



SUBMISSION TO THE COMMITTEE ON HEALTH, COMMUNITY DEVELOPMENT AND SOCIAL SERVICES

THE PHARMACEUTICAL MANUFACTURING INDUSTRY IN ZAMBIA: CHALLENGES AND OPPORTUNITIES

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BACKGROUND

- The pharmaceutical industry in Zambia is an important component in the health sector critical to delivering a healthy and productive population. Kalachi et al (2014) indicated that Zambia has five main manufacturers of pharmaceutical products. The report projected that the local production represents between 10-15% of the demand for pharmaceuticals in Zambia.
- Zambia, like several other developing African countries is not able to produce and meet most essential drugs to supply its population as the country is largely dependent on medical imports from other countries especially India (Chongo & Chituta, 2021).
- Currently about 80% of the African continent's medical & pharmaceutical products are imported. Shortages of medications and lack of products such as vaccines in most African countries during the pandemic, brought into question the sustainability of highly depending on life-saving pharmaceutical imports and revealed a gap for which the pharmaceutical industry in Africa can take up.
- However, the government of the Republic of Zambia is trying to reduce costs on the importation of conventional medicine by promoting the setting up of local manufacturing of essential medicines.
- **However developing a strong pharmaceutical industry in Zambia will require the Government to invest in pharmaceutical Research and Development (R&D) facilities coupled with strong partnerships with private sector players in ensuring that Indigenous Knowledge Systems (IKS) are utilised.**

POTENTIAL OPPORTUNITIES FOR PROMOTING THE LOCAL PHARMACEUTICAL MANUFACTURING INDUSTRY

The COVID 19 pandemic represents the most significant motivation for local manufacturing of goods in Zambia. As the pandemic gathered momentum beginning March 2020, it became apparent that this would affect imports of the bulk of goods consumed in the country. This is a major push factor for the manufacturing sector to step in and meet market demand, including the demand for pharmaceutical products. Zambia has identified the manufacturing sector as one of the leading sectors in the effort to revitalise the economy.

The potential opportunities for the pharmaceutical manufacturing industry are best identified through the challenges. The challenges that are most apparent in the discussion around limited growth of the industry include:

- a) Lack of incentives
- b) Lack of adequately trained human resource
- c) Lack of capital
- d) Limited market size
- e) Infrastructure and regulatory capacity on standards is inadequate
- f) No partnerships for technological transfer.
- g) Reliance on imported finished products

An evaluation of the factors influencing the establishment of the domestic pharmaceutical manufacturing industry by Kachali et al (2014) sheds light on the downward trend in local pharmaceutical manufacturing capacity, which has led to a declining growth of the industry. The evaluation highlighted push and pull factors including political, social, economic and technological. It also assailed the procedures for establishing manufacturing plants for medicines

– for example, in relation to compulsory manufacturing licences, that standards for acquiring the licences are too high. This forces out some players from the industry.

It is therefore imperative to support the manufacturing sector, recognised as one of the key drivers of economic growth, employment creation and poverty reduction. With economic diversification being on the national agenda, emphasis is shifting to manufacturing thus creating a conducive environment for business.

Political will is one of the factors that will open the way for partnership between Government and the private sector in this regard as can be seen with the 2022 National Budget to support the manufacturing sector. The private sector can drive this process, and Government is keen to support this. It can be argued that the economic status of the country is poised to shift towards favourable. It is expected that Zambia's economy will return to growth in 2021-2022, following the recession in 2020. The resultant strained fiscal situation means there is need to scale back spending on medicines that can be produced locally. This would help strengthen the local currency. The pharmaceutical manufacturing industry has an element of importation of raw materials because of challenges with local sourcing. This is one of the areas that can be used to lobby for government intervention so that production is not stifled.

It has been recognised that for the manufacturing sector in general and by implication, the pharmaceutical industry to grow, local capacity is crucial. Government, through various national development plans, commits to using budget allocations for drugs to procure locally manufactured pharmaceuticals. This should be emphasised with the Ministry of Health.

Lastly the Indigenous Knowledge Systems should be pursued and promoted as there lies a great opportunity for growing and transforming our local pharmaceutical industry.

ADEQUACY OF THE POLICY AND LEGAL FRAMEWORK GOVERNING THE SECTOR

At national level, the principle legislation in the legal framework for the manufacture of pharmaceuticals is the Medicines and Allied Substances Act No. 3 of 2013. It establishes the Zambia Medicines Regulatory Authority (ZAMRA) as the statutory national regulatory body for medicines. Under section 3 of the Act, ZAMRA is vested with authority to regulate and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances. **This regulatory function is a combination of legal, administration and technical measures taken to ensure quality, safety and efficacy of medicines.** Under the Act, manufacture is defined thus: in relation to a medical or allied substance, this includes any process carried out in the course of making that medicine or allied substance. However it does not include:

- a) Dissolving or dispensing a product in, or diluting and mixing it with, some other substance for purposes of administering it, or;
- a) The incorporation of a medicine in any animal feed.

This definition automatically cuts out secondary production i.e. formulation of bulk pharmaceuticals into various dosage forms does not qualify as manufacturing.

The legal requirements for medicines control provide effective implementation of regulatory processes and a framework for compliance. The supply chain is also governed by the law – cutting across marketing, authorisation, inspection of facilities, advertising and promotion of post-marketing surveillance. It is requirement under the Act that medicines should be registered if they are intended to be placed on the Zambian market and this is effected through product licencing and marketing authorisation. It is important to note that the ultimate goal of drug regulation is the promotion and protection of public health.

The Act is enforced through a number of guidelines, as follows:

- i) Agro-Vet Shop Permit Regulations
- ii) Dispensing Certificate Regulations
- iii) Health Shop Regulations
- iv) Fees Regulations
- v) Medicines and Allied Substances Regulations
- vi) Certification of Registration

Other laws include the **Zambia Bureau of Standards Act Chapter 416 of the laws, the Public Health Act Chapter 295**. In addition to the Ministry of Health, the Zambia Bureau of Standards (ZABS) is one of the collaborating institutions ensuring that the efficacy and safety of medicines in Zambia is guaranteed.

The legislation is supported by the National Drug Policy 1999.

At regional and international level, Zambia subscribes to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, an agreement administered by the World Trade Organisation (WTO), setting down minimum standards for the many forms of intellectual property regulations. Zambia is a member country of the WTO. The African Union has also taken a policy position on local production of generic medicines to make full use of TRIPS. Access to medicines is an issue discussed at continental level in light of the common health challenges in the member countries.

Notwithstanding this framework, there are some shortcomings. Enforcement is a challenge, particularly in relation to quality control of imported goods.

THE ROLE OF NON-STATE ACTORS IN COMPLEMENTING GOVERNMENT'S EFFORTS TO PROMOTE THE LOCAL PHARMACEUTICAL MANUFACTURING INDUSTRY

- a) Advocacy:** Non-state actors have a coordinated voice when it comes to advocacy. Their advocacy, therefore, results into the formulation of favourable and progressive policies and strategic frameworks, among other things.
- b) Resource Mobilisation and Financing:** In complimenting the Government's efforts towards addressing specific health issues in the country, non-state actors mobilise resources usually from cooperating partners. With the erratic funding from the Government to the health sector, it is almost impossible for Zambia to promote the local manufacturing industry without additional resources from non-state actors.
- c) Providing Technical Support to the Ministry of Health:** Non-state actors are instrumental in providing technical support to the Ministry of Health.
- d) Research:** Non-state actors are also key in conducting research in order to generate empirical evidence for strategic policy and programmatic decision-making. This measure is commendable as long as they operate within the policy and legal framework of the country and are accredited by the Health Professions Council of Zambia (HPCZ).

MEASURES BY GOVERNMENT TO ENHANCE THE LOCAL PHARMACEUTICAL MANUFACTURING INDUSTRY

Health systems cannot function without pharmaceutical industry. The pharmaceutical industry is critical to complementing other types of health-care services and can reduce morbidity and

mortality rates and enhance quality of life. Access to health care and essential medicines is therefore increasingly viewed as a fundamental human right. It is also important that pharmaceuticals are accessible, of proven quality and safety and that they are properly used to save lives, reduce suffering and improve health.

There are a number of factors that contribute to the challenges in the pharmaceutical sector including poverty, market and government failures. The latter often result, at least in part, from a lack of transparency in the pharmaceutical system. **Lack of transparency in the sector is increasingly becoming an issue of concern because bad practices can waste resources, which in turn reduces the availability of essential medicines and threatens the well-being of populations.**

To deal with these issues and promote this industry here in Zambia, Government has:

- Sought to reform the pharmaceutical sector with the Pharmaceutical Act No. 14 of 2004, which established the Pharmaceutical Regulatory Authority (PRA), and repealed and replaced by the Medicines and Allied Substances (MASA) Act No.3 of 2013. The MASA called for the continuation of the mandate of PRA but renamed it the Zambia Medicines Regulatory Authority (ZAMRA)

ZAMRA responsible for the registration, 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.

ZAMRA has been tasked with:

- Registration of pharmaceutical products for use on the Zambian market.
- Submission of evaluation reports to the Medicines Committee for consideration before inclusion of products on the register.
- Forecasting and quantification of medicines, which is done by the Ministry of Health's Directorate of Clinical Care and Diagnostics Services, Pharmacy Unit, in liaison with cooperating partners. This unit is also responsible for capacity building in pharmaceutical management in public sector health institutions.

CHAZ also has been involved in medicines supply management as a complementary service (about 20– 30%) to the Government supply system. Through a revolving drug fund CHAZ sells essential medicines to member institutions and other not for profit organizations, including Government health institutions. In addition, with support from cooperating partners, CHAZ runs an antiretroviral therapy (ART) programme that includes procurement, storage and distribution.

- In addition Government through the multi-facility economic zones did provide incentives for local pharmaceutical companies intending to go into manufacturing of drugs in Zambia.

CHALLENGES FACED BY GOVERNMENT TO HEIGHTEN MANUFACTURING IN THE LOCAL PHARMACEUTICAL INDUSTRY

Although some strides have been made to grow local manufacturing in the pharmaceutical industry with institutions such as Yash Life Sciences, International Drug Company, Sterlin Diagnostics among others, challenges to meet market demands still exist.

These include:

1. Inadequate infrastructure investment in the pharmaceutical industry

- There is limited investment in the industry, perhaps this can be attributed to the capital intensive investment required for the industry to develop and thrive.
- Equally, limited investment in technological advancements and equipment poses a challenge for advancing local clinical research and trials for drug development.
- The shortage of critical medical supplies at the peak of the COVID-19 pandemic in India and China caused disruptions in access to medical care and some drugs in Zambia.
- We can cite the distribution and logistical challenges that were heightened by the COVID-19 pandemic as a clear example of why Zambia needs to boost investment in its pharmaceutical industry in order to meet local and regional demand for medical supplies.
- Investment in the local pharmaceutical industry should help drive the cost of quality health care to an affordable standard.
- Hence, there is need to priorities investment in the pharmaceutical industry to support the local manufacturing of medical supplies.

2. Inadequate human resource

- There are limited opportunities for specialisation and continuous professional development that is needed to boost the local industry.
- Equally, opportunities for the development of skills through skills transfer are a potential challenge for the advancement of the local pharmaceutical industry.
- Therefore, there is need to invest in developing technical expertise to conduct clinical trials and research in order to grow the sector.
- There is also need to offer incentives to attract personal capacity for technical development and expertise among scientists, academia and practitioners in order to encourage the development of human capacity and skills.

3. Inadequate funding towards research & development

- Prioritisation of funding towards research and development in clinical research and trials is essential in the development of new knowledge which is key in the pharmaceutical industry and the development of ground breaking treatments.
- Equally, funding towards research and development could help exploit and leverage on indigenous knowledge that has proved to be critical in responding to societal needs.
- Funding towards research can also be channelled to the development of traditional medicines into clinical standard drugs. This could help recognise indigenous knowledge and spearhead the safeguarding of intellectual property in Zambia.
- Limited technical expertise hinders research and development potential that is necessary for the industry to thrive.
- Equally, limited collaborative linkages hamper advancements in innovation, science and technology.
- The low levels of R&D therefore inhibit increased opportunities for collaboration among stakeholders with the pharmaceutical industry, whose role is to scale up and commercialize pharmaceutical products.
- There is need for increased engagement with development partners and the need to attract private sector financing in the development of clinical research to advance the local pharmaceutical industry.

Recommendations

- PMRC urges government to priorities investment in the pharmaceutical industry to support the manufacturing of medical supplies to meet local and regional demands.
- There is need to invest in developing technical expertise and strengthening collaborative efforts among scientists, academia and medical personnel to facilitate the development of clinical trials and research in order to grow the sector.
- There is need to offer incentives to attract personal capacity for technical development and expertise among scientists, academia and practitioners in order to encourage the development of human capacity and skills.
- PMRC urges government to strengthen engagement with development partners as well as attract private sector financing in the development of clinical research to advance the local pharmaceutical industry.
- PMRC urges government to strengthen the legal framework and Policy provisions that are aimed at encouraging the pharmaceutical manufacturing industry to thrive.

Local pharmaceutical manufacturing should be supported in all facets as it will help resolve the issue of medicine accessibility, preventing discontinuities of medical supplies contribute to poverty reduction in the country by contributing to the good health and wellbeing of citizens, it will also provide employment and consequently increase government revenue through taxes.

WAY FORWARD

1. The policy framework should be strengthened to ensure local production is stimulated
2. Drug funds should have an allocation reserved for the purchase of locally produced pharmaceuticals.
3. Pharmaceutical production is capital, technology and knowledge intensive. Strategic alliances with big pharmaceutical companies should be aggressively pursued, with support from Government.

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