THE LIFE SCIENCES LAW REVIEW

SEVENTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

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PREFACE

The seventh edition of *The Life Sciences Law Review* covers a total of 34 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

The past year has seen a number of significant developments. After many years of negotiations and false starts, the United States and EU have finally begun to implement a programme of mutual recognition of inspections of drug manufacturing establishments, thus simplifying the shipment of drug products between the jurisdictions and freeing resources to carry out more inspections in third countries. In the meantime, the United States continues to debate whether to repeal the comprehensive medical care legislation enacted during the Obama administration, and is now considering measures to improve the transparency of pricing for prescription drugs. The United Kingdom is addressing changes to drug regulatory systems that must accompany the country's planned withdrawal from the EU, and drug and device manufacturers are actively planning for the effects of Brexit on their supply chains. The governments in India and China continue to consider changes in their regulatory systems for drugs and medical devices.

It is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems, which govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this annual publication will be helpful in this respect.

All of the chapters have been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2019

Chapter 26

SOUTH AFRICA

Vaughn Harrison, Mandi Krebs and Abrianne Marais[1]

I INTRODUCTION

The South African pharmaceutical environment is highly regulated. Recent amendments to the Medicines and Related Substances Act 101 of 1965 (the Medicines Act) brought about the replacement of the Medicines Control Council – the regulatory body responsible for the pharmaceutical industry, which reported to the National Department of Health (the Department of Health) – with the newly established South African Health Products Regulatory Authority (the Authority).

The Authority has a broader mandate than its predecessor, including the regulation of complementary and alternative medicines (CAMs) and medical devices. Being an independent organ of the state, the Authority levies fees in respect of applications for licensing and the registration of medicines.

II THE REGULATORY REGIME

i Classification

In terms of the Medicines Act, the term 'medicine' is broadly defined to include a substance (or mixture of substances) used, manufactured or sold for use in the diagnosis, treatment, mitigation, modification or prevention of disease or for restoring, correcting or modifying any somatic or psychic, or organic function in humans, and which includes any veterinary medicine.[2]

The term 'complementary medicine' is broadly defined to include a substance (or mixture of substances) that originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substances determined by the Authority and is used, manufactured or sold for use in maintaining, complementing or assisting the physical or mental state; or in the diagnosis, treatment, mitigation, modification, alleviation or prevention of disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human or an animal.[3]

CAMs are classified into sub-categories based on whether they constitute discipline-specific medicines (with such disciplines as may be determined by the Authority) or health supplements.

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1 Vaughn Harrison is a partner, Mandi Krebs is a senior associate and Abrianne Marais is an associate at Hogan Lovells (South Africa) Inc.

2 Section 1 of the Medicines Act.

3 Regulation 1 of the General Regulations, as amended, to the Medicines Act.

The term 'medical device' is broadly defined in the Medicines Act to mean any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, including certain hazardous substances intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following purposes such as the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury, the investigation, replacement, modification or support of the anatomy or of a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; or providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and that does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but that may be assisted in its intended function by such means.

The Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (the Foodstuffs Act) defines a 'foodstuff' as any article or substance (except a medicine as defined in the Medicines Act) ordinarily eaten or drunk by a person or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part or ingredient of any such article or substance.[4]

Consequently, if a product is a medicine, as contemplated in the Medicines Act, by definition it cannot be a foodstuff. Foodstuffs are not subject to any registration process in South Africa, however, the labels of all foodstuffs must comply with the provisions of the relevant labelling regulations,[5] as well as any guidelines published thereunder.

ii Non-clinical studies

The National Health Research Ethics Council, which was established under the National Health Act 61 of 2003 (the National Health Act) is, *inter alia*, authorised and mandated to set norms and standards with respect to research conducted on animal and human subjects.[6]

In terms of the General Regulations to the Medicines Act, as amended (the General Regulations), persons desiring to initiate or conduct a clinical study are required to apply to the Authority, in the prescribed form, for authorisation to conduct such a clinical study.[7]

Other legislation, guidelines and standards that must be taken into account when clinical studies are initiated and conducted include the Animals Protection Act 71 of 1962, the South African Medical Research Council's (SAMRC) Guidelines for Ethics of Medical Research: Use of Animals in Research and Training, and the South African Bureau of Standards' South African National Standard for the Care and Use of Animals for Scientific Purposes.

4 Section 1 of the Foodstuffs Act.

5 Labelling of Foodstuffs must comply with the provisions of the Regulations relating to the Labelling and Advertising of Foodstuffs (1 March 2010) as published under the Foodstuffs Act. Draft Regulations relating to the Labelling and Advertising of Foodstuffs (Draft Labelling Regulations) were published for comment on 29 May 2014. The Draft Labelling Regulations contain provisions regarding functional claims, and specify the manner in which such claims may be included on the label of a foodstuff.

6 Section 72(6) of the National Health Act.

7 Regulation 30 of the General Regulations.

iii Clinical studies

No person may conduct a clinical study without the authorisation of the Authority.[8]

Clinical studies in respect of living persons must comply with the provisions set forth in the following:

a the National Health Act and the Medicines Act, and the regulations thereto; and

b regulations, guidelines on ethics and professional standards and other norms and standards set by institutions such as the Department of Health, SAMRC and relevant Research Ethics Committees (RECs) such as the National Health Research Ethics Council, in respect of procedural and substantive matters.

In terms of the General Regulations, persons desiring to initiate or conduct a clinical study are required to apply to the Authority, in the prescribed form, for authorisation to conduct such a clinical study.[9] Such application must include, as a minimum, the clinical study protocol, the investigator's brochure, details regarding the investigators, supporting documents regarding the qualifications of the investigators, study insurance, professional indemnity insurance, participant information forms, informed consent documents and the approval by the relevant REC.[10]

All clinical studies must be conducted in accordance with guidelines for good clinical practice as may be determined by the Authority from time to time.

The person authorised by the Authority to conduct the clinical study is further required to submit milestone and special reports to the Authority.[11] Notwithstanding the latter, the principal investigator is also required to inform the Authority of any suspected adverse events, or safety concerns, occurring as a result of the use of any medicine during the conduct of a clinical study.[12]

iv Named-patient and compassionate use procedure

Access to unregistered pharmaceutical products may be achieved by means of submitting an application to the Authority in terms of Section 21 of the Medicines Act.

Although the Authority is empowered to authorise the supply of an unregistered medicine, this power is only exercised in emergency situations, in which case the requesting entity will be required to record the names of those persons to which the unregistered medicine is being supplied.

Section 21 Applications are generally made on a named-patient basis and must be initiated by the patient's treating physician. The Section 21 Applications must be on in the prescribed form and, *inter alia*, set out details regarding the unregistered medicine. A duly completed and witnessed informed consent document is also required.[13]

The person under whose supervision the unregistered medicine is prescribed, is required to submit a progress report to the Authority no later than six months after the commencement of the use of the unregistered medicine, or earlier if requested.

8 Regulation 30(5) of the General Regulations.

9 Regulation 30 of the General Regulations.

10 Regulation 30(2) of the General Regulations.

11 ibid.

12 Regulation 30(7) of the General Regulations.

13 ibid.

In addition, reporting in respect of the outcome of the treatment, as well as any adverse drug reaction, is required. A further progress report must be submitted to the Authority within 30 days after the completion or termination of the use of the unregistered medicine.[14]

In the case of unregistered biological medicines, the Authority may require that:

a the number of samples of every batch, together with one copy of the protocol in respect of the testing of the bulk batch and filling batch and one copy of the certificate of release issued by the competent authority in the country in which the biological medicine was manufactured, be submitted to the Authority as a batch release condition; and

b at least the number of samples of every batch, together with one copy of the protocol in respect of the testing of the bulk batch and filling batch of the biological medicine manufactured in South Africa, be submitted to the National Control Laboratory of the Authority, as a batch release condition.

v Pre-market clearance

The Medicines Act provides that, save for certain limited exceptions, no person shall sell any medicine that is subject to registration by virtue of a declaration published, unless it is registered.

The definition of 'sell' includes to import, offer or supply or dispose of a medicine to any person whether for a consideration or otherwise.

In principle, and in respect of a specific product, if the product falls within the broad definition of a medicine it will be subject to compulsory registration in terms of the Medicines Act if it is in a class or category of medicines that has been called up to registration by the Authority in terms of Section 14(2).

In terms of the Medicines Act, every application for the registration of a medicine, medical device or *in vitro* diagnostic (IVD) devices shall be submitted to the Authority in the prescribed form and shall be accompanied by the prescribed particulars, samples of the relevant medicines and the prescribed registration fee.[15]

If the Authority is satisfied that the medicine is suitable for the purpose for which it is intended, complies with the prescribed requirements, and is safe, efficacious and of good quality, the Authority is required to issue the applicant with a certificate of registration in respect of the relevant medicine.[16] Regard must also be had to the General Regulations and the forms and guidelines issued and revised from time to time by the Authority.

In South Africa, these registration certificates are not publicly available documents.

As regards the renewal of registration certificates, strictly speaking, the Medicines Act provides that the registration of medicines is valid for a period of five years, however, practically speaking, the pharmaceutical industry does not attend to the five-yearly renewal of any medicine registrations.

In recent years, CAMs have been called up by the Authority and are now subject to registration in accordance with the provisions of the Medicines Act. As such, the manufacturers, distributors, importers and exporters of CAMs are equally required to be licensed in accordance with the Medicines Act.

14 Regulation 29(3) of the General Regulations.

15 Section 15(1) of the Medicines Act.

16 Section 15(3) of the Medicines Act.

Subject to certain exceptions, medical devices were previously not heavily regulated in South Africa. Prescriptive requirements for medical devices were not in force and advertisers and marketers of medical devices had few legislative and regulatory formalities to comply with.

As of December 2016, the local regulatory framework governing medical devices underwent a substantial legislative change, requiring, *inter alia*, the registration of medical devices, the licensing of manufacturers, wholesalers and distributors of medical devices and further providing guidelines regarding the advertising and labelling of medical devices.

The primary purpose of the Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices (the Device Regulations) is to provide for the registration of medical and IVD devices, including matters related thereto.

vi Regulatory incentives

There is no connection between the regulatory approval process for medicines and the patent and intellectual property protection regime in South Africa.

South Africa currently has a deposit-based patent filing system with no examination and opposition. Accordingly, and provided that the prescribed formal requirement for the lodging of a patent is complied with, such application will be granted.

The Cabinet of South Africa recently adopted and published a new intellectual property policy[17] that, *inter alia*, addresses proposed reforms to the intellectual property 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 Rights rules of the World Trade Organization and for the purpose of promoting public health, local manufacturing, research and development, transfer of technology and socio-economic development.

This includes the introduction of a system of substantive search and examination (SSE) for patents to replace the current depository system in respect of certain fields of technology, with pharmaceuticals being identified as prime candidates. It is envisaged that SSE 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.

vii Post-approval controls

Persons that have applied for the registration of medicine and persons that are holders of certificates of registration (HCRs) with regard to medicines are required to inform the Authority of new or existing quality, safety or efficacy concerns related to any medicine or scheduled substance, including but not limited to any adverse drug reactions (ADRs).[18] In addition, such persons are required to maintain or have access to records of the reports and case reports made.

More generally, HCRs are required to have an appropriate pharmacovigilance system, which they must adequately maintain.[19]

17 Intellectual Property Policy of the Republic of South Africa Phase I (Notice 518 of 31 August 2018).

18 Regulation 40 of the General Regulations.

19 The Authority in its Post-marketing Reporting of Adverse Drug Reactions to Human Medicines in South Africa Guideline.

The Authority in its Post-marketing Reporting of Adverse Drug Reactions to Human Medicines in South Africa guideline sets out the framework that HCRs are required to follow in terms of reporting any ADRs. This guideline also addresses the management of safety data during post-registration and post-marketing clinical trials.

It is generally advisable that a suitably qualified pharmacovigilance officer be nominated by the responsible pharmacist.[20]

Certificates of registration may be transferred from the existing HCRs to any other appropriately licensed person, subject to an application being made in the prescribed form and the same being granted by the Authority.[21]

viii Manufacturing controls

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.

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 or the Pharmacy Act 53 of 1974 (the Pharmacy Act), or a failure to comply with GMP or GDP.

Manufacturers of medical devices must ensure that they have adequate quality management systems in place, with ISO 13485:2016 being the benchmark. The benefit of this is that manufacturers can decide whether or not they wish to have a quality management system for each of their sites or just one system that will apply to multiple sites.

ix Advertising and promotion

The advertising to the public of medicines listed per Schedule 2 or above is prohibited in terms of the General Regulations.

In addition, Regulation 21 of the Device Regulations provides that only Class A or Class B medical devices may be advertised to the 'public or a lay person'. In terms of the Device Regulations, Class A refers to medical devices that are classified as 'low risk', and Class B refers to medical devices that are classified as 'low–moderate risk'.

Advertisement is defined in the Medicines Act as, *inter alia*, as any written, pictorial, visual or other descriptive matter or verbal statement or reference that is intended to promote the sale of a product.

Furthermore, the advertising and promotion of medicines and medical devices to healthcare professionals and the public is regulated in terms of the South African Code of Marketing Practice for Health Products (the Code), a voluntary marketing code that 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.

20 ibid.

21 Section 15B of the Medicines Act.

x Distributors and wholesalers

Section 22C(6) of the Medicines Act provides that no manufacturer, wholesaler or distributor may manufacture, import, export, act as a wholesaler of or distribute, as the case may be, any medicine, scheduled substance or medical device, unless licensed.

In respect of a pharmaceutical manufacturer licence, this may include a licence to import or export medicines, or to act as a wholesaler of medicines.

Guidelines have been issued by the Authority, which are revised from time to time and relate to various matters including GMP and 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 (the 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 relevant 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 or the Pharmacy Act, or the failure to comply with GMP or GDP.

The Device Regulations provide, *inter alia*, for the following:

a the process for the application by a manufacturer, wholesaler or distributor of medical and IVD devices for a manufacturer, distributor or wholesaler licence. The Device Regulations go further to indicate the period of validity of a licence and provide for the renewal thereof; and

b details regarding the application process for the registration of medical and IVD devices as well as the classification thereof.

Notwithstanding the above, the Authority has not yet called up medical devices for registration; however, the Authority has initiated the licensing process for parties engaging in medical devices-related manufacturing, distribution and wholesale activities.

Applicants are required to appoint an 'authorised person', and the Device Regulations provide that such person needs to be 'suitably qualified' when it comes to the medical device or categories of medical devices held, imported or manufactured by the relevant applicant. If an applicant has multiple sites of manufacture and distribution, an application must be submitted per site, with an authorised representative appointed in respect of each site.

xi Classification of products

There are four basic categories of medicines, and each category is further subdivided into a number of listed pharmacological classes.

The four categories are:

a Category A: medicines that are intended for use in humans and that are, without manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine;

b Category B: medicines intended for use in humans and animals that cannot normally be administered without further manipulation;

c Category C: medicines intended for veterinary use that are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine; and

d Category D: complementary medicines intended for use in humans and animals that are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine.[22]

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

xii Imports and exports

No person may import or export any Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance, unless a permit has been issued by Director-General of the Department of Health in the prescribed manner.[23]

xiii Controlled substances

Schedule 0 medicines may be sold to the public in an 'open shop'.[24] This means that sales of such medicines are not restricted to pharmacies, whereas medicines of Schedule 1 and above may only be sold to the public in a pharmacy. Medicines of Schedule 3 and above require the prescription of a medical practitioner or another applicable healthcare professional.

xiv Enforcement

The Medicines Act, the regulations thereto and the National Health Act set out their own list of offences and penalties, and include both monetary penalties and criminal offences. In addition the Authority has wide powers that include the authority to launch inspections, request documents and information, and revoke and suspend registrations and licences.

III PRICING AND REIMBURSEMENT

i Transparent pricing

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 pharmaceutical 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 on an annual basis.

The extent to which the SEP of a medicine may be increased is determined by factors such as the increases in the average Consumer Price Index for the preceding year, the increase

22 Regulation 9 of the General Regulation.

23 Section 22A(11) of the Medicines Act.

24 The concept of an 'open shop' is included in Section 22A(3) of the Medicines Act; however, the term is undefined.

in 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 in South Africa.[25]

ii 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.

iii Logistics fees

Presently, any logistics fees 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 of Health, 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. However, these regulations have yet to be published in final form.

iv Incentives

The Medicines Act prohibits the supply of any medicine or medical device according to a bonus system, rebate system or any other incentive scheme (Prohibited Activities).

Although no definitions in respect of these Prohibited Activities have been included in the Medicines Act, considerable guidance as to the meaning thereof has previously been sought from a number of court decisions. However, on 1 December 2017, the Minister of Health published proposed regulations that are intended to provide further guidance regarding the Prohibited Activities included in the Medicine Act.

More specifically, the proposed regulations provide proposed definitions for each of the three Prohibited Activities, and further propose penalties for the transgression thereof.

v Health technology assessments

In respect of medical devices, health technology assessments (HTAs) are well established in South Africa and are often required by private healthcare organisations and medical schemes when assessing new technologies with regard to efficacy and cost.

Previously, it has been suggested that the Department of Health may consider directly establishing an HTA agency that will be independent and will undertake HTAs to support the key policy reforms in respect of health and medical care.

25 National Health Insurance Policy (Notice 627 of 30 June 2017).

However, and subsequent to the proposed implementation of the NHI scheme (detailed below), it is contemplated that an HTA Ministerial Advisory Committee will be established to advise the Minister of Health in respect of HTA, and which will serve as a precursor to an HTA Agency that will regularly review the available range of health interventions and technology, by using the best available evidence on cost-effectiveness, and allocative, productive and technical efficiency.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

The Promotion of Administrative Justice Act 3 of 2000 (PAJA) aims to promote the right to administrative action that is lawful, reasonable and procedurally fair. PAJA and the public law jurisprudence that have been developed over many years allow for a framework in which administrative action by the state and certain statutory bodies such as the Authority may be challenged.

However, the internal appeals process provided for in terms of the Medicines Act, and the regulations thereto, must be exhausted before the procedures and remedies available under PAJA may be pursued.

The Medicines Act does provide for the Minister of Health to confirm, set aside or vary a decision of the Director-General of Health, and in the case of the decisions by the Authority, such decisions may be considered by an appeal committee to be convened by the Minister of Health on request.

V FINANCIAL RELATIONSHIP WITH PRESCRIBERS AND PAYERS

The Health Professions Act 56 of 1974 (the Health Professions Act) and the various guidelines published by the Health Professions Council of South Africa, established under the Health Professions Act, are aimed at setting and maintaining excellent standards of ethical and professional practice by healthcare providers, and this includes the following restrictions:

a a healthcare practitioner may not participate in the manufacture for commercial purposes, or in the sale, advertising or promotion of any medicine or medical device;

b a healthcare practitioner may not participate in any other activity that amounts to selling medicine or medical devices to the public or keeping an open shop or pharmacy; and

c a healthcare practitioner shall not engage in or advocate the preferential use or prescription of any medicine or medical device that, save for the valuable consideration he or she may derive from such preferential use or prescription, would not be clinically appropriate or the most cost-effective option.[26]

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Consumer Protection Act

In terms of the Consumer Protection Act (CPA), strict liability is imposed on all persons in a supply chain, for example, manufacturers, importers, distributors and retailers, in respect

26 Ethical and Professional Rules of the Health Professions Council of South Africa – Booklet 2.

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 manufacturer, importer, distributor or retailer, as the case may be, and it is therefore important that provision is made for suitable guarantees, warranties and indemnities between all parties in the supply chain, including the manufacturers, importers and distributors.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

On 5 July 2018, the Competition Commission of South Africa (Commission) published its provisional findings and recommendations (the Provisional Report) in respect of an investigation held into the private healthcare market known as the Health Market Inquiry (HMI).

The HMI is focused primarily on determining the factors that presently, and allegedly, distort and lessen competition in the private healthcare sector, which encompasses numerous interrelated markets, and is aimed at improving competition and increasing transparency to allow for value purchasing.

The Commission has been tasked to make recommendations that support the achievement of accessible, affordable, high-quality and innovative private healthcare in South Africa, and following the publication of the Provisional Report, has requested that stakeholders engage with them and make submissions in relation to the Provisional Report. These submissions are still being considered, and as at the time of writing, the final report of the Commission has yet to be published.

Going forward, it is expected that the Commission's recommendations will materially influence the continued debate regarding the future regulatory structure of both the private and public healthcare sectors in South Africa, and will have far-reaching implications for all stakeholders including healthcare practitioners, healthcare establishments, businesses in the pharmaceutical and medical devices industries, healthcare funders, medical scheme members, and industry and statutory bodies.

VIII CURRENT DEVELOPMENTS

During 2018, the South African Cabinet approved the highly anticipated National Health Insurance Bill (the NHI Bill). The aim of the NHI scheme is to establish a single-payer and single-purchaser fund for all patients in South Africa.

It is intended that the NHI Bill will apply to public and private health establishments, which include institutions, facilities, buildings or places, whether for profit or not, that are operated or designed to provide in-patient or outpatient treatment, diagnostic or therapeutic interventions, nursing, or rehabilitative, palliative, convalescent, preventative or other health services.

It is proposed that the NHI scheme will be funded by means of cross-subsidisation of medical services. Currently, the reserves held by medical schemes are equivalent to 33 per cent, notwithstanding that statutorily the reserves required are 25 per cent.

In addition to the NHI Bill, the Cabinet approved the draft Medical Schemes Amendment Bill in 2018. This amendment bill proposes doing away with prescribed

minimum benefits and replacing them with 'basic benefits', but little guidance has been provided as to what this constitutes. Currently, medical schemes are required to cover the costs related to the diagnosis, care and treatment of those receiving prescribed minimum benefits. It can, however, be stated that much interaction will be required between the public and private sectors to finally modify, align, implement and fund the above-mentioned and proposed healthcare reforms.

Appendix 1

ABOUT THE AUTHORS

VAUGHN HARRISON

Hogan Lovells (South Africa) Inc

Vaughn Harrison is a partner at Hogan Lovells and has over 25 years' experience in the life science sector. This includes advising clients on market entry, including licensing, and obtaining market authorisations; classification and registration of medicines, complementary medicines and medical devices; assisting with labelling and advertising of pharmaceuticals, foodstuffs and personal use products; and drafting and vetting complex commercial agreements as well as assisting multinational clients with the preparation and vetting of tenders, pitches and contracts in the healthcare and pharmaceutical industries.

He also has experience in representing clients in the healthcare, pharmaceutical, medical devices, foodstuffs and related industries in litigation, arbitration and the resolution of disputes.

Over the years he has assisted numerous multinational groups and other clients in setting up and operating businesses in South Africa and the rest of Africa.

of the statutory framework governing Dubai Healthcare City's healthcare professionals and operators. Separately, she provides legal advice to various institutions, including the Health Promotion Board, the National University of Singapore and the National Council of Social Services.

MANDI KREBS

Hogan Lovells (South Africa) Inc

Mandi Krebs is a senior associate at Hogan Lovells and advises various multinational companies in the pharmaceutical and medical device industries on legal and regulatory matters, including marketing authorisations, licensing, product labelling, advertising and marketing activities as well as pricing and reimbursement matters in South Africa.

In addition, Mandi advises multinational pharmaceutical companies regarding market entry into various jurisdictions across Africa.

Mandi has valuable experience in advising clients on matters related to interactions with healthcare professionals and patients, reimbursement models, and challenging competitor's claims.

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