

# The South African pharmaceutical regulatory environment

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Our local pharmaceutical environment is highly regulated. The most important legislative provisions are found in the Medicines Act and the Pharmacy Act.

Recent amendments to the Medicines Act brought about the replacement of the Medicines Control Council, being the regulatory body that sat under the National Department of Health (Department of Health), with the newly incorporated South African Health Regulatory Products Authority (the Authority). The Authority has a broader mandate that includes the regulation of complementary medicines and medical devices. Being an independent organ of state, the Authority will levy fees in respect of applications for licensing and the registration of medicines and it is anticipated that such fees will be utilised to appoint skilled and experienced persons to assist the Authority in fulfilling its objects and functions.

Fortunately for the pharmaceutical industry, the Authority has advised that in the coming months, it will focus on enhancing and streamlining the evaluation and assessment process in respect of medicines, the registration of which previously averaged around four to six years for originator medicines and around three to four years in respect of generic medicines.

**An overview of certain important facets of the pharmaceutical regulatory environment in South Africa, including the requirements to enter the local market**  
**Licensing**

The Authority requires that a pharmaceutical manufacturer or wholesaler be licensed to manufacture, which may include a licence to import and/or export medicines, or to act as a wholesaler of medicines.

Guidelines are issued by the Authority, from time to time, which relate to various matters including Good Manufacturing Practices (GMP) or Good Distribution Practices (GDP). All pharmaceutical manufacturers and wholesalers are required to comply with such guidelines.

In addition, a pharmaceutical manufacturer or wholesaler must be licensed and recorded as a manufacturing or wholesale pharmacy, as the case may be, with the South African Pharmacy Council (Pharmacy Council) and must further be recorded as a pharmacy owner.

Additional requirements of the Pharmacy Council include the appointment of a dedicated responsible pharmacist who is required to continually and personally supervise the operations of the manufacturing or wholesale pharmacy.

The Department of Health further requires that premises licences be held by the relevant pharmaceutical manufacturer or wholesaler. Such a licence may be withdrawn in the event of any contravention of the provisions of the Medicines Act and/or the Pharmacy Act, or the failure to comply with GMP and/or GDP.

### **Transparent pricing**

In terms of the Medicines Act, medicines and substances are classified in terms of a scheduling system from Schedule 0 through to Schedule 8, with the latter being the most highly controlled.

A transparent pricing system, which includes a single exit price regime for medicines and scheduled substances, was introduced within the framework of the Medicines Act in 2004.

A manufacturer, importer, distributor or wholesaler may not charge any fee or amount other than the single exit price (SEP) in respect of the sale of a medicine or scheduled substance to a person other than the state.

Maximum allowable price increases are set by the Minister of Health (Minster) on an annual basis.

The extent to which the SEP of a medicine may be increased is determined by factors such as the average Consumer Price Index for the preceding year, the average Producer Price Index for the preceding year, changes in the rates of foreign exchange, purchasing power parity and the need to ensure the availability, affordability and quality of medicines and scheduled substances.

### **Benchmark pricing systems**

The Department of Health has indicated its intention to price medicines according to

an international benchmarking system that will essentially require the SEP of a particular medicine or scheduled substance to match the lowest price at which it is sold in a selected basket of countries, including South Africa.

Although proposed regulations relating to this benchmarking methodology were published during 2014, the regulations have not yet been finalised and have thus not yet come into force. It has, however, been industry practice for pharmaceutical companies to include, together with their applications for single exit pricing approval, information relating to the benchmark pricing of medicines and scheduled substances, in several other jurisdictions, including Australia, Canada, New Zealand and Spain.

### **Logistics fees**

Presently, the logistics fee payable to wholesalers and distributors is determined by agreement between the provider of logistical services and the relevant pharmaceutical manufacturer or importer.

On 18 September 2012, the Minister, on the recommendation of the Department of Health's pricing committee, published draft regulations that, once in force, would provide for a capped logistics fee.

Manufacturers/importers and wholesalers/distributors will still be free to negotiate logistics fees up to the capped maximum.

### **Incentives**

The Medicines Act prohibits the supply of any medicine according to a bonus system, rebate system or any other incentive scheme.

During December 2017, the Minister published proposed regulations (Proposed Fee Regulations) in terms of the Medicines Act, which are intended to provide further guidance regarding the prohibited activities included in section 18A of the Medicines Act.

More specifically, the Proposed Fee Regulations provide proposed definitions for each of the three prohibited activities, and further propose penalties for the transgression thereof.

### **Marketing and advertising**

The advertising and promotion of medicines to healthcare professionals and the public is regulated in terms of the SA Code of Marketing Practice (Code), which is intended to signify the industry's commitment to ensure that the marketing of health products is carried out in a responsible, ethical and professional manner.

The enforcement of the Code has been entrusted to a Marketing Code Authority and enforcement is generally based on the principle of self-regulation through the handling of complaints raised.

It is important to note that the advertising to the public of medicines listed per schedule 2 or above, is prohibited in terms of the general regulations published under the Medicines Act.

## **Consumer Protection Act (CPA)**

In terms of the CPA, strict liability is imposed on all persons in a supply chain, for example manufacturers, importers and/or retailers, in respect of harm caused wholly or partly as a consequence of supplying any unsafe goods, a product failure, defect or hazard in any goods, or inadequate instructions or warnings provided to the consumer pertaining to any hazard arising from or associated with the use of any goods.

Liability arises irrespective of whether the harm resulted from any negligence on the part of the producer, importer, distributor or retailer, as the case may be, and it is therefore important that we provide for suitable guarantees, warranties and indemnities between the manufacturers, imports and/or distributors.

## **Intellectual property (IP)**

The Cabinet of South Africa recently adopted and published a new intellectual property policy (IP Policy), that, inter alia, addresses proposed reforms to the IP regime in South Africa.

It is envisaged that government will leverage off of the flexibilities allowed in terms of the Trade-Related Aspects of Intellectual Property Right (TRIPS) rules of the United Nations and for the purpose of promoting public health, local manufacturing, research and development, transfer of technology, socio-economic development, etc.

This includes the introduction of a system of substantive search and examination (SEE) for patents to replace the current depository system in respect of certain fields of technology, with pharmaceuticals being identified as a prime candidate. It is envisaged that SEE will benefit patent holders by granting rigorously assessed rights and ensuring that market exclusivity is only granted when appropriate. In addition, it is also envisaged that new patentability criteria will be adopted to address South Africa's public health and environmental concerns, as well as industrial policy objectives.

## **Conclusion**

It is clear that the pharmaceutical regulatory environment in South Africa is complex and influenced by the country's socio-economic paradigm. We have also highlighted proposed regulations and the policies that are expected to give rise to new legislation over the coming months and years.

It is therefore imperative that manufacturers, importers, distributors, wholesalers and retailers of pharmaceuticals be fully apprised of their obligations and duties under the South African pharmaceutical regulatory regime and to ensure that risks are managed and the sustainability of their

business are ensured.

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