the country owned and

[15] Health Sector Profile; Zambia Development Agency (ZDA), June 2013. Retrieved 29th December 2021.
[16] COUNTRY PROFILE: ZAMBIA - The Center for Health Market https://healthmarketinnovations.org › default › files
[17] National Heath in All Policies Strategic Framework 2017-2021, 2018 MoH, Zambia. https://www.afro.who.int/sites/default/files/201905/NATIONAL%20HEALTH%20IN%20ALL%20POLICIES%20%20STRATEGIC%20FRAMEWORK%20%20%283%29.pdf. Retrieved 4th January 2022
[18] 2014 Zambia Malaria Concept Note (link is external) (link is external) for the Global Fund

managed by Government with 13% owned and managed by the private sector and 5% owned and managed by the faith-based organizations.

11. In addition to investments in physical infrastructure, 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, 2018[19] 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.

Figure 1. Examples of hospitals in Lusaka, Zambia.

	
Levy Mwanawasa Teaching Hospital	Lusaka Specialised Hospital

REGULATORY FRAMEWORK

12. 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 system[20]. The Zambian generic medicine regulatory system includes institutions and legislation as follows.

MINISTRY OF HEALTH (MoH)

13. The Ministry of Health (MoH) is the superintendent of the health system in Zambia and provides information about health and delivery of health services[21]. The MoH has the ultimate responsibility for delivery of health care services within Zambia[22]. Leadership within the health system includes setting priorities and an overall vision and direction for the health system[23]. The MoH is additionally responsible for health policy formulation and oversees

[19] https://www.nhima.co.zm

[20] 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.

[21] "Ministry of Health". moh.gov.zm. Retrieved 5th January 2022.

[22] "Ministry of Health". www.moh.zm. Archived from the original on 28 July 2015. Retrieved 5th January 2022.

[23] https://ab-network.jp/wp-content/uploads/2014/07/Health-Sector-Profile.pdf

referral of health services from Level 2 provincial hospitals up to Level 3 tertiary hospitals, health training institutions and health statutory boards[24].

ZAMBIA MEDICINES REGULATORY AUTHORITY (ZAMRA)

14. 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 substances[25]. 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 practices[26].

ZAMBIA MEDICINES AND MEDICAL SUPPLIES AGENCY (ZAMMSA)

15. 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 furnishing to the nation good quality drugs and medical equipment at accessible prices[27]. 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 country[28]. ZAMMSA was established under the Companies Act (current 1999)[29]. The Company's original mandate was to carry out procurement, storage and distribution of all essential drugs for Zambia's public health sector[30].

THE PATENT AND COMPANY REGISTRATION AGENCY (PACRA)

16. 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 with the registration and enforcement of patent rights. Zambia recently reviewed its patent law to align

[24]World Health Organization (WHO). (2014, August 03). Country Corporation Strategy: Zambia. Retrieved from World Health Organization: http://www.who.int/countryfocus/cooperation_strategy
[25] https://ab-network.jp/wp-content/uploads/2014/07/Health-Sector-Profile.pdf
[26] Zambia Medicines Regulatory Authority (ZAMRA). https://www.zamra.co.zm
[27]https://www.parliament.gov.zm/sites/default/files/documents/committee_reports/REPORT%20ON%20HEALTH%20-%202021_0.pdf
[28]https://www.zamra.co.zm/wp-content/uploads/2021/02/ZAMBIA-PHARMACOVIGILANCE-Handbook-March-2020.pdf
[29] Ibid 39
[30] Ibid 40

with international best practice and provides for a patent period of 20 years, exhaustion of rights and compulsory licensing.

COMPETITION AND CONSUMER PROTECTION COMMISSION

17. 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 markets including the pharmaceuticals as well as consumer protection.

ZAMBIA PUBLIC PROCUREMENT AUTHORITY

18. 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 procurement[31]. 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 pricing[32].

PROCUREMENT OF MEDICINES IN ZAMBIA

19. 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 involvements 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 sites[33].

20. Effective procurement and distribution of essential medicines and medical supplies is critical for maintaining the health of Zambia's citizens[34]. 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

[31] https://www.zppa.org.zm › public-procurement-act
[32] Ibid 31
[33] https://www.devex.com/organizations/medical-stores-ltd-98363
[34] https://www.usaid.gov/zambia/fact-sheets/usaidzambia-health-office-global-health-supply-chain-procurement-and

Limited (MSL)[35]. Secondary distribution fell under the responsibility of District Health Management Teams (DHMTs) reporting to the MOH[36]. The MSL hubs function as 'Cross docking' hubs which entails those orders, from facilities across Zambia are assembled from the central MSL and transported to regional hubs that the transport respective stock to its facilities[37].

21. 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 direct 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)[38].

22. 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 Agency[39]. Effectively, all procurement, management and distribution of essential medicines and medical supplies are now the preserve of the Zambia Medicines and Medical Supplies Agency.

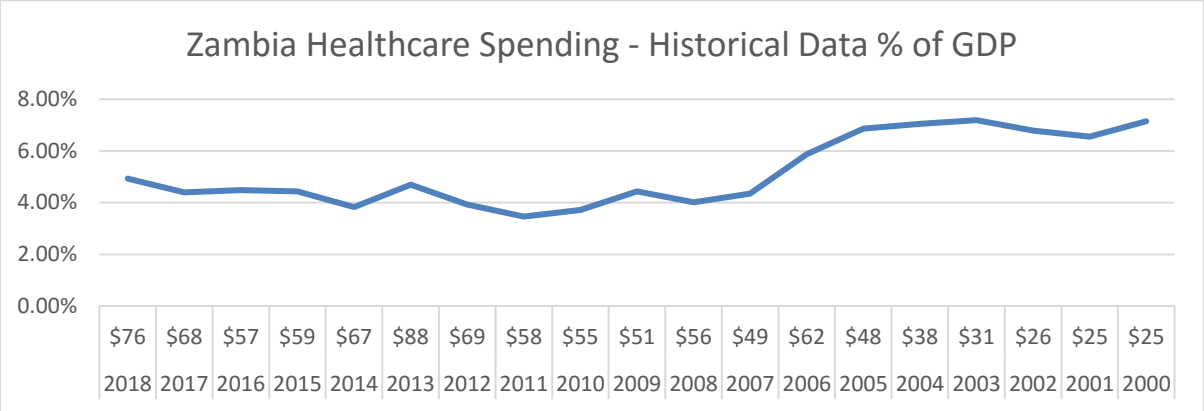
GOVERNMENT EXPENDITURE

23. Zambia's Public Budget system has undergone substantial changes. Most notable, from the period 1991 to 2000s. 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 result oriented[40].

[35]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.
[36]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
[37] https://www.medstore.co.zm/services-4/distribution/
[38] https://www.idc.co.zm/industry-sectors/health-care-2/medical-stores-limited/
[39] https://www.parliament.gov.zm/node/8205

[40] https://transectscience.org/the-zambian-public-budget-system-has-under-gone-significant-transformations/

Figure 2: Zambia Healthcare spending – Historical data of GDP[41]



24. Over the past 8years, government expenditure of 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 that its regional peers on per capita basis. For example, the 2019, expenditure at $57 was lower compared to $86 for Lesotho and $221 for Swaziland. Household expenditure accounting 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 has only been around 9.5% with an average change in per capita allocation of 11%[42].

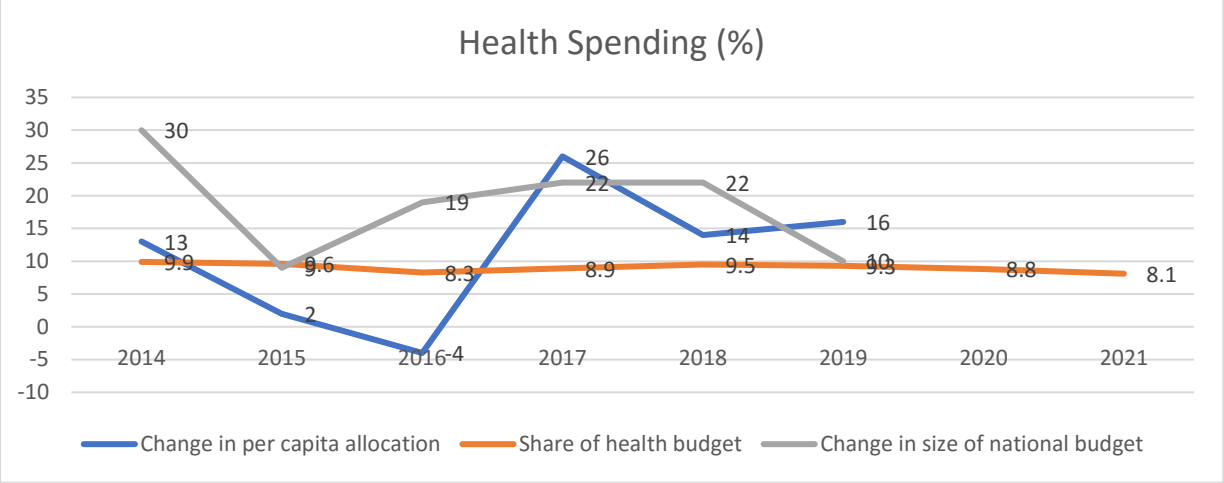
25. The MOH's buys essential medicines and medical supplies through framework contracting, with the goal of ensuring a guaranteed and uninterrupted supply of the commodities. Through a competitive bidding process, suppliers receive two-year procurement contracts. During this period, contracts lock in 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% has reduced the real value of the allocation. This decrease in real value reduces the quantity of imported drugs and medical supplies from a given budget allocation while the debt service on purchased products increases[43].

[41] Source: https://www.macrotrends.net/countries/ZMB/zambia/healthcare-spending

[42] https://www.pwc.com/zm/en/assets/pdf/zambia-budget-2018.pdf

[43] Source: Republic of Zambia Ministry of Health - Health Financing Strategy: 2017 – 2027

Figure 3: Health Spending[44]



OUT OF POCKET EXPENDITURE ON HEALTH

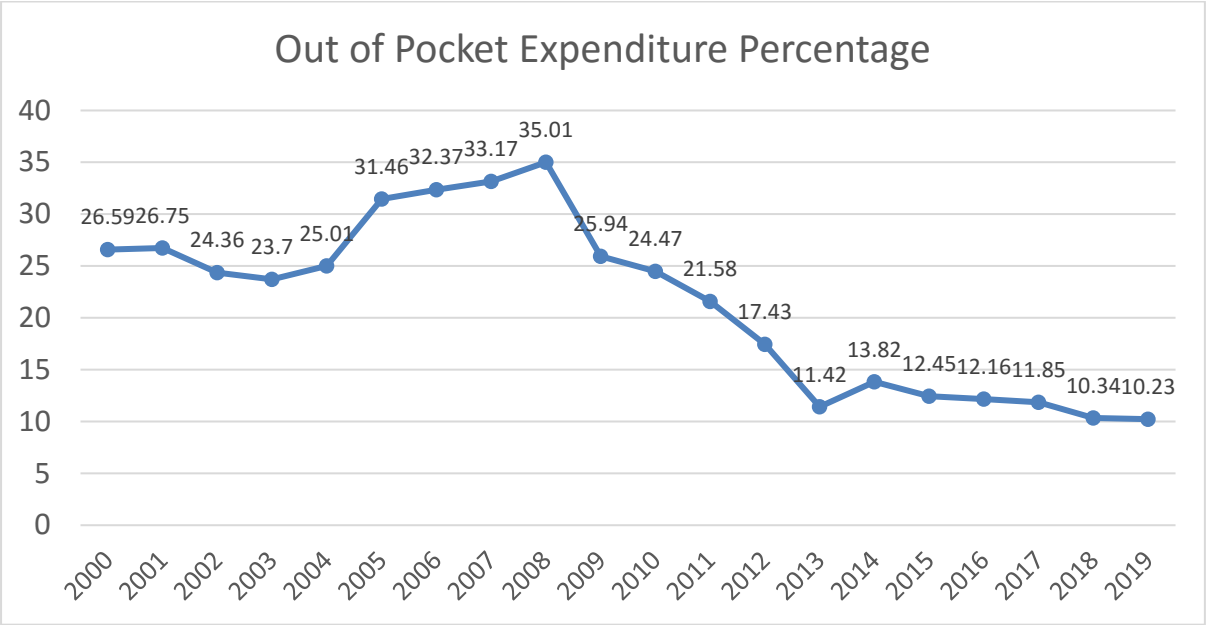
26. Out of Pocket expenditure (OOP) on health spending, is considered as an inequitable source of health spending, it has remained a significant source of health expenditure in Zambia. Evidence shows that only 20% of households pay using OOP to access public health services while the majority seek for primary health services by not paying using OOP, thus, minimal fees such as user fees do not hinder access to healthcare[45]. 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)[46].

[44]Source:https://www.unicef.org/esa/media/5006/file/UNICEF-Zambia-2019-Health-Budget-Brief.pdf and https://www.parliament.gov.zm/node/8121

[45]https://www.afro.who.int/sites/default/files/2020-09/Health%20Care%20Financing%20Strategy.pdf

[46] Ibid[77]

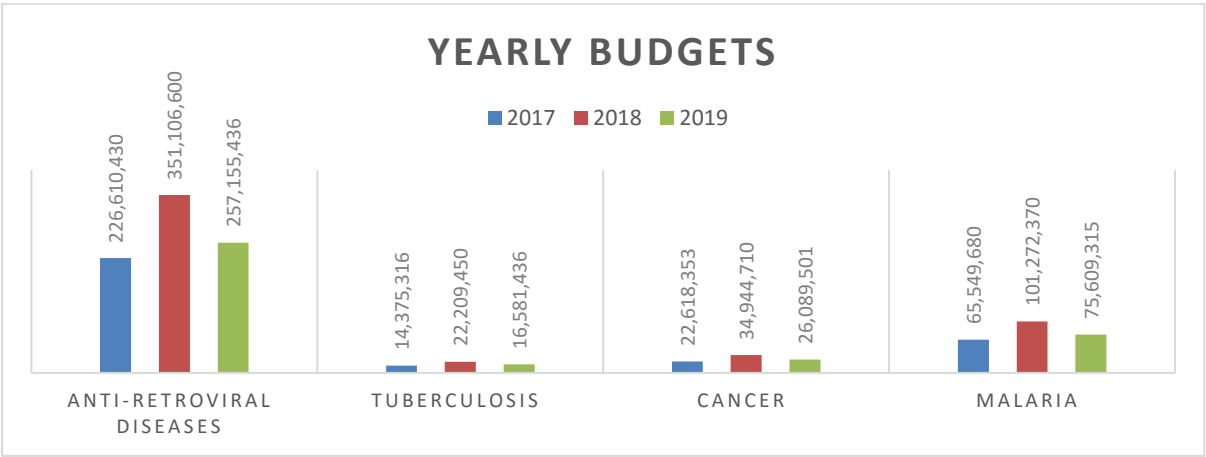
Figure 4



PROCUREMENT OF DRUGS

27. 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 Tuberculosis, Cancer and Malaria equally saw an increment from 2017 to 2018 before a decline in 2018 to 2019[47]. In 2022 the annual budget towards essential drugs and medical supplies procurement was K1.1 billion, a 36.2% increment from K718 million for 2021[48].

Figure 5: Procurement of drugs[49]



[47] 2017 to 2019 yellow books
[48] https://www.parliament.gov.zm/node/9885
[49] Source: Yellow books from 2017-2019

28. Procurement of medicines and medical supplies has equally seen a fair share of support from corporation partners such as the USAID, Swedish International Development Cooperation Agency (SIDA), European Union (EU), World Health Organization (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 medicine and medical supplies[50].

ZAMBIA DISEASE BURDEN

29. 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.

30. The disease burden in Zambia varies according to region with the most prevailing diseases being Malaria, HIV/AIDS, Tuberculosis, Diarrhea and Lower Respiratory tract infections[51]. Recently Zambia seen a sudden non-communicable disease (NCDs) such as Hypertension, Diabetes, Chronic respiratory disease, cardiovascular disease, and Cancer (cervical) [52].

31. Data indicate that 29%[53] of all deaths in Zambia are attributed to NCDs. This is high, 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 inactivity[54].

COMMUNICABLE DISEASES (CDS)

32. 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

[50] Ibid[70]
[51] 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
[52]Health Sector Profile; Zambia Development Agency (ZDA), June 2013. Retrieved 29th December 2021.
[53]2016 WHO NCD country profiles,
[54] https://www.afro.who.int/publications/prevention-and-control-non-communicable-diseases-zambia-case-investment

reservoir to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector, or environment[55]. Communicable diseases can cause epidemics and pandemics which have the potential to overwhelm the capacity of communities; with serious health and socio-economic consequences[56]. There are five main Communicable diseases of public health interest in Zambia: malaria, HIV/AIDS, Diarrhea, Lower Respiratory disease and TB[57].

NON-COMMUNICABLE DISEASES

33. Non-communicable diseases (NCDs) have been traditionally defined as chronic diseases that were non-infectious by nature[58]. 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 diabetes[59]. There has been growing concern over NCDs particularly in low and middle-income countries like Zambia as they contributed significantly to mortality and morbidity[60]. 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 NCD[61]. Figure 6 below illustrates the NCDs cause of death.

[55]Fighting the Top Diseases in Zambia Through Collaboration: https://borgenproject.org/fighting-top-diseases-in-zambia/ Retrieved 5th January 2022

[56]Health Emergency and Disaster Risk Management Communicable diseases: Health Emergency and Disaster Risk Management Fact Sheets: December 2017. https://www.who.int/hac/techguidance/preparedness/risk-management-communicable-diseases-december2017. 4th January 2022

[57]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.

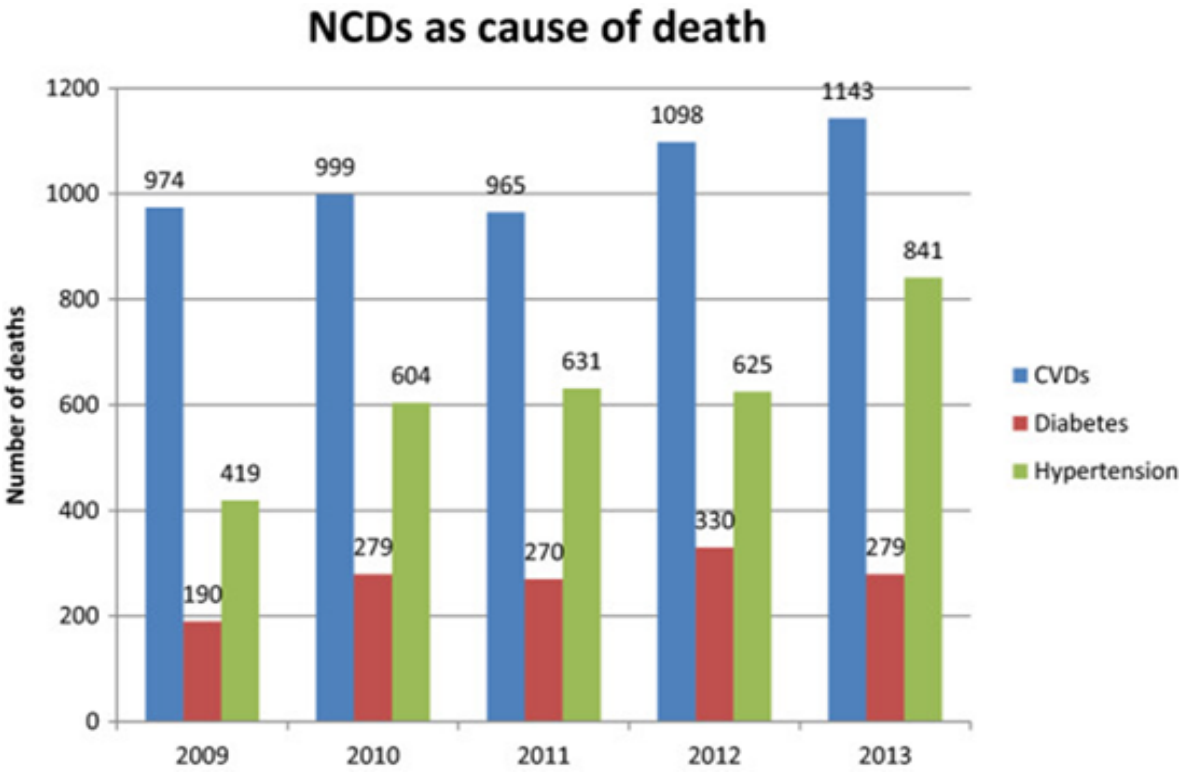
[58]Zambia National Health Strategic Plan 2017-2021

[59]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.

[60] Responding to Non-communicable Diseases in Zambia: a Policy Analysis: Mulenga M. Mukanu, Joseph Mumba Zulu, Chrispin Mweemba and Wilbroad Mutale https://health-policy-systems.biomedcentral.com › articles

[61] WHO Country Profile: Zambia. (2016, June 9). Retrieved from World Health Organization: http://www.who.int

Figure 6: NCDs cause of death



34. 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 illnesses[62].

PHARMACEUTICAL PROFILE

35. Zambia has a total of sixty-seven (167) registered wholesalers of pharmaceutical products and ten (10) registered pharmaceutical manufacturers these 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

[62] Ministry of Health Zambia - Prevention and control of non-communicable diseases in Zambia - The case for investment

Life Sciences Limited, Mylan Laboratories Limited, Missionpharma Zambia Limited and Yash Pharmaceuticals Limited[63].

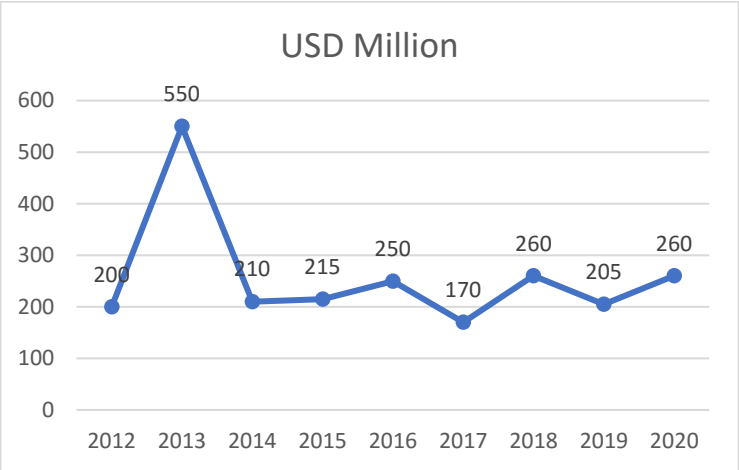
36. It is estimated that the local production represents between 10-15% of the demand for pharmaceuticals in Zambia. The country has no multinational pharmaceutical companies, the current operating pharmaceutical companies can be categorized as Uni-national pharmaceutical companies[64]. These companies mostly do the secondary production which is the formulation of bulk pharmaceuticals into various pharmaceutical dosage forms.

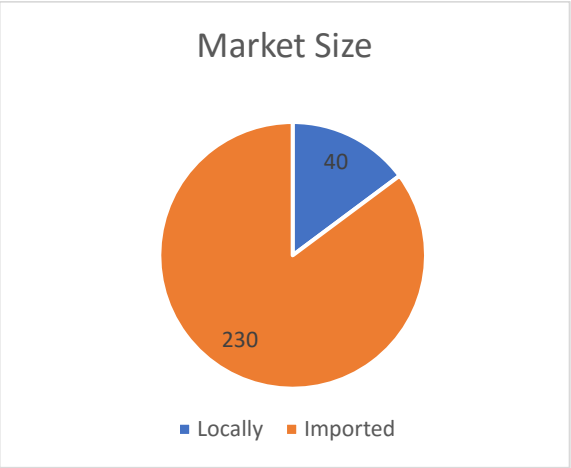
37. The local manufacturing of essential medicines in Zambia meets with manifold challenges related to internal dimensions of manufacturing and, the operating environment[65]. The country's manufacturers of pharmaceutical products do not meet the World Health Organization (WHO) pre-qualification standards, which then limits their production and excludes them from participating in international public tenders[66]. 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 pandemics.

38. Zambia's imports of pharmaceutical products were around US$260.07 Million during 2020[67] 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 million[68].

Figures 7: Zambia's imports of pharmaceutical products 2012-2020 and percentages of Zambia's locally produced and imports pharmaceuticals.

[63] ZAMRA submission
[64] https://zambiatrade.work/top-7-importers-of-pharmaceutical-products-in-zambia/
[65] https://www.cgdev.org/sites/default/files/Procurement-factsheet-generics-competition.pdf
[66] https://joppp.biomedcentral.com/articles/10.1186/s40545-021-00337-4
[67] United Nations COMTRADE database on international trade
https://tradingeconomics.com/zambia/imports/pharmaceutical-products
[68] 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





BARRIERS TO ENTRY AND EXPANSION

39. 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 rate of innovation to produce lifesaving medication. Investment into state-of-the-art laboratory, research facilities and research personnel in Zambia's health sector has lagged and affected the level of patented innovations.

40. Zambia has remained one of the worst performers in innovation and ranked 122 out of 131 countries in terms of innovation[69]. 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.[70]

41. Another major challenge for manufacturing growth in the sector is that excise duty is charged on raw materials and products of the pharmaceutical sector. Whilst there are no import duties on final pharmaceutical products that are imported into Zambia, disincentivizing local manufacturing. Therefore, trading and distribution become easier for Zambia pharmaceutical companies as they would rather import and distribute rather than manufacture locally[71].

42. Moreover, the lack of pharmaceutical product intellectual property registration in developing countries which increases production costs

[69] Global Innovative Index by the World Intellectual Property Organisation (WIPO),
[70] Patents and Companies Registration Agency (PACRA) 2020 annual report,
[71] http://zam.co.zm/propelling-big-pharmaceuticals-in-zambia/?utm_source=rss&utm_medium=rss&utm_campaign=propelling-big-pharmaceuticals-in-zambia

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 advantage of this large market to establish a big pharmaceutical industry, whilst also having strong export markets in several developing nations[72].

ZAMBIAN PATENT SYSTEM

43. 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.

44. 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.

45. Indications are that Zambia is largely an importer to a large extend 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 distributions.

46. 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 AVAILABLE GENERIC DRUGS

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

47. Drug availability and its alternatives determines 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 drugs[73]. 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/AIDS drug owned by Merck[74] 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 drug[75].

48. Besides compulsory licensing, parallel imports are applicable to a WTO member under the exhaustion of rights. In addition to making drugs available and increasing competition, they also reduce incidences market segmentation and price discrimination by patent holders on a regional or international scale[76].

PROMOTION OF PHARMACEUTICALS

49. 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 leave 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 countries' patent regimes. Countries moving to long product-patent terms reduced drug launch lag times by 55 percent[77].

COMPETITION ASSESSMENT

[73] https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm
[74] ournal of International Business and Law, Vol. 8, Iss. 1 [2009], Art. 9
[75] 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."'
[76] Mwalongo, Buchisa K. (2013) **Applicability of compulsory license under the Zambian Patent law.** **http://dspace.unza.zm/bitstream/handle/123456789/2902/MWALONGO.K.B1.PDF?sequence=1&isAllowed=y**
[77] https://itif.org/publications/2018/08/24/spread-compulsory-licenses-threatens-undermine-latin-americas-innovation

50. Zambia is among the 152 developing countries in the world[78]. 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 markets[79]. For a country where payment of pharmaceuticals is mainly "out-of-pocket" and health insurance is rare, escalating and unrealistic prices play a central role in denying access to patients of life-saving medicines[80]. 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 customers[81].

51. 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 drugs[82]. Price competition from generic medicines leads to price reductions appears to vary according to the market share of generic medicines. High generic market share countries have seen a larger decrease in medicine prices than low market share countries[83]. 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 generic entry into the market[84].

ZAMBIAN PHARMACEUTICAL MARKET

52. Zambia has 167 registered wholesalers as well as ten (10) manufacturers of pharmaceutical products and has no multinational pharmaceutical companies. The ten currently operate as Uni-national pharmaceutical companies[85]. These companies mostly do secondary production which is the formulation of bulk pharmaceuticals into various pharmaceutical dosage forms[86]. Table 1 below shows the registered manufacturers and their product range;

Table 1; Range of products produced in Zambia

[78] https://www.worlddata.info/developing-countries.php
[79] https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf
[80] https://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf
[81] https://pubmed.ncbi.nlm.nih.gov/21797288/
[82] https://www.oecd.org/competition/generic-pharmaceuticals-competition.htm
[83] https://pharmaceutical-journal.com/article/news/market-competition-a-predictor-of-changes-in-generic-drug-prices-concludes-us-study
[84] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7540181/
[85] Cardino Shaping Future Report (2011:11)
[86] Management Science for Health (1997:47)

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
Pharmanova (Zambia)Limited	Analgesics including NSAIDS, antipyretics, lexativs, 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

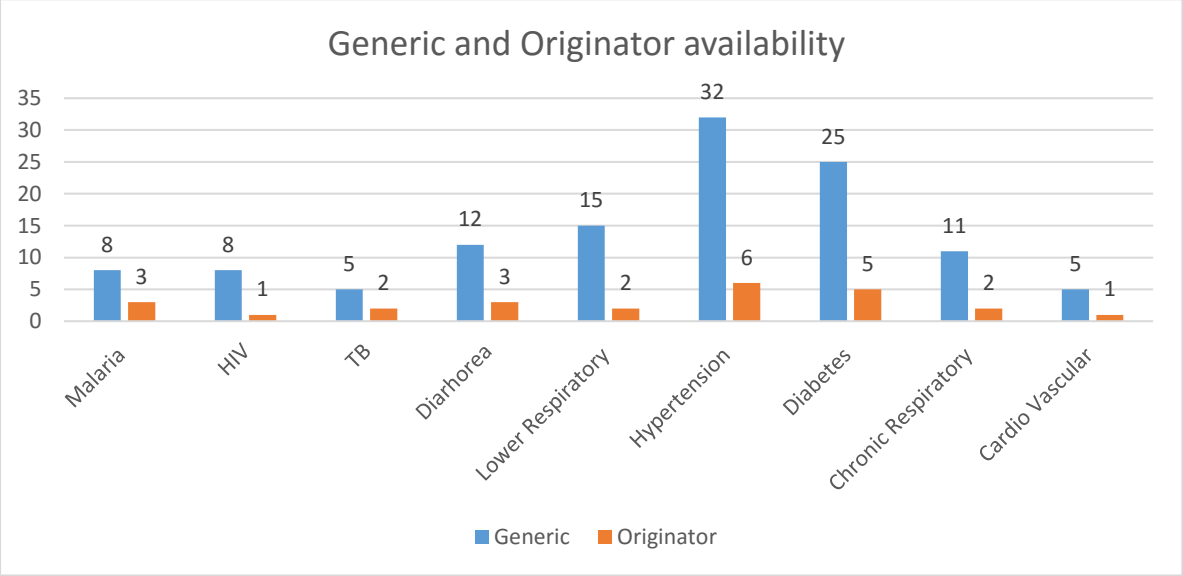
53. A generic drug is created to be the same as an existing approved brand-name drug in dosage form, safety, strength, method of administration, quality, and performance characteristics[87]. Generic medications, like branded drugs, require generic market competition before costs decline; two to three years after losing exclusivity protection. Generic drug prices typically fall by 60–70

[87] US Food and Drug Administration (FDA)

percent relative to their branded counterparts[88]. Even for very old unpatented pharmaceuticals, sustained market competition is required to keep prices down.

54. 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. Hypertension and diabetes were two NCDs with a significant number of generics on the market while Malaria and Diarrhea had a fair number of generic. In addition to generic offering competitive pressure on originator drugs, significant samples of generic medicines were equally expected to create intra-generic drug market competition. The Figure 8 below show the distribution of sampled drugs per illness.

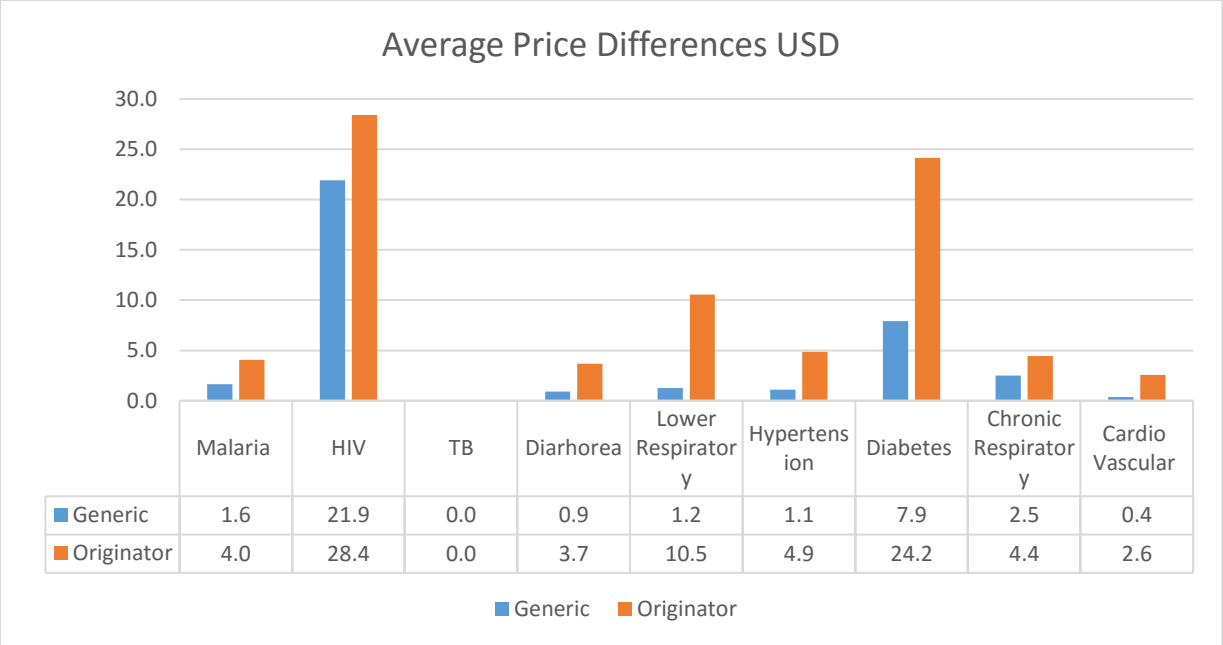
Figure 8: Generic and Originator drugs available



55. 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, originators were USD10.5 while generics were USD1.2 dollars. The onset of the COVID 19 pandemic may partly explain the high prices difference and the existence of the large varieties on the market. The Figure 9 below shows the price difference in USD per disease class.

Figure 9: Price difference in disease class

[88]https://www.europeanpharmaceuticalreview.com/article/166397/generic-drug-market-growth-insights-to-2030/



	Malaria	HIV	TB	Diarhorea	Lower Respiratory	Hypertension	Diabetes	Chronic Respiratory	Cardio Vascular
Generic	1.6	21.9	0.0	0.9	1.2	1.1	7.9	2.5	0.4
Originator	4.0	28.4	0.0	3.7	10.5	4.9	24.2	4.4	2.6

56. The Lower Respiratory diseases and the cardiovascular diseases recorded the highest price differences with 746% and 579% respectively. Hypertension and Diarrhea diseases recorded 338% and 301%, followed by Diabetes with 205% and Malaria with 148%. Chronic Respiratory diseases and HIV were at the least end with 77% and 30% respectively.

MALARIA

57. Malaria is a tropical disease which is treated using drugs with active ingredients which include Artemether 20mg + Lumefantrine 120mg tablets, Artesunate 200mg + Sulfamenthoxypyrazine 500 mg + Pyrimenthamine 25mg and Sulphadoxine 500mg + Pyrimethamine 25mg. The Originator brands for the three active ingredients are Coartem, Co-Arinate and Fancidar while the generic drugs included Artefan, Shal-Artem and Lonart comprising Artemether + Lumefantrine, Paludoxin and Maladox comprising and Sulphadoxine + Pyrimethamine while the active ingredient Artesunate + Sulfamenthoxypyrazine + Pyrimenthamine had no generic drug. While Malaria recorded many around 8 generic drugs and 3 originator drug, there were still may generic drugs on the market which included Fantem, Komefan, Lumether, Lumartem and sulphadar.

58. Malaria recorded a price difference between the originator brands and the generic brand of 148% with the originators averaging $4 while the generic brands averaged $1.6.

HIV

59. HIV drugs on the Zambian market a preserve of the government as they are distributed at government hospitals. The drugs are highly controlled and sticked by very limited pharmacies across the country. The study looked at 8 generic brands and 1 originator drugs 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.

TUBERCULOSIS

60. Tuberculosis drugs are highly controlled in Zambia and are a 100% preserve of the government. When abused, the tuberculosis drugs can become resistance 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.

DIARRHEA

Diarrhea is usually a symptom of an intestinal tract infection. A variety of bacterial, viruses and parasites can cause diarrhea. The infection is usually spread through contaminated food, or drink or from person to person due to poor hygiene. Diarrhea is treated by using antibiotics or a combination of antibiotics. These include Oral Rehydration Salt, Novalyte (ORS), Metronidazole (per strip), Cotrimoxazole (per strip), Zentel, Albenza, Nalidixic Acid (500g), Metroz 200, Trim-480, Azilidixic Acid, Nalix 500mg, Loperamide which are generic brand of the originators Flagyl, Septrin, Albendazole and Imodium. The price difference between the generic brands and the originators was 301% different.

LOWER RESPIRATORY TRACT INFECTIONS

61. The lower Respiratory Tract Infections (RTI) occur when an infection affects the lungs or the lower airways. The RTI are usually caused by a virus (most

infections), bacteria or any other organisms (less common). The most common RTIs include flu, bronchitis and pneumonia. The study sampled 15 generic drugs and 2 originator drugs with the average price difference of 746%. The RTI recorded the highest price differences among all the diseases. This could be attributed to the increase in the demand for RTI form 2019 due to the Covid-19 pandemic which mainly used medication like Azythromicin (generic) and Zithromax (Originator) as a major part of the treatment.

62. Azithromycin is a licensed, widely available, cheap, and generally safe drug which was proposed as a treatment for COVID-19[89]. Azythromicin recorded the highest prices among the generic drugs while Zithromax recorded the highest between the 2 originator drugs. It was also observed that the ratio of the originator brands was very low compared with the generics present on the market, as such, the price of the originator drugs was comparatively high due to limited competition. with regards to the generic brands, the variety offered a wider choice resulting in lowere prices, with an exception of Azithromycin which was used in the treatment of Covid-19.

63. The 15 generic drugs sampled included Benzylpenicillin, Penicillin, Agycin, Catox, Ceftriaxone (Shalina), Ceftriaxone, Ciprofloxacin (Otiprio), Cipron, Cipro (Ciprofloxacin), NegGram, Doxycone, Doxycycline, Erythrone, Erythromycin and Azithromycin. The 2 originator drugs sampled included Rocephin and Zithromax.

HYPERTENSION

64. 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, Amlo-denk, 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%.

[89] https://www.thelancet.com/article/S0140-6736(21)00461-X/fulltext#:~:text=Azithromycin%2C%20a%20licensed%2C%20widely%20available,including%20SARS%2DCoV%2D2.&text=et%20al.

DIABETES

65. 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 price. 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.

66. Diabetes generic drugs 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 Asphart, 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).

CHRONIC RESPIRATORY DISEASE

67. The Chronic Respiratory Diseases (CRDs) are diseases of the airways and other structures of the lungs. Some of the most common CRDs include asthma, chronic bronchitis and pulmonary hypertension. CRD is mainly treated with an active ingredients Salbutamol and hydrocortisone, whose generic drugs include Salbutamol, Salbutamol (inhaler), Ventis, Asthalin (Sabutamol), Aerocort, Aminophylline, Bonair, Aminophylline, Galcort, Predinisolone and Intravenous steroids (Hydrocortisone cream and injection). The originator drugs used to treat CRDs include Ventolin and Hydrocortisone. The price difference between the generic and originator brands was 77% with the originator brand averaging $4.4 while the generic brand averaged $2.5.

CARDIOVASCULAR DISEASES

68. Cardiovascular diseases are characterized by diseases affecting the heart. These include abnormal heart rhythms, congenital heart diseases, heart attack, heart failure, coronary artery disease and deep vein thrombosis. The generic drugs sampled include acetylsalicylic, Kaydigo, Kausikh, Frude -5 and

Frusemide. Only one originator drug, Aspirin, was sampled. The price difference between the generic and originator brands was 77%, indicating that Aspirin was 77% more expensive than the generic brands.

CONCLUSION

69. 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.

70. 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 of out-of-pocket expenditure.

71. 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.

72. 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 of her 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.

73. 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. Despite a significant presence of generics on the market, some class of diseases like Diabetes still had large price differences between generics and originators.

RECOMMENDATIONS

74. 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 countries potential and capacity to produce its own generics and or panted drugs. Therefore, based on the above facts and findings, the following recommendations were made:

Issue	Concern	Recommendation	Expected Impact	Key Actors
Increase inter and intra-drug competition	Moderate drug competition in some disease classes	Expanded approved drug list of generics for Zambia	Increased competition between generic and branded and within generics	ZAMRA
Low competition at distribution level of generic drugs	Few distributors engaged in the distribution of generic drugs contributes to high prices of drugs	Foreign generic drug manufacturers should not be allowed to have sole distributors of their drugs on the Zambian market	Increased competition in the distribution of generic drugs	ZAMRA

ANNEX 1: IDENTIFIED COMMUNICABLE AND NON-COMMUNICABLE DISEASES, TREATMENT FOR EACH OF THE DISEASES, SELECTED MEDICINE DOSAGES

These top five CDs/NCDs and there known treatments are listed in the table below;

Communicable Disease		**Dosage/Treatment/Active ingredients**
1	Malaria	-Coartem (120/20mg) (480mg/80 mg)
		-Artemether 20mg + Lumefantrine 120mg tablets
		-Sulphadoxine 500mg + Pyrimethamine 25mg is a single treatment of half a tablet
2	HIV/AIDs	-Ritonavir/Atazanvir: 100 mg Unable to tolerate ritonavir: 400 mg
		efavirenz: 400 mg (with ritonavir 100 mg)
		Tenofovir: 400 mg (with ritonavir 100 mg)
		Nevirapine 200mg tablets/Suspension 50mg/5ml
3	Tuberculosis	The following dosages of anti-TB medicines should be used daily for the treatment of TB:

		isoniazid (H)	10 mg/kg (range 7–15 mg/kg); maximum dose 300 mg/day
		rifampicin (R)	15 mg/kg (range 10–20 mg/kg); maximum dose 600 mg/day
		pyrazinamide (Z)	35 mg/kg (range 30–40 mg/kg)
		ethambutol (E)	20 mg/kg (range 15–25 mg/kg)
4	Diarrhea	- Oral Rehydration Salt (ORS) solution or any fluids after each loose stool -Loperamide 2mg three times daily -Metronidazole 400mg 8 hourly orally for 7 days	

		-Cotrimoxazole 960mg four times daily orally for 10 days -Cryptosporidia – Albendazole 400mg twice daily orally for one month -Nalidixic Acid. Adult: 1g orally 4 times a day for 7 days Child: 50mg/ kg body weight orally in 4 divided doses for 7 days -Ciprofloxacin - children 15mg/kg; adults 500mg twice daily for 3 days -Doxycycline One single dose (Adults 300mg/Children nil) -Erythromycin Adults: 4 times daily for 3 days Children: 3 times daily for 3 days (Adults 250mg/Children10mg)
5	Lower Respiratory Tract Infections	• Benzylpenicillin 1-2MU intravenously 6 hourlies for 5 days adults, children 25,000-50,000 units/kg intravenously/intramuscularly in 4 divided doses for 7 days (as soon as the symptoms and respiratory rates are controlled change to oral medication i.e. Amoxycillin 250mg for adults and 125 mg/5ml in children) or • Ceftriaxone 1g - 2g daily adults, children 20 50mg/kg daily intravenously/intramuscularly for 7 days. if allergic to penicillin or 183 • Azithromycin 500mg adults, orally 6 hourly for 7 days, children 20- 30mg/kg in 4 divided doses for 7 days • Oxygen is indicated if respiratory distress or cyanosis is present Non-opiate analgesics; Paracetamol 500mg - 1g orally 3 - 4 times daily adults, children 10-20mg/kg orally 3 - 4 times daily.

Non - Communicable Disease		**Active ingredients**
1	Hypertension	-Step 1. Start with Diuretics (e.g. Amiloride + Hydrochlorothiazide (5/50mg) orally daily) OR 199 Calcium channel blockers (Nifedipine retard 20mg two times daily orally or Amlodipine 5 -10 mg once daily orally; OR Angiotensin-

		converting enzyme inhibitors (Captopril 25-50mg two or three times daily orally, Enalapril 5-20mg once daily orally). Those who cannot tolerate ACEI may be given Losartan potassium 50-100mg once daily orally. -Step 2. Use a combination of drugs from different groups (e.g., Diuretic + ACEI, or Calcium channel blocker + ACEI, or, Diuretic + Calcium channel blocker). Other treatments: -Step 3. Use a combination of Diuretic + ACEI + Calcium channel blocker
2	Diabetes	i. Soluble insulin 5-10 units (0.1 units/kg/hour intravenously), as a continuous infusion NOTE: Soluble Insulin given as an intravenous bolus is rapidly destroyed within a few minutes. Intravenous insulin must always be given as a continuous infusion. When blood sugar levels reach 10 -14 mmol/L reduce to 2-4U/h (0.05 units/kg/hour) or titrate against blood glucose levels and when a patient is able to take oral feeds give soluble insulin 2-3 times before meals OR ii. Initially soluble insulin 20 units intramuscularly stat then 5-10 units intramuscularly hourly until blood sugar is 14mmol/L. When blood glucose is 10 – 14mmol/L give 8 units 4 hourly subcutaneously until the patient is able to take oral feeds. When the patient is taking food orally, change to soluble subcutaneously twice or three times before meals.
3	Chronic respiratory disease	-Salbutamol 100mcg inhaler 2 – 10 puffs every 10 to 20 minutes -Salbutamol via nebuliser if SaO2 < 92% 2.5 - 5 mg every 20-30 minutes - Ipratropium bromide - If symptoms are refractory to 2 agonist treatment 250-500 mcg/dose mixed with salbutamol •-Steroid therapy Steroid tablets Give Prednisolone early in the treatment of acute asthma attacks 20 mg in children 2-5 years, 40 mg in children >5 years.

		• Intravenous steroids for severe exacerbations or children who are vomiting. Hydrocortisone 4 mg/kg 4 hourly • Inhaled steroids. No evidence of additional benefit. Can be maintained in children already on long term therapy 193 Second-line treatment of acute asthma • In children > 2 years, IV Salbutamol in severe cases with no response to inhaler therapy 15 mcg/kg over 10 minutes; 1-5 mcg/kg/min infusion. Monitor ECG, Potassium levels. • In children > 2 years, cont. IV aminophylline; No benefits for mild to moderate asthma, common and troublesome side-effects 4mg/kg over 20 minutes, 1 mg/kg/hour infusion
4	Cardiovascular disease	-Aspirin, 600mg 3 – 4 times daily -Paracetamol, 500mg – 1g orally 3 – 4 times daily in adults, - children; Paracetamol, 10 – 20mg/kg 3 times daily
5	Cervical Cancer	Medication and dosage depend on stage of the disease. This depends on the stage of the cancer i. Surgery for stage IB1 or less. Note surgery should not be done in cases with stage IB2 and above. ii. Chemoradiation for stages IB2 - IVA There is no role of chemotherapy alone in stage IB2