Regulatory Requirements for Establishing a Pharmaceutical Manufacturing Plant in Zambia

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Abstract

Manufacturing plays a key role in ensuring that quality, safe and cost-effective medical products are made available to the community. This article describes the regulatory requirements and the key institutions in Zambia that govern or oversee the manufacturing of medical products.

Keywords: Manufacturing, GMP, regulatory requirement, compliance

Introduction

Manufacturing plays a key role in ensuring that cost effective medical products are made available to the community and that these products continue to meet the set standards of quality, safety and efficacy. As such, regulatory authorisation of medical products in any country ensures that a particular medical product is manufactured following strict set processes that meet good manufacturing practice (GMP) standards [1]. Medicines regulatory authorities have a responsibility to license facilities for the manufacturing of medical products and ensure that such facilities continue to maintain GMP standards [2]. This article describes the regulatory requirements and the key institutions in Zambia that govern or oversee the manufacturing of medical products. This information is important to institutions and companies that wish to set up

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manufacturing plants or manufacture medical products in Zambia. Local manufacturing offers availability of cost-effective medical products to the local communities.

Governing institutions

In Zambia, the Zambia Medicines Regulatory Authority (ZAMRA) established under the Medicines and Allied Substances Act no. 3 of 2013 has the mandate to regulate the manufacture of medicines and allied substances [3]. Under this mandate, ZAMRA conducts GMP inspections of the proposed manufacturing site and if the site is found to comply with the set GMP standards, a pharmaceutical license is granted and a GMP certificate issued. Its ambit extends to the granting of marketing authorisation before medical products can be marketed in Zambia, regulation of clinical trials, inspection of storage and distribution facilities, and testing of medical products among various other functions [3]. As such, several regulations, guidelines, and standards have been published by ZAMRA and various health institutions to guide the set up and execution of manufacturing medical products in Zambia. However, various institutions play key roles in the licensing of the pharmaceutical manufacturing site before ZAMRA can conduct GMP inspection and grant a pharmaceutical license. These institutions include:

- Local Government Authorities (Municipal or City Councils) and ministry of lands who are responsible for trading licenses and land administration [4, 5, 6].
- The Zambia Development Agency (ZDA) issues a certificate of registration to a company that wishes to set up a manufacturing plant in the multi-facility economic zone (called MFEZ permit) [7].
- Patents and Companies Registration Agency (PACRA) the agency is responsible for the registration of companies in Zambia [8].
- The Zambia Environmental Agency (ZEMA) issues an environmental impact assessment report for the proposed site of setting up the manufacturing plant. Additionally, ZEMA issues an emission license to allow for emission or discharge of pollutants or contaminants into the environment [9].
- The National Biosafety Authority approves the production or development of medical products involving genetically modified organisms [10].
- The Metrology Agency provides for consumer protection, health, safety and environmental management through legal metrology measure [11].

Key documents for establishing a pharmaceutical manufacturing plant

For a manufacturing plant to be granted a Pharmaceutical license and a GMP certificate, it must meet the GMP standards. Zambia has adopted international guidelines on Good Manufacturing Practices. Therefore, the plant layout and operations must meet these standards in addition to regulatory requirements for the Pharmaceutical License [1, 12]. The key documents required to obtain a pharmaceutical license include:

- Practicing license for the responsible person;
- Contract of employment of the responsible person with the applicant;
- A site master file; and
- Certificate of registration /incorporation issued by PACRA.

Procedure for obtaining a pharmaceutical license.

Before applying for a pharmaceutical license, the documents stated above must be prepared and uploaded on the online application system called IRIMS. These documents are accompanied by proof of payment of applicable fees. The Medicines and Allied Substances Act (fees) Regulation, 2016 (Statutory Instrument No. 38 of 2016) provides the regulatory fees presented in Table 1 that must be paid depending on the manufacturing activities to be carried out.

Table 1. Application fees for grant of Pharmaceutical License

Type of Manufacturing activity	**Application fee in Zambian Kwacha**
Complete Manufacture	19,360.00
Primary Repackage of Medicine	10,620.00
Secondary Repackage of Medicine	5,310.00
Local Manufacture of Natural Remedies	10,620.00

Upon receipt of the application, ZAMRA reviews the submitted documents and schedule a GMP inspection. The site is inspected and depending of the observation, the pharmaceutical license may be issued or defer the application and request the applicant to submit additional information. ZAMRA can also reject the application if it does not meet the requirements or when requested additional information is not submitted within the specified timelines. For a manufacturer that successfully obtains a pharmaceutical license, the license is valid for 2 years and an application

for renewal of the pharmaceutical license must be made at least 90 days before expiry [12]. Other processes post-licensing include:

- Application for amendments in case of critical changes that affect the pharmaceutical license;
- Regular GMP inspections;
- Registration of the medical products to be manufactured using the established marketing authorisation guidelines; and
- Application for an import permit for the importation of raw materials in line with import permit requirements or application for an export permit in case of exporting the manufactured medical products [13].

CONCLUSION

Zambia has an established regulatory framework for the manufacture of medical products with regulatory requirements aligned with international standards for GMP. ZAMRA is the main regulatory agency responsible for the regulation of establishing a manufacturing plant and manufacturing of medical products.

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