

Pharmaceutical Manufacturing Strategy in Zimbabwe (2021 - 2025)



FOREWORD

The Pharmaceutical Strategy in Zimbabwe (2021-2025) has been necessitated by the realization that the local industry is contributing marginally to the local medicine consumed locally (only 12%). The Strategy 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. The pharmaceutical sector is a priority in the National Development Strategy 1 (2021-2025) and Zimbabwe National Industrial Development Policy (2019-2023). Further, the COVID 19 pandemic has shown that there is need for countries to be self-reliant due to closure of borders.

The main challenges in the sector include low level of local production, huge imports, low exports, lack of financial resources, antiquated equipment, low purchases by Natpharm, cumbersome registration process, low compliance to Good Manufacturing Practices and lack of commercialization of traditional medicines.

Notwithstanding these challenges, the sector has potential to contribute to the national economic development as witnessed by some companies which are already exporting in the region. The strategy's main pillars include: implementation of a Good Manufacturing Practice (GMP) roadmap; strengthening of national medicine regulatory capacity, export focus and product development.

My sincere gratitude goes to United Nations Industrial Development Organization who funded the baseline study.

It is my hope that the private sector is at the forefront of implementing the strategy while Government plays its facilitatory role.

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ACRONYMS

AfCFTA	African Continental Free Trade Area
AIBST	African Institute of Biomedical Science and Technology
API	Active Pharmaceutical Ingredient
ASYCUDA	Automated System for Customs Data
BA/BE	Bioavailability/ Bioequivalence
GMP	Good Manufacturing Practice
COMESA	Common Market for Eastern and Southern Africa
DFID	Department for International Development
ELMS	Electronic Logistics Management Information
EML	Essential Medicine List
LLP	Local Pharmaceutical Production
MCAZ	Medicines Control Authority of Zimbabwe
MoFED	Ministry of Finance and Economic Development
MoHCC	Ministry of Health and Child Care
MoHTESTD	Ministry of Higher and Tertiary Education, Science and Technology Development
MoJLPA	Ministry of Justice, Legal and Parliamentary Affairs
MLAFWRR	Ministry of Lands, Agriculture, Fisheries, Water and Rural Resettlement
Natpharm	National Pharmaceutical Company
NTB	Non- Tariff Barrier
PEPFAR	President Emergency Plan for AIDS Relief (US)
PMA	Pharmaceutical Manufacturers Association
SA	South Africa
SADC	Southern African Development Community
SEZ	Special Economic Zone
SI	Statutory Instrument
SMEs	Small and Medium Enterprises
TB	Tuberculosis
UNIDO	United Nations Industrial Development
VAT	Value Added Tax
WHO	World Health Organization
ZaZiBoNa	SADC medicines registration harmonization (originally Zambia, Zimbabwe, Botswana Namibia medicine registration initiative)

ZIMRA
ZNIDP
ZNMP

Zimbabwe Revenue Authority
Zimbabwe National Development Policy
Zimbabwe National Medicine Policy

EXECUTIVE SUMMARY

Introduction/Context

The local Industry has been seriously impacted by the inability to match market needs and low levels of local production, inadequate Research and Development, low demand from the major buyer, the Government, limited financial support and incentives required by the sector.

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)

Situation Analysis

The policy framework in Zimbabwe as it relates to local pharmaceutical manufacturing, it is generally coherent in statement and intent. The Zimbabwe pharmaceutical industry consists of 9 companies. Eight out the nine said companies manufacture finished human medicines and one manufactures animal medicines. Most locally produced products are of oral solid and liquid dosages. The production of parenteral products is currently being revived.

The main components of the market are imported medicines, Developmental Partner medicines and locally produced medicines. The product portfolios of the domestic manufactures consist of older generation medicines, not well aligned with major needs and market demand. This is one reason for low market share of locally produced medicines. Local companies cannot participate in Developmental Partners procurement due to their inability to meet prescribed procurement requirements. Developmental Partners require WHO Prequalification for a company to participate in the procurement of medicines. The market share for the local industry is 12%.

Export of medicines is not significant. The competitiveness of the local manufactures is affected by their inability to manufacture products that are high value imports. However, local companies do compete in the case of certain molecules whereby the market price of domestic medicines is lower than that of imported medicines. Non-tariff barriers render local medicines uncompetitive in

foreign markets due to high prices which are as a result of air freight charges. Local manufactures can take advantage of the African Continental Free Trade Area and capture market share.

Financial weakness and inadequate capacity to conduct Research and Development hinder companies from developing new products. There is no drug development system in the country. Local manufactures can use research and development to develop and patent traditional medicines.

The Strategies include:

- Increased Production;
- Competitiveness;
- Market Expansion;
- Product Diversification;
- Upgrading of manufacturing quality to international GMP standards;
- Export Development;
- Improve Ease of doing business; and
- Mobilization of required financial resources

A first approximation estimate of the financial requirement for implementation of the Strategy is US\$45 million composed of US\$ 43 million for the costs for GMP upgrading and product development and US\$ 2 million for support infrastructure. The Government of Zimbabwe needs to play a key role in this endeavor.

1.0 INTRODUCTION

- 1.1 Historically, the Zimbabwe Pharmaceutical Industry has proved to be strategic in terms of meeting the drug and exports requirements. In-order to strengthen local production of essential medicines, the sector has thus been prioritized for resuscitation in the National Development Strategy 1 (2021-2025), Zimbabwe National Industrial Policy (2019 – 2023) and the Local Content Strategy.
- 1.2 Strengthening of the Local Pharmaceutical Production (LLP) in Africa has been identified as key in improving access to medicines. The Summit of Heads of State and Government held in Ghana in 2007 endorsed the vision of the Pharmaceutical Manufacturing Plan for Africa, ‘Strengthening our ability to produce high quality, affordable pharmaceuticals across all essential medicines, will contribute to improved health outcomes and the realization of direct and indirect economic benefits.’
- 1.3 The overreliance on imported medicines presents a potential risk to medicines security and hence public health. Further, the outbreak of COVID 19 pandemic has disrupted global supply chains and this calls for urgent need to localize production of the pharmaceutical products and ensure health for the citizens.

2.0 SITUATIONAL ANALYSIS

- 2.1 The Zimbabwean pharmaceutical industry consists of 9 pharmaceutical companies. The companies which manufacture human medicines are: CAPS Pharmaceuticals, Varichem Pharmaceuticals, Pharmanova, Datlabs, Plus Five Pharmaceuticals, ZimPharm Graniteside and Gulf Drug whilst Ecomed manufactures veterinary products.
- 2.2 The local companies use imported Active Pharmaceutical Ingredients (APIs) to produce generic medicines. There are differing levels of capacity in developing formulations for new products. Most of the locally produced products are oral solid and liquid dosages. The country is no longer producing parenterals (drips). However, two local facilities for parenteral production (Small Volume Parenterals (SVPs) and Large Volume Parenterals (LVPs)) are in the process of refurbishment. One company re-opened the production of penicillin in September 2019.
- 2.3 Generally the pharmaceutical companies in Zimbabwe are classified as Small to Medium Enterprises (SMEs) whereby each company has less than US\$ 15 million annual sales. The industry has a wide product portfolio which range from 3 to 129

products of different dosage forms. Varichem achieved World Health Organisation (WHO) Prequalification (PQ) for an ARV at one time, but that PQ status has since lapsed.

- 2.4 The major components of consumption of medicines in the Zimbabwean market are imported, from Development Partners and locally-produced medicines. Medicines from Development Partners are imported and procured through funding from international agencies such as the Global Fund, the US Government's President's Emergency Plan for AIDS Relief (PEPFAR) program the European Union and Department for International Development (DFID). The medicines are principally for the treatment of HIV / AIDS as well as malaria, TB, and Opportunistic Infections (OI). Local manufacturers export medicines and re-exports are not significant.
- 2.5 The pharmaceutical market size of Zimbabwe is estimated at US\$ 244.5million. The local manufacturers produce US\$ 31.5 million worth of products while the remaining are imports. Exports of pharmaceutical products constituted about US\$ 3 million in 2019.

3.0 PROBLEM STATEMENT

- 3.1 The major challenge facing the local pharmaceutical industry is low levels of production which account for only 12% of the medicines which are consumed locally, whilst 88% are imports by the private sector and from Development Partners. The low levels of production have been attributed to industry producing pharmaceuticals products which are not on high demand and limited procurement by Government institutions amongst other things. The use of obsolete and antiquated equipment, cumbersome registration procedures and limited innovation have also affected the competitiveness of the sector.
- 3.2 The local companies are not compliant to standards set by the World Health Organization (Good Manufacturing Practices). There are only 2 local companies which are nearing compliance whilst the other 6 have facilities which are considered unsuitable for pharmaceutical production.
- 3.3 The sector is also experiencing low exports due to the prevalence of non-tariff barriers, such as the requirement to airlift pharmaceutical products and restrict transit of medicines through land borders. The Air-freight transit cost 5 times more than the road. Lack of information on the exports markets has restricted local companies to penetrate other countries.

4.0 RATIONALE

The low level of local production especially on products which are on demand in the market poses a health threat to the economy. Implementation of the strategy will provide direction to increase local production of essential medicine both for local and export.

5.0 VISION

To become a major player in the SADC market through providing quality, affordable essential medicines while contributing towards positive public health outcomes.

6.0 MISSION

To facilitate and promote the development of quality, reliable and competitive pharmaceutical industry for improved health and economic growth.

7.0 OBJECTIVES

7.1 The following strategic objectives are targeted, for the local pharmaceutical sector by the end of the five (5) year period.

- To increase market share of local pharmaceutical products from 12% to 35% by 2025.
- To increase local production of essential medicines from 30% to 60% by 2025.
- To increase sales revenue of local production from US\$31.5 million to US\$ 150 million by 2025.
- To increase new local product registration from 5% to 20% by 2025.
- To improve compliance to Good Manufacturing Practice for at least four companies by 2025.
- To improve exports of pharmaceutical products from 10% to 25% by 2025.

8.0 GUIDING PRINCIPLES

The pharmaceutical strategy will be guided by the following principles:

- 1) Stable macro-economic environment;
- 2) Policy consistency;
- 3) Upgrading and modernization of industrial equipment and machinery;
- 4) Effective cooperation between private sector and government; and
- 5) Strong research and innovation.

9.0 PILLARS

9.1 The following are the key pillars which will help in the improvement of the pharmaceutical sector performance:

Research and Development;

Expedited registration processes;

Export orientation;

Compliance with Good Manufacturing Practices; and

Government support .

9.2 Research and Development- It is crucial that the companies meet the market demands and thus product development is important. Currently, one or two companies can 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. There is need for continual dialogue between the MCAZ and the local manufacturers on how the option will be handled to ensure safety, quality, and efficacy of a new product (MCAZ's primary concerns, for consumer protection) and also to enable the industry to venture into technology transfer through purchase of dossiers for new products.

9.2.1 The use of Scientific Industrial Research Development Centre (SIRDC) for research and development should be highly encouraged.

9.3 Expedited Registration Process- The domestic pharmaceutical industry needs

assistance to make rapid progress in becoming more competitive, improve 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 continuous reduction of the processing time is critical to attract investments and new products in the sector.

- 9.4 **Export Oriented-** Currently, some of the companies in the industry are exporting pharmaceuticals. There is need for an aggressive drive towards increasing exports to generate foreign currency. Further, if a company is to invest in huge production it can not only focus internally as the market is too small and can only be widened by exporting.
- 9.5 **Compliance with Good Manufacturing Practice-** An analysis on the local manufacturing plants compliance with WHO-GMP (Good Manufacturing Practice) standards by UNIDO revealed that local manufacturing plants are not meeting the WHO-GMP standards. The facilities in the manufacturing companies were graded from A to C, with A being the highest grade denoting compliance with WHO-GMP standards and C being the lowest. Of the 8 companies in the local industry, only 2 companies managed to attain a B-grade for compliance to WHO standards whilst 6 scored the C-grade, meaning the facilities are highly inadequate or unsuitable for pharmaceutical production.
- 9.6 **Role and support of Government** - Given the state of the sector today, local industry will require strong and ongoing support from Government institutions; - line Ministries, the regulator, and the Zimbabwe 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.

For example, the South African Department of Trade and Industry continues to support the sector through designations of local participation in public tenders, mobilization of public investment in infrastructure, subsidization of training and skills development among others. Similar participation and commitment will be required from Government institutions to revitalize the pharmaceutical sector in Zimbabwe.

10.0 STRATEGIES

10.1 Increased Production

10.1.1 In order to increase capacity utilization, the implementation of the local content strategy will be fast-tracked and Government will ensure that the directives to procure locally are adhered to.

10.1.2 In line with the ongoing researches, commercialization and patenting of traditional medicines which are derived from natural herbs will be pursued in order to promote innovation and development of new products. In addition, local farming of traditional medicines both at communal and commercial levels will be encouraged to increase medicinal output. Holding awareness campaigns in-order to popularize and de-mystify the use of traditional medicines will be done.

10.1.3 Government will promote the establishment of centres of excellence and the existing private and public research institutes to ensure that they build a strong knowledge base and a network of innovation and research.

10.1.4 Plant upgrade and modernization of will be necessary to improve productivity and competitiveness in the manufacturing of pharmaceutical products. Domestic and international financiers will be engaged to extend lines of credit to support the modernization by companies.

10.1.5 Industry will be assisted to utilize the local Science and Technonolgy Institutes Capacitating locals for scale and specialization for new medicinal molecules, BE/BA studies will address this requirement for generics manufacturing companies in Zimbabwe and at competitive rates of less than 50 000 USD/product compared to the US\$ 100 000 being charged in other countries.

10.2 Competitiveness

10.2.1 Government in consultation with pharmaceutical sector will continuously revise and update list of pharmaceutical raw materials exempted from import duties and VAT to ensure that local products are competitive. In addition, the granting of Special Economic Zone Status will improve competitiveness through the incentives offered.

10.3 Market Expansion

10.3.1 The Government through 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 will monitor and control the procurement of medicines. The initiative should be supported, and expenditure of public funds on medicines needs to be monitored closely.

10.3.2 The adequate funding of NatPharm would promote local procurement from the local industry. The entity's central role in procuring and distributing medicines will promote the expansion of public health expansion.

10.4 Product Diversification

10.4.1 In order to meet local pharmaceutical requirements, manufacturers have to introduce new products such as diclofenac and ceftriaxone. The existing local product portfolios do not match market dynamics.

10.4.2 Government-industry-academia- collaboration on developing formulations for new product (Triple Helix Model) will continue to be pursued. The model anchors on boosting innovations.

10.4.3 Funding to conduct for Research and Development should be provided for in the national budget and also within the companies in the sector.

10.5 Upgrading of manufacturing quality to international GMP standards

10.5.1 A reputation for quality manufacturing to international standards is necessary for the Zimbabwean pharmaceutical sector to become a major player in Africa.

10.5.3 A program of GMP upgrading of industry (plant refurbishments and improvements in Quality Management Systems) will be implemented. In this regard, MCAZ will design a program for enforcing minimum standards over an established period in order to promote quality improvements. An awareness-raising about concepts of Quality Assurance and skills training will also be undertaken.

10.5.3 The drug development system will assist the sector to improve its international competitiveness as there will be a wider range of products to choose from.

10.6 Export Development

10.6.1 The opening up of new markets through implementation of regional Trade Agreements at SADC, COMESA and the recently launched African Continental Free Trade Area (AfCFTA) presents an opportunity for ready markets hence the need to promote exports of local products.

10.6.2 Government will continue to negotiate for the elimination of Non-Tariff Barriers such as transportation of pharmaceutical products by air only.

10.6.3 The pharmaceutical industry to undertake market intelligence from all SADC member countries. Information is already available for original Zazibona countries (Zambia, Zimbabwe, Namibia, and Botswana) through National Medicines Regulatory Authorities (NMRAs).

10.7 Improve Ease of doing business

10.7.1 MCAZ will need financial, technical support and capacity-building in order to improve ease of doing business environment in the pharmaceutical sector.

10.7.2 In line with ease of doing business thrust, the registration processes will be carried with a minimum possible time. The successful registration is also depended on the quality of the products from the industry.

10.7.3 Promotion of cross-registration of local-company products through the ZaZiBoNa track will be undertaken. Local companies would benefit if 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. Currently, no products from local manufactures have been assessed through ZaZiBoNa as the quality is not up to the required guidelines

10.7.4 IT infrastructure at MCAZ will be improved to ensure that data on imported medicines is collected electronically and linked to ASYCUDA World. This will allow ease tracking of the processes from issuance of import permit to customs clearance.

10.8 Mobilization of required financial resources

10.8.1 The financial requirement for implementing the Strategy is US\$ 45 million. The US\$ 45 million is composed of US\$ 43 million for the costs for GMP upgrading and product development and the remaining US\$ 2 million is for support infrastructure. Possible sources to secure funding for the sector include: Treasury, Foreign Direct Investment (FDI), Local Banks and Joint ventures and setting up of Pharmaceutical Sector Revitalization Fund (PSRF).

11.0 INSTITUTIONAL COORDINATION MECHANISMS

11.1 Implementation of the Strategy will be spearheaded by the Ministry of Industry and Commerce and pharmaceutical value chain players. Other key Ministries are: Health and Child Care, Finance and Economic Development, Ministry of Higher and Tertiary Education, Science and Technology Development, Justice, Legal and Parliamentary Affairs, Lands, Agriculture, Fisheries, Water and Rural Resettlement.

12.0 IMPLEMENTATION OF THE STRATEGY

12.1 Successful implementation of the strategy will depend on strong collaboration among the key stakeholders, comprising of Government, private sector, academia and civil society. The formation of Pharmaceutical Working Group (PWG) with the key stakeholders will be critical. The working group will be co- chaired by the Government and Private sector. The strategy is also underpinned on institutional framework that develops tools for operationalization, monitoring and evaluation, to ensure desired outcomes.

ANNEXURE 1: Implementation Matrix

STRATEGY	RESPON SIBILIT	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
1: Increased production						
1. Establish centres of excellence	MoIC, PMA			X	X	X
2. Commercialize traditional medicine	MoHCC, PMA	X	X	X	X	X
3. Import substitution of inputs	MoIC, PMA	X	X	X	X	X
4. Encourage farming of local herbal medicines	MoLAFWR R	X	X	X	X	X
5. Modernise equipment	PMA, MOIC, MoFED	X	X	X	X	X
2: Competitiveness						
1. Duty free import of raw materials	PMA, MoFED	X	X	X	X	X
2. Implement the local content policy	PMA, MoIC	X	X	X	X	X
3. Upgrading of equipment	PMA,	X	X	X	X	X
4. Grant special economic zones incentives	PMA, ZimSEZA	X				
4.0 Quality compliance	PMA, MCAZ	X	X	X	X	X
3: Market development						
1. Monitoring and directing public procurement of medicines	MoHCC,		X			
2. Fund NatPharm	MoFED,			X	X	X
3. Encourage Medical Aid Societies to source locally produced medicines	PMA, MoHCC, MoIC	X	X	X	X	X
4: Product						
1. Invest in the research and	MoHTESTD		X	X	X	X

2. Facilitate industry-academia –	PMA, MoIC,	X	X			
3. Facilitate establishment of	PMA, MCAZ		X			
4. Patenting of new products	PMA, Mo J LPA			X	X	X
5: Upgrading of manufacturing quality to						
1. Skills training and capacity building in the pharmaceutical companies l	MCAZ, PMA, MoHCC		X	X		
2. Implement stepped program of GMP upgrading in industry	PMA, MCAZ		X	X	X	X
3. Innovation through University hubs and SIRDC	MoHTESTD, Universities MoIC, PMA	X	X	X	X	X
6: Export Development						
1. Continue to push for elimination of the NTB barrier to exports to the	MoIC, MoHCC,	X	X	X		
2. Initiate a Zazibona program for pharmaceutical market	MCAZ, MoHCC		X	X		
3. Adhere to quality requirements in export markets	PMA. MCAZ	X	X	X	X	X
4. Access to market intelligence	PMA, MoFAIT, MoIC	X	X	X		
7: Improve Ease of doing business						
1. Streamline registration process product registration	MCAZ	X				
2. Clarify qualification / certification procedures and requirements for local	MCAZ	X				
3. MCAZ Acquire Stringent Regulatory Authority (SRA) status	MCAZ		X	X	X	X

4. Promote cross registration of local company products	MCAZ	X	X	X	X	X
5. Improve IT infrastructure in MCAZ to capture	MCAZ		X	X	X	
8: Mobilization of required financial resources						
1. Mobilize required funding	All Stakeholders	X	X			
2. Promote FDI as and when sector conditions and	All Stakeholders				X	X

ANNEXURE 2: Interface with other Policies

The pharmaceutical strategy recognizes the existence of other policies such as the National Development Strategy 1, Zimbabwe National Industrial Development Policy and Zimbabwe National Medicine Policy.

2.1 National Development Strategy 1 (NDS 1) 2021–2025

The availability of locally produced medicines is critical in ensuring sustainability of health care in the country. During NDS 1, the goal is to gradually improve the contribution of the secondary sector, (the pharmaceutical sector included) to GDP from the current 11% to 20% by 2025. In this regard, NDS1 will pursue the following: - Increase the number of locally produced Essential Medicines from 30% to 60% of the essential medicines list by 2025; Increase the proportion of companies complying fully with category A of World Health Organisation Good Manufacturing Practice Standards from 0 to 50% by 2025.

2.2 Zimbabwe National Industrial Development Policy (2019-2023)

The Ministry has developed the Zimbabwe National Industrial Development Policy (ZNIDP) and this will be used as a guiding tool for industrialization. The ZNIDP is aimed at promoting investment, innovation and export led industrialization. Pharmaceutical sector is identified among those priorities for development and strengthening of industrial value chains.

2.3 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 aims include:

- To ensure the highest possible availability of essential medicines throughout the country
- 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
- To assure the quality, safety, and efficacy of medicines
- 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.
- To ensure sufficient funding to implement the ZNMP, including allocation of funds to the public sector for the procurement of medicines

2.4 Cross Cutting Issues

The implementation of the strategy should take into account cross cutting issues such as technology, environment, the role of women, youth and the disadvantaged, green industry and capacity building.