Business Regulatory Review Agency

Regulatory Impact Assessment Report on Medicines and Allied Substances (Marketing Authorization of Medicine) Regulations

September 2022

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1. INTRODUCTION AND BACKGROUND

The impact of regulation on long-term investment is a complex matter. This is not only due to the fact that investments involve a variety of products, market players, and jurisdictions. It is also because the inhibiting effect of regulation is often difficult to see and to quantify. The problem is not only with the regulations that exist but also with absence of regulations. In circumstances where regulation could have a positive impact on long-term investment but is lacking, it needs to be created (McKinsey, 2022).

According to the World Bank (2005), a good investment climate, which addresses the local institutional, regulatory and policy environment in which firms operate, stimulates economic growth by providing firms with the incentive to invest and improve productivity.

Excessive regulation is considered to be an outcome of inefficient institutions. More recent studies have focused on different aspects of regulation in product markets and their effect on investment and long-term economic growth. In an empirical study to investigate the effect of regulatory reform on investment in several sectors of 21 OECD countries, results show that regulation is a significant determinant of investment. The results provide sufficient evidence to show that product market regulation can influence the costs that existing firms face when expanding their productive capacity. The overall assessment shows that regulatory reforms substantially lower entry barriers (OECD, 2020).

Data on regulation from the Economic Freedom of the World Index (EFW), highlight significant findings that countries with less overall regulation have higher rates of private investment. Business entry regulation is a significant determinant of investment.

Investments in emerging economies is influenced by security of property rights and the degree of business entry regulation. In particular, the evidence shows that where there are fewer administrative procedures required to formalise a business, there is a positive and significant effect on investment in the economy. In addition, fewer procedures to register property or to secure business licences have a positive and significant effect on investment (Korutaro and Biekpe, 2013). The foregoing shows that less regulation encourages investments.

Pharmaceutical regulation is designed to ensure safety, efficacy, and quality of drugs available to consumers. This is accomplished through a range of regulatory activities over the course of a drug's life cycle including premarket screening and evaluation of new pharmaceuticals, inspection of manufacturing facilities, regulation of drug labeling and promotional activities, and the post marketing surveillance of drugs following approval. This regulation extends to drugs and biologics that are intended for use in the diagnosis, treatment, prevention, and cure of diseases (Olson, 2014).

PROBLEM STATEMENT

Zambia lacks a developed pharmaceutical manufacturing industry to supply locally made essential drugs. As of 2022, there were ten registered pharmaceutical manufacturing companies in Zambia, seven of which are undertaking full manufacturing while three were involved in the repackaging of finished pharmaceutical products. Of the seven companies undertaking full manufacturing, only four were active. These companies were mostly engaged in the manufacturing of generic small and large volume parenteral, oral solid dosage forms, liquid dosage forms, powders, external preparations and medical supplies. Data from the Zambia Medicines Regulatory Authority (ZAMRA) indicated that only 123 registered medicines were produced locally, out of over 8,154 medicines on their register as of June 2022. Therefore, it was, estimated that the local production of medicine represented between 10 to 15 percent of the demand for pharmaceuticals in Zambia. (Parliamentary Committee Report on Health and Community Services, 2022).

As a result the country has been relying on imported drugs. The importation of pharmaceutical products has further resulted in the Government accumulating debt owed to players in the pharmaceutical sector for the provision of various goods and services. The resultant effect of this debt was the shortage of medicines and medical supplies in most public health facilities. The shortage of medicines had impacted the patients negatively as they bear the cost of accessing medicines and medical supplies from private pharmacies.

According to the United Nations COMTRADE database on international trade, Zambia's import for pharmaceutical products was US$208,422,130 in 2019 and US$260,058,974 in 2020 as indicated in the table below:

YEAR	VALUE (USD)	VALUE (ZMW)
2015	223,748,437	2,058,341,148
2016	249,627,428	2,563,189,045
2017	173,420,050	1,648,264,910
2018	269,886,125	2,831,970,494
2019	208,422,130	2,648,185,848
2020	260,058,974	4,856,295,395

This costly undertaking resulted in the Government accumulating debt of about K3 billion as of 31st January 2020, owed to players in the pharmaceutical sector for the provision of various goods and services.

The Zambia Pharmaceutical Business Forum attributes the failure to attract investments in the sector to a range of issues such as taxes on inputs into manufacturing process and other customs impediments. The Forum also attributes the problem to high regulatory fees under the Zambia Medicines Regulatory Authority. It is this later issue that this regulatory impact assessment focusses on.

The fees referred to are contained in the Medicines and Allied Substances (Marketing Authorization of Medicine) Regulations, Statutory Instrument No. 79 of 2019. The fees are reportedly too high and contribute to the already high cost of doing business for the pharmaceutical industry. The fees are categorized as follows:

Marketing Authorization

Description	Applicable fee	Application approval timeline
Human Medicine generic	USD 2000/product	12 – 18 months

New Chemical Entities (NCE)	USD 2800	12 – 18 months
Biologicals	USD 2800`	12 – 18 months
Allied substances	USD 500	6 – 12 months

Amendment to Marketing Authorization

Description	**Applicable fee**	**Application approval timeline**
Minor Amendment	USD 100/change	unknown
Major amendment	USD 500/Change	Unknown

Importation of Medicines & Allied substances (Import permit)

Description	**Applicable fee**	**Application approval timeline**
Registered Products	1.5% of Invoice FOB value	5 – 14 working days
Unregistered Products	5% of Invoice FOB value	5 – 14 working days
Donation of products	1% of Invoice FOB value	5 – 14 working days

Other fees

Description	**Applicable fee**	**Application approval timeline**
MA Renewal	USD 1,200/Product	unknown
Annual Retention	USD 800/ Human Medicine product	N/A

	USD 200/ Allied substance	

Good Manufacturing Practices (GMP) fees

Description	**Applicable fee**	**Application approval timeline**
Fees for GMP document evaluation (Desk audits)/Manufacturing site	USD 3500	Unknown

The Pharmaceutical industry represented by the Zambia Pharmaceutical Business Forum have argued that, the fees charged by ZAMRA in the above categories are too high and in some cases the waiting time is too long or is unspecified. The Business Regulatory Act requires regulations to specify condition for granting or denial of applications including how long it takes for the application to be processed.

2. POLICY OBJECTIVES

To improve the investment climate in the pharmaceutical manufacturing sector in order to increase by 50% production of medicines locally by 2030.

2.1. Specific objectives

a) To reduce regulatory costs on the Pharmaceutical manufacturing sector in order to reduce the cost of doing business in the sector by 2023.
b) Streamline and simplify market authorization procedures for medicines in order to reduce turnaround period by 50% by 2023.
c) To incentivize pharmaceutical industry in order to make available all essential drugs and allied substances in public health facilities by 2030.

3. POLICY OPTIONS

3.1. Do nothing

This options means that Government maintains the status quo. The Zambia Medicines Regulatory Authority continues to implement current regulations at the current fee structure. The implications of this policy option is that businesses will continue to wait longer periods for marketing authorizations and incurring high regulatory fees. The resultant effect will be delayed introduction of medicines on the market and a stagnant pharmaceutical manufacturing sector.

3.2. Self-Regulation

Under this option, the Pharmaceutical industry in Zambia will self-organize and regulate themselves. This means that the industry association ie the Zambia Pharmaceutical Business Forum as opposed to the Zambia Medicines Regulatory Authority sets and enforces rules and standards, which govern behaviors and use 'self-policing' as the primary mechanism to ensure compliance and provide remediation. In discussing this option, the case of Australia has been used. Australia is at the forefront of international policy initiatives to promote regulatory reform and effective self-regulation. The Victorian Government has an objective of lowering regulatory costs on business and improving market outcomes for consumers, by encouraging self-regulation, where this is the most effective option for addressing an identified problem. The Government also has the objective that industry should take increased ownership and responsibility for developing efficient and effective self-regulation. Self-regulatory schemes tend to promote good practice and target specific problems within industries, impose lower compliance costs on business, and offer quick, low cost dispute resolution procedures. Effective self-regulation can also avoid the often overly prescriptive nature of regulation. In Australia, an audit of self-regulation came to the following conclusions:

a) Self-regulation is likely to be most effective where there are clearly defined problems but no high risk of serious or widespread harm to consumers;
b) Self-regulation is more likely to be effective in a competitive market as industry participants are more likely to be committed to it, either to differentiate their products or in fear of losing market share;

c) Self-regulation is less effective where there is a broad spread of smaller businesses that do not communicate with each other;
d) A more mature industry may be able to administer more effective self-regulation, as industry participants are more likely to have sufficient resources and be more committed;

In Zambia, it is clear that the pharmaceutical manufacturing industry is still in its infancy stages with only four firms currently active in manufacturing. On the retailer side, equally, there are a lot of micro businesses that may not have the incentive and resources to engage in self-regulation.

3.3. Revision of Medicines and Allied Substances (Marketing Authorization of Medicine) Regulations, Statutory Instrument No. 79 of 2019.

This option entails revising SI No 79 of 2019 to address issues raised by the industry. The issues of concern relate to the level of applicable fees which have been deemed to be too high, long turnaround periods and in some cases the waiting durations are unspecified. This, therefore calls for streamlining application procedures and reducing turnaround periods for market authorizations.

The factors hampering the growth of the pharmaceutical manufacturing sector in Zambia stretch beyond regulatory costs and administrative burdens for acquiring necessary authorizations. This option is unlikely to address the other factors such as delays by Government in paying for medical supplies, challenges with VAT and customs issues on inputs into manufacturing.

4. STAKEHOLDER CONSULTATION

The Business Regulatory Review Agency requested the Zambia Pharmaceuticals Business Forum to make a submission on the matter of regulatory challenges. The Forum made a submission and their comments are summarized below.

Summary of Stakeholder Comments

	ISSUE	STAKEHOLDER COMMENTS	GOVERNMENT RESPONSE
1	**Marketing authorization**	- For Injectable medicines, each volume is considered separately e.g. Paracetamol injection 1ml (USD 2000), Paracetamol injection 2ml (USD 2000), etc. Approval timelines often times exceed 24 months. - Registration timelines need to be respected as the field of medicine is very dynamic and constantly evolving. A product submitted today for registration may no longer be the preferred treatment in the next 3 years as newer molecules would have been developed. Therefore, by the time approval is granted, the product has no place in practice- wasted investment by the manufacturer.	
2	**Amendment to Marketing Authorization**	- These could be changes to the address of the manufacturer, artwork on the carton box, safety updates, etc. - If one product has 5 major changes, the cost of application automatically becomes more than registering a new product (Human Medicine generic).	

		- If you are making a major amendment to an Allied substance, for instance, the cost is the same as registering a new product (USD 500). - The fees are exorbitant and need harmonized revision. - All these costs are recovered through pricing to the end user, making access to quality, effective and safe medicines expensive.	
3	**Importation of Medicines & Allied substances (Import permit)**	- For registered products the applicable fee is 1.5% of Invoice FOB value and the process takes 5 – 14 working days. The current fee requirement is subjective and tend to discriminate against companies that invest in quality systems. Products of superior quality will cost more to import than products of low quality). Please note that the reference to low quality does not imply that these products cannot be consumed by the public. They have the minimum acceptable quality. However, there are companies that exceed the minimum acceptable quality and invest in systems to ensure quality improvement. The cost of achieving this implicates on the cost to the end user.	

		- For unregistered products the applicable fee is 5% of Invoice FOB value and the process take 5 – 14 working days. Some products are unregistered because there NO existing guidelines for registration. It is unfair to charge highly when registration is not the cause of the importer, it is purely due to non-existing of respective guidelines. This should be treated different from products that have guidelines but not registered. - Donation of products attract a fee equivalent to 1% of the FOB value. Charging donors for donating is absurd. - Fees for importation of medicines must be revised in the spirit of access and affordability	
4	**Marketing authorization renewal and retention**	- Done every five years at a cost of USD 1,200/Product. The approval time is not specified. - Annual Retention is charged at USD 800/ Human Medicine product and USD 200/ Allied substance. These fee is applicable to all registered Medicines & Allied substances. - Despite payment of annual retention fees, importation still attracts import	

		fees as stated above. For products like condoms and Latex grove, importers are required to pay pre-clearance for quality assurance fees to ZAMRA and testing fees to the Zambia Compulsory Standards Agency (ZCSA).	
5	**Good Manufacturing Practices (GMP) fees**	- The fees is USD3500 with unknown approval time. - The fee requirement is too high for review of documents (desk review). Could ZAMRA give a work plan that justifies USD3500 for desk review of documents.	
6	**Pharmaceutical Licences (Retail, Wholesale & Manufacture)**	- There are a lot of fee requirements from different government agents for various certificates. E.g. The local council now require a health permit despite the licence issued by ZAMRA, which licence confirms compliance to Good Manufacturing, Storage and Distribution practices	

6. SELECTION OF PREFERRED OPTION