THE PHARMA LEGAL HANDBOOK

SOUTH AFRICA

PHARMA BOARDROOM

THE PHARMA LEGAL HANDBOOK ANSWERS ESSENTIAL QUESTIONS ABOUT THE LEGAL AND REGULATORY ENVIRONMENT FOR PHARMACEUTICALS IN SOUTH AFRICA. IT IS A MUST-HAVE FOR ANY COMPANY OPERATING IN THE COUNTRY OR LOOKING TO ENTER THE MARKET.

PREPARED IN ASSOCIATION WITH FASKEN, A LEADING INTERNATIONAL LAW FIRM, IT SHOULD ANSWER ANY QUESTIONS LINKED TO REGULATION, PRICING, CLINICAL AND PRECLINICAL TRIALS, MARKETING, MANUFACTURING, TRADEMARKS AND PATENTS.

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THE AUTHOR

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Martha is a partner at Fasken's Johannesburg office in South Africa and a member of the firm's Life Sciences practice group. Qualified as both a registered nurse and lawyer, she is also a registered member of -the Law Society of the Northern Provinces in South Africa, -the South African Medico-Legal Society, -the South African Nursing Council and -the New Zealand Nursing Council. She also holds a current Good Clinical Practice Certificate for Clinical Research. Martha brings compelling experience in the legal, medical and pharmaceutical industries.

Having practised as a litigation attorney and legal advisor in the corporate sector as well as coordinating clinical trials from a data management perspective for an international pharmaceutical company, she is able to bring the best of both worlds with on the ground experience, in finding innovative solutions for clients and businesses in the Life Sciences Industry.

Martha's area of practice mainly focuses on compliance and regulatory issues and she has advised on matters such as registrations, licensing applications and transfers, Clinical trial monitoring and reporting structures to name a few.

Martha's practical experience of having worked across a number of professional health bodies and corporates has afforded her first-hand knowledge and an in-depth understanding of the challenges, opportunities and regulatory environments of this sector.

LANGUAGES

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- Afrikaans

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

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

The South African Health Products Regulatory Authority (SAHPRA), previously known as the Medicine and Control Council (MCC).

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

The legislation regulating the framework for the authorization, pricing and reimbursement of drugs, biologicals and medical devices include the Medicines and Related Substances Act (as amended), Act No 101 of 1965 (the Medicines Act) and its Regulations. There are also Industry Rules and Guidelines which supplement the Act and its Regulations. These Rules and Guidelines are published by SAHPRA.

Price control is managed through different processes, one being a Pricing Committee which is appointed by the Minister of Health in terms of Section 22G of the Act. The Pricing Committee has the authority to make recommendations to the Minister to make regulations on the introductions of a transparent pricing system for all medicines and Scheduled Substances sold in the Republic. Such recommendations include an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C1 (a) and/or on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.

The transparent pricing system referred to, includes a single exit price in terms of this Section and is the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.

Medical Schemes also exist in South Africa whereby an undertaking of liability is present in return for a premium or contribution to make provision for obtaining any relevant health service. This liability includes the rendering of a relevant health service either by the medical scheme itself or by any supplier or group of suppliers in association with or in terms of an agreement with a medical scheme.

The above-mentioned reimbursement of drugs, biological and medical devices is regulated by the Medical Schemes Act, No 131 of 1998.

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

The process to develop, test and market is regulated under the Medicines Act and by SAHPRA.

The Conduct of clinical trials for humans and animals are set out in Regulation 30 of the General Regulations under the Medicines Act.

The application document to conduct a Clinical Trial can be obtained from the SAHPRA website and provides detailed information on the required documentation and information prior to submitting an application.

An applicant for registration of a medicine has to adhere to specific requirements which include but are not limited to the following:

- must be eligible to do business in South Africa, which include for example that they must be a person, body corporate/juristic person, company, residing and doing business in South Africa; or any other type of company/business; and
- the application must be signed by the Responsible pharmacist authorized on behalf of the company/ juristic person to communicate with the Regulator; and
- the applicant should also submit a Site Master File in accordance with the Guideline which govern and set out the requirements in this regard.

4. What are the approximate fees for each authorization?

Fees for different applications differ. The fees are set out in Government Gazette No 39154 dated 1 September 2015. The fee for an application for a new Chemical Entity for example (other than vaccines) which have been processed by the abbreviated registration process is ZAR 49 000-00.

For each application sought in the different categories, the specific details are contained in the Gazette.

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

A Registration certificate is issued in terms of Section 15 of the Medicines Act and the process of application for such registration is contained in Regulation 16 under this Act.

Once the Registration certificate is issued, a license must be obtained for the relevant activity to be conducted, e.g. licence for manufacturing, licence to distribute and/or a wholesaler's licence.

In terms of Section 22E of the Medicines Act, the Director-General has the authority to suspend or revoke the license should the applicable annual fee not be paid.

A licence is valid for a period of 5 years from the date of issue. To renew a licence issued in terms of Section 22C, an application to the Regulatory Authority must be made as set out in regulation 24 of the General Regulations contained under the Medicines Act.

The application for renewal must be made at least 180 days before the expiry of the existing licence.

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

An applicant/proposed holder of the certificate of registration must be eligible to apply for the registration of the medicine in the first place.

These eligibility criteria are contained in the General Information document of the South African Regulatory Body which is available on their website.

The application for registration of a brand name and generic is done through the use of one application document. The document contains a section which require the particulars of the medicine to be registered, the differentiation between which category of medicine (generic or branded for example) is to be registered, is to be provided by the applicant in this section.

Currently there are 5 different categories of medications for which an application for registration (and obtaining of market authorization) can be made:

- New chemical entity applications
- Multisource/generic applications and innovator product line extension applications that include clinical information in support of efficacy and safety of the formulation/dosage form, or indication/s or dosage regimen.
- Multisource/generic applications and innovator line extension applications that include comparative bio-availability/bioequivalence studies as proof of efficacy.
- Multisource/generic applications and innovator line extension applications
  - o that include comparative dissolution studies as proof of efficacy
  - o that include any other comparative studies as proof of efficacy
  - o others not mentioned above e.g. liquids/solutions.
- Biological medicines: Biopharmaceuticals and Biosimilars

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

Combination products is also Regulated by the Medicines Act and the Regulations under the Act, as well as Guidelines from SAHPRA regarding Registration of Medicines.

Where the combination products are medications or medications together with biologics, the General Regulations under that Act apply.

A combination of medications with a medical device, a biologic combined with a medical device or where a medication, biologic and medical device is combined, is regulated by the Regulations under the Medicines Act relating to medical devices and In Vitro Diagnostic medical devices (IVDs).

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?

Regulation and compliance is monitored by means of implementation of Section 26 of the Medicines Act. This Section provides that the Chief Executive Officer can authorize persons as inspectors in order to ensure the proper enforcement of this Act.

Section 28 set out the specific powers of an Inspector with regards to how they are able to enforce the requirements of this Act.