

DRAFT



Challenges Faced by Local Pharmaceutical Manufacturers in Zambia

Prepared for MeTA Zambia by



NANGOMA CONSULT LIMITED
Plot No. 8, Mungulube Road
Thorn Park
P. O. Box 35238
Lusaka

E-mail: ngoni@nangoma.com , mwewa@zambia.co.zm
Phone: +260 976 212 967
www.nangoma.com



TABLE OF CONTENTS

List of Tables	6
Abbreviations	7
Executive Summary.....	9
1. Introduction	9
1.1 Background to Zambian Health Sector	9
1.2 Background to MeTA	10
1.3 Terms of Reference.....	11
1.4 The Study Methodology	12
1.4.1 Questionnaire Interviews	12
1.4.2 Literature Review	13
1.4.3 Key Informant Interviews	13
1.4.4 Analysis of Data	13
1.4.5 Outline of the Report	13
2. Conceptual Background.....	15
2.1 The Legal Framework of the Pharmaceutical Sector in Perspective.....	15
2.2 Procurement of Medicines and Raw Materials	16
2.3 An Environmental Scan of the Pharmaceutical Sector	17
2.4 Pharmaceutical Products Manufactured Locally	19
2.5 Markets for Manufactured Pharmaceutical Products	20
2.6 Impact of TRIPS on Local Pharmaceutical Manufacturers	20
3. The Challenges of Local Manufacturers – Study Findings	22

3.1	High Taxation and Unfavourable Policy Issues	22
3.2	High Production Costs.....	22
3.3	Access to Raw Materials	23
3.4	Insufficient Appropriate and Experienced Staff.....	23
3.5	Availability of Market.....	23
3.6	Internal Managerial Capacities/Corporate governance.....	24
3.7	Impact of Cheaper Imported Medicines.....	25
3.8	Role of Civil Society Actors (NGOs and mission hospitals).....	25
3.9	Challenges of Corruption and Bribery.....	25
3.10	Regulation and Fees.....	26
3.11	Prohibitive Investment and Financing Support	26
4.	Conclusions and Recommendations	27
4.1	Study Conclusions.....	27
4.2	Recommendations for MeTA Advocacy.....	28
Appendices		30
Appendix 1: List of Key Informants and Manufacturer Interviewees		30
Appendix 2: Applicable Incentives for Local Manufacturers.....		31
Appendix 3: Pharmaceutical Regulatory Authority Schedule of Fees, 2010.....		33
Appendix 4: Key Informant Questionnaire Guide		38
References.....		41





List of Tables

Table 1:	Status of Individual TORs in Report
Table 2:	Types and Number of Manufactured Local Products
Table 3:	Examples of High Markups Observed in the Supply Chain
Table 4:	Recommendation for MeTA Advocacy
Appendix 1:	List of Key Informants and Manufacturer Interviewees
Appendix 2:	Applicable Incentives for Local Manufacturers
Appendix 3:	Pharmaceutical Regulatory Authority Schedules of Fees, 2010



Abbreviations

API	Active Pharmaceutical Ingredients
BHCP	Basic Health Care Package
CHAZ	Churches Health Association of Zambia
CSO	Central Statistical Office
DfID	Department for International Development
DSBL	Drug Supply Budget Line
KII	Key Informant Interview
LIB	Limited International Bidding
MCTI	Ministry of Commerce Trade and Industry
MDG	Millennium Development Goals
MeTA	Medicines Transparency Alliance
MOH	Ministry of Health
NDP	National Drug Policy
NGO	Non Governmental Organisation
OTC	Over The Counter
PBA	Pharmaceutical Business Association
PSZ	Pharmaceutical Society of Zambia
PRA	Pharmaceutical Regulatory Authority
RHC	Rural Health Center
TRIPS	Trade Related Intellectual Property Rights
UHC	Urban Health Center
VAT	Value Added Tax
WHO	World Health Organisation
ZDA	Zambia Development Agency
ZPBF	Zambia Pharmaceutical Business Forum

ZPPA

Zambia Public Procurement Authority



Executive Summary

1. Introduction

1.1 Background to Zambian Health Sector

The provision of good health to its citizens is one of the fundamental goals of any government across the world. Indeed the significance of good health is so important that three of the Millennium Development Goals (MDGs) are specifically crafted to capture health related targets.¹ This is achieved through the provision of medicines that are *effective, affordable* and *accessible* to as many people as possible. Unfortunately in many third world countries, essential medicines are still not easy to come by, let alone affordable or with guaranteed efficacy to the majority poor. Millions as a result die from sicknesses and diseases which are alien to their counterparts in developed countries.

Zambia is one of those third world countries with a key role of the health sector. To this end, the overarching goal of the Zambian health sector is “equity of access to assured quality, cost-effective and affordable health services as close to the family as possible, in order to ensure equity of access in health service delivery and contribute to the human and socio-economic development of the nation.”² With a population currently estimated at around 12 million and an annual average growth rate of 3 percent and life expectancy at birth of 50 years³, the role of the health sector cannot be underestimated in national development. The predominantly young population needs to be kept healthy even in the face of HIV/AIDS. Generally, the overall performance of the health sector has shown some improvement, especially in the past ten years as reflected in the trends of basic health delivery indicators, such as health center outpatient per capita attendance, first antenatal coverage, and fully immunized children under 5 years. Despite these service improvements, overall health status has stagnated and the disease burden has continued to increase in the face of the increasing burden of HIV/AIDS coupled with the high poverty levels.

One draw back is that, in comparison to a number of other African countries and the world, the role played by the private sector (medicines volumes manufactured) in Zambia is very small and constitutes only around 10%-15% of the total health care sector. As a matter of fact, the number of local manufacturers has been static since the 1990s at around six. On the other hand the number of pharmaceutical import and wholesale outlets ballooned to seventy two as of January 2010, reflecting increasing demand, with some former and even current manufacturers now being active importers as

¹ Targets 4, 5 and 6 of the Millennium Development Goals

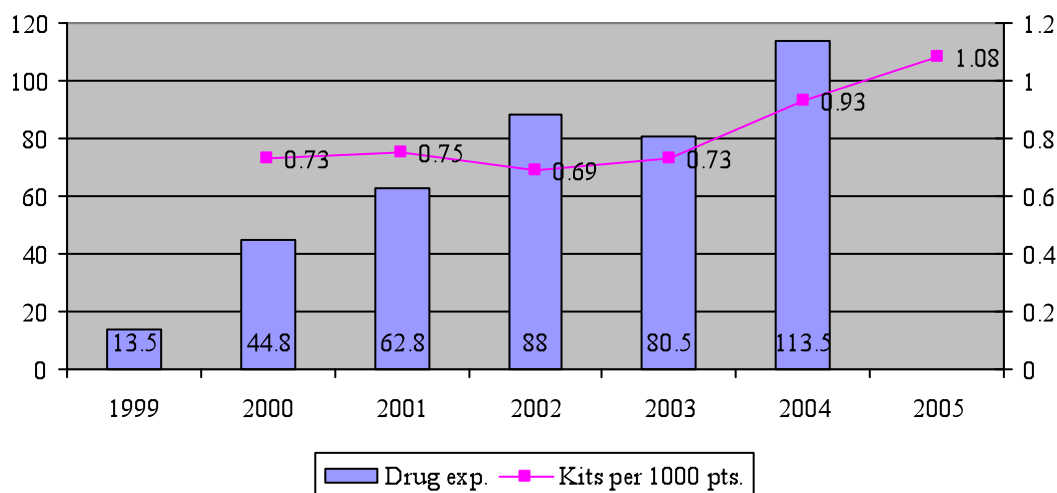
² Progress Report of the Fifth National Development Plan, 2008, Page 67

³ Living Conditions Monitoring Survey, CSO, 2004

well. Most of these are importing medicines from mainly India and a little from South Africa and supplying the local market. The Pharmaceutical Regulatory Authority (PRA) estimates that as much as 80 - 90% of all medicines used in Zambia are imported with the remaining 10 - 20% being manufactured locally.⁴ Aart van Os puts the figure of imports at a hefty 95%. **Section three** details the implications arising out of this high dependence on imported medicines on the local manufacturing industry for medicines, among other challenges.

On the part of the Ministry of Health (MoH), the records show a consistent nominal increase in budgetary allocations and actual releases for purchases of medicines. As **figure 1** shows, expenditure has been increasing and equally, the number of patients with access to drug kits has improved. However, since the bulk of these medicines are not manufactured locally the sub sector is not benefiting as much as it would if these drugs were manufactured within Zambia. These weaknesses in the supply chain of medicines are the motivation behind the birth of the Medicines Transparency Alliance (MeTA) project in Zambia.

Figure 1. Drug Expenditures⁵ (ZK Billion) and Drug Kits Opened Per 1,000 Patients, 1999-2005
(Source: Health PETS Study, pg 53)



1.2 Background to MeTA

The MeTA project was launched in 2008 globally as an international multi-stakeholder initiative, made up of government, civil society organizations and the private sector with the aim of promoting increased

⁴ Key Informant Interview with the PRA conducted on 30.04.2010

⁵ The drug expenditure data were taken from the NHA series, as broken down into primary, secondary, and tertiary facilities. It is likely that this series also included expenditures from vertical projects, which are not included in the GRZ + Basket Funds budget.

transparency in the supply of essential medicines as well as ensuring that there is equitable access to medicines for low income and disadvantaged people in developing countries like Zambia. With the support of the Department for International Development (DFID), MeTA is being piloted in seven countries namely; Ghana, Jordan, Kyrgyzstan, Peru, the Philippines, Uganda and Zambia. It is envisaged that by tackling the root of the problem – the lack of transparency – medicines will be much more available to those who need them and lives will be saved.

In Zambia, the MeTA project was launched in May 2008. The Zambian Ministry of Health (MoH), confirmed its participation in the global MeTA initiative thereby giving the entire project in Zambia the necessary political support at the ministerial level. The private manufacturers are represented in MeTA Zambia through the Zambia Pharmaceutical Business Forum (ZPBF) and have so far been very active members but it remains to be seen how they can remain engaged if they are unable to identify benefits for their members.

The project is therefore a national initiative although in its pilot phase, it is targeting only selected provinces and districts. Specifically, the MeTA project in Zambia seeks to:

- Increase transparency in the selection, regulation, procurement, distribution, supply and use of essential medicines
- Improve equitable access to affordable essential medicines
- Strengthen the country's capacity to collect, analyse and disseminate data on the medicine supply chain.

It is therefore within the framework of contributing to the achievement of these objectives that this study was commissioned. The study also further builds on the previous work by Aart Van Os (Private Sector Mapping Study), Dalberg Global Development Advisors and MIT/Zaragoza International Logistics Program (Private Sector Role in Health Supply Chains) and the World Bank (Zambia Health Sector Public Expenditure Tracking Survey).

1.3 Terms of Reference

The summarised specific Terms of Reference and the way they have been addressed in this report are reflected below:

Table 1: Status of Individual TORs in Report

No.	TOR	Status
1	Establishing the pharmaceutical products manufactured locally	Done: Refer to section 2.4

2	Establishing sources of raw materials used in the production process	Done: Refer to section 2.2
3	Establishing constraints faced by the manufacturers in the procurement and production processes	Done: Refer to section 3.0
4	Establishing the markets for the products and the constraints they face in accessing these markets	Done: Refer to section 2.5 and 3.0
5	Establishing how the constraints in turn affect the availability, affordability and accessibility of medicines	Done: Refer to section 3 and 4
6	Discussing the impact of TRIPS on local manufacturers and how (increased) product registration fees affect local pharmaceutical manufacturers	Done: Refer to section 2.6

1.4 The Study Methodology

In contributing towards the achievement of the objectives set out above, MeTA Zambia engaged the services of Nangoma Consult Limited to investigate the 'Challenges Faced by Pharmaceutical Manufacturers in Zambia'. This is because MeTA Zambia perceives that the manufacture and distribution of medicines is a key process in ensuring that the key goal of availability, accessibility and efficacy of medicines is achieved. Pertinent supply side issues such as availability of raw materials, the unfavorable economic environment within which manufacturers operate (the cost of production, tax issues, government incentives, etc), availability of qualified labour, market for products, intellectual property constraints, etc, all have a bearing on the capacity of manufacturers to produce medicines successfully and ultimately for the medicines to be accessed by the patients in health centers.

The methodology which was employed in undertaking this study was principally simple but multi faceted in approach. The simplicity was intended to make it easy for both the investigators and the client (MeTA Zambia) to easily follow the process at every stage. It was also multi faceted because it required the use of different approaches and tools in collecting the required information to ensure that all the necessary institutions, companies, bodies and individuals who would add value to the assignment were consulted.

Study Approach

The three pronged approach used involved structured questionnaire interviews (questionnaires included as **Appendix 5.**), extensive literature review and Key Informant Interviews (KIIs). These are detailed below:

1.4.1 Questionnaire Interviews

A detailed questionnaire was developed for the purposes of extracting information in a systematic manner from all the known pharmaceutical manufacturers. To this end, a list of manufacturers was

collected from the PRA. All the operational manufacturers were then targeted for interviews. Additionally, to ensure that the problems of those manufacturers who had wound up their operations, diversified into other business or had failed to re-register with PRA for the 2010 financial year were captured, some of the former manufacturers were deliberately targeted. The actual number of firms which were interviewed was three for operational firms and one for non operational firms.

1.4.2 Literature Review

This study was to be further enriched with extensive literature on the Zambian pharmaceutical industry with a special focus on the challenges identified by other similar studies. Unfortunately, there were very few studies done in the past that focused on the subject matter exclusively. This study is therefore quite unique and as such significantly adds to the dearth of knowledge on the sub sector. The literature for the review was accessed mainly from the three reports mentioned earlier, official internet pages of the relevant organisations and a couple of other relevant sources.

1.4.3 Key Informant Interviews

Unlike questionnaire interviews which were highly structured, the Key Informant Interviews (KIIs) were much more flexible in structure and application such that they took the form of a discussion though the key themes in a checklist (refer to **Appendix 4** for the checklist used). The Key Informants interviewed included; the Directors of PRA, the Manager of the Drug Supply Budget Line (DSBL) in the Ministry of Health, the President of the ZPBF, the Chairman of the Lusaka branch of the Zambia Pharmaceutical Society and some retailer pharmacies (list of interviewees is included as **Appendix 1**).

1.4.4 Analysis of Data

The data collected from all the three sources was then analysed individually, compared and common threads in the information given drawn. The literature review was particularly useful in cross checking any conclusions which have been drawn. The report is interspaced with tables and figures from the interviews as well as those borrowed from the literature review.

1.4.5 Outline of the Report

The report is presented in four major sections. The first section gives a backdrop to the Zambian Health sector as well as to the MeTA project in Zambia. Additionally, it highlights a methodological discussion of how the study was conducted while the second section provides the context within which the pharmaceutical sub sector is situated. This includes the key players/actors, including the economic and legal environment. The most important section of this report – section 3 - has been written primarily by

drawing on the findings of the manufacturer and key informant interviews conducted by the consultants with some reference to secondary studies. The fourth and final section provides some conclusions and recommendations on how the sub sector can be assisted within the MeTA framework to expand their production leading to increased accessibility, availability and quality of locally manufactured medicines.

A draft report of this study was availed to MeTA Zambia's Research and Survey Committee for their initial comments while a powerpoint summary presentation was also made committee. Comments received were then noted and incorporated into the final draft which was then submitted to the MeTA Zambia council on the advice of the committee. A presentation was also made to the council in the form of a powerpoint presentation. Final comments from the MeTA council were then incorporated into the report leading to the final copy. Three bound copies of the final report and an electronic copy were then submitted to the MeTA Zambia secretariat.

2. Conceptual Background

2.1 The Legal Framework of the Pharmaceutical Sector in Perspective

Prior to 2004, the pharmaceutical industry in Zambia was primarily operating within the framework of the National Drug Policy (NDP) of 1999 which is based on the requirements of the Basic Health Care Package (BHCP). This policy is what gave birth to the PRA and though it is now undergoing review, it was still in effect as at the time of writing this report since the new drug policy had not yet come into being. It is worth noting that the NDP of 1999 was quite favourable in principle to the growth of pharmaceutical manufacturing. The Ministry's Strategic Plan (2006-2010) is also categorical in specifying that the ministry would encourage the 'establishment of a strong local pharmaceutical and chemical industry to lower the costs of drugs'.⁶ However, it is the implementation of the provisions in the policy and the Strategic Plan which is another issue altogether evidenced by the collapse of over half of the manufacturing entities during this period.

Section 5 of the NDP, dealing with 'Local Production of Pharmaceuticals' for instance makes provision that discriminating tariffs in favour of imported finished pharmaceuticals was to be abolished. The reality is that finished imported medicines now attract little or no taxes thereby disadvantaging the local manufacturers. Furthermore the policy mentions that 'the MoH shall use Government drug funds to procure locally manufactured pharmaceuticals in preference to finished products as much as possible'.⁷ This approach was to be applied even in the case where donor funds were involved whereby the funds were to be used to procure raw materials to be used by local manufacturers. This study has however found that cheaper imported finished products are procured in very large quantities thereby disadvantaging local manufacturers. The focus in procuring medicines at the tender process is now more inclined towards lower price contrary to the support to local industry as well, originally envisaged in the policy.

The main piece of legislation that regulates the pharmaceutical business in Zambia is now the Pharmaceutical Act No. 14 of 2004. The Act establishes the PRA which is responsible for registration and regulation of pharmacies; registration and regulation of medicines, herbal medicines and allied substances intended for human use and for animal use; regulation and control of the manufacture, importation, exportation, possession, storage, distribution, supply, promotion, sale and use of medicines, herbal medicines and allied substances. The key functions to achieve this include the registration of medicinal products, inspections of facilities and products, licensing of pharmaceutical premises (retail, wholesalers, and manufacturing sites) and issuing of import and export licenses and

⁶ GRZ, National Health Sector Strategic Plan, 2006 - 2010

⁷ GRZ, National Drug Policy, 1999, pg 10

permits.⁸ Registration of pharmaceutical products for use on the Zambian market is done by the PRA through the directorate of Product Registration. The products registered by the PRA are charged a fee (product registration fees). These fees were recently increased by the PRA.

2.2 Procurement of Medicines and Raw Materials

The procurement of medicines for government health institutions is done by the Procurement and Supplies Unit of the Ministry of Health. Currently the Ministry of Health has undergone restructuring which has also included this unit. The Head of Procurement reports directly to the Permanent Secretary. The sources of funding for procurement of medicines are the government and cooperating partners. For 2007-2008, the Ministry of Health embarked on Framework Contracts with pharmaceutical suppliers to improve (i.e ensure consistent uninterrupted) supply of medicines and other pharmaceuticals.

The Ministry of Health in its procurement operations is guided by the Zambia Public Procurement Authority (ZPPA) laid down procedures for public procurement. All procurements above the authorized thresholds (US\$1,000,000 for MOH) are channeled through procurement methods as per ZPPA guidelines. The procurement methods recommended by ZPPA includes: the International Competitive Bidding (ICB); Limited International Bidding (LIB) and; National Competitive Bidding (NCB).

Procurement of medicines is one of the key roles of the MOH Procurement and Supplies Unit. However, statistics on quantities of medicines imported, etc was very difficult to get. The PRA which may have this information could not provide records and as such it was difficult to make a computation of sources and quantities to compare with what is locally manufactured. Suffice to say, that nearly all types of legal medicines can be imported into Zambia as long as one has a licence. The storage and distribution of pharmaceuticals and medical supplies is done by Medical Stores Ltd, a parastatal company owned by the Ministry of Finance and the Ministry of Health. Medical Stores Ltd's mandate is storage and distribution of medicines and allied products to district health offices and hospitals.

Other than the MoH, other players such as the Churches Health Association of Zambia (CHAZ) are also involved in medicines supply management as a complementary service (about 20 – 30%) to the government supply system. With 136 members they are responsible for around 30% of health care services in the country (hospitals, clinics, training of personnel, like nurses and laboratory Technicians etc.). Donor supplied drugs are budgeted for about US\$ 20m per year with more than 95% directly imported (60% HIV/AIDS; 10% anti malaria; 20% reagents supplies and 10% others). CHAZ takes care of its own distribution to 62 hospital and health centre outlets.⁹

⁸ The Pharmaceutical Act, No.14 of 2004

⁹ Os, Van Aart, **Private Sector Mapping Study**, MeTA, 2009

CHAZ through a revolving drug fund sales essential medicines to member institutions and others not for profit organizations including government health institutions. In addition CHAZ with support from cooperating partners runs antiretroviral therapy and malaria treatment programs which include procurement, storage and distribution.¹⁰

Illegal importations of medicines do occur but the PRA insisted that the quantities that are smuggled into the country are insignificant to upset the market share of local manufacturers. Indeed manufactures themselves did not dwell much on illegal imports. Principally, such imports enter Zambia through Tanzania and other neighbouring countries. On occasion, government procured drugs (complete with the MoH logo, find their way into the private market).

Zambia and Ghana: A Comparison

The market for pharmaceuticals in Ghana is larger than that in Zambia, encouraging actors to enter the space. Furthermore, trade policy and import duty structure is more favorable to local manufacturers in Ghana than it is in Zambia. As a result, the 35 local manufacturers in Ghana produce roughly 30% of total medicines (prescription and over-the-counter), while in Zambia, the 6 local manufacturers account for a much smaller fraction of the supply

Source: *Private sector role in health supply chains: Review of the role and potential for private sector engagement in developing country health supply chains*

The study established that apart from sugar and water, all other raw materials (packaging material, excipients and active pharmaceutical ingredients, (API) are imported. There are raw materials like ethanol, calcium hypochlorite and sodium hypochlorite that are procured from third parties locally but whose original source is still foreign. It was also established that the bulk of imported pharmaceutical raw materials are either sourced from China or India and a few from South Africa and the UK.

Apart from one, all the manufacturer respondents could not provide a list of the raw materials used in their production processes. The general perception by the companies was that this type of information borders on trade secrets and as such cannot be divulged at all. The composition of the ingredients used in each product was however obtained from the PRA but even then, it is of limited use in as far as establishing the actual *raw materials* used as the bulk of these are themselves imported as finished products.

2.3 An Environmental Scan of the Pharmaceutical

¹⁰ www.chaz.org.zm/pharmaceuticalandlogistics.php and Os, Van Aart, **Private Sector Mapping Study**, MeTA, 2009 and, Dalberg Global Development Advisors and MIT/Zaragoza International Logistics Program, **Private sector role in health supply chains: Review of the role and potential for private sector engagement in developing country health supply chains**, 2008

Sector

According to some reports, the Zambian private sector is one of the smallest in the world with no more than 10 - 15% of total health care services. In 2009 there were no more than 70 registered pharmacy retail outlets, 80 pharmaceutical importers/wholesalers, 300 private (dispensing) clinics (1 to 2 doctors), private health insurers with no more than 30.000-50.000 people privately insured, six officially registered manufacturers of which only 3 were operational with a very limited product portfolio.¹¹ There are no Multi National Pharmaceutical Enterprises operating in Zambia.

Some investments were made in manufacturing facilities in the past (over 10 years ago) but the businesses have failed to grow because of harsh economic circumstances which are particularly unfavourable to manufacturing. This has failed to create a sustainable working environment for local production. The pharmaceutical manufacturing sub sector is beset by problems such as the lack of a national quality control laboratory (the companies generally have own in-house labs). The PRA itself has to outsource its quality control functions to laboratories abroad. Naturally because of the limitations of the market, local manufacturers are highly dependant on government contracts for their survival. However, the competition from cheaper Indian pharmaceuticals is making it difficult for local producers to thrive. The Indian government, for instance, provides a significant export subsidy of up to 30%.

Meanwhile, finished pharmaceutical products, APIs and Intermediates can be imported into the country duty free; whereas excipients, inactive materials and packaging materials such as bottles, containers, ampoules etc. may carry an import duty of up to 50%. Import duty is also charged on machinery and capital equipment which goes into manufacturing thereby making local manufacturing very expensive indeed compared to imported finished product. The rationale behind the government's import duty policy is that some of the inactive ingredients are also utilized in the manufacture of non-pharmaceutical products.¹² As a coping mechanism, local manufacturers are now actively engaged in the importation of finished pharmaceutical products while some have completely abandoned local manufacturing.

Having a vibrant local pharmaceutical manufacturing industry is advantageous (as opposed to importing finished products) in that it reduces the pressure on foreign exchange demands, over time it helps develop and sustain a cadre of professionals in the sector and also creates career opportunities for individuals who have studied pharmacy and its affiliate disciplines, etc. This is one sure way of developing an economy in the long term.

¹¹ Os, Van Aart, **Private Sector Mapping Study**, MeTA, 2009 and, Dalberg Global Development Advisors and MIT/Zaragoza International Logistics Program, **Private sector role in health supply chains: Review of the role and potential for private sector engagement in developing country health supply chains, 2008**

¹² Ibid

2.4 Pharmaceutical Products Manufactured Locally

Table 2 shows the types of pharmaceutical products that were licenced by the PRA as at January 2010. Clearly, the numbers of licenced products and the variety is still very limited. Only Circle Pharmaceuticals of Ndola appears to have a wide range of products on its list. Even then, at the time of writing this report, media reports indicated that the plant had temporarily ceased operations.

Table 2: Types and Number of Manufactured Local Products

Manufacturer	Types of Products	No. of Licensed Products
International Drug Company (Both Plants)	<ul style="list-style-type: none"> • Solutions for infusions • Syrups/Solutions for oral use • Ointments and lotions • Uncoated tablets • Suspensions • Injectables 	33
Kings Pharmaceuticals Limited	<ul style="list-style-type: none"> • Syrups/Solutions for oral use • Ointments and lotions • Uncoated tablets • Drops • Cream 	30
Teejay Pharmaceuticals Limited	<ul style="list-style-type: none"> • Injectables • Syrups/Solutions/suspensions for oral use • Drops 	47
Pharmanova Zambia Limited	<ul style="list-style-type: none"> • Syrups/Solutions for oral use • Uncoated tablets • Capsules • Dusting powder 	19
Circle Pharmaceuticals Limited	<ul style="list-style-type: none"> • Syrups/Solutions for oral use • Injectables • Drops • Uncoated tablets • Suspensions • Capsules • Ointments 	189 ¹³

With such obvious output limitations, one cannot expect the local manufacturers to be in a position to satisfy the local market for pharmaceutical products even if the government was to give supply contracts to all the local manufacturers. The manufacturers require their internal capacities to be built up before they can fully compete and meet local demand.

¹³ Some of the products have been taken off the market (eg Chloroquine preparations)

2.5 Markets for Manufactured Pharmaceutical Products

The bulk of locally manufactured products are bought by the MoH for distribution to health facilities. Manufacturers also sell their products to wholesalers, private health facilities (hospitals, clinics, etc), retail pharmacies and for export – in that order. The export market is still not very well developed as Zambian pharmaceuticals are produced at high cost thereby making them uncompetitive in the region. One manufacturer is currently exporting medicines to Malawi.

2.6 Impact of TRIPS on Local Pharmaceutical Manufacturers¹⁴

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organization (WTO) that sets down minimum standards for many forms of intellectual property regulation as applied to nationals of other WTO Members. TRIPS contains requirements that national laws must meet for copyright rights - including the rights of patents for pharmaceutical products. The rationale behind this protection and enforcement of intellectual property rights is to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of the technology or innovation.

In 2001, developing countries, concerned that developed countries were insisting on an overly narrow reading of TRIPS, pushed for the Doha Declaration which stated, among other things, that TRIPS can and should be interpreted in light of the goal "to promote access to medicines for all." Further, a 2003 agreement loosened the domestic market requirement,¹⁵ and allows developing countries to export to other countries where there is a national health problem as long as drugs exported are not part of a commercial or industrial policy.

The obligations under TRIPS apply equally to all member states, however developing countries like Zambia, were allowed extra time to implement the applicable changes to their national laws, in two tiers of transition according to their level of development. The transition period for developing countries expired in 2005. The transition period for least developed countries was extended to 2016, but discussions are underway to extend beyond that date.

The main controversy with TRIPS has mainly been that developed countries are in a vantage position being massive net-exporters of copyright-, patent- and trademark-related royalties. The TRIPS standard of requiring all countries to create strict intellectual property systems is therefore inimical to poorer countries. TRIPS' is considered as having wealth redistribution effects from the poor to the rich.

¹⁴ This entire section has been largely adapted from http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm and http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm

¹⁵ A provision that used to say that compulsory licences must be granted mainly to supply the domestic market (paragraph (f) of Article 31) of the agreement

At the moment there are no local manufacturers utilising TRIPS related flexibilities to locally produce on-patent essential medicines. Firstly, even on the WHO list of essential medicines, there are less than 10% of on-patent medicines. Secondly, the existing manufacturing plants do not meet the required standards for acquiring compulsory manufacturing licences that would permit local firms to produce on-patent medicines. The exceptions probably are the non operational Circle Pharmaceuticals and closed Pharco plant. There is also a lack of local trained personnel to fully benefit under TRIPS related flexibilities.

The government has put forward Intellectual Rights legislation as stipulated by the WTO. Pharco was to be the first local manufacturing firm to use the compulsory license law in the country to manufacture on-patent anti-retro viral medicines locally.

However, under the same law, research and development Pharmaceutical manufacturers in the west are able to manufacture cheaper generics of on-patent medicines for export to impoverished third world countries through NGOs like Medicines Sans Frontier at discounted prices. In this case it is the NGO that applies for a compulsory license in the country of destination in cases of “emergencies” to import generics of on-patent medicines. What is not reported is that these manufacturers benefit from fiscal incentives provided by their governments and therefore would be in a position to still out price local manufacturers using the same law. This is why it is important to have a cadre of well trained local manpower to help in decision making.

3. The Challenges of Local Manufacturers – Study Findings

3.1 High Taxation and Unfavourable Policy Issues

There is a disconcerting uncertainty on taxation of imported pharmaceutical excipients in the industry that was established in the study. Whereas the respondents to the questionnaire had excise duty and VAT on raw materials as one of the major constraints that push up their product prices on the market in comparison to their biggest competitors - the imported finished medicines that come in duty and VAT free - further probing on one of the respondents revealed that after individual lobbying, the firm had actually succeeded in having duty on some raw materials removed. However, the list of these raw materials could not be given to the consultants because it was deemed “sensitive” information. Other respondents however said that they actually do not pay duty on excipients anymore and that VAT on imported raw materials is refundable.

Interviews conducted with key informants did confirm that there is indeed tax charged on raw materials imported for manufacturing of medicines. The implications of this scenario are that locally manufactured pharmaceutical products are much more expensive than the imported ones because of the high input costs. The competitiveness of local manufacturers is therefore reduced as a result.

3.2 High Production Costs

Factors contributing to the high cost of production were mentioned as the high duty and VAT imposed on excipients, high transportation costs and raw material procurement lead time of between 2 to 3 months, high inventory costs of about six months and an inadequate supportive industry. Furthermore, local pharmaceutical manufacturers, like all other manufacturers in Zambia, have to pay for energy costs which are currently quite high and unreliable.

On the other hand, the mark ups which are placed on manufactured products seem to suggest that there is much more at play than what initially one is told as illustrated below:

Table 3: Examples of high markups observed in the supply chain

	Product type (anti-biotic vial)	Product type (anti-rabies vaccine)
Input price	1200 ZK	100,000 ZK
Wholesaler price	3000 ZK	150,000 ZK
Retail price	7000-9000 ZK	600,000-800,00 ZK

*Source: Dalberg Global Development Advisors and MIT/Zaragoza International Logistics Program, **Private sector role in health supply chains: Review of the role and potential for private sector engagement in developing country health supply chains, 2008***

3.3 Access to Raw Materials

The study established that apart from sugar and water, all other raw materials are imported and as such taxed. Even for raw materials that are procured locally, there is still VAT that is paid. The other problem is that the local suppliers of local raw materials, where they exist, are not well established and compounded with the challenges of poor infrastructure, the delivery periods for materials can be a challenge especially when the materials are needed urgently.

3.4 Insufficient Appropriate and Experienced Staff

The local pharmaceutical industry is purely second level i.e. it is only able to manufacture finished dosage forms from APIs and excipients but not able to manufacture APIs and intermediates from basic chemical and biological material. Therefore, they only meet the barest minimum requirements by the PRA. The respondent firms each had only one pharmacist in employment. At this level, the manufacturers are and have remained basic making it difficult for them to move to higher levels of manufacturing sophistication such as the manufacturer of generics.

3.5 Availability of Market

Currently, all manufactured pharmaceutical products can only supply around 10% of the local market. Furthermore, nearly all the manufacturers only produce for the local market. Clearly there is a lot of potential for local manufactures if the right policies were fostered. The bulk of locally manufactured products are bought by the MoH for distribution to health facilities.

Challenges Faced by Pharmaceutical Manufacturers Draft Report

Respondents indicated that with good policies in place to support growth of the local pharmaceutical manufacturing industry, the existing local firms could be able to produce up to 50% of the required public essential medicines needs. This is in view of the fact that they all operate on an 8 hour shift per day. The general feeling is that if the MOH were to work with them, they could scale up their production levels to three shifts a day. As it is they could not give current production forecast figures for essential medicines because they only produce when need arises. For survival they mainly depend on production of off patent Over-The-Counter (OTC) brands and other cheap generic non essential drugs.

Local tenders favour local importers because they are able to quote cheaper and it takes a shorter period to bring in finished medicines as compared to raw materials. According to the respondents, local manufacturers are not privy to the MoH essential medicines requirements and as such are unable to procure the necessary raw materials at the beginning of a new tender cycle. Even if they did, there are no guarantees the MoH will procure from them.

3.6 Internal Managerial Capacities/Corporate governance

The respondents did not feel this subject is an impediment to their operations. However modern good management practices demand for a well structured management system. That system should have a broad based Board of Directors or Advisory Board. Apart from ensuring good corporate governance practices, the board members can bring to the board diverse experiences in business that a firm could tap from.

Although there is no obvious financing gap in the remaining operational firms, if the sector was to receive full support through implementation of the good government policies espoused in the NDP of 1999, capital needs would arise to modernise these firms' factories and financing institutions nowadays look favourably on those firms with solid governance practices.



Lessons in Best Practice – The Case of Nigeria and Ghana

Nigeria: The government of Nigeria banned importation of a long list of drugs that are manufactured locally, resulting in the local manufacturing industry supplying more than 30% of all medicines in the country.....There are now more than 80 local manufacturing companies

Ghana: The government of Ghana introduced a system whereby medicines are grouped in three categories: 1) medicines provided only through local production; 2) medicines that can be imported but attract tax; and, 3) medicines imported free of tax. There are also attempts to raise the price entry barrier in order to free market space for greater participation by locals

Source:

http://www.medicinestransparency.org/fileadmin/uploads/Documents/MeTA-Uganda_AfricaHealth.pdf

3.7 Impact of Cheaper Imported Medicines

As alluded to earlier, imported medicines, mainly from India and a few from South Africa have a huge bearing on the demise of the local pharmaceutical manufacturing industry. Worse still, the pharmaceutical sector in India is well protected and supported by the government with subsidies and stiff import tariffs making it cheaper for them to export. Importers of finished medicines do not pay any taxation on their imports whereas local manufacturers do. Lag time on an imported medicine is shorter compared to that for several different raw materials, usually from different sources, needed to make the same medicine. All these factors conspire to make locally produced medicines uncompetitive on the local markets ultimately making local manufacturing unsustainable.

3.8 Role of Civil Society Actors (NGOs and mission hospitals)

It was the view of the respondents that importation of medicines, either donated or paid for by these organisations only further shrinks their market. A suggestion was put forward that these organisations would do well to channel their resources through the MoH who in turn would work with the local manufacturers to produce medicines for them. It is important to note that these organisations sometimes do procure medicines locally but it is always at short notice and local manufacturers are not able to produce at such short notice considering that they often will not have the required raw materials on their inventory list and this affords the wholesalers the opportunity to supply.

Other respondents however felt that the market share for medicines (particularly donations from NGOs) form an insignificant portion of the total supply and as such does not really impact the market considerably.

3.9 Challenges of Corruption and Bribery

There are perceptions of corruption in drug procurement processes but the respondents were quick to say that there is no evidence to suggest that this is an impediment to their operations. However, it is the opinion of the consultants that opportunities for corruption could arise particularly when tenders are called at short notice and known only to a few. It is common practice for example when one visits a private hospital to find all kinds of trinkets that pharmaceutical companies have given to the medical personnel or the health facility. One then wonders what else could be provided/offered behind the scenes to secure a particularly lucrative tender at the expense of other suppliers and the patient who now has to pay a higher price for medicines.

3.10 Regulation and Fees

Whereas registration fees are generally considered high, some respondents did not feel this is an obstruction to their ability to manufacture.¹⁶ However they particularly felt that retention fees on medicines that are produced a few times a year could be reduced or removed. This includes essential medicines that are produced in small quantities. Another problem cited was that the time required to register a new drug can vary significantly although prioritized registration is carried out in special circumstances. The variability in the approval time is attributed to the lack of people and skills to evaluate the dossiers. The PRA relies on quality and safety data provided by the manufacturers and has limited capacity to do its own tests and quality checks. The PRA itself is further constrained due to a huge staff shortfall making it difficult to fully inspect manufacturing companies and provide necessary guidance. One respondent shared with the study team that inspections are not regular and sometimes they (manufacturers) have had to ask the PRA to come and inspect.

3.11 Prohibitive Investment and Financing Support

The cost of borrowing especially from commercial banks is prohibitively high in Zambia thus making it very difficult to finance new investments in the business. With interest rates in the region of 20 – 25%, the rates are not attractive at all and could lead a business to sink rather than swim.

¹⁶ Some authors have argued (and so has the PRA), that the fee for registering a new drug is only \$150 as compared to \$1000 in some other countries in the region.

4. Conclusions and Recommendations

4.1 Study Conclusions

This study on the challenges of local manufacturers has brought out a number of interesting issues which require the immediate intervention of policy makers to address them. Paramount among these is the fact that the tax regime in Zambia favours importation of medicines as opposed to local manufacturing. The rationale for importation is merely that it ultimately leads to cheaper prices for consumers (affordability) since these products are imported cheaper and tax free from the source. On the other hand though, the local manufacturing sector is not in a position to satisfy the demand for medicines even if they were offered exclusive contracts. This vicious cycle can only be broken with the introduction and implementation of government policies which seek to deliberately promote local production such as access to cheaper credit (possibly via a scheme like Citizen Economic Empowerment, guaranteeing a certain percentage that is locally purchased, banning certain imports, etc).

While the market share which local manufacturers control has little or no bearing on the availability of medicines (the bulk is imported), it appears to have an impact on their affordability especially OTC medicines as shown in **Table 3**. Such high margins, justified or not, have serious life or death consequences on the poor. This is particularly so considering that despite increases in supply of medicines (a large portion of the medicines budget goes into purchasing Anti Retro Virals for HIV/AIDS and anti Tuberculosis medicines), the public health facilities still have serious shortages of essential medicines for the usual ailments. Only those with money can therefore access the expensive medicines which are provided through private retail outlets.

The government tender processes for procuring medicines has been improving but there is still a lot that requires to be done to make it even better. The 'emergency' procurement arrangements whereby only those manufacturers who have the medicines in stock can supply, disadvantages some manufacturers and can open up opportunities for corruption in competing for limited tenders under strict deadlines. This has implications on the availability of medicines and obviously if corruption creeps in, the consumer pays a high price.

Finally, local production of medicines needs to be seen within the broader framework of the benefits which would arise. These can be explained as follows:

- i. It saves on foreign exchange which can be rechanneled into the purchasing of more medicines thereby improving access, availability and affordability of medicines,

- ii. It creates jobs, thus alleviating poverty and promoting social development which in turn reduces the disease burden,
- iii. It facilitates technology transfer thereby lowering costs of production and the affordability of medicines,
- iv. It stimulates exports, increases foreign exchange income and consequently re-investment in the sector leading to lower product prices, affordability and access for the poor,
- v. Raw materials produced locally would be readily available and cheaper which in turn affects prices and access,
- vi. Local production improves/enhances self-sufficiency in drug supply.

4.2 Recommendations for MeTA Advocacy

Table 4 illustrates some of the advocacy recommendations which MeTA Zambia could adopt in contributing to addressing the challenges of local manufacturers and consequently positively impacting the accessibility, affordability and availability of medicines:

Table 4: Recommendation for MeTA Advocacy

Advocacy Target	Advocacy Objective	Description of Advocacy Activity
International Donors	Enabling environment for pharmaceutical manufacturing/ investment	Contribute to the development of public goods like policy, financial, and information which donors can base decisions on
International Donors	Increase manufacturers involvement in donor initiatives targeting medicines supply chain	Improve and include the manufacturers vertical programs
International Donors	Alignment between approaches of different sectors	Encouraging donors to provide financing, secured orders, and capacity building
Government/MoH	Reduced hindrances in production process leading to improved production	Lobby for a framework to support local manufacturers in manufacturing a number of essential drugs for the government market. This framework would have to be designed taking into account financing, import duties, local taxes, volumes to provide critical mass and continuity, credit terms, quality and reasonable profit margins.
MoH/PRA	Protect consumers	Advocate for strong regulatory and enforcement role that reduces the downside of private sector profit motive
Local Manufacturers	Increased collaboration leading to common positions on issues of interest to all	Increased engagement with the ZPBF to develop mutual action plans funded by the ZPBF with technical support from MeTA

Government/MoH	Selective tendering favouring local manufacturers	MeTA should engage with relevant bodies to lobby for increased allocation of tenders to local manufacturers
Government/MoH	Overarching policy measure for pharmaceutical manufacturing	Support/lobby for the revision or writing of a National Industrial or Medicines Policy.
PRA/Manufacturers	Regulatory fees	Engage both the PRA and manufacturers to arrive at fee structures that are more conducive for local manufacturers

Appendices

Appendix 1: List of Key Informants and Manufacturer Interviewees

No.	Name of Key Informant	Organisation	Position
1	A. Nithyanathan	Zambia Pharmaceutical Business Forum	
2	Bernice Mwale	Pharmaceutical Regulatory Authority	Director - Regulation
3	Esnart Mwape	Pharmaceutical Regulatory Authority	Director General
4	Bonface Fundafunda	Ministry of Health	Manager - Drug Supply Budget Line
5	Ruth Mudondo	Zambia Pharmaceutical Business Forum	-
6	Lameck Kachali	Medical Stores/Lusaka Pharmaceutical Association	Senior Technical Officer/Branch Chairperson - PSZ
7	A. Nithyanathan	Kings Pharmaceuticals Limited	Director
9		Pharmanova Zambia Limited	
10	Cosmas Banda	Tejay Pharmaceuticals Limited	Quality Assurance Manager
11	Obert Mulenga	Supreme Care Pharmacy	Pharmaceutical Manager
12	Lameck Kachali	Link Pharmacy	Locum Pharmacist