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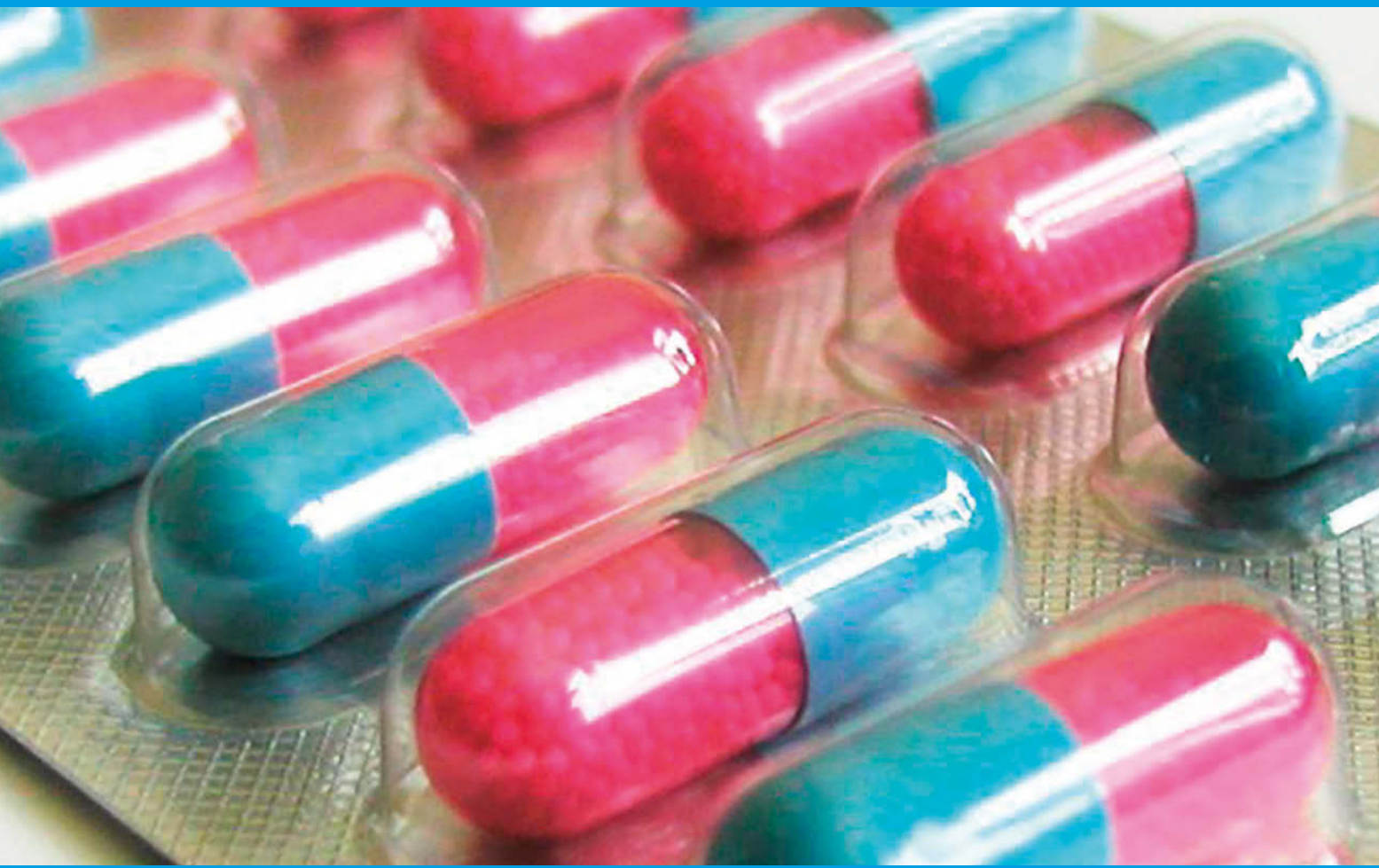

Sector Development Strategy for Pharmaceutical Manufacturing in Zimbabwe

2017-2022

INCLUSIVE AND SUSTAINABLE INDUSTRIAL DEVELOPMENT

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Sector Development Strategy for Pharmaceutical Manufacturing in Zimbabwe

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FOREWORD

Historically, the Zimbabwean pharmaceutical industry has proved to be strategic in terms of meeting the drug requirements of the economy and has therefore been identified as one of the priority sectors earmarked for resuscitation in the Industrial Development Policy (2017-2021) in order to strengthen local production of essential medicines. Over the years, the industry has encountered operational challenges that have inhibited its growth as evidenced by the shrinking of the combined market share of local production of medicines to low levels of 10 percent in 2014.

The challenges facing the industry are manifold, some of which include; a weak demand caused by discontinued purchase by the national pharmaceuticals procurement agent (Nat Pharm) due to lack of funding, limited competitiveness in production caused largely by a tariff structure that favours cheaper medicine imports, and partly by industry delays for registration of new products or by lack of capacity of the industry to produce quantities required nationally. Other challenges include; a growing mismatch between market needs and local industry production and limited financial support and incentives required by the industry.

It is against this background that Government has come up with the Zimbabwe Pharmaceutical Development Strategy (2017-2022) to revitalize the industry to produce more of the country's essential drugs, mobilize the financial resources necessary in the short-to-medium term for working capital and rehabilitative upgrades to improve the sector's performance leading to social and economic development of the country.

The strategy's main pillars include: implementation of a GMP roadmap; strengthening of national medicine regulatory capacity; devising of time-limited incentives package for upgrading of industry with a particular focus on improving access to affordable finance; developing necessary human resources; investment and business linkage promotion (technology transfer); as well as installation of a sustainable market information collection & monitoring facility.

The Zimbabwe Pharmaceutical Development Strategy (2017-2022) is therefore designed to take the pharmaceutical industry to the next level by promoting local production and exports of medicines into the region and the rest of the world, in line with the Zimbabwe Agenda for Sustainable Socio-Economic Transformation (ZIM ASSET) and SADC Industrialization Strategy and Roadmap.

In recognition of the significance of the pharmaceutical industry to the country's economy, in terms of employment creation, value addition, contribution to the country's GDP, Government remains committed to the resuscitation of the industry which it regards as strategic by putting in place the necessary supportive policy infrastructure to stimulate local production.

The launch of the Zimbabwe Pharmaceutical Development Strategy (2017-2022) will mark a significant milestone in the development of the industry and the private sector is urged to ensure the full implementation of priority action lines to the benefit of industry and the Zimbabwe economy.

Honourable Dr. M.C. Bimha (MP)
MINISTER OF INDUSTRY AND COMMERCE

ACRONYMS AND ABBREVIATIONS

AiBST	African Institute of Biomedical Science & Technology
API	Active Pharmaceutical Ingredient
ASYCUDA	Automated System for Customs Data
BA/BE	Bioavailability / Bioequivalence
CAPEX	Capital Expenditure
cGMP	current GMP
cif	cost insurance freight
CRO	Contract Research Organization
CTD	Common Technical Document
DALY	Disability-Adjusted Life Years
DFID	Department for International Development (British aid agency)
eLMIS	electronic Logistics Management Information System
EML	Essential Medicines List
GMP	Good Manufacturing Practice
HS	Harmonized System (coding system used by Customs authorities)
HVAC	Heating, Ventilation, and Air Conditioning
IDP	Industrial Development Policy
LPP	Local Pharmaceutical Production
MCAZ	Medicines Control Authority of Zimbabwe
MoFED	Ministry of Finance & Economic Development
MoHCC	Ministry of Health & Child Care
MoIC	Ministry of Industry & Commerce
NAC	National AIDS Council
NatPharm	National Pharmaceutical Company
NEPAD	New Partnership for Africa's Development
NTB	Non-Tariff Barrier
NTP	National Trade Policy
OTC	Over The Counter
PEPFAR	President's Emergency Plan for AIDS Relief (US Govt. program)
PMA	Pharmaceutical Manufacturers' Association
SA	South Africa
SADC	Southern African Development Community
SARPAM	Southern African Regional Progamme on Access to Medicines
SEZ	Special Economic Zone
SI	Statutory Instrument
SME	Small and Medium Enterprise
TB	Tuberculosis
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
VAT	Value Added Tax
WHO	World Health Organization
Zazibona	SADC medicines registration harmonization initiative
ZIMASSET	Zimbabwe Agenda for Sustainable Socio-Economic Transformation
ZIMRA	Zimbabwe Revenue Authority
ZIMSTAT	Zimbabwe National Statistics Agency
ZNMP	Zimbabwe National Medicines Policy

EXECUTIVE SUMMARY

Introduction / Context

HIV / AIDS, TB, and malaria remain as leading causes of morbidity in Zimbabwe, though both the prevalence rate of HIV and the malaria incidence rate are declining. Other infectious diseases, and acute respiratory infections, are also significant contributors to Disability-Adjusted Life Years (DALYs).

The Government's budget allocation for procurement of medicines in public healthcare institutions is presently meagre; most medicines consumed in Zimbabwe are bought by international donors or the private sector. Tenders from NatPharm which played the role of a National Medicines Procurement Agency used to be the mainstay for domestic pharmaceutical manufacturers. The local industry has been seriously impacted by the inability of NatPharm to continue playing its role as a major procurer of medicines for the public sector. Today, Zimbabwe is dependent on imported medicines, much of which is donated.

Situation Analysis

With regard to the policy framework in Zimbabwe as it relates to local pharmaceutical manufacturing, it is, on the whole, generally coherent, in statement and intent. The major policy documents, ZIMASSET, the Industrial Development Policy (IDP), National Trade Policy (NTP), and Zimbabwe National Medicines Policy (ZNMP), are, by and large, consistent with each other, but there are significant gaps in execution and implementation of the measures discussed.

The Zimbabwean pharmaceutical industry consists of 8 pharmaceutical companies manufacturing finished human medicines. Their products are formulated from imported Active Pharmaceutical Ingredients (APIs) and excipients. All the companies produce generics. Most locally-produced products are of oral solid and liquid dosage forms; the production of parenteral products such as large volume parenterals and injectable penicillins has ceased. There is presently unused capacity to produce parenterals in two plants.

The main components of the market are imported medicines, donated medicines (also imported), and locally-produced medicines. Export of medicines is not significant. Information on imported medicines is not systematically compiled by MCAZ; analysis of the data available from MCAZ and ZIMRA (through ZIMSTAT) produced an estimated figure of US$ 124 million (cif) imported commercially in 2014. Donated medicines accounted for US$ 97 million, which consisted of drugs for HIV / AIDS, TB, and malaria, and also essential medicines. Only US$ 24 million by value of medicines were produced locally, meaning a market share of just under 10% for the local industry.

In 2014, the local industry produced less than a third of the medicines on the 7th Essential Medicines List of Zimbabwe. The product portfolios of the domestic manufacturers consist of older-generation medicines, not well-aligned with major needs and market demand. This is one reason for the low market share of locally-produced medicines. Financial weakness and technical capacity limitations hinder companies from developing new products. Options for new product acquisition include purchase of dossiers, company-level product development, and collaboration with academia to develop new formulations. For these avenues to be viable, MCAZ guidelines on technology transfer, and MCAZ's qualification / certification of local product development partners is necessary, so that industry can avail of needed services from such partners.

Another reason for the low market share of local product is that local companies cannot participate in donor procurement. For their procurement of medicines for HIV / AIDS, TB, and malaria, donors require WHO-Prequalification; no local company is currently WHO-Prequalified for these products. Local companies are even essentially disqualified from donor procurement of essential medicines, due to donor requirements and procurement policies / procedures.

The cessation of local production of parenteral products, including penicillin-based parenterals, has also contributed significantly to the low contribution of local companies to the domestic and export markets.

With regard to the competitiveness of the local industry, domestic manufacturers do not make some medicines that are high-value imports, even exclusive of medicines for HIV / AIDS, TB; and malaria. For medicines that they do produce, price comparisons with imported product show a mixed picture. Local companies do compete in the case of certain molecules; for many others, the market price of local product is significantly higher. That indicates the need for major effort to enhance the competitiveness of local companies. Some measures to improve competitiveness have already been promulgated. The industry has been provided with relief from import duties and VAT on pharmaceutical raw materials, and a form of import protection is in place for 23 molecules. Another direct measure is urged: a package of time-limited incentives as part of a Special Economic Zone. Finally, expedited registration by MCAZ of locally-manufactured products would also provide a competitive edge.

Assessments of gaps in compliance with WHO GMP (Good Manufacturing Practice) standards were conducted for all the domestic pharmaceutical companies. Cost estimations have been completed for bringing these companies up to WHO-GMP requirements.

Public procurement is often used as a tool to promote local production of medicines. As mentioned before, NatPharm is not a major procurer of medicines any more, and so NatPharm procurement cannot serve this purpose. The National AIDS Council (NAC) has been trying to procure locally as much as possible, but it could only source about a third of its medicines requirements in 2014, because local companies do not make all the products needed by the NAC. Some procurement of medicines is also done by public health facilities at different tiers, but the visibility on the procurement done by them is quite poor at the moment. Proper systems and procedures would first have to be deployed to monitor this public procurement, and then perhaps steer some or all of this procurement towards local sourcing.

Medical aid societies are already doing reimbursements for a significant share of private expenditure on medicines. As such, they could promote purchase of local medicines through their prescription guidelines and their reimbursement policies. Some of the medical aid societies are already direct purchasers of medicines themselves. Local industry should look for opportunities to engage with the medical aid societies, and foster cooperation on supply of medicines to them.

There was minimal export of medicines by Zimbabwean pharmaceutical companies in 2014, despite a US$ 4 billion+ market for all pharmaceuticals in neighboring South Africa. However, like the donor market, the South African market is effectively shut out to Zimbabwean medicine producers because of a Non-Tariff Barrier (NTB) put in place by the South African Government. The NTB renders local product uncompetitive in terms of price in the SA market, as well as the markets within South African borders, namely Lesotho and Swaziland. Elimination of this NTB through dialogue with the South African Government would be the one single change that would most positively impact the prospects for revitalization of the local pharmaceutical sector in the regional export market. Within the entire SADC region, most of the medicines consumed are imported, which represents an opportunity for the Zimbabwean pharmaceutical industry to capture market share from imports by taking advantage of the SADC Free Trade Area (FTA). Exports to the SADC region (other than South Africa) are, however, hampered by a lack of information on the pharmaceutical markets in the other countries. Lengthy product registration periods in other countries of the region is also a significant problem; therefore, exports would be helped by any available facility to quickly register local product in neighboring countries. Zazibona is an initiative involving the regulators in member countries of SADC, including Zimbabwe, which offers simultaneous registration in all jurisdictions after going through a joint dossier evaluation. Unfortunately, Zazibona, as implemented so far, has not helped local companies much.

Sector Development Strategy

Based on the Situation Analysis, a strategic vision for the Zimbabwean pharmaceutical industry has been determined, together with some particular strategic objectives to be attained by 2022. A Sector Development Strategy for pharmaceutical manufacturing has been recommended, consisting of 7 Strategy Components, with associated Sub-Tasks. The Strategy Components are:

- Direct measures to enhance competitiveness of sector
- Expansion of market space for local industry (measures to enhance sector competitiveness indirectly)
- Revamping of industry product portfolios
- Upgrading of manufacturing quality to international GMP standards
- Establishment of medicine exports as a major foundational pillar of the industry
- Support for MCAZ deliverables, and regulatory capacity-building
- Mobilization of required financial resources

A first-approximation estimate of the financial requirement for implementation of the Strategy is US$ 45 million: US$ 2 million in grant aid (for preparatory assistance, support infrastructure / systems and technical help from experts), and US$ 43 million in direct expenditure by companies for new product development and GMP upgrading of plant and quality systems.

The next step is to mobilize the required financing from potential sources, including development partners. The Government of Zimbabwe needs to play a key role in this endeavor, which is in line with the priority attached to the pharmaceutical sector in the Industrial Development Policy, and the broader goals of ZIMASSET.

I. INTRODUCTION

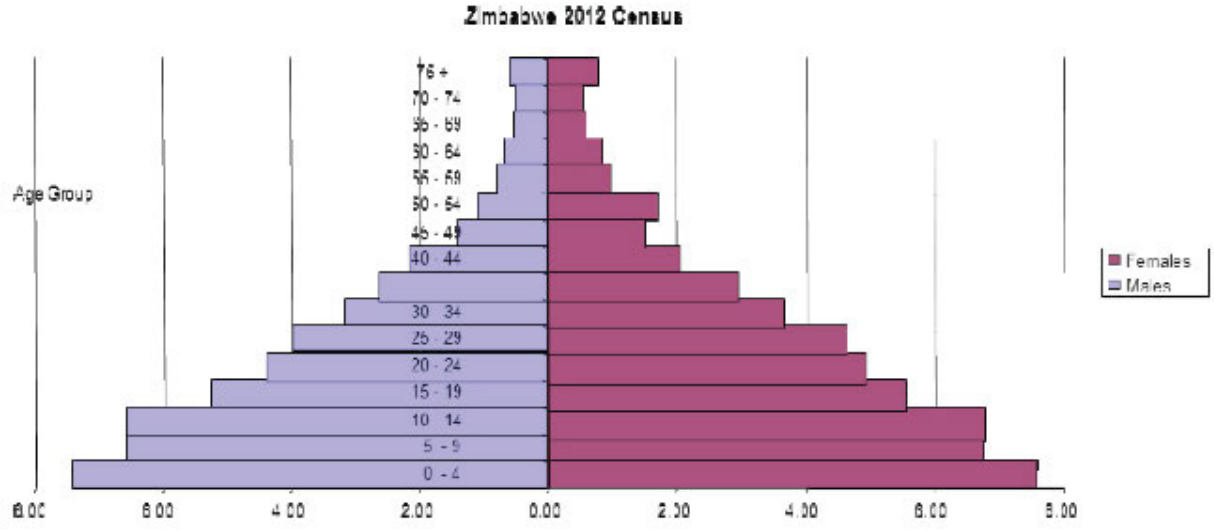
Strengthened local pharmaceutical production in Africa has been identified as having a major contribution to make in improving access to medicines. The Local Pharmaceutical Production (LPP) agenda is now mainstreamed, on the basis of framework documents such as the African Union Commission's Business Plan for accelerated implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA BP)[1] and the SADC Pharmaceutical Business Plan 2015-2019. Prior work specific to Zimbabwe's pharmaceutical industry was also done in 2011 by UNIDO in producing a Pharmaceutical Sector Profile[2].

It is in this background that a Pharmaceutical Sector Development Strategy for Zimbabwe has been formulated. The Strategy formulation built on existing insights, and has been informed by a multi-stakeholder consultative process over an 18-month period, which helped foster an understanding of the multiple, interlinked factors that influence the strategic, business, and operational environment in which the domestic pharmaceutical companies must function. Some specific investigations were undertaken to shed more light on particular needs for industry upgrading, and the results of these investigations are reflected in targeted Strategy Components and their estimated implementation costs.

II. CONTEXT

According to the last official Census 2012[3], the population of Zimbabwe was 13.1 million. The population was found to be relatively young, with 41% at or under 15 years of age, as shown in the population pyramid below.

Figure 1: Population Pyramid



The population is expected to reach 16 million in 2016, despite external migration[4]. The World Health Organization[5] estimates that the average life expectancy at birth in 2015 was 59 years for men and 62 years for women

As of 2012, the burden of disease profile in Zimbabwe appeared as shown in Figure 2.

1 apps.who.int/medicinedocs/documents/s20186en/s20186en.pdf

2 https://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Zimbabwe_Pharma%20Sector%20Profile_032011_Ebook.pdf

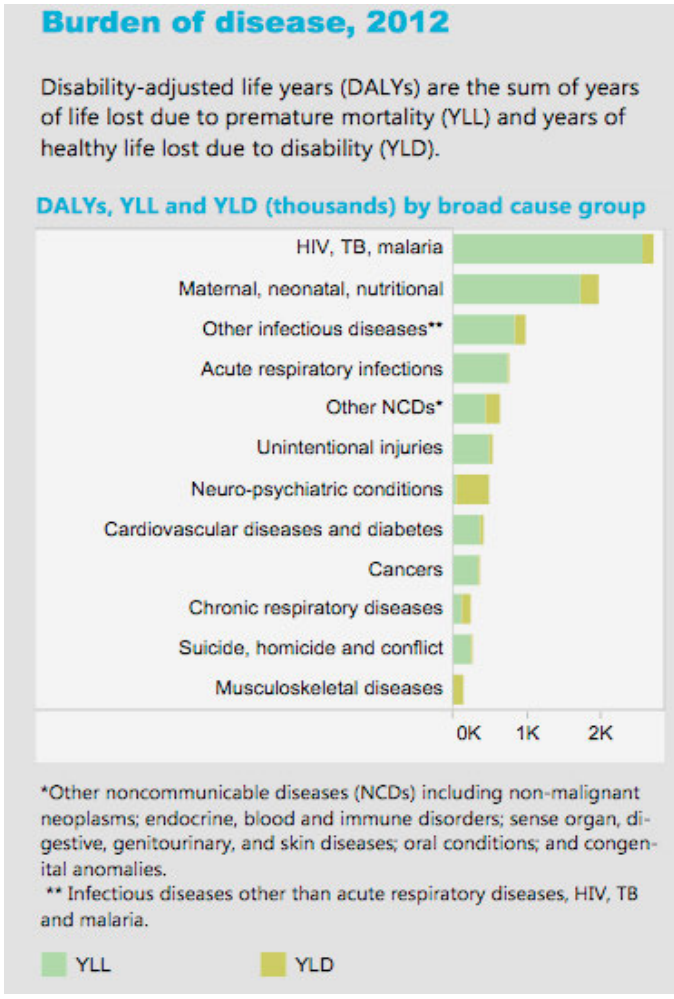
3 National Report, Census 2012, Zimbabwe National Statistics Agency (ZIMSTAT)

4 http://countrymeters.info/en/Zimbabwe

5 http://www.Zimbabwe.int/countries/zwe/en/

HIV/AIDS, TB, and malaria remain leading causes of morbidity. The number of Zimbabweans estimated to be living with HIV/AIDS is about 1.4 million, and the HIV prevalence rate among adults 15-49 years was 14.7% in 2015. This prevalence rate has been declining in recent years[6]. TB incidence in Zimbabwe in 2014 was about 278 per 100,000 population (including HIV / TB co-infection), which makes it a high-burden country for TB[7]. The co-infection rate is about 68%. Malaria is also a major health problem in Zimbabwe, with approximately 50% of the population at risk of contracting the disease[8]. Malaria incidence was reported to be 29 cases per 1000 population in 2013, but it seems to be declining overall. Infectious diseases other than HIV/AIDS, TB and malaria, and acute respiratory infections, are also significant contributors to Disability-Adjusted Life Years (DALYs).

Figure 2: Disease Burden in Zimbabwe



Source: Zimbabwe – WHO Statistical Profile

Zimbabwe's Total Health Expenditure (THE) per capita in 2014 was about US$ 115, with the Government share of this expenditure estimated to be less than 50%; the rest is financed by private, out-of-pocket expenditure, and the international donor community. With regard to expenditure specifically on medicines, the Government share is much less. In May, 2016, the Government allocation for procurement of medicines in public healthcare institutions for 2016 was reported to be only US$ 3.5 million[9], out of a total consumption of medicines projected to be about US$ 270 million[10] for the year.

6 Zimbabwe Country Report, Global AIDS Response Progress Report 2015

7 Zimbabwe: Tuberculosis Profile, WHO

8 "Zimbabwe agonizes over malaria", The Financial Gazette, June 2016

9 Zimbabwe Pharmaceuticals & Healthcare Report, July 2016, BMI Research

10 UNIDO estimate, based on import and ex-factory values (not including medical supplies)

Zimbabwe's health system has been severely impacted by the country's recent economic difficulties. In the area of pharmaceuticals, in previous years, the domestic pharmaceutical industry had been buoyed by the local procurement of medicines by the Government-owned National Pharmaceutical Company of Zimbabwe (NatPharm). However, NatPharm stopped receiving funding for such procurement from the national Treasury, and participation in national NatPharm tenders was no longer possible for Zimbabwean pharmaceutical manufacturers. Thus, while contending with deteriorating infrastructure and other inimical factors in the operating environment, the industry has also had to re-focus its efforts into selling its products in the private market. As a result, this sector has suffered a period of decline and eroding market share, particularly in the period 2005-2014.

Presently, Zimbabwe is largely dependent on imported medicines, a significant proportion of which is procured and donated by international agencies such as the Global Fund, the US Government, and other donors. The domestic market share of local pharmaceutical companies was reduced to less than 10% by 2014. It is in this context that the Government of Zimbabwe (GoZ) has selected pharmaceutical manufacturing as one of the target industrial sectors for revitalization, and the Ministry of Industry & Commerce asked the United Nations Industrial Development Organization (UNIDO) to formulate a Pharmaceutical Sector Development Strategy.

Accordingly, UNIDO initiated a Project as per the request from the Ministry of Industry and Commerce. The Zimbabwe Pharmaceutical Sector Development Strategy has been completed through a multi-stakeholder consultative process, escorted by regular interactions with a Pharmaceutical Working Group (PWG), specially constituted for the purpose to facilitate regular interactions on issues confronting the local pharmaceutical industry. The PWG had representatives of key stakeholders, viz.

- Ministry of Industry and Commerce (MoIC)
- Ministry of Health and Child Care (MoHCC)
- Ministry of Finance and Economic Development (MoFED)
- Medicines Control Authority of Zimbabwe (MCAZ, the semi-autonomous medicines regulatory authority)
- Zimbabwe Revenue Authority (ZIMRA)
- Pharmaceutical Manufacturers' Association (PMA)

The PWG was chaired by the Senior National Adviser to the UNIDO Project, who was also the Chairman of the Zimbabwe Investment Authority (ZIA). Project progress was reported periodically to a Steering Committee chaired by the Secretary, MoIC.

Exchanges among relevant stakeholders in the PWG were underpinned by a number of focused investigations which informed the development of the Strategy.

III. SITUATION ANALYSIS

III.1 Policy / Regulatory Framework

The Zimbabwean pharmaceutical industry operates within an environment shaped by Government policies and regulatory structure. Key policy documents and important institutional players within this environment are mentioned below.

Zimbabwe Agenda for Sustainable Socio-Economic Transformation (ZIMASSET)

ZIMASSET is the economic blueprint for the country's national development, covering the 5-year period of October 2013 – December 2018. The Agenda is based on four Strategic Clusters: Food Security and Nutrition, Social Services and Poverty Eradication, Infrastructure and Utilities, and Value Addition and Beneficiation.

Naturally, the issue of Infrastructure and Utilities cuts across many industrial sectors, including the pharmaceutical manufacturing sector, with its critical need for reliable, low-cost electricity and clean water. Therefore, the initiatives outlined in ZIMASSET to stabilize the electric supply, provide regular and clean water supply, improve the transport network, and develop the IT infrastructure, when realized, can only help.

The Cluster Outputs mentioned in the Social Services and Poverty Eradication Cluster are of more direct relevance to the pharmaceutical industry, in that there are specifically mentioned outputs for:

- treatment of HIV, TB, diarrhea
- re-capitalization of NatPharm
- stocking of medicines at health institutions, and
- **facilitation of local production** of selected pharmaceutical products

In the Value Addition and Beneficiation Cluster, one of the Cluster Outcomes is "improved supply of locally-produced drugs", and the resuscitation of one pharmaceutical manufacturer, CAPS (which has recently been acquired by the Government of Zimbabwe from private ownership), is listed as a desired Output. This Cluster also makes the Ministry of Industry & Commerce responsible for negotiating market access and boosting export revenues. The latter is of particular importance to the pharmaceutical sector with regard to the South African market (for more, see Section III.10.1).

Overall, then, ZIMASSET is both broadly and specifically supportive of development of the domestic pharmaceutical industry, as outlined in the document. However, the benefits to the industry will only accrue when the Cluster Outputs are implemented and realized.

Industrial Development Policy (IDP)

The Industrial Development Policy of Zimbabwe, produced by the Ministry of Industry and Commerce, was meant to cover the period 2012-2016. Among the Government's policy documents, it is the clearest in its commitment to enhancement of the pharmaceutical sector, in that it specifically identified pharmaceuticals as one of four priority sectors for development. Perhaps just as significant, if not more, than the selection of pharmaceuticals as a priority sector, are the fundamental principles laid out in the IDP which recognize that:

- there is a need to refurbish, modernize, and upgrade plant, machinery, and equipment, and to enhance human resource skill sets through training
- industrial sectors may need temporary protection from imports
- financing mechanisms to bolster development are a serious lack, and that Development Finance Institutions (DFIs) have a "critical role … in financing … real sector activities at affordable interest rates"

The IDP emphasizes Value Addition, and states explicitly that the Government's "tariff regime … will be primarily an instrument of industrialization with revenue aspects being secondary".

From the perspective of the local pharmaceutical industry, therefore, the IDP hits all the right notes. The main issue, as in the case of ZIMASSET, is execution of the strategies / actions delineated.

National Trade Policy (NTP)

The National Trade Policy (2012-2016) was drawn up to complement and leverage the Industrial Development Policy. The objectives of the NTP that are relevant to the pharmaceutical industry are to:

- increase export earnings
- consolidate and expand existing export markets, and to explore new markets
- expedite trade flows by reducing and/or eliminating barriers to trade
- give guidance on trade policy instruments, such as tariffs, non-tariff measures, and trade defense mechanisms with the aim of promoting trade and protecting local industry from unfair trade practices

The guiding principles of the NTP are stated to include:

Export-Led Industrialization

4 priority sectors are recognized, consistent with the IDP. Value addition is again emphasized.

Export Development and Promotion

The NTP commits to export incentives, and full retention of export earnings. In the area of trade finance, it says that the Government will prioritize the mobilization of export support funding, and work with local financial institutions to secure structured trade finance for exporting companies. An Export Credit Reinsurance Fund was to be resuscitated, and the usual activities related to trade promotion, export diversification, and trade facilitation, especially with regard to simplifying import/export procedures, and eliminating Customs delays, were highlighted.

Exploitation of Regional and Multilateral Trading Arrangements

There is a stated willingness to review bilateral trade agreements; the bilateral trade agreement with South Africa, for instance, is not reciprocal.

Use of Trade Policy Instruments

Tariff-based instruments, non-tariff measures, and trade defense mechanisms are all to be deployed for the generation and promotion of trade. Among non-tariff measures, import and export licensing are specifically mentioned, as is the use of standards to verify the quality and specifications of both imports and exports. In regard to trade defense mechanisms, the NTP also shows awareness of the specific right to impose trade remedies to countervail or correct for unfair trade practices when they cause serious injury to local industry, as well as safeguard measures to give temporary protection to local industry.

In fact, there are a wide array of measures that Governments can use, even within WTO rules, to both encourage exports and give local industry relief from the competitive pressure of imports, particularly in the case of weakened industries operating in an environment of economic decline. The NTP lists a number of such measures, and indeed the Government has shown a willingness to use some of these instruments recently for the benefit of the domestic pharmaceutical industry. However, the NTP was for a 5-year period, and is near the end of its validity, and a number of other remedies mentioned that would boost local pharmaceutical manufacturing remain unused. It is hoped that these remedies will be taken up and implemented through a renewed NTP.

Zimbabwe National Medicines Policy (ZNMP)

The ZNMP was produced by the Ministry of Health and Child Care in June 2011. As is outlined in its Introduction, the ZNMP is meant to serve as a guide for implementation of the essential medicines concept, and the management and financing of medicines in the country. It covers quality assurance and control, regulation, procurement, production, distribution, sale, import / export, advertising, and use of medicines, and provision of information about them. In addition, it deals with training and development of human resources, advancement of R&D, monitoring and evaluation of health services, and promotion of national and international collaboration. It specifically targets promotion of the local pharmaceutical industry through achieving coherence between industrial policy and public health policy, and through support of strategies outlined in the IDP.

The aims of the ZNMP that are most relevant to the concerns of the domestic pharmaceutical industry include:

- **to ensure the highest possible availability of essential medicines throughout the country**
  Particular measures mentioned in order to achieve this are to provide and disseminate information on current needs for medicines and the supply situation, and to optimize the processes of financing, procurement, and local production of medicines.
- **to ensure successful implementation of the ZNMP through enactment and updating of appropriate legislation and regulations**
- **to promote the use of generic medicines, and to meet the need for good-quality, safe, and efficacious medicines at a reasonable price through the procurement of generics**
  This is important since all Zimbabwean manufacturers of medicines produce generics only.
- **to assure the quality, safety, and efficacy of medicines**
  The MoHCC is charged with ensuring that only medicines of acceptable quality, safety, and efficacy are permitted to be produced, imported and used in Zimbabwe. The ZNMP further stipulates that only medicines registered by MCAZ will "ordinarily" be permitted to be produced, imported, or sold in the country.
- **to promote cost-effective production of medicines within Zimbabwe in accordance with current Good Manufacturing Practice (cGMP) standards**
- **to procure safe and effective medicines of acceptable quality, in the required quantities at the lowest cost**
  Again, the ZNMP states that only medicines registered by MCAZ shall "ordinarily" be eligible for public or private procurement. NatPharm is mentioned as the agency that will undertake public procurement, and the ZNMP states clearly that the Government will support the status and viability of NatPharm. All else (e.g. cost, quality, and reliability of supply) being equal, NatPharm is meant to give priority to locally-produced medicines in its procurement.
- **to ensure sufficient funding to implement the ZNMP, including allocation of funds to the public sector for the procurement of medicines**
  To this end, the MoHCC is expected to quantify the national need for medicines in the public and private sectors, *on an annual basis*.

There are gaps between the statements of policy in the NMP and the realities on the ground. For instance, NatPharm has not been re-capitalized, there are weaknesses in quality assurance of imported medicines, and some essential medicines donated by international agencies are, in fact, not registered by MCAZ. These circumstances are discussed later in this document. In spite of these discrepancies, the ZNMP is broadly supportive of Local Pharmaceutical Production (LPP).

Compared to some other countries in sub-Saharan Africa, the policy framework in Zimbabwe as it relates to local pharmaceutical manufacturing is, on the whole, generally coherent, in statement and intent. The major policy documents, ZIMASSET, the IDP, NTP, and ZNMP, are, by and large, consistent with each other, but there are significant gaps in execution and implementation of the measures discussed. Given the macroeconomic situation of the country in recent years, and the financing constraints faced by the Government, this may be understandable, but the fact remains.

III.2 Overview of Pharmaceutical Industry Structure

The Zimbabwean pharmaceutical industry consists of 8 pharmaceutical companies manufacturing finished medicines. All of them are involved in the formulation of finished medicines from imported Active Pharmaceutical Ingredients (APIs) and excipients. All the companies produce generics. Most locally-produced products are of oral solid and liquid dosage forms. No parenterals are being produced any more in the country. However, two local facilities for parenteral production (SVPs and LVPs) are currently lying idle, in need of refurbishment and licensing before production can be started in them. A strong portfolio of parenteral products registered by local companies, including sterile penicillins, already exists. There is then significant potential for export of these products to South Africa and other SADC regional markets.

Five of the companies (CAPS Pharmaceuticals, Graniteside, Gulf Drug, Pharmanova, and Varichem) are located in or around Harare; the factories for three companies (Datlabs, Plus Five, and ZimPharm) are in Bulawayo. CAPS started out as a Government-owned company, was privatized, experienced financial difficulties, and is now once again, effectively back in Government hands, since the privately-owned shares have been acquired by the Government of Zimbabwe recently. Datlabs is a subsidiary of the South African Adcock Ingram Group. All the other companies are wholly privately-owned.

All the companies can be considered to be SMEs; the annual sales of every company is under US$ 15 million. There is quite a range in age, size, and technical capacity among the companies. CAPS used to be the flagship pharmaceutical company in Zimbabwe, and has been around for decades, whereas Gulf Drug only started production in 2014. Product portfolios range in size from companies producing five products to a company which produced over 125 products of different dosage forms in 2014. Varichem achieved WHO Prequalification (PQ) for an ARV at one time, but that PQ status has since lapsed[11]. There are differing levels of capacity in developing formulations for new products.

III.3 Market Diagnostics

The major components of consumption of medicines in the Zimbabwean market are imported medicines, donated medicines, and locally-produced medicines. Donated medicines refer to medicines which are procured through funding from international agencies such as the Global Fund, the US Government's PEPFAR program, the European Union, DFID, and other donors. Donated medicines are sourced from outside Zimbabwe, and are therefore also imported, but they represent a special category of imports. There is some export of medicines by local manufacturers, and re-exports are not significant.

To get insight into the market situation, UNIDO undertook to gather data for 2014 on the different market components.

III.3.1 Imported Medicines

This section refers to medicines which are imported into Zimbabwe by commercial importers. According to MCAZ, there are 30 such authorized importers.

It is not easy to get accurate data on the quantity and value of imported medicines by medicine category. There are two sources for import data:

a) MCAZ

When commercial importers wish to import medicines into Zimbabwe, they first apply to MCAZ for an import permit. Among other information on the import permit application submitted to MCAZ, there is information on the names of medicines to be imported, the registration numbers of the medicines, and the *pro forma* value of the medicines. The import permit application is submitted to MCAZ in hard-copy, and the import permit is issued in hard-copy. Information from the import permit process is not captured electronically anywhere within MCAZ;

11 More on GMP status of the industry follows in Section III.7

it resides in stored stacks of hard-copy documents. Once the import permit is issued, presently, no further use is made of the data to capture market information on imports.

When a consignment of imported medicines arrives at a Port of Entry, it is up to Customs to check the import permit against the import documents. Sometimes visual checks are made. Medicines come into Zimbabwe through the airports at Harare and Bulawayo, and the land border ports of Beit Bridge, Plumtree, and Forbes. Approximately 85% of the imported medicines come in through Beit Bridge and Harare International Airport. MCAZ inspectors have been present at the airport in Harare for a long period; MCAZ has assigned an inspector at Beit Bridge from 1st August, 2016. There are no MCAZ inspectors at the other Ports of Entry. There is no randomized analytical testing for quality of imported medicines at the Ports of Entry.

An import permit, when issued, is valid for 6 months, and there may be multiple consignments against that import permit over that period. Once a consignment has been cleared, there is a notification to MCAZ about the cleared consignment, but again, this information is not electronically recorded at MCAZ. ZIMRA (Customs) and its records are relied on to ensure that succeeding consignments of imported medicines against the same import permit do not violate the overall volume authorized by the import permit.

There is a critical need for electronic processing of information on import permits during the import authorization process at MCAZ, and for tracking notifications and verifications of cleared import consignments as they happen. Ideally, there should also be provision for data exchange and sharing between the ZIMRA and MCAZ systems, so that information is available not only on authorized imports from the import permits but also on actual imports, from the port clearance documents.

To get perspective on the import situation, UNIDO worked with MCAZ to do manual data entry from about 6,000 import permits issued in 2014 to electronic form.

b) ZIMRA / ZIMSTAT

When import consignments arrive at the Port of Entry, import documents are filed with the Customs Division of ZIMRA. From these import documents, it is possible to get quantities and values for the medicines that actually are cleared to enter the country, but the information on actual names of medicines, or medicine category is not captured. Rather, the information at ZIMRA is categorized by HS Code, which is not useful in determining medicine classification. ZIMRA passes the available information on to ZIMSTAT.

UNIDO also reviewed the information on medicines imported in 2014 that was available from ZIMSTAT, and through comparative analysis of the data from both MCAZ and ZIMSTAT, the value of imported medicines **(not including donated medicines**) for 2014 was found to be US$ 123.6 million.

From this analysis, the highest-value imports for 2014 (excluding donated medicines) are tabulated below.

Table 1: Highest-Value imported Medicines (2014)

Product	Import Value (cif) (US$)
Nifedipine	1,310,142
Amoxycillin Trihydrate / Potassium Clavulanate	1,179,519
Diclofenac Sodium	1,115,443
Paracetamol	836,808
Celecoxib	793,872
Sodium chloride	769,055
Amlodipine besylate	756,032
Ceftriaxone sodium USP	681,800

Oxytetracycline	676,197
Enoxaparine sodium	435,340
Diphenhydramine / Paracetamol / Pseudoephedrine	291,290
Diphenhydramine hydrochloride / Ammonium chloride / Menthol	287,978
Ciprofloxacin hydrochloride	271,196
Orciprenaline sulphate / Bromhexine hydrochloride	265,350
Dextromethorphane hydrochloride	255,887
Salbutamol	255,772
Rabeprazole sodium	170,848
Promethazine / Codeine Phosphate / Ephedrine hydrochloride	163,589
Guaphenesin	153,273
Omeprazole sodium HCL	135,562
Total	**1,236,000**

Source: UNIDO analysis, from import permit data of MCAZ, and figures from ASYCUDA World system of ZIMRA, availed through ZIMSTAT

These medicines represent about 9% of the total value of imported medicines (not including donations) that came into Zimbabwe in 2014.

III.3.2 Donated Medicines

Donated medicines are also imported, but the procurement of these medicines are funded by international donors. Import of donated medicines has to follow the same import procedures of MCAZ as other medicines imported by commercial actors, but of course, donated medicines are not subject to import duties. Donated medicines are principally for the treatment of HIV / AIDS, but medicines were also donated in 2014 for malaria, TB, and Opportunistic Infections (OI). In addition, there were also donations of other Essential Medicines. Donated medicines for HIV / AIDS, TB, and malaria that come into Zimbabwe are largely registered, but many of the essential medicines that come in as donations are exempted from registration by MCAZ.

At MCAZ, the distinction between donated medicines and medicines that are commercially imported is not very clear from the import permits. One has to try and identify donations from whether import duties were imposed, or from the import consignee. Again, donations will need to be identified and tracked better in any future system deployed at MCAZ, including registration status of the medicines being donated.

Quantity and value data on donated medicines is, however, maintained electronically by the Directorate of Pharmacy Services at the Ministry of Health and Child Care.

HIV Drugs

Major donors for HIV drugs in 2014 were the Global Fund, the US Government, and DFID. The total value of HIV drugs donated was US$ 85.0 million, according to the distribution shown below.

Table 2: Donations of HIV drugs

Product	
Efavirenz/Lamivudine/Tenofovir 600/300/300mg 30 Tabs	69,521,597
Lamivudine/Tenofovir 300/300mg 30 Tabs	5,881,482
Lamivudine/Nevirapine/Zido 30/50/60mg disp 60 Tabs	4,104,677
Nevirapine 200mg [Viramune] 60 Tabs	1,439,817
Atazanavir/Ritonavir 300/100mg 30 Tabs	679,176
Abacavir/Lamivudine 60/30mg 60 Tabs	654,978
Efavirenz 600mg 30 Tabs	606,346
Lopinavir/Ritonavir 100/25mg [Aluvia] 60 Tabs	534,101
Lopinavir/Ritonavir 200/50mg [Aluvia] 120 Tabs	506,149
Abacavir/Lamivudine 600/300mg Scored 30 Tabs	360,315
Lamivudine/Zidovudine 30/60mg 60 Tabs	243,205
Efavirenz 200mg 90 Caps	233,966
Lopi/Rito 80/20mg/ml [Kaletra] OS cool BTL 5x60ml	205,882
Nevirapine 10mg/ml [Viramune] OSUS BTL 240ml	71,687
Total	**85,043,378**

Source: Ministry of Health and Child Care

Anti-malarials

The major donor for anti-malarials in 2014 was the US Government. The total value of anti-malarials donated was US$ 2.2 million, as per the distribution shown.

Table 3: Donated malaria drugs

Product	Value (c&f) in US $
Artemether/Lumefantrine (6x4)	1,372,731
Artemether/Lumefantrine (6x3)	408,763
Artemether/Lumefantrine (6x1)	215,234
Sulphadoxine/Pyrimethamine 500/25MG Tablets	111,300
Artemether/Lumefantrine (6x2)	73,020
Quinine 600MG/2ML Injection	30,360
Artesunate/Amodiaquine 100/270 Adult	7,232
Artesunate/Amodiaquine 100/270mg Child	2,401
Artesunate/Amodiaquine 50/135mg	1,526
Artesunate/Amodiaquine 25/67.5mg	1,048
Total	**2,223,615**

Source: Ministry of Health and Child Care

Drugs for TB and Opportunistic Infections (OI)

The Global Fund donated approximately US$ 426 thousand towards the purchase of anti-TB medications, about half of which was used to procure Streptomycin injections. About US$ 1.5 million was donated for OI drugs, of which the Global Fund provided approximately US$ 1.2 million for acquisition of Cotrimoxazole 480 mg tablets.

Other Essential Medicines

UNICEF supplied about US$ 7.7 million worth of other essential medicines to Zimbabwe in 2014, the major part of which is shown below.

Table 4: Donated essential medicines

Product	Value (c&f) in US $
Sulfamethoxazole -trimethoprim 400MG+80MG/tab	3,224,986
Amoxicillin 250mg 1000 Caps	1,191,336
Paracetamol 500MG/tab TABLET (PO)	763,765
Erythromycin 250MG/tab TABLET (PO)	446,796
Sulfamethoxazole -Trimethoprim 120MG Disp Tabs	359,010
Oxytocin 10IU Injection	313,992
Lidocaine hcl 20MG/vial VIAL (INJ)	246,216
Amoxicillin 250mg Dispersible, 100 tablets	242,162
Doxycycline 100mg , 100 tablets	130,393
Oral rehydration salts 1EACH/1L POWDER (PO)	128,703
Tetracycline hcl 10MG/G OPHT OINT (OPHT)	101,607
Metronidazole 250MG/tab TABLET (PO)	88,905
Ferrous salt-folic acid 200MG+0.4MG/tab TABLET	88,736
Hydrochlorothiazide 25MG/tab TABLET (PO)	82,977
Paracetamol 100mg dispersible , 100 tablets	69,432
Total	**7,700,000**

Source: Ministry of Health and Child Care

III.3.3 Locally-produced medicines

Systematic collection of industry data on locally-produced medicines is a challenge, because there is no established mechanism for compilation of this information at the present time. This is a problem that needs to be addressed, since locally-produced medicines are an important component of market consumption, and it is not possible to form a composite picture of the overall pharmaceutical market in Zimbabwe without accurate information on local production of medicines.

For the purposes of the following analysis, production / sales data were specially collected from the eight domestic pharmaceutical manufacturers in Zimbabwe to get perspective on the size of the domestic industry, and the product portfolios of the local companies. The total output of the industry (based on ex-factory prices) that was supplied to the domestic market was worth just over US$ 24 million. The 20 highest-value products manufactured by domestic producers are shown in Table 5.

Table 5: Top 20 locally-produced medicines in 2014 by value

Product
Ascorbic Acid
Aspirin + caffeine
Chlorpheniramine + paracetamol
Codeine phosphate + ammonium chloride + diphenhydramine
Cough Syrup
Enalapril Maleate 20MG - 100;S
Flucloxacillin
Fluconazole 200mg Caps.
Gees (Opiate Squill) Linctus
Griseofulvin
Lamivudine/Zidovudine
Magnesium Triscilicate Suspension
Metformin
Nevirapine
Paracetamol
Paracetamol + codeine phosphate
Paracetamol + phenylephrine
Stavudine / Lamivudine / Nevirapine
Theophylline + hydroxyllin
Zidovudine / Lamivudine / Nevirapine

Source: UNIDO analysis

The products shown above represent 47% by value of the total production of the local pharmaceutical industry that was supplied to the domestic market in 2014. Paracetamol and paracetamol combinations constitute 9% of the annual output of local industry.

III.3.4 Exported medicines

In 2014, local manufacturers exported only US$ 1.4 million worth of medicines. Data available from MCAZ on re-exports is incomplete, and local trade interviews indicate that re-exports are not significant. So, re-exports have not been considered.

III.3.5 Relative market shares

Table 6 shows the value contributions of each market component to the consumption of medicines in the domestic market.

Table 6: Market contributions (value) by market component

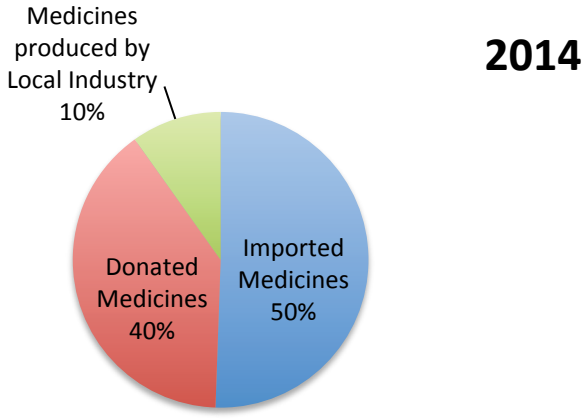
	2014 (US $, millions)
Imported Medicines	123.6
Donated Medicines	96.8
Medicines produced by Local Industry	24.1
Total	244.5

Source: UNIDO Analysis

It is important to understand what the figures in Table 6 reflect – what they include, and what they do not include. The figures are for finished medicines, including vaccines, but not including medical supplies and consumables. The numbers shown reflect cif import values for imported and donated medicines, and ex-factory values for locally-manufactured product. Clearly, as these products cascade down the distribution chain, the retail values of these products circulating in the local market or the product values at point of consumption, will be higher, perhaps by as much as a third or more.

The % market shares are given in Figure 3.

Figure 3: Shares of Domestic Market, by Market Component



Source: UNIDO Analysis

The local industry's share of the market was generally thought to be around 30% by local stakeholders, but as the compiled data indicated, the real market share of local pharmaceutical production was actually much lower, at just under 10% in 2014. Obviously, in the formulation of a Pharmaceutical Sector Development Strategy, it is important to try and understand why this market share of local products is this low.

III.4 Product Portfolio of Local Industry

As of July 2016, the situation with regard to product registrations by local pharmaceutical companies was as shown in Table 7.

Table 7: Local product registrations (July 2016)

	Total registrations (Foreign + Local Cos.)	Local Co.* Registrations only	Local Co. registrations (as % of Total)
All product registrations	1,925	440	23
Number of unique product registrations**	941	214	23

*Note: Products registered by Adcock Ingram, but showing Datlabs as the Manufacturer, have been counted as local registrations

**Note: If identical products in the same strength and dosage form are registered by multiple companies, these were counted as one "unique" product registration

Source: UNIDO Analysis of MCAZ Human Medicines Register, as of July 2016

The top row in the above Table shows all the human medicinal products registered by MCAZ as of July, 2016. Products registered by local companies are about 23% of the total. The figure for all product registrations includes multiple registrations by different companies of the same molecule. So, an attempt was made to correct for this, by only counting unique product registrations by molecule, combination, or dosage form. If there were multiple product registrations for the same exact product, only one was counted. This was done for all product registrations. Again, coincidentally, the number of unique products registered by local companies was about 23% of the number of unique products registered in total. Then, if the total number of product registrations is taken as a crude proxy for all pharmaceutical products circulating in the Zimbabwean domestic market, it appears that, as a first approximation, local companies are producing less than a quarter of the products in demand.

Another indicator is the % coverage of essential medicines by local product. The revised 7th Essential Medicines List of Zimbabwe (EDLIZ) came out in 2015, and it contains 313 essential medicines. In 2014, the local industry produced 246 medicines in all. Some of the local products were not essential medicines, and some were duplicates, i.e. the same product made by different companies. **Analysis reveals that the local industry produced 93 unique essential medicines, which is less than a third of the medicines on the Essential Medicines List.** It is therefore clear that local industry needs to make more of the medicines that are required, not only to increase its market share but also to be a better contributor in meeting the public health needs of the population.

There are indications that local companies are not producing even some of the highest-value products that are being consumed in the market. For instance, **of the twenty highest-value imported medicines (excluding medicines for HIV / AIDS, TB, and malaria) shown in Table 1 earlier, there are existing product registrations by local companies for only eight of them, and only seven are being produced by local companies presently.**

A more detailed investigation of the companies' product portfolios commissioned by UNIDO showed that the companies' product offerings were disconnected from market needs with:

- limited fulfillment of Essential and Vital local / regional medicine requirements
- poor alignment between private market needs and existing product portfolios; disconnect with major needs and market demand in both prescription and OTC market segments
- no or little presence in highly necessary and profitable therapeutic areas (e.g. oncology, diabetes, niche therapeutic domains …)
- portfolios composed only of old generation basic drugs

So, among the reasons for low market share of local companies, one is that the product portfolio of the local industry does not include a number of the molecules / fixed-dose combinations in dosage forms that the market is presently consuming. In fact, many of the products being produced by local manufacturers are older molecules that have been part of company portfolios for many years.

There needs to be a broad revamping of company product portfolios overall, and the local manufacturers are aware of this. However, the present trend with regard to new registration applications from local companies is not encouraging. Table 8 shows relevant data, presented by MCAZ.

Table 8: New product registration applications from local companies

Year	NEW APPLICATIONS			NEW REGISTRATIONS		
2014		Number	%		Number	%
	Total	**189**	**100**	**Total**	**148**	**100**
	Local	*4*	*2.1*	*Local*	*3*	*2*
	Foreign	185	97.9	Foreign	145	98
2015		Number	%		Number	%
	Total	**266**	**100**	**Total**	**183**	**100**
	Local	*12*	*4.5*	*Local*	*14*	*8*
	Foreign	254	95.5	Foreign	169	92

Source: MCAZ

New product registration applications from local companies have been less than 5% of the total number of registration applications, and successful product registrations from local companies have been less than 10% of the total.

Both financial and technical capacity are factors that hinder domestic producers from acquiring and launching new products.

Some of the companies are not financially robust. In these cases, there is a lack of working capital, and weaknesses in CAPEX. In some cases, there is a high level of debt. Clearly, then, financial fragility would have to be addressed first, before considering future product development plans.

III.4.1 New product development through purchase of dossiers

With regard to technical capacity, only one or two companies can currently develop formulations for new products on their own. Even for these companies, it is an expensive and time-consuming process. For some companies, having this technical capability or not, a quicker way to obtain dossiers for new products might be to buy them from other companies, perhaps from India or South Africa[12]. However, under present circumstances, purchase of new product dossiers is a risky proposition for local companies, because it is unclear how MCAZ would treat the purchased dossier in the product registration process. For instance, would MCAZ accept the stability data from a purchased dossier, or would the stability testing have to be redone? For those products without a biowaiver, would the BA/BE data from a purchased dossier be acceptable? There is a need for clear guidelines from MCAZ on what can be used from a purchased dossier, otherwise it is impossible for local manufacturers to know what they should look for in a purchased dossier, and / or how much to pay for one. During preparatory work for the formulation of this Strategy, a MCAZ-industry dialogue was organized to promote a better understanding of issues related to dossier purchase among the concerned parties. The objective is a way to ensure the safety, quality, and efficacy of a new product (MCAZ's primary concerns, for consumer protection) and also to enable the industry to avail of technology transfer through purchase of dossiers for new products.

12 It would be easier to get the new product registered with MCAZ if the purchased dossier was from a country with a Stringent Regulatory Authority (SRA), but dossiers from such countries are likely to be prohibitive in cost for Zimbabwean pharmaceutical manufacturers. On the other hand, it is possible to get quality dossiers from Indian and South African companies, but one does have to be selective.

III.4.2 Industry-academia collaboration for product development

Another possible longer-term option for industry for the development of new product formulations is to collaborate with local Schools of Pharmacy. Presently, the School of Pharmacy at the University of Zimbabwe and the Department of Pharmaceutical Technology at the Harare Institute of Technology have both expressed an interest in deepening collaboration with industry on development of formulations for new products.

There is a history of industry collaboration with the School of Pharmacy, University of Zimbabwe in the past, going back some years ago. The School of Pharmacy presently intends to establish a Centre of Drug Formulation Studies, envisioned to be a Centre of Excellence for medicine formulation. The School has produced a Proposal to this end, which can be reviewed in Annex I. In the Proposal, the stated "aim is to conduct pre-formulation and formulation studies as part of Development Pharmaceutics" and "serve as a Research & Development Centre for industry to utilize". The School of Pharmacy plans to engage with the Indian National Institute of Pharmaceutical Education and Research in this effort. The Proposal from the School of Pharmacy indicates a need for US$ 100k in funding for additional renovations to an existing building for the drug development centre, and about US$ 200k to acquire pharmaceutical development equipment.

The Department of Pharmaceutical Technology at the Harare Institute of Technology (HIT) has also proposed to establish a Centre for Drug Development. HIT's Proposal can be seen in Annex II. The stated objective in the Proposal is to "establish a full-fledged resource centre focused on research and formulation development of pharmaceutical products in order to assist local manufacturers to increase their product range". HIT's Proposal indicates a need for US$ 1.12 million in funding for acquisition of miniaturized equipment for early formulation development of medicines in different dosage forms, and US$ 2.23 million for purchase of needed analytical instruments.

III.4.3 BA / BE centre

In the long-term, the pharmaceutical industry will have to tackle the development of more products which will require the provision of BA/BE data for registration. At present, this is a very expensive proposition for local companies, because there are no Contract Research Organizations (CROs) in Zimbabwe which are licensed by MCAZ to generate such data, and whose data will be considered to be acceptable in the product registration process. The nearest pre-qualified Phase 1 Clinical Trial Units are in South Africa, and companies could easily have to spend around US$ 100,000 to get BA/BE data generated for a prospective new product from these or other such Units. In Zimbabwe, the African Institute of Biomedical Science & Technology (AiBST) has made the most progress in setting up a Clinical Trial Unit and attached Bioanalytical Laboratory in Harare. The Institute also needs financial support for its endeavors. However, in the end, having a BA/BE centre in Harare that has been qualified by MCAZ to provide BA/BE data would facilitate the generation of such data.

Naturally, cost considerations are important. AiBST needs to be able to undertake BA/BE studies at reduced costs comparable to, if not lower than, Indian CROs. One near-term concern of AiBST is whether the local industry can be the source of a sufficient volume of business for AiBST to make its undertaking economically viable, and that also has cost competitiveness implications.

AiBST's plans for its Clinical Trial Unit can be reviewed in Annex III.

III.5 Market Space: Non-Participation of Local Companies in Donor Procurement

As Figure 3 has shown earlier, donated medicines account for roughly 40% of the domestic market for medicines by value. Local companies do not participate in this donor procurement at all, so they are effectively out of 40% of the market. That is naturally another factor why the local companies' share of the overall domestic market is low.

An analysis of drug donations from 2014 reveals that the major donation was for HIV drugs, to the tune of US$ 85 million. In fact, almost US$ 70 million of that was for one ARV combination of Efavirenz / Lamivudine / Tenofovir. Donors require that producers of these ARVs be WHO-Prequalified to supply these drugs, and since local producers are presently not WHO-Prequalified for manufacture of ARVs, they cannot participate in this procurement. Donor procurement is done in bulk through international tenders, and even if a local producer did achieve WHO-PQ for any of these medicines, it is not clear that they could supply the volumes called for in this international procurement, or compete on price. In any case, achieving WHO-PQ is a multi-year, expensive process. One local company, Varichem Pharmaceuticals, did invest to achieve WHO-PQ for two ARV products a few years ago. WHO-PQ is specific to a product, and the treatment regimen for HIV/AIDS has changed, and those molecules are no longer used in volume. Due to the complex and dynamic nature of standard treatment guidelines, it is unlikely that local companies will invest in WHO-PQ again without specific assurances that donors will procure locally. So, prospects for participation of local companies in donor procurement that requires WHO-PQ are limited to non-existent, for the moment.

Drug donations for malaria, TB, and OI (Opportunistic Infections) were under US$ 2.5 million for each category, and therefore, were not large components of the market in 2014. However, there may be potential for local companies to supply OI medicines under donor programs, subject to GMP certification either by WHO or the particular donor organization involved.[13]

There were also US$ 7.7 million worth of donations of other essential medicines in 2014: these medicines were procured and supplied by UNICEF. Many of the products supplied are shown in Table 4. These products are not covered by WHO-PQ; in fact, many of them are produced by local manufacturers already. Of the US$ 7.7 million, about US$ 7 million worth of these medicines, or 90% by value, could have been supplied by local manufacturers with products that local manufacturers have already registered with MCAZ. In contrast, many of these essential medicines coming into Zimbabwe through this donor route are not registered by MCAZ. So, this is, in effect, a channel for the donor-selected vendors to supply products for consumption in Zimbabwe, without the complexities and costs of product registration in Zimbabwe. With some coordination, perhaps all of these medicines could eventually be supplied by local manufacturers.

On the face of it, it would seem to make little sense for these medicines to be procured and supplied from abroad, when the same medicines are being produced and sold side by side in the domestic market by local manufacturers. Why then are these essential medicines not being procured locally? The issues, it appears, are price and donor concerns about quality, compounded by donor procurement policies and procedures.

As with the procurement for HIV drugs, UNICEF procures these essential medicines through international tenders, and there is an established process for qualification of vendors. The donor stance is that local companies are welcome to try and qualify as a vendor, and participate in these international tenders. According to PMA, the local manufacturers' trade association, domestic manufacturers are willing to invest to meet the quality standards, as long as there is a reasonable assurance that the medicines will be procured from them, and they can recoup their investment.

With regard to price considerations, at the time of tendering, the ultimate landed cost to any destination country cannot be taken into consideration. Information on the final landed cost of these medicines into Zimbabwe is, however, available, and is shown in Table 9.

13 The Federation of African Pharmaceutical Manufacturers' Associations (FAPMA) is working with a major donor, the Global Fund, to come up with a certification scheme that will allow African pharmaceutical producers to supply OI medicines. This is planned to start with 21 companies, 7 selected from each region (SADC, EAC and West Africa), participating in the program. Selection criteria for the 21 companies are expected to be based on GMP standards.

Table 9: "Landed" cost for donated essential medicines in 2014

Product	Unit	"Landed" cost per Unit (US $)
Amoxicillin 250mg	1000 Caps	16.88
Amoxicillin 250mg Dispersible	100 Tablets	2.56
Doxycycline 100mg	100 Tablets	1.85
Erythromycin 250MG/tab	Tablet (PO)	4.73
Ferrous salt-folic acid 200MG+0.4MG/tab	Tablet	6.29
Hydrochlorothiazide 25MG/tab	Tablet (PO)	0.59
Lidocaine hcl 20MG/vial	Vial (INJ)	1.15
Magnesium sulfate 500MG/vial	Vial (INJ)	0.75
Metronidazole 250MG/tab	Tablet (PO)	6.30
Miconazole nitrate 20MG/G	Cream (TOP)	0.37
Oral rehydration salts 1EACH/1L POWDER (PO)		0.09
Oxytocin 10IU Injection	Injection	1.18
Paracetamol 100mg dispersible	100 tablets	0.98
Paracetamol 500MG/tab	Tablet (PO)	5.78
Povidone iodine solution 10%		3.20
Salbutamol inhaler 200DS	Inhaler 200DS	2.06
Sulfamethoxazole -Trimethoprim 120MG Disp	Tablet	1.27
Sulfamethoxazole -trimethoprim 400MG+80MG/tab	Tablet	6.35
Tetracycline hcl 10MG/G	Ointment (OPHT)	0.48
Zinc Sulfate 20MG/tab	Tab-Cap (PO)	1.75

Source: UNIDO Analysis of data from Ministry of Health & Child Care

If local companies can meet or beat those costs, perhaps there should be a mechanism whereby they can participate in this donor procurement to provide quality product at a comparable price. There is a need for the Government of Zimbabwe, particularly MCAZ and MoHCC working together, to play a role in bringing donors and the local industry together in encouraging local procurement of registered medicines, at least for the essential medicines that the industry is already producing[14]. In parallel, the importation of unregistered medicines by donors should be discouraged.

Finally, if MCAZ were to attain the status of a Stringent Regulator (through membership of PIC/S, for instance, as is the case with the Medicines Control Council of South Africa), that could also be an avenue for locally-produced medicines in general which are registered with MCAZ to qualify for donor-funded procurement programs.

III.6 Competitiveness of the Local Pharmaceutical Industry

Though product portfolio considerations and lack of participation in a large segment of the market may be contributing factors, ultimately the local industry must increase its market share by competing robustly in the market with the products that it makes.

There is, of course, a link between market share and competitiveness, and the link is through capacity utilization in the industry. In November, 2014, capacity utilization in the industry was reported to be at around 30%. If market share can be increased, and the industry starts producing more, capacity utilization will also rise, leading to greater manufacturing efficiency, and lesser unit costs. That, in turn, will make local industry more competitive, and

14 The Supply Division of UNICEF has indicated a willingness to consider local procurement for certain medicines, At least one Zimbabwean manufacturer has been assessed as a potential supplier to UNICEF, and has been asked to make improvements in order to qualify.

perhaps allow the industry to increase its market share further. This virtuous cycle can also be triggered through direct measures to increase competitiveness. In other words, interventions that increase capacity utilization will in general serve to improve price competitiveness.

So, how is the industry faring now, with regard to competitiveness? No recent data was available on a systematic price survey of locally-produced medicines versus imported medicines, but some indicative prices for medicines taken from Table 1, the highest-value imported medicines, and from Table 5, the highest-value locally-produced medicines, are shown in Table 10. For local products, the price shown was taken from the manufacturer's price list. Similarly, for imported product, the price shown is from the price list of the authorized importer. If there were multiple manufacturers, the lowest, most competitive price was taken.

Table 10: Price point indications for selected medicines

Medicine	Price of local product	Price of imported product	% difference
ACYCLOVIR TAB 200MG	7.8	6.5	20.0
AMLODIPINE TAB 10MG 100s	10.5	13.0	-19.6
AMLODIPINE TAB 5MG 100s	7.2	7.7	-5.9
CHLOPHENIRAMINE TAB 4MG 1000s	8.5	6.5	30.8
CIPROFLOXACIN TAB 250MG 100s	3.6	3.5	2.9
CIPROFLOXACIN TAB 500MG 100s	6.9	6.5	5.4
CLINDAMYCIN CAPSULES 150MG	10.0	8.3	20.1
CLOXACILLIN CAPSULES 250MG 1000s	47.3	41.3	14.5
DOXYCYCLINE CAPSULES 100MG 100s	3.6	3.2	12.5
ENALAPRIL TAB 10MG	6.2	6.4	-3.1
ENALAPRIL TAB 20MG	8.8	12.5	-29.6
FLUCANOZOLE CAPSULES 200MG	2.6	1.4	83.6
GRESIOFULVIN TAB 500MG 500S	88.0	105.0	-16.2
INDOMETHACIN CAPSULES 25MG	17.4	14.0	24.3
NEVIRAPINE TABS 300MG 60S	9.6	5.0	92.0
NOFLOXACIN 400MG	6.0	10.3	-41.7
PREDNISOLONE TAB 5MG 1000s	18.0	15.0	20.0
SALBUTAMOL TAB 4MG 1000S	15.0	9.0	66.4

Source: UNIDO compilation from manufacturers' and importers' price lists

As can be seen from the above Table, the local product is competing effectively with imports for some medicines; for others, the local product is almost double the price of the imported equivalent. Medicines for which the local product is not presently competitive are shown in red. Overall, the price point comparisons seem to suggest that while it is indeed possible for the local product to compete with the same imported molecules, competitiveness of local products is an issue that needs to be addressed.

One of the issues considered by the previously-mentioned Pharmaceutical Working Group was competitiveness of the industry. In the course of its work, since early 2015, the PWG has been instrumental in pushing through two measures aimed at increasing the competitiveness of the industry.

III.6.1 Roll-back of duties and VAT on pharmaceutical raw materials

Prior to 2014, finished pharmaceutical products were being imported into Zimbabwe with no import duties or VAT. This had been done to lower the cost of medicines on the market, and thereby increase access to medicines by the local population. At the same time, however, the raw materials used in pharmaceutical manufacturing had been subject to import duty and VAT. This therefore created a non-level playing field, in that there was a higher duty and VAT cost involved in importing pharmaceutical raw materials for Local Pharmaceutical Production (LPP) than in importing finished medicines. The Pharmaceutical Manufacturers' Association (PMA) had been lobbying for a roll-back of import duties and VAT on pharmaceutical raw materials for some time before the PWG came into being, but the PWG gave fresh impetus to the process. Ultimately, through discussions in the PWG and between MoHCC, MoIC, MoFED, and PMA, a list of 254 pharmaceutical raw materials (including 21 packaging materials) was drawn up, and agreed on for duty / VAT relief. A Statutory Instrument, SI 179 / 2014, was promulgated to this effect. In implementing the SI, considerable help was given by ZIMRA, also a member of the PWG. Now, local companies are already exploiting the duty / VAT relief, and this is already contributing to a reduction of manufacturing costs.

III.6.2 Institution of an import licensing requirement for certain finished medicines

After years of decline and little investment, the pharmaceutical industry in Zimbabwe needs some market space and temporary, short-term relief to bolster its competitiveness. To this end, the Government has instituted a licensing requirement for import of 23 pharmaceutical molecules, over and above the normal import permitting process. A Statutory Instrument to this effect was promulgated in 2016 (SI 18).

With this SI in effect, importers wishing to import any of these 23 products will have to obtain a licence for such import from the Ministry of Industry and Commerce, over and above the usual import permit issued by MCAZ. This is a relatively new measure still, and implementation modalities are in the process of being worked out. The 23 products were chosen through discussions between MoHCC. MoIC, and PMA, to ensure that local industry has sufficient capacity to meet the market need for these products. In addition, the line Ministries are expected to monitor availability and market prices of these medicines. This SI thus gives rise to a continuous need to verify whether local industry is managing to adequately supply the domestic market with the medicines covered by the SI at a reasonable price.

The idea behind the SI is that as long as local manufacturers can meet demand for these medicines at prices deemed to be reasonable, requests for import licences for these products will be denied by MoIC. However, there are safeguards; should there be price hikes for these products in the local market, or market shortages, import licences would be granted, and the import window would open again.

It needs to be noted that this SI is only intended to be a temporary stimulus for the revival of the local pharmaceutical industry; its main objective is to increase capacity utilization in local companies to levels that are commensurate with cost competitiveness with imported medicines.

III.6.3 Special Economic Zone for pharmaceutical manufacturing

Another measure to boost competitiveness of domestic pharmaceutical manufacturing has been much discussed by the Pharmaceutical Working Group. The Government's overall strategy document for economic development, ZIMASSET, specifically mentions the introduction of Special Economic Zones as a key success factor, and since the pharmaceutical sector has been prioritized for development, the MoIC is considering creation of a Special Economic Zone for pharmaceutical manufacturing. The industry has appealed for certain special incentives for some time, and given the need for re-tooling and new product development and enhancing competitiveness of the industry in the near-term, there is a case for time-limited incentives to allow the industry to achieve a stronger footing.

Special Economic Zones (SEZs) are not necessarily geographic; they refer to special regulatory and institutional benefits, mostly with a financial impact, that are to be enjoyed by a particular set of enterprises. The framework legislation for SEZs in Zimbabwe has been signed into law in November, 2016. It is therefore now appropriate to

initiate a serious consideration of the type of practical incentives for the pharmaceutical industry which would promote major objectives for its development.

III.6.4 Market authorization – registration of new medicines

The domestic pharmaceutical industry needs assistance to make rapid progress in becoming more competitive, improving capacity utilization, and gaining market share. A key competitive edge, compared to foreign suppliers, that could be provided to local companies is through faster registration of local products by MCAZ. MCAZ already provides a concessionary fee structure to local companies for fast-tracking registrations, but more than the fee reduction, the reduction of time to market is critical for domestic manufacturers.

In 2014, an initial review indicated that local product registrations were taking as long as 18 months or more. A number of steps have been taken to reduce this time period. UNIDO has facilitated industry exchange with MCAZ on the common causes of delay in reviewing dossiers, so that the process can become more efficient; MCAZ has explained the requirements of the CTD format in this forum. With cooperation from both sides, a backlog of local industry applications for registration was cleared. MCAZ has also committed to reduce local product registration times to 6 months.

Going forward, it will be important to remember that time to achieve market authorization is a competitiveness factor. MCAZ has discussed electronic tracking of registration applications, so that delays can be monitored and redressed. It is hoped that such a tracking system can be deployed soon.

III.7 Quality Standards in Local Pharmaceutical Manufacturing

Nominally, Zimbabwean pharmaceutical manufacturers are expected to follow WHO-GMP standards in their manufacturing. These standards are well-known to MCAZ, and as a matter of practicality, MCAZ has had to take a risk-based approach to enforcement of these standards, so that companies could continue to operate while the most critical GMP deficiencies are mitigated. However, since the pharmaceutical sector has been targeted as a priority sector in the Government's Industrial Development Policy, and the stated objective is that the industry should become an important regional player, it is important for the local industry to be known, both within and outside Zimbabwe, to comply closely to international pharmaceutical manufacturing quality standards. Accordingly, in the course of formulation of this Strategy, GMP assessments of the plants and quality systems of each domestic producer have been done, and confidential reports on their GMP status have been produced. Estimations were also provided to each company on costs for upgrading to full WHO-GMP compliance.

III.7.1 GMP Assessments of Local Pharmaceutical Manufacturers

All companies were assessed on 17 key quality elements, as outlined in the WHO-GMP standards. Companies were rated both on the quality of:

a) the "**site**", i.e. the physical entity of main premises, utilities, and equipment used in manufacturing, and

b) the "**QMS**" or Quality Management System, i.e. the system of procedures, protocols, and documentation that denotes managerial and procedural quality

Each company was then categorized, based on two axes for GMP compliance:

- Compliance of the **site** with WHO GMP standards
- Compliance of the **QMS** with WHO GMP standards

A score of "1", "2" or "3" was assigned to both **site** and **QMS** to describe their compliance with WHO GMP, with a score of "3" representing low compliance and a score of "1" representing high compliance. The categorization matrix is shown below in Figure 4.

Figure 4: Matrix for categorization of companies, based on compliance to GMP standards

			Quality Management System (QMS)		
			No QMS in place *(or highly inadequate)*	Requirements are implemented sporadically only; a systematic approach to GMP is not in place	A systematic approach in line with WHO GMP in place and implemented
			3	2	1
SITE	Site is in general compliant with WHO GMP	1	C	B	A
	Site shows significant deficiencies from WHO GMP, but does not impair production safety	2	C	B	B
	Site unsuitable for pharmaceutical manufacturing. Production safety impaired	3	C	C	C

Source: White Paper on UNIDO's GMP Roadmap Concept; Design of a Stepwise Approach for the Pharmaceutical Industry in Developing Countries to Comply with WHO GMP

The results of the categorization of the eight Zimbabwean pharmaceutical manufacturers, according to this matrix are shown in Table 11.

Table 11: Categorization of companies, based on compliance with WHO- GMP

Company ID	Overall GMP rating
Company 1	B
Company 2	B
Company 3	C
Company 4	C
Company 5	C
Company 6	C
Company 7	C
Company 8	C

Source: GMP Assessment of Existing Manufacturing Practices in the Zimbabwean Pharmaceutical Industry, UNIDO / PCS, August, 2016

The table above indicates the existing GMP gaps to WHO GMP standards that exist in Zimbabwean pharmaceutical companies presently. However, while the challenge to upgrade to full compliance to WHO GMP is not to be minimized, experience from other countries (e.g. India, Kenya) shows that improvement in GMP leading to full compliance with international GMP standards is possible over time. The way to achieve this would be for the regulator to devise, and then enforce, a stepped program to full compliance, with clearly identified milestones that represent increasingly more stringent GMP enforcement over time.

There is a technical challenge in devising such a stepped program, because it would have to encompass certain features simultaneously:

1) the milestones must represent minimum standards at any given time that would have to be enforced equally in all companies, so that there is a "level playing field" for market players, and no company is allowed a market advantage through non-uniform enforcement of GMP standards in the industry
2) the milestones in the stepped program must take into account differences in complexity of manufacturing for the various products that different companies may be producing at any time

WHO and UNIDO have been working jointly on a collaboration to bring these concepts together, and progress has already been made, particularly in thinking through the GMP requirements in manufacturing products of different risk levels in the production environment[15]. MCAZ, as the regulatory body, needs to be provided with technical assistance[16], if and as required, in devising such a stepped program to bring local industry in compliance to WHO GMP.

III.7.2 Estimation of GMP Upgrading Costs

Costs were collected and/or calculated for the following areas:

1. Production environment (HVAC and rooms)
2. Warehouse and building
3. QC laboratory
4. Equipment
5. QC equipment

Each company was given a ROM (Rough Order of Magnitude) cost estimation for the above areas. A number of factories are in need of "modernization"; many old pieces of equipment were observed. Therefore, the projected budgets are not only for GMP reasons, but also for necessary replacement of certain equipment.

The total sum for Items 1 to 5 was then used as a basis for calculating additional support in order to fulfill WHO-GMP requirements. The support envisioned included costs for

6. Engineering
7. Validation
8. Project Management
9. Consultancy
10. Contingency

The cumulative results of those estimations and calculations are given in Table 12.

15 In such a conceptualization, it is recognized that product manufacturing risk is lesser in producing some products than others, say, cough syrup versus penicillins. Therefore, the GMP requirements for producing cough syrup could be covered and enforced in an earlier milestone in the stepped program, while giving more time to a penicillin producer to upgrade GMP to full compliance for its production, by a later milestone.

16 www.who.int/medicines/publications/druginformation/WHO_DI_30-1_ConceptPaper.pdf?ua=1; White Paper on UNIDO's GMP Roadmap Concept; Design of a Stepwise Approach for the Pharmaceutical Industry in Developing Countries to Comply with WHO GMP

Table 12: Cost estimation for GMP upgrading of Zimbabwe's pharmaceutical industry

Budget Item	Cost (in '000 US $)
Production environment	8,923
Warehouse & buildings	3,164
QC Laboratory	915
WH/MF Equipment	10,085
QC Equipment	1,514
Engineering	2,072
Validation	1,936
Project Management	1,036
Consultancy	3,462
Contingency	2,111
Total	**35,218**

Source: GMP Assessment of Existing Manufacturing Practices in the Zimbabwean Pharmaceutical Industry, UNIDO / PCS, August, 2016

III.8 Public / Pooled Procurement of Medicines

Public procurement is usually considered an effective tool to be used by Governments to support local pharmaceutical production; other neighboring countries in the region such as South Africa, Botswana, Swaziland, and Lesotho all have provisions for a price preference of 15-30% for local companies which participate in public tenders for medicines. In Zimbabwe, since NatPharm receded as a significant market player in the domestic market due to lack of funding from the Treasury, public procurement has not been a major support for the Zimbabwean pharmaceutical industry. Still, there is some continued spending by Government institutions on procurement of medicines, and this is outlined below.

III.8.1 National AIDS Council (NAC)

NAC has procured medicines for HIV / AIDS programs directly in the past. The monies for this procurement do not come from the Government's health budget *per se*; rather, it is funded by the National AIDS Trust Fund (NATF), through a levy charged to individuals, companies, and trusts at a rate of 3% of their income tax assessed. Since it is a percentage of income tax assessments, and 70% of the workforce of Zimbabwe is working informally, the NATF contributions can, of course, only be collected from the remaining 30% that are involved in formal employment. Also, the level of collected contributions can fluctuate, since it is naturally affected by the economic swings in the country.

As a matter of policy, at least 50% of the NATF was spent by NAC on ART programs. In 2014, the NATF contribution amounted to US$ 38.65 million, 55% of which was spent on HIV / AIDS medicines, reagents, testing equipment, etc. About 80% of this cut was spent on medicines, which therefore amounted to approximately US$ 16 million. NAC procured medicines through both national and international tenders. In recent years, NAC had been an active supporter of local pharmaceutical companies, and has procured from local producers as much as possible (to the extent of advancing working capital to local winners of its tender). Even with that effort, though, it could only procure about 30% of its medicine requirements from local companies, due to the limited range of needed products available from domestic manufacturers. Procurement for NAC is now being done by Natpharm since 2015.

III.8.2 Hospitals, and other public health facilities

Zimbabwe's health system has a tiered structure, from rural health centres and rural hospitals providing primary health care to district hospitals, provincial hospitals, and central hospitals. Some of these hospitals are allocated Government funds for procurement of medicines; some apparently also purchase medicines from their own earned funds. However, the visibility of their expenditure on medicines is quite poor at the moment. In some cases, the problem apparently lies with both the availability of personnel and infrastructure (computer systems) to track this spending, so that overall spending figures are available, but not detail on what amounts were spent on which medicines. In other cases, information is available on the quantities of medicines that were procured, but not the prices or values. Mainly, the issue seems to be that the health facilities were not required in the past to report details of quantities and values of the medicines they purchased. So, since there is inadequate information on the type and value of medicines being procured, it has not been possible to determine the share of locally-produced medicines in this procurement, or to direct this procurement toward locally-produced medicines.

Recently, the Ministry of Health and Child Care has initiated a project financed by the Global Fund to deploy an electronic Logistics Management Information System (eLMIS) that may offer an opportunity to effect better reporting, monitoring and control of medicines procurement and supply by public health facilities. The eLMIS is primarily conceived as an inventory and dispensing management system to monitor the stock situation of health commodities at the national and sub-national level at any given time. However, perhaps this system can also include the functionality of monitoring the procurement of medicines. Eventually, the eLMIS is expected to cover 1,560 health facilities, and it is being deployed in phases. In Phase 1 of the project, 155 hospitals (Central, provincial, district, general and mission hospitals) are meant to be connected with appropriate IT infrastructure and systems in 2016 / 17. A budget of US$ 1.7 million has been identified for acquisition of necessary hardware and software, deployment and personnel training on the system, and post-implementation assessment. Two succeeding phases will extend coverage to the balance of 1,405 rural hospitals and clinics. A tentative Phase 2 of the project (not yet funded) is expected to extend the system to another 500 facilities in 2018; then a Phase 3 is planned for the remaining 905 facilities by 2020.

The eLMIS can provide improved visibility on public procurement of medicines, which (albeit of relatively low value presently) could be directed towards the purchase of locally-manufactured medicines, as stated in the National Medicines Policy.

III.8.3 NatPharm

NatPharm has not been functioning as the National Medicines Procurement Agency since 2009, but it is being used by donors to store and distribute medicines. Since 2015, NatPharm has also been procuring medicines utilizing the NATF funding from the National AIDS Council. Therefore, NatPharm is generating income from the storage, distribution, and handling fees charged to its partners / clients. NatPharm is also trading a limited range of medicines on its own account with some of this generated revenue. So, it also has been procuring some medicines, but more as a wholly Government-owned wholesaler / trader rather than as a national procurement agency for medicines. The Global Fund is currently providing mentorship to NatPharm to restore its capacity as a Procurement Agency.

In the long run, it will be difficult for Zimbabwe to establish health security through donated medicines only, without a viable and sustainable system of public-sector medicines procurement. It is therefore hoped that when Treasury allocations to Natpharm improve substantially and Natpharm is eventually re-capitalized, this very important institution will once again play a pivotal role in resuscitating the local pharmaceutical manufacturing industry.

III.9 Procurement of Medicines by Medical Aid Societies

There is no national health insurance in Zimbabwe; however, medical insurance is offered by medical aid societies. The medical aid societies operate on a pooled protection concept. Members choose and buy from offered service coverage plans, and pay monthly premiums. In return, their membership cards provide them with access to medical service from public and private health facilities (depending on plan coverage), and medicines from pharmacies. The health facilities and pharmacies are then reimbursed for services and medicines provided to members by the medical aid societies.

Some of these medical societies have been operating in Zimbabwe for decades; the oldest private medical aid society, the Commercial and Industrial Medical Aid Society (or CIMAS) was started 70 years ago. Some medical aid societies are tied to particular organizations, and are only open to persons affiliated to those organizations. Other medical aid societies are free for any individual or company to join. The biggest medical aid society, the Premier Service Medical Aid Society (or PSMAS) has over 600,000 members, 80% of whom are Government employees.

The medical aid societies had been flourishing till recently. At its peak, 29 medical aid societies provided medical coverage to 1.6 million subscribers, more than 10% of the country's population. They had also been self-regulating. In 2014, only 9 medical societies disbursed US$ 24.2 million for consumption of medicines. Some of the larger medical aid societies started integrating backwards to starting medical facilities and pharmacies themselves, and directing members to preferred service providers (moves that are viewed dimly by Zimbabwe's Competition & Tariff Commission). As such, they became market participants as buyers of medicines themselves.

Of late, though, the medical societies are facing difficult times, squeezed by rising costs for medical services, declining membership (as formal employment has been shrinking due to the country's economic problems), inability to collect outstanding membership premiums, and increasing oversight by the MoHCC (including Government-mandated fees to be paid to physicians). Thus, the medical aid societies have been trying to raise membership subscription rates, amid outstanding payments due to service providers.

There are also arrears due to the pharmaceutical manufacturers from medical aid societies that purchased medicines from local producers previously. The local industry is therefore reluctant to continue to supply medical aid societies such as PSMAS until the dues have been cleared, particularly in the light of the financial problems facing the medical aid societies presently.

However, when present issues have been resolved, medical aid societies will continue to play a role in the disbursement of monies for consumption of medicines, and in time, may become important direct procurers of medicines, either singly as in the case of the larger medical aid societies, or in some kind of pooled procurement arrangement among themselves.

III.10 Export of Finished Medicines

The pharmaceutical manufacturing sector was once the second-biggest earner of export revenue among the manufacturing industries of Zimbabwe. As mentioned in Section II.3.4, however, local pharmaceutical companies exported only US$ 1.4 million worth of medicines in 2014. If viewed in the context of a greater than US$ 5 billion market for pharmaceuticals in the 15 countries of the Southern African Development Community (SADC) of which Zimbabwe is a part, the export performance must appear as lackluster indeed. Currently, only 24% of all essential medicines consumed in SADC are produced within the region[17]; the rest is imported. Therefore, this represents an opportunity for Zimbabwean pharmaceutical manufacturers to capture market share from imported products by exploiting the SADC Free Trade Area (FTA) and protocols that support intra-regional trade, and also regional harmonization of registration processes. In this context then, what are the factors contributing to the unimpressive export situation?

17 Strategy for Regional Manufacturing of Essential Medicines and Health Commodities in SADC (2016-2020), page 5

III.10.1 Non-Tariff Barrier (NTB) to Exports to South Africa

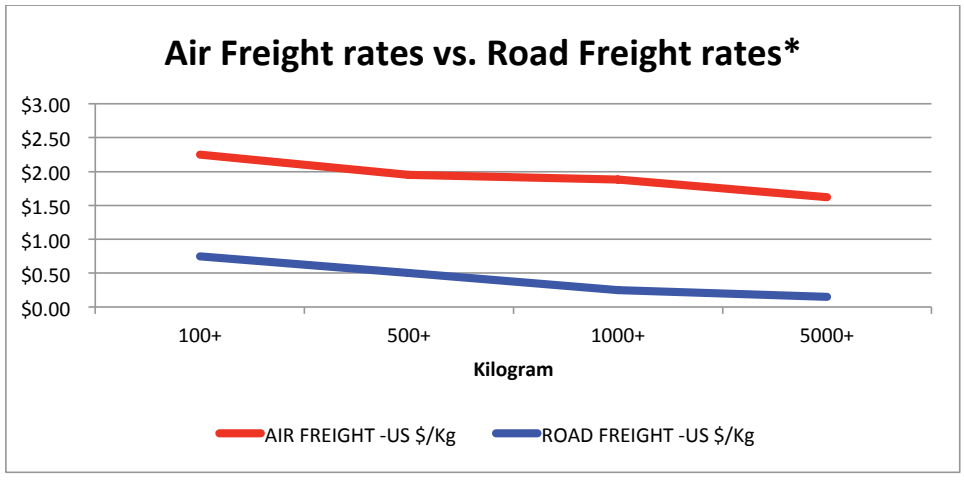
The biggest single country market for pharmaceuticals in SADC, and in fact in all of Africa, is Zimbabwe's neighbor, South Africa. The South African market for **all pharmaceuticals** (not just finished medicines) was US$ 4 billion, in 2012[18]. Yet, there are only meagre exports of Zimbabwean medicines to South Africa.

A major reason for this is that there is a non-tariff barrier to Zimbabwean export of medicines to South Africa. South Africa does not allow the transit of medicines through the land border ports of Beit Bridge-Musina between the two countries. Instead, potential Zimbabwean exports of medicines to South Africa (and also to Swaziland and Lesotho) must be air-lifted to Oliver Tambo Airport in Johannesburg. The reason provided by the South African Government for not permitting the land transit of medicines from Zimbabwe is the risk of counterfeit medicines coming into South Africa through this channel, and the lack of an adequate number of inspectors at this Port of Entry from the South African medicines regulatory agency, the Medicines Control Council (MCC).

Among countries neighboring South Africa (SA), Zimbabwe is the only country with a pharmaceutical industry that could compete effectively with South African companies in the SA market. In fact, Zimbabwean companies were exporting to SA before the institution of this NTB. Today, four Zimbabwean pharmaceutical manufacturers have products that are registered in SA, and all could potentially export to Swaziland and Lesotho.

A perspective on the impact of the NTB on export of medicines to South Africa, Swaziland, and Lesotho can be gained from a consideration of freight costs by road relative to freight costs by air, as shown in Figure 5 below.

Figure 5: Relative transport costs by road and air (Harare to Johannesburg Airport)



* from Harare to Oliver Tambo International Airport, Johannesburg

Source: quotations from freight forwarders

For typical weights and volumes of pharmaceutical shipments, air freight costs are 5 times the freight costs by road.

The price impact can be illustrated by a real case of a tender in Swaziland. The pertinent numbers for the tender are shown in Table 13.

18 Industrial Policy Action Plan 2014/15-2016/17, Department of Trade & Industry, South Africa

Table 13: Example of Swaziland tender, showing impact of road & air freight costs

Swaziland Tender 2015/16		Freight Cost / kg.	Freight Cost, as % of Total
Potential Total Export Value of Zimbabwe Manufactured Drugs	$15,971,899		
Total Weight (tonnes)	2,128		
Road Freight Cost	$332,061	$0.16	2%
Air Freight Cost	$3,473,005	$1.63	22%

Source: PMA

By analyzing the medicines requirements in this tender, identifying the products that could be supplied by Zimbabwean companies, and using international reference prices for these medicines, it was determined that the tender represented an export opportunity of about US$ 16 million. The total shipment was estimated to necessitate the transport of 2,128 tonnes of medicines. For this weight, the relative road and air freight costs are shown. Air transport, relative to transport by road, therefore creates a price premium of 20%. Certain products, such as liquids with high water content (syrups) or bulk high-volume tablets, which are common products produced by Zimbabwean manufacturers, are most affected by the difference in freight costs. In some cases, the freight cost may actually exceed the product cost. For instance, previous winning tender prices for 1000 ml. of normal saline were about US$ 1.10, while the air transport price of this product would itself be US$ 1.62 before other charges, compared to road freight of this product of US$ 0.15.

In circumstances where tenders are won or lost on price differentials of a few cents in unit costs, the NTB renders Zimbabwean export of medicines to South Africa, Swaziland, and Lesotho uncompetitive, and effectively shuts out local producers from these markets. In fact, **if there is a single change that would most significantly and most positively impact the prospects for revitalization of the pharmaceutical sector in Zimbabwe through exports, it would be the elimination of this NTB.**

Repeated approaches have been made by the Ministry of Industry and Commerce of Zimbabwe to its South African counterpart on this issue, but with little apparent progress. Some have proposed retaliatory measures by treating pharmaceutical imports from SA to Zimbabwe through Beit Bridge similarly, so that South African exports of medicines do not transit through Musina-Beit Bridge either. Preliminary estimates from MCAZ data indicate that in 2014, export of medicines from South Africa to Zimbabwe amounted to about US$ 14 million. In that same year, South Africa's export of pharmaceuticals was over US$ 200 million; so exports to Zimbabwe are under 7% of South Africa's pharmaceutical exports. There was no readily available information on whether, or how much of, South African medicine exports transit through Musina-Beit Bridge to other countries, e.g. Zambia. So, if Zimbabwe also shut down transit of South African medicines through this land port, perhaps the local pharmaceutical industry would gain some business in providing market replacement of the medicines presently imported from South Africa. However, the greater benefit to local industry would, of course, accrue from gaining competitive access to the larger South African market rather than sealing the Zimbabwean market to South African imports.

Finally, it should be mentioned that besides the NTB represented by the non-allowance of land transit of medicines from Zimbabwe to South Africa through Beit Bridge – Musina, there are other barriers to export of medicines to SA. The Medicines Control Council, the National Medicines Regulatory Authority in South Africa, does not allow direct registration of products by foreign manufacturers; product registration is only possible through local agents. Also, every imported batch of medicines must be tested after arrival of the import consignment by a registered laboratory in SA. These requirements are effectively other administrative NTBs.

III.10.2 The SADC Regional Market (other than South Africa)

South Africa is the biggest pharmaceutical market in Zimbabwe's near-region and in SADC, but other countries in the region are also important markets. The prospects for market penetration by Zimbabwean pharmaceutical manufacturers in these other countries are discussed below.

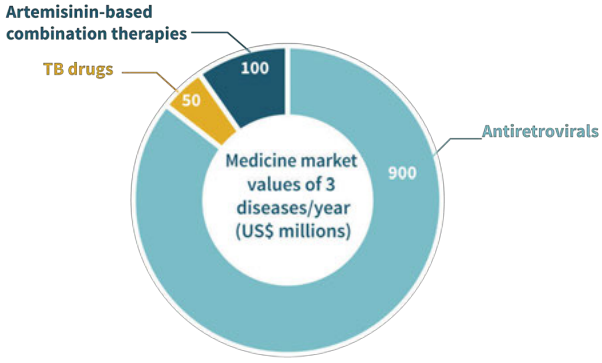
III.10.2.1 Market Information in non-SA SADC (or the lack thereof)

Most of the available information on the pharmaceutical market in SADC is outdated. A Pharmaceutical Market Analysis was completed on the basis of 2010 data by the Southern African Regional Programme on Access to Medicines and Diagnostics[19] which reported on the price preference given to local companies in public procurement tenders for medicines in eight Member States. The SADC Situational Analysis and Feasibility Study on Pooled Procurement of Essential Medicines & Medical Supplies[20], published at the end of 2012, provided data on the duties and taxes imposed by Member States on the import of raw materials used in pharmaceutical production and also finished medicines.

Recently, SADC undertook a Feasibility Study on the Regional Manufacturing of Medicines & Health Commodities, which was completed in January, 2016. It reported that eight Member States presently provide for a domestic preference for local companies in their tenders for public procurement of medicines. This takes the form of a percentage deduction of the offered tender bid price during the financial evaluation of the tender bids from local companies; in other words, local companies are given a percentage price preference. Zimbabwean companies could also take advantage of this offered price preference by establishing local partnerships with distributors in these SADC countries, and then submitting joint bids in the tenders. In fact, establishment of distribution companies in the region focused on Zimbabwean pharmaceutical products could be a key strategic initiative for local industry.

The above-referenced Feasibility Study focused on HIV / AIDS, TB, and malaria, and reported on spending figures for medicines for these diseases from the Global Fund PQR and the US Government's PEPFAR databases. Overall, it estimated a 2015 market of US$ 1.05 billion, as shown in Figure 6.

Figure 6: Relative Market Value of Medicines for 3 Diseases in SADC



Source: SADC Feasibility Study on the Regional Manufacturing of Medicines and Health Commodities

The total SADC market in 2016 for medicines and medical supplies for all diseases is estimated to be US$4.7 billion by this SADC Feasibility Study.

19 SADC Pharmaceutical Market Analysis, SARPAM, January 2011

20 http://www.sadc.int/files/6614/1890/8516/SADC___SADC_POOLED_PROCUREMENT_OF_ESSENTIAL_MEDICINES_AND_MEDICAL_SUPPLIES.pdf

In late 2013, SADC set up the SADC Medicines Database (SMD) with assistance from SARPAM, where Member States were meant to report on the quantities and prices of medicines procured through their public procurement tenders. The idea was that if this information was shared, it would enable National Medicines Procurement Agencies to achieve better prices in their public procurement, and thereby produce savings in their medicines procurement costs. Though a worthwhile objective, not all Member States reported their public procurement results, and over time, the database has languished, and proved not to be sustainable. A recent check of the website showed that the last reported purchase of medicines was in November, 2014.

So, all in all, there is no ready source for reliable information on the non-SA market in SADC for both prescription medicines and OTC products, by particular medicine or medicine category. This data, for both the public and private sector market segments, is critical for market players to identify market opportunities and address them with their product offerings, particularly for the market segments which have not been "captured" by donors, i.e. medicines for diseases other than HIV / AIDS, TB, and malaria. The lack of useful market information for the broader SADC market is a handicap for Zimbabwean manufacturers interested in boosting their exports, and needs to be addressed. Incidentally, this is also critical information for the implementation of SADC's plans to implement pooled procurement of essential medicines.

III.10.2.2 Market authorization (registration) in the SADC Region

Just as for the domestic Zimbabwean market, faster registration of products in the broader SADC market would also help local companies to enhance their presence in, and share of, the regional market. In this respect, ongoing efforts to harmonize product registration by regulatory authorities in the SADC countries are very much in line with local companies' aspirations to sell regionally. In this context, it should be noted that the African Medicines Regulatory Harmonization (AMRH) Programme is currently being implemented in SADC by NEPAD (New Partnership for Africa's Development). A tripartite agreement has been concluded between NEPAD, the World Bank, and the SADC Secretariat to provide financial and technical support to the SADC Member States for implementing their regional medicines regulatory harmonization programme[21].

In fact, the regulator in Zimbabwe, MCAZ, has already been involved in a cooperative effort with the regulators in Zambia, Botswana, and Namibia to review medicine registration applications jointly during the pilot phase of an initiative named ZaZiBoNa. The benefit in the case of these applications being considered under the Zazibona scheme, is that the registration dossiers thus reviewed jointly and simultaneously by all four regulators, would, once approved, result in a simultaneous registration of the product in all four countries. By not going through the registration process separately with each regulator, the applicant for the product registration can then save much effort, time, and costs, and bring the product much quicker to market. The Zazibona initiative has recently been broadened to include all SADC Member States; it was adopted as a SADC Medicines Co-Operation mechanism in 2015. This means that the Zazibona program now encompasses all SADC countries, including South Africa. It therefore presents an opportunity for Zimbabwean companies to achieve quick registration and access into the regional export markets.

In its initial phase, however, the Zazibona program prioritized the registration of **new** products to go through the Zazibona process, particularly products for which there had already been separate applications pending with each of the regulators involved. Given that few domestic pharmaceutical manufacturers are regional market players now, and since (as we have seen) Zimbabwean pharmaceutical companies have few new product registration applications anyway, most of the product registration applications that have been considered under Zazibona were from foreign manufacturers or larger importers. For Zazibona to benefit local companies, even products that are already registered under one participating regulatory agency need to be allowed to go through the Zazibona track, so that there can be quick access to the markets in the other countries for the products that the local companies are already selling in the domestic market. This requires a change in the policies and priorities of the Zazibona initiative, which all regulators involved may have to be lobbied for. Perhaps this should be a broader advocacy matter with the regulators in each country through the Southern African Generic Medicines Association (SAGMA). In general, though it is understood that Zazibona is a regulatory mechanism and cannot promote

21 http://www.nepad.org/nepad-on-the-continent?nid=all&tid=2044&pid=407

specific categories of products, qualifying criteria for the Zazibona process should not impede the participation of domestic companies in any SADC country.

It should be noted, though, that registration evaluations under the Zazibona program also involve GMP inspections. So, local manufacturers will have to upgrade their compliance to international GMP standards, and ensure that their products qualify for the more stringent Zazibona registration requirements.

IV. SECTOR DEVELOPMENT STRATEGY

Despite Zimbabwe's economic difficulties in recent years, and a seriously cash-strapped economy presently, the pharmaceutical market has proved to be remarkably resilient. BMI Research reported a 4.7% growth in the market from 2015 to 2016; the total pharmaceutical market (which includes finished medicines, plus medical supplies and health commodities) is also expected to grow between 2016 and 2020 at a Compound Annual Growth Rate (CAGR) of 4.1% in terms of retail values[22]. Assuming this growth rate translates back to cif import and ex-factory prices, and discounting by a third to estimate the finished medicines component (standard approximation), that would amount to a domestic medicines market of about US$ 315 million in 2020[23].

The broader regional market looks much more robust. The total SADC market for medicines and medical supplies was estimated to be US$ 4.7 billion today[24], and was projected to increase to US$ 6.5 billion in 2020.

In this context, a Pharmaceutical Sector Development Strategy for Zimbabwe should pay attention to a number of basic considerations:

1. Exports

The local pharmaceutical industry has of late (and perhaps out of necessity) been focused on the domestic pharmaceutical market. However, in the end, Zimbabwe has only 4.6% of the population of SADC as a whole, and market growth rates within the country are likely to be smaller than the overall SADC growth rate in pharmaceuticals in the near term. Even taking the SA market out of the equation due to the already-discussed NTB barrier, the broader regional market still represents a significant opportunity for the industry. Local companies have to focus to a much greater extent on exports, for the same considerations of increasing market share and volumes discussed earlier in this document: to avail of the benefits of higher capacity utilization, and thereby greater manufacturing efficiency and competitiveness.

2. Role and support of Government

Given the state of the sector today, local industry will require strong and ongoing support from Government institutions - from the line Ministries, the regulator, and the Revenue Authority. In the major and minor success stories of the pharmaceutical sector in developing countries (India, Bangladesh, Tunisia), the Government has always played a leading role through supportive policies and incentives. South Africa is the classic case nearer to home. Though the South African pharmaceutical industry is unquestionably far ahead of the pharmaceutical sectors in other SADC Member States, the Department of Trade and Industry continues to support the sector in SA through designations of local participation in public tenders, mobilization of public investment in infrastructure, subsidization of training and skills development, etc. Similar participation and commitment will be required from Government institutions to revitalize the pharmaceutical sector in Zimbabwe.

22 Zimbabwe Pharmaceuticals & Healthcare Report, BMI Research, November 2016

23 cif import prices, and ex-local factory values

24 This is an under-estimation, since the South African domestic market alone is already over US$ 4 billion, Final Report, Volume 1, " SADC Feasibility Study on Regional Manufacturing of Medicines and Health Commodities", p.54

3. Public health orientation of the local industry

Not least because of the need to ensure this continued support, the local industry has to realize that the revitalization of the pharmaceutical sector cannot just be solely about maximizing the profits of the pharmaceutical companies. There has to be a larger agenda that is broadly subscribed to, in order to maintain the drive and energy to propel the sector. In fact, local industry needs to be perceived as actively contributing to social needs, and needs to align itself with the achievement of positive public health outcomes. So, companies have to move away from the mindset of making similar products and simply trying to capture marginal market share from another domestic competitor, but think about and push for quantum improvements through a broader calculation of self-interest, **with** the help of other stakeholders. For this, the industry also needs to contribute towards broader social objectives.

Out of these strategic considerations, one can articulate a strategic vision for the development of the local industry: **to become a major player in the SADC market through providing quality, affordable essential medicines while contributing to positive public health outcomes.**

Making strides towards such a vision for the industry from its current base is certainly a multi-year effort. This Strategy has therefore been written with a 6-year horizon in mind, 2017-2022. Certain groundwork / early implementation steps, particularly the mobilization of required financing, will take time, as other parties, specially development partners, will have to be made familiar with conditions in the pharmaceutical sector. Once financing is mobilized, developments, such as the product development / registration / market launch cycle, and GMP improvements also take long to implement, and may take up to five years before the industry can be considered to have reached a higher plateau.

Some particular strategic objectives can be targeted, though, for the local pharmaceutical sector by the end of this period.

By 2022,

1. Achieve minimum US$ 150 million in total annual sales revenue
2. Supply 60% of the number of Essential Medicines on the Essential Medicines List of Zimbabwe (from 30% presently)
3. Improve quality: at least 4 companies to comply fully with WHO-GMP standards (reach “A” category, as per Figure 4)
4. Reach minimum one-third share of domestic market (from present 10%), i.e. reduce share of imports by a quarter
5. Derive 25% of annual sales from exports (from negligible exports today)

Strategy Components to achieve these strategic objectives are discussed below. It is important to note that all Strategy Components described are inevitably interlinked. It may be possible, within limits, to stagger work on particular Strategy Components depending on availability of financial resources to address them. However, it is not reasonable to cherry-pick among the Strategy Components to work on some, and ignore others.

IV.1 Strategy Component I: Direct measures to enhance competitiveness of sector

Some measures to enhance competitiveness have already been undertaken, such as the roll-back of import duties and VAT on pharmaceutical raw materials, and the introduction of a licensing requirement by MoIC on the import of certain finished medicines. However, both the implementation and the impact of these measures, on the companies and the domestic market, need to be continuously monitored.

Sub-Task 1: Revise and update list of pharmaceutical raw materials exempted from import duties and VAT, as required.
(Reference: Section III.6.1)
As the product portfolios of local companies change, this list would also have to be modified.

Sub-Task 2: Revise and update list of medicines requiring licences for import
(Reference: Section III.6.2)
For the 23 medicines whose import has been restricted by the institution of a licensing requirement, MoHCC needs to keep watch on the supply and prices of these medicines on the local market, and, in consultation with PMA, advise MoIC accordingly on whether it is necessary to continue restricting or to ease the issuance of import licences. If the measure continues to work well without causing market shortages or price hikes, then consideration can be given to expanding the list of medicines requiring import licensing. Effective control measures also need to be put in place to plug any loopholes that might result in infiltration of imports of the restricted products into the domestic market without licence from the MoIC, thereby negating the expected benefits to local manufacturers. When reviewing the effectiveness of the import restriction measures, the overall objective of an increase in capacity utilization for local industry should be kept in mind.

Sub-Task 3: Promulgate special, time-limited incentives in Special Economic Zone (SEZ) for pharmaceutical sector
(Reference: Section III.6.3)
Zimbabwe is lagging behind other SADC countries in the implementation of incentives for its pharmaceutical industry. A review of incentives offered by Member States in SADC is provided by the recently-completed Feasibility Study on Regional Manufacturing of Medicines and Health Commodities[25]. The PMA has also proposed a set of incentives for the pharmaceutical industry, to be included in the package of incentives for a Special Economic Zone for the sector.

There is considerable work to be done in structuring incentives for the SEZ, and on the qualifying criteria for companies to benefit from some or all such incentives. Incentives can be of different forms and types. In the particular circumstances of the local pharmaceutical industry in Zimbabwe, some important incentives that could be considered are

- export incentives (such as tax relief on export profits, assistance with trade promotion)
- removal of import duties and VAT on import of equipment for plant upgrading
- tax relief on investments in product development
- designated quotas, or price preference for purchase of locally-produced medicines by public procurement agencies, such as Natpharm, local authorities or health facilities, and the State Procurement Board, as is the case in other countries in the region, e.g. South Africa
- grants / subsidies for employee training or skills development

IV.2 Strategy Component II: Expansion of market space for local industry (measures to enhance sector competitiveness indirectly)

This Strategy Component is also aimed at increasing competitiveness of the sector, but through measures that could help to increase the share of market of local companies, thus increasing production volumes and impacting efficiency of manufacturing operations positively.

Procurement from important market segments needs to be directed towards local sourcing, starting with whatever level of public procurement is occurring presently. The National AIDS Council has already been supporting local pharmaceutical companies through its procurement policies.

Sub-Task 1: Monitor, and direct, public procurement of medicines to local sourcing; assist MoHCC to deploy eLMIS
(Reference: Section III.8.2)
The eLMIS initiative of MOHCC (discussed in Section II.8.2) should be supported, and expenditure of public funds on medicines needs to be monitored closely, piggybacking on the eLMIS. Even though the level of procurement by public health facilities may be quite low today, the systems should be established whereby public procurement helps local industry when the procurement quantities and values increase. It is recommended that a contribution

25 pg. 46, Volume 1, Final Report

amount of US$ 200k be allocated to the roll-out of this system by MoHCC to cover systems development and training costs in Phase 2, so that public procurement is more effectively directed towards purchase from local companies.

Sub-Task 2: Re-capitalize NatPharm
(Reference: Section III.8.3)
Clearly, the re-capitalization of NatPharm would be a boon to local industry if NatPharm would return to its once-central role in procuring and distributing medicines. Given the current financial position of the Government, this is unlikely to happen soon, but perhaps this can be re-examined in later years of this Strategy period. However, this may need to be given a higher priority should donor support in supplying needed medicines be reduced.

Sub-Task 3: Engage with medical aid societies to monitor, and help direct, procurement of medicines purchased (or reimbursed) by them to local sourcing
(Reference: Section III.9)
Looking beyond the present difficulties of the medical aid societies, there is little doubt that in the future, in the absence of national health insurance, the reimbursement for medicines by the medical aid societies will account for a larger share of the consumption of medicines. Even without getting directly involved in the purchase of medicines, there is much that the medical aid societies can do to influence the purchase of medicines through their prescription and reimbursement policies. They can, for instance, encourage the use of generics, or place price caps on their reimbursement, to encourage the purchase of the most competitively-priced medicines. As has already been noted, some medical aid societies are already involved in the direct purchase of medicines for the hospitals, clinics, and pharmacies that they have started to run themselves. Therefore, the local pharmaceutical industry needs to remain an interested observer of business developments with regard to the medical aid societies, and identify opportunities with them as they arise.

Sub-Task 4: Engage with donors to promote consideration of direct donor procurement (particularly of essential medicines) from local manufacturers
(Reference: Section III.5)
While it is understood and accepted that manufacturing quality improvements have to be made in the domestic pharmaceutical companies, once these improvements have been realized in one or two companies, the Government of Zimbabwe needs to encourage donors to support local procurement. Import of essential medicines funded by donors should be obviated if the same medicines of good quality and comparable price are available locally. At that point, if only donor procurement procedures and policies are in the way of local sourcing, the Government has to discuss changes in these procedures and policies with the relevant donors, so that the local industry is enabled to participate in donor procurement.

IV.3 Strategy Component III: Revamping of industry product portfolios

Industry product portfolios have already been discussed in Section II.4. Some high-value imported molecules (e.g. diclofenac, ceftriaxone, as shown in Table 1) are not made by the local industry. It is impossible to compete with imports, if local companies are not even on the field.

Most of the local pharmaceutical manufacturers have limited technical capacity to develop formulations of new products. For them, the easiest way to acquire new products would be to buy product dossiers. It is unclear how the regulator, MCAZ, would treat or accept the information contained in purchased dossiers at the time of registration. That needs to be addressed before purchase of dossiers becomes a viable option for local companies to get new products. In any event, the pharmaceutical companies will need financial and technical expert assistance to access product dossiers.

Sub-Task 1: Facilitate sourcing and purchase of product dossiers
(Reference: Section III.4.1)
The cost of purchased dossiers is a concern. Purchased dossiers from a jurisdiction with a Stringent Regulatory Authority (SRA) could cost in the range of US$ 80-100k or more, depending on the product, which is prohibitive for Zimbabwean companies. However, it is possible to buy quality dossiers from certain Indian or South African companies. If MCAZ guidelines on a purchased dossier require test data (such as for stability, and / or BA/BE) to be regenerated, then average development cost per new product (mix of product development and dossier acquisition, including BA / BE, stability testing data, plus support for formulations up to production of first sample batch) could run to US$ 50k per product. On average, the product portfolios of the local producers are not suited to present market dynamics / demands. To meet local demand more effectively, and to penetrate new, more profitable markets, one should envision 50% new products for the industry over this Strategy period. In 2014, the eight pharmaceutical manufacturers produced 296 products. Using that as a base, the cost of acquisition of dossiers alone for 148 new products would be US$ 7.4 million. At least one company has already tried to source product dossiers on its own, and has not made much headway. That indicates that ongoing, part-time support from technical expertise would be useful to guide the companies through identification of product priorities, finding and contacting appropriate vendors of dossiers, assisting in negotiating and closing deals, and following up with the companies on their product development. Over the first 2 years of the Strategy period, such technical expertise could add US 0.3 million to the costs of new product development, as per an estimate made by a UNIDO-retained expert.

Acquisition of product dossiers would be greatly aided by innovative financing solutions, specially in the form of public-private partnerships. For instance, a Government entity or fund could be established to provide the up-front financing for acquisition of dossiers for essential medicines not currently being produced locally, and then the investment could be recouped through collection of royalties from the companies, once the product is being manufactured and sold. That would also promote the public health objective of having more essential medicines that Zimbabwe needs being produced locally. Companies could also perhaps share purchased dossiers, in the sense that one or more companies could use the same formulation for a medicine, but then produce and sell the medicine under separate branding.

Sub-Task 2: Facilitate industry-academia collaboration on developing formulations for new product
(Reference III.4.2)
The School of Pharmacy, University of Zimbabwe, and the Department of Pharmaceutical Technology at the Harare Institute of Technology have indicated in separate Proposals their funding requirements for facility upgrade costs in order to gear up to be able to support industry on new formulation development (Annex I and Annex II)). It is recommended that a contribution amount of US$ 600k be included in the implementation of this Sector Development Strategy for assistance to these institutions in becoming effective partners in the development of the pharmaceutical sector in Zimbabwe.

Sub-Task 3: Facilitate establishment of BA/BE capability in Zimbabwe
(Reference III.4.3)
The issue of the high costs for BA/BE studies must be addressed if the domestic pharmaceutical industry is to be assisted to develop many new products that are in line with market needs. AiBST's Project Plan (Annex II) indicates an immediate need for financial support of US$ 112 k for infrastructural and other equipment costs to complete the Clinical Trial Unit, and do its first BA/ BE study. Again, to cover ancillary personnel training, and start-up costs till the Clinical Trial Unit can become self-sustaining, financial assistance of US$ 250k is recommended for AiBST towards establishing BA/BE capability in the country.

IV.4 Strategy Component IV: Upgrading of manufacturing quality to international GMP standards

For the Zimbabwean pharmaceutical sector to be a major regional player in SADC, a reputation for quality manufacturing to international standards is a must.

Sub-Task 1: Skills training and capacity building in the pharmaceutical companies
(Reference: Section III.7)
In the course of the GMP assessments of the local pharmaceutical companies undertaken by UNIDO, it became clear that in some companies, there is a lack of understanding of basic concepts of QA as part of a PQS, among the very people who were meant to implement these systems. In addition, there is a general need to introduce validation and qualification concepts, including awareness of the pre-requisite activities before validation / qualification should start. Therefore, awareness-raising about concepts of Quality Assurance and skills training are necessary preparation within the companies for a GMP-upgrading program.

Sub-Task 2: Implement stepped program of GMP upgrading of industry (plant refurbishments and improvements in Quality Management Systems)
(Reference: Section III.7.1)
Besides the recognition of the value of a reputation for quality as a market advantage, the motivation of the companies to upgrade quality will also have to be reinforced by regulatory enforcement. So, MCAZ has a vital role to play here. There is a need for MCAZ to complete a clear program for stepped enforcement of tightened minimum standards over an established period, communicate this program to industry, and then enforce it vigorously (for more on this, see Strategy Component VI, Section IV.6).

From Section II.7.2, a ROM (Rough-Order-of Magnitude) estimation of costs for GMP upgrading of industry to international standards is US$ 35.2 million.

IV.5 Strategy Component V: Establishment of medicine exports as a major foundational pillar of the industry

Given the size of market in the region, and the existing market opportunities in SADC compared to the size of the domestic Zimbabwean market, the need to focus on exports is obvious. Some of the important requisites for the industry to enhance its export performance --- making products that are in demand, a reputation for quality --- have already been explored in previous Strategy Components II and IV. Overall, it could be a good strategy for companies to focus their new product development and registrations on the top best-selling products in the regional markets. Revenues from one high-demand product could, for instance, far exceed that from a number of lesser-performing products in these markets. So, in order to realize efficiencies from limited resources, the industry needs to consider product development and market access efforts carefully.

Facilitating regional market access through a different mode of implementation of the Zazibona initiative which would bring more benefit to local medicine producers has also already been discussed earlier. Since MCAZ is the Zimbabwean stakeholder involved in Zazibona, the recommended Sub-Task to address this has been grouped as Sub-Task 4 under a later Strategy Component VI specifically associated with MCAZ.

The remaining success factors are information on the regional market, which would enable Zimbabwean companies to identify opportunities, and access to these markets.

Sub-Task 1: Continue to push for elimination of the NTB barrier to exports to South Africa
(Reference: Section III.10.1)
No matter how difficult this may be to achieve, the seriously negative impact of this NTB on the prospective fortunes of the pharmaceutical industry in Zimbabwe requires that the imperative to try and eliminate this NTB remain on the table.

Sub-Task 2: Initiate a program for compilation of information on pharmaceutical markets with other countries in the region
(Reference: Section III.10.2.1)
The paucity of reliable market data on the broader (non-SA) SADC market, i.e. information on the consumption of medicines (quantities and values), by medicine type or category, has already been mentioned. Compiling such information from the 15 SADC countries should perhaps be a SADC priority. However, there is an opportunity to collect and compile such data for imported medicines in the four original Zazibona countries (Zambia, Zimbabwe, Namibia, and Botswana), since much of the information on imports (which constitute the bulk of the market, anyway) is or can be made accessible from the National Medicines Regulatory Authorities (NMRAs). The NMRAs in these four countries already have a history of working together on the Zazibona initiative on joint product registration, and correspondingly, an initiative for compiling pharmaceutical market information can also be envisioned which involves these four regulatory bodies. Getting a more accurate picture on the consumption of imported medicines in these countries on an ongoing basis could be of interest to each agency. With a prior agreement on sharing of data, local pharmaceutical companies in Zimbabwe could at least then gain perspective on the medicines markets of the nearest non-SA neighbors through such a program.

Through UNIDO experience of such programs elsewhere, a ROM cost for implementing such a program in the four countries mentioned would be about US$ 400k.

IV.6 Strategy Component VI: Support for MCAZ deliverables, and regulatory capacity-building

Apart from the pharmaceutical companies themselves, the national stakeholder having the most direct influence on the prospects for a successful revitalization of the pharmaceutical sector is MCAZ. A number of aspects of the Strategy Components discussed before are critically dependent on certain MCAZ deliverables (described below). For timely output of these deliverables, MCAZ will need technical support and capacity-building. It may also need financial support.

Sub-Task 1: Complete guidelines on the treatment of purchased dossiers in product registration
(Reference: Section III.4.1)
The requirements for this MCAZ deliverable have already been discussed earlier.

Sub-Task 2: Clarify qualification / certification procedures and requirements for local service providers (School of Pharmacy, AiBST)
(Reference: Section III.4.2 and Section III.4.3)
In order for the pharmaceutical companies to confidently use the services and support of say, the School of Pharmacy for formulation development, and / or AiBST for BA/BE data, they need to understand the acceptability to MCAZ of the results furnished by these service providers. Therefore, MCAZ needs to clarify the circumstances under which local companies could avail of such services.

Sub-Task 3: Produce, and communicate, stepped program for tightened GMP enforcement to full compliance to international standards
(Reference: Section III.7.1)
MCAZ already applies, in effect, a risk-based approach to GMP enforcement. For the purposes of a GMP upgrading program over a period (say 5 years), this approach can be made more explicit and transparent.

In addition to site and QMS considerations, the product risk dimension should also be taken into consideration, in formulating a stepped program of GMP enforcement to successively more stringent minimum standards (taking into account the complexity and cost of upgrade necessary to comply) till compliance to international standards is reached.

MCAZ could need technical assistance to complete the above Sub-Tasks 1,2, and 3. It is recommended that US $ 60k be allocated for such technical support.

Sub-Task 4: Promote cross-registration of local-company products through the Zazibona track
(Reference: Section III.10.2.2)
It is recognized that Zazibona is not run by MCAZ alone; other regulatory agencies are involved. However, a change in policy and priority for Zazibona processing can be promoted, so that Zazibona does not primarily benefit multinationals with simultaneous new-product applications in all the Zazibona countries. Local companies would benefit if local-company products which are already registered in Zimbabwe are allowed to go through Zazibona registration. In this case, local companies should be prepared to meet additional requirements under the Zazibona process, as required, from the initial product registration with MCAZ. There may, for instance, be a need to update the initial product registration dossier to current Zazibona CTD requirements.

Sub-Task 5: Deploy / Improve IT infrastructure in MCAZ to capture import data, and track product registration applications
(Reference: Section III.3.1 and Section III.6.4)
The present situation with regard to the disorganized storage of data on imported medicines has already been discussed earlier in this document. This import information would be particularly useful, if it was collected and compiled electronically in a systematic way, and was combined with medicine classification so that the resultant database could be queried for quantities and values of medicines, by medicine classification or category. A system designed to collect and compile such import data should ultimately be linked to the import data collected within ASYCUDA World at ZIMRA, so that imported medicines can be tracked from issuance of import permit by MCAZ to Customs clearance of the shipment of medicines at the Port of Entry.

Another important capability that needs to be designed into IT systems in MCAZ is the tracking of new product registration applications through the registration process so that registration times (and delays) can be monitored, and reasons for any delays identified.

MCAZ has already been considering development and deployment of institution-wide IT infrastructure. a contribution of US$ 225k towards this IT deployment at MCAZ is recommended to cover the capacities important to pharmaceutical sector development.

Sub-Task 6: Acquire Stringent Regulatory Authority (SRA) status, through PIC/S accession
The usual justification for requiring WHO-Prequalification or GMP certification (in donor procurement, for example) is that the National Medicines Regulatory Authorities (MNRAs) in Africa are not stringent enough, or that the NMRAs lack capacity to ensure WHO GMP standards. As a result, medicines produced under the jurisdiction of these NMRAs are also not considered to be of international quality standards. If MCAZ attained SRA status though, and enforced strict compliance to international quality standards in local medicines manufacturing, this would facilitate access to donor procurement programs by the local industry, SRA status not only in Zimbabwe but in regional and international markets. Attaining SRA status could take time, but this should be accepted as a principal objective for MCAZ.

IV.7 Strategy Component VII: Mobilization of required financial resources

Adding up all the costs mentioned in the prior Strategy Components, the financial requirement for implementing the Strategy appear as follows.

Costs for GMP Upgrading & Product Development:	U$$ 42.6 million
Costs for Preparatory Assistance,	
Support Infrastructure / Systems, Expert Help	US$ 2.1 million

Thus, it is necessary to mobilize approximately US$ 45 million to implement this Strategy.

The costs for GMP Upgrading and Product Development, about US$ 43 million, are monies to be expended by the pharmaceutical companies directly. They represent investment costs, which are expected to be recouped. So, this funding could theoretically be in the form of equity or debt financing for the companies. In their present

financial and business situation, though, it is doubtful that any of the Zimbabwean pharmaceutical companies are "bankable" for the amounts required. In any case, in the present financial crisis that the country is in, the commercial banks are not in a position to provide loans, anyway, or the interest rates on offer would be so high that it would not be commercially viable for the companies.

The other US$ 2 million component is for the deployment of necessary infrastructure and systems, preparatory support, and expert technical help (plus allocation for fund-raising). This portion is best financed through grant assistance. Since this expenditure is for a number of activities that are preparatory in nature, i.e. laying the groundwork for other implementation sub-Tasks, it is more front-loaded in the Strategy period.

In summary then, the financial need is for about US$ 2 million in grant aid, and US$ 43 million in some form of concessionary, soft credit. The second component is perhaps best disbursed through a special Pharmaceutical Sector Revitalization Fund (PSRF), which could be set up as a special entity[26] receiving and funding investment proposals from pharmaceutical companies directly, or set up as a lender to lenders, i.e. providing financing for onward lending to the pharmaceutical companies through financial intermediaries, such as the commercial banks.

Funding options to finance implementation of the Sector Development Strategy include:

a) Development assistance from development partners, such as Development Finance Institutions, e.g. World Bank, African Development Bank, or other donors
b) Foreign Direct Investment (FDI) in the domestic pharmaceutical companies, through strategic partnerships with foreign firms.

The FDI approach would involve efforts that are specific to each company, because the circumstances of each company are different. It would encompass analysis of a company's financial position, technical capacity, market positioning, and the attitudes and preferences of company management and ownership. Companies may need assistance to think through strategic options for their business, and to prepare a detailed business plan or Prospectus to adequately describe the opportunity that a company would like to present to potential investors. The business plan or Prospectus would also have to address broader investor issues and concerns beyond particular company circumstances, such as national investment legislation and country risk. Attracting private investment is therefore necessarily a complex endeavor, and as a result, financial resource mobilization through attracting FDI into the local pharmaceutical producers may be difficult in the early years of implementation of the Sector Development Strategy. However, as some of the Strategy Components are implemented, particularly with regard to execution of measures to improve competitiveness and the market space available to domestic companies, the industry would then be in a position to present a more compelling case to foreign investors. The case for FDI may also be strengthened if country risk perceptions decline with time.

As such, it is recommended that seeking development assistance be taken up as a priority, since it is the most likely source of near-term funding for implementation of the Strategy Components. It is the favored mode of financial resource mobilization at the moment, because the focus is on funding for revitalization of the pharmaceutical sector as a whole, i.e. funding not just for the pharmaceutical companies, but also for improvements in other ancillary institutions that impact the operating environment of the companies. FDI could be more actively promoted in later years of the Strategy period, as companies are developed into more attractive investment options, with perhaps improvements in the climate for foreign investment in the country as well.

Sub-Task 1: Mobilize required funding from development partners

Sub-Task 2: Promote FDI as and when sector conditions and investment environment improve

26 e.g. along the lines of the Export Development & Agriculture Investment Fund (EDAIF) in Ghana

V. NEXT STEPS

V.1 Incentives for pharmaceutical industry in Special Economic Zone

As discussed in Section III.6.3 and in Sub-Task 3 of Strategy Component I (Section IV.1), the framework legislation for Special Economic Zones has already been signed into law. So, an immediate next step that could be taken up is the structuring of time-limited incentives to enhance competitiveness of the pharmaceutical sector, and allow local companies to exploit increased market space and thereby gain market share. In particular, two incentive considerations could have significant near-term impact:

- SI 18 of 2016 already requires special licensing for certain LVP products, i.e. the import of these products is restricted. There is domestic parenteral manufacturing capacity that is presently lying idle, while large volumes of parenterals are being consumed in public health facilities. To the extent that local manufacturers can be incentivized to replace import of LVPs and SVPs, and bring unused and / or new capacity for LVP / SVP production on line, this should be a priority.
- There are ongoing efforts to engage with South African authorities to eliminate the NTB to export of medicines from Zimbabwe to South Africa. While these inter-Governmental negotiations could take time, thought could be given to export incentives for local industry that would serve to mitigate or neutralize the approximately 20% price disadvantage that is imposed by the NTB on local producers, with regard to competing in the South African market. That could serve to improve the prospects for greater exports to the large market in SA.

V.2 Funds mobilization

As discussed under Strategy Component VII (Section IV.7), mobilization of the required finances for Strategy implementation is a critical next step. The Ministry of Industry and Commerce would probably have to take the lead in approaching potential development partners for this financing, in consultation with the Ministry of Health and Child Welfare and the Ministry of Finance. That would also highlight the inter-connectedness of industrial development and public health concerns in this initiative. Any or all other stakeholders could be called in as necessary to help make the case for provision of this funding for revitalization of the pharmaceutical sector.

To help visualize the prioritization of the Sub-Tasks for the Strategy Components, a rough sequencing for the Sub-tasks is shown in the graphic below.

Table 14: Prioritization / Sequencing of Strategy Component Sub-Tasks

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Strategy Component I: Direct measures to enhance competitiveness of sector						
1. Revise and update list of pharmaceutical raw materials relieved from import duties and VAT, as required						
2. Revise and update list of medicines requiring licences for import						
3. Promulgate special, time-limited incentives in Special Economic Zone (SEZ) for pharmaceutical sector						
Strategy Component II: Expansion of market space for local industry (measures to enhance sector competitiveness indirectly)						
1. Monitor, and direct, public procurement of medicines to local sourcing; assist MoHCC to deploy eLMIS						
2. Re-capitalize NatPharm						
3. Engage with medical aid societies to monitor, and help direct, procurement of medicines purchased (or reimbursed) by them to local sourcing						
4. Engage donors and direct donor procurement (particularly of essential medicines) to local manufacturers						
Strategy Component III: Revamping of industry product portfolios						
1. Facilitate sourcing and purchase of product dossiers						
2. Facilitate industry-academia collaboration on developing formulations for new product						
3. Facilitate establishment of BA/BE capability in Zimbabwe						
Strategy Component IV: Upgrading of manufacturing quality to international GMP standards						
1. Raise awareness within the industry about concept of Quality Assurance as part of Pharmaceutical Quality System (PQS)						
2. Implement stepped program of GMP upgrading in industry (plant refurbishments and improvements in Quality Management Systems)						

Strategy Component V: Establishment of medicine exports as a major foundational pillar of the industry						
1. Continue to push for elimination of the NTB barrier to exports to South Africa						
2. Initiate a Zazibona program for pharmaceutical market information						
Strategy Component VI: Support for MCAZ deliverables, and regulatory capacity-building						
1. Complete guidelines on the treatment of purchased dossiers in product registration						
2. Clarify qualification / certification procedures and requirements for local service providers (School of Pharmacy, AiBST)						
3. Produce, and communicate, stepped program for tightened GMP enforcement to full compliance to international standards						
4. Promote cross-registration of local-company products through the Zazibona track						
5. Deploy / Improve IT infrastructure in MCAZ to capture import data, and track product registration applications						
Strategy Component VII: Mobilization of required financial resources						
1. Mobilize required funding from development partners						
2. Promote FDI as and when sector conditions and investment environment improve						

Once the scale of the funding acquired is known, a more detailed Action Plan can be formulated.

A Note on implementation of the Zimbabwe Pharmaceutical Sector Development Strategy (ZPSDS)

As mentioned in Section II of this document, this Strategy has been formulated through multi-stakeholder consultations in a Pharmaceutical Working Group (PWG) hat was specially convened for the purpose. The deliberations in one forum on key issues confronting the domestic pharmaceutical industry proved to be effective in considering and recommending solutions that balanced the needs and concerns of the involved stakeholders. As such, it is recommended that a similar approach be adopted for implementation of the ZPSDS going forward, and a Sector Strategy Implementation Group (SSIG) be constituted along similar lines to the PWG, to bring together (at the Director or Unit Head level):

- Ministry of Industry and Commerce (MoIC)
- Ministry of Health and Child Care (MoHCC)
- Ministry of Finance and Economic Development (MoFED)
- Medicines Control Authority of Zimbabwe (MCAZ)
- Zimbabwe Revenue Authority (ZIMRA)
- Pharmaceutical Manufacturers' Association (PMA)

The activities of the working-level SSIG could be guided, in turn, by a Steering Committee, constituted as follows:

- The Secretary, MoIC (Chair)
- The Secretary, MoHCC
- The Secretary, MoFED
- The Director-General of MCAZ
- The Chairman, PMA

Such a monitoring and governance structure for the implementation of the Strategy will ensure effective coordination of activities, which will be very important, since the implementation of the Strategy Components described in this document requires simultaneous execution on a number of fronts.

VI. CONCLUSION

In October 2011, the then Chairman of the Pharmaceutical Manufacturers' Association in Zimbabwe issued an SOS about the perilous state of the pharmaceutical industry. It may have been a timely warning, but fortunately, both the pharmaceutical market in Zimbabwe and the pharmaceutical companies have proven to be resilient. In the last two years, some of the market measures called for by the industry then have come to pass. There is a more "level playing field" with imported products, because import duties and VAT have been removed from many pharmaceutical raw materials just as with finished medicines. There may, in fact, now be a tilt in favor of pharmaceutical manufacturers, with the introduction of import licence requirements on some medicines. Most importantly, various arms of the Government of Zimbabwe are supportive of the industry, as seen from their active participation and cooperation in the Pharmaceutical Working Group which was formed during this UNIDO project.

This Strategy document dissects and analyzes the present circumstances of the pharmaceutical industry for all interested parties. That was done to increase awareness, not only of the challenges facing the industry, but also of the opportunities left to exploit. It sets out directions for improvements / enhancements to further strengthen the industry, and provides evidence-based figures on financial requirements to go down these paths. Now, the challenge is for Government and industry to work together with other partners to mobilize the financing, and implement the Strategy Components. It is all doable.

So, in the end, it is perhaps appropriate to issue another clarion call, but this time to impel, rather than warn. The Zimbabwean pharmaceutical industry was once known throughout the region as a reputable supplier of quality medicines. It is time to rope in the help needed from the right quarters, and regain that status.

ANNEX

PROPOSALS RECEIVED IN SUPPORT OF STRATEGY COMPONENT III: REVAMPING OF INDUSTRY PRODUCT PORTFOLIO

1. University of Zimbabwe School of Pharmacy: Multi-Initiative Funding Request

The University of Zimbabwe's (UZ) School of Pharmacy plans on undertaking several initiatives to boost its profile. Firstly, with the creation of the Centre of Drug Formulation Studies, the school aims to attract local manufacturers to conduct pre-formulation and formulation studies in developmental pharmaceuticals and to serve as a research site for industry to utilize. The Centre's benefits are envisaged as:

1. Strengthening the relationship between the UZ and industry
2. Continued training of post-graduate studies in formulation studies who may be employed by industry
3. Attainment of a cGMP facility such that products created in the centre may get market authorization
4. Assistance of local manufacturers in troubleshooting for product development

State of the art equipment has been sourced to help identify small molecules and potential contaminates and troubleshoot manufacturing problems.

Secondly, the School of Pharmacy will also create a retail pharmacy to serve as an actual licensed pharmacy with real products and allied medical devices both as way for industry to advertise their products and conduct product launches as well as for students to learn about pharmacy business models.

Thirdly, the School's will continue to collaborate with the regulator MCAZ which has previously resulted in a laboratory to develop a national drug quality and bioequivalence surveillance program to extend access to quality essential medicines for HIV/AIDS, tuberculosis and malaria—in response to the rise of counterfeit products and need for more affordable generic drugs.

With these ventures in mind, the School will pursue a marketing plan to promote its activities and its role in the pharmaceutical industry. The plan involves three broad objectives:

1. Attracting local manufacturers to conduct pre-clinical research and pre-formulation developmental pharmaceutics at the School
2. Establishing PhD grants/scholarships for research into emerging technologies
3. Revamping the drug surveillance and bioequivalence program

The first objective will require:

- Re-establishing the connection between the School and industry by hosting a symposium for local manufacturers
- Performing additional relevations to the drug development formulation centre such as installing air-conditioning and worktops, partitioning work areas, and replacing cisterns and wash basins
- Equipping the centre with pharmaceutical instruments towards attaining a regional centre of excellence status in 5 years and engaging the regulatory authority to attain acceptable cGMP standards
- Equipping and licensing the retail pharmacy with new purchases, ICT services, dispensing aids and tools and refrigerators for cold-chain products

The second objective for creating PhDs for biotechnology, nanotechnology and traditional herbal medicines will require:

- Conducting a wide consultation and feasibility studies on the program and identifying personnel to nurture it,
- Establishing the programs and
- Creating memorandums of understanding with academic institutions in leading developing countries

The third objective will require:

- Re-engaging quadripartite symposiums
- Selecting countries for participation with a central office that would coordinate regional activities and combine data; appointing focal points as Drug Inspection Officers in each country
- Setting up programs for sample collection, analysis and reporting: by convening an initial meeting with focal points of laboratories in countries to train and network them, promoting reactive response to counterfeit reports, holding annual meetings, and evaluating trends in quality

2. Harare Institute of Technology: Resource Center for the Pharmaceutical Industry in Zimbabwe

Harare Institute of Technology's Department of Pharmaceutical Technology, is proposing establishing the Centre for Drug Development (CDD) with external support. The main goal of CDD is to be a resource centre for drug development for the manufacturing pharmaceutical industry in Zimbabwe.
HIT wishes to acquire miniaturized equipment to be used for research and formulation development of medicines.

The objectives are as follows:

- To establish a fully-fledged resource centre focused on research and formulation development of pharmaceutical products in order to assist local manufactures to increase their product range.
- To source miniaturized equipment to be used for research and formulation development of medicines.
- To undertake research and development of pharmaceutical products with the aim of having the products registered by MCAZ and capacitating local manufacturers to produce the products.
- To renovate identified space that will accommodate the Centre for Drug Development (CDD).
- To undertake stakeholder mobilisation and consultation in order to obtain consensus regarding the role of CDD.
- Strengthening co-operation between HIT and the pharmaceutical industry through the HIT Pharmaceutical Industrial Advisory Board.

3. AiBST Clinical Trial Unit & Bioanalytical Lab: Project Plan and Progress Towards BE/BA Studies

The African Institute of Biomedical Science and Technology's (AiBST) Clinical Trial Unit and Bioanalytical Lab is the only initiative in Zimbabwe towards establishing a Phase I Clinical Trial Unit to meet WHO requirements for conducting bioequivalence/bioavailability (BE/BA) studies for pre-qualification of generic drug formulations. Without these studies, which are already costly to undertake, African capacity to manufacture and test new formulations will remain limited. AiBST's uniqueness is the dual development of the Clinical Trial Unit and an advanced Pharmacokinetics and Bioanalytics Unit, key elements for the conduct of BE/BA studies.

To achieve its objective to start offering Bioequivalence and Bioavailability studies. AiBST was working towards attaining a positive WHO audit to conduct BE/BA studies for the prequalification of generic products. This will require the completion of development of our Clinical Trial Unit and a Pharmacokinetics and Bioanalytics Laboratory to meet WHO standards.

The 28-bed Clinical Trial Unit will have a capacity for 5-7 studies a year and at competitive costs in the 50-70 000 USD range per BE/BA study. There are still outstanding items for the completion of the Unit to meet the WHO standards on infrastructure including:

- Synchronized watches to time clinical trial events
- Emergency Medical Trolley
- Tablets and Software for volunteer information data capture
- Patient side patient service and data capture units
- Sample Biosafety Hood for sample processing
- Centrifuge for plasma sample preparation on site before transport
- Small -80 °C temporal sample storage freezer

The Pharmacokinetics and Bioanalyticals Laboratory requires the following to complete WHO standards on infrastructure as well as ISO 15189 certification:

- Servicing of the 2 HPLCs and 2 LC-MSMS
- Purchase of a bigger backup generator (10KV)
- Undergoing the ISO 15189 certification evaluation process

Following the first BE/BA study in September 2016 will be a WHO audit with respect to:

- Organization and management
- Study protocols
- Clinical phase of a study
- Bioanalytical phase of a study
- Pharmacokinetic and statistical analysis and
- Study report

The AiBST's activities towards meeting WHO requirements include:

- Complete Clinical Unit and Bioanalytical facility infrastructure, procedures, processes.
- Training of the AiBST Clinical Trial Research Team
- To qualify equipment and computers used in the Clinical study
- Conduct a specialized Clinical Trial Training and conduct a mock Clinical Trial Unit and Bioanalytical Unit for compliance with WHO guidelines

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