The Pharma Legal Handbook

Zimbabwe

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms

PHARMA BOARDROOM

Zimbabwe

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Zimbabwe.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Honey & Blanckenberg, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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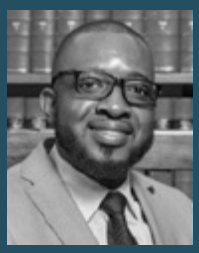

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Honey&Blanckenberg

Established 1893

Honey & Blanckenberg is a full service law firm with over 125 years of experience in the legal field in Zimbabwe. It has provided advisory services in several large transactions, and owing to its stellar reputation, represents several local and international entities across various economic sectors, including listed companies, regulatory bodies, non-governmental organisations, municipal authorities and private individuals.

The firm is ranked in Chambers Global Guide and is a member of Nextlaw Global Referral Network.

Honey & Blanckenberg and its individual partners and professional assistants are members of a number of professional bodies, which include amongst others, the Law Society of Zimbabwe, the Zimbabwe Institute of Patent and Trademark Agents, the International Bar Association, Zimbabwe Lawyers for Human Rights and the Zimbabwe Energy Council.

The Firm's Relevant Experience Generally

Honey & Blanckenberg has a wealth of experience. Our Practice Areas include, but are not limited to:

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- Registrations with ARIPO and ZIPO
- Corporate and Commercial Law
- Trusts, Wills and Estates
- Conveyancing and Notarial Practice
- Insurance
- Labour Law
- Family Law
- Human Rights and Constitutional Law
- Criminal Law

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CONTENTS

01

REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

3. What are the steps to obtaining authorization to develop, test, and market a product?

4. What are the approximate fees for each authorization?

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

9. What is the potential range of penalties for noncompliance?

10. Is there a national healthcare system? If so, how is it administered and funded?

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The Medicines Control Authority of Zimbabwe (MCAZ) is the authority tasked with regulation of drugs and medical devices in Zimbabwe. It is established in accordance with the provisions of **the Medicines and Allied Substances Control Act [Chapter 15:03] (hereinafter "the Act")**.

It must be noted that only two medical devices (namely condoms and gloves) are currently regulated (under **Statutory Instruments 183 of 2005 and 1 of 2016 respectively**).

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

This is also governed in terms of the **Medicines and Allied Substances Control Act.** MCAZ authorises the manufacture, sale, registration and cancellation of registration of drugs. Dangerous drugs are governed in accordance with the provisions of the **Dangerous Drugs Act [Chapter 15:02]**. Authorisation to manufacture and sell drugs in terms of this Act is granted by the Minister on such terms and subject to such conditions, including, in the case of a license, the payment of a fee, as the Minister may fix.

There are however no regulations for the pricing and reimbursement of drugs, biological and medical devices in Zimbabwe. Drugs for the treatment of HIV and AIDs, malaria and tuberculosis are subsidised through grants and the payment of an AIDS levy by companies and individuals **(Section 14(7) of the Finance Act [Chapter 23:04])** and are therefore more reasonably priced in Zimbabwe (see **Schedule 2 – Limitations and Exclusions – National Social Security Authority Voluntary Informal Sectors Schemes Notice, 2018**).

The lack of available foreign currency in Zimbabwe, together with high overhead costs, has, however, caused a sharp increase in the pricing of all drugs – both in the private and public sector (see **Report to Parliament of Zimbabwe, dated 5 September 2019 - https://www.parlzim.gov.zw/national-assembly-hansard/download/2748_e5266 cde422c832cb75729a001cc16b9**).

3. What are the steps to obtaining authorization to develop, test, and market a product?

3.1 Developing a drug

To develop a product, the manufacturer must make an application, which is accompanied by a dossier of the product to the Medicines Control Authority of Zimbabwe (**Section 68 of the Medicines and Allied Substances Control (General) Regulations, 1991**, hereinafter "the Regulations" as read with **Sections 30 and 38 of the Act)**. The dossier must include all information relating to the product. The Registration department will thereafter review the dossier to ensure that the manufacturing of the product complies with

the World Health Organisation Good Manufacturing Practices (GMPs) as set out in the **MCAZ Good Manufacturing Practice Guidelines**. If the product is registrable in Zimbabwe, the MCAZ inspectors will thereafter inspect the manufacturing plant at the manufacturers cost.

3.2 Testing a drug

MCAZ has an established laboratory for purposes of quality control testing. The laboratory is a functional part of the MCAZ and they do not contract the service elsewhere (**Section 25A of the Act**).

In accordance with **Sections 16 to 21 of the Act** as read with **Section 100 of the Regulations**, to test a product through clinical trials, a signed application in the prescribed form, seeking authorisation of the Authority must be submitted to the Director-General. Where the medicine is to be tested on human beings, their names and physical identification particulars must be included in the application. Where the trials are conducted on animals, the kind of animals will take part in the clinical trial, and the names and addresses of the owners must also be included in the application. If the trial is to be conducted in a hospital or other medical institution, the medical superintendent or a senior medical officer of comparable rank of such hospital or medical institution must countersign the application. The Director General will thereafter submit the application to MCAZ, which will consider the application and consult with the Secretary. Where the application is granted, the trial shall only commence where:

(a) voluntary written consents of all adult persons, taking part in the clinical trial have been freely obtained; and

(b) in the case of a medicine for the treatment, the voluntary written consents of parents or legal guardians, as the case may be, of minors or persons under legal disability have been freely obtained; and

(c) the voluntary written consents of the owners of all animals taking part in the clinical trial have been freely obtained; by the person conducting the trial.

3.3 Marketing a drug

Prior to marketing both human and animal medicines in Zimbabwe, registration and approval by MCAZ is compulsory (**Sections 29 and 30 of the Act**). The application for registration must be done by or on behalf of the principal medicine owner. The applications for registration of conventional medicines are made through completing a statutory application form and providing MCAZ with a dossier of supporting documents (**Section 31 of the Act**). A prescribed form must be completed and submitted to the Evaluations & Registration Division by the applicant. The division staff will complete the form and send it back to the client with appropriate fees for the service required. There are the three main types of medicine applications that require different application fees namely generic medicines, new chemical entities and line extensions. Applications may only be submitted after payment for the application has been made.

In relation to finished pharmaceutical products, the following is also required:

(i) a list the countries in which: