THE LIFE SCIENCES LAW REVIEW

Ninth Edition

Editor
Richard Kingham

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NINTH EDITION

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PREFACE

The ninth edition of *The Life Sciences Law Review* covers a total of 28 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 been dominated by the covid-19 pandemic, and this will undoubtedly be true of 2021 as well. Manufacturers of healthcare products have expedited the development and testing of drugs, biologics, diagnostics and personal protective equipment. Vaccines, many making use of novel technologies, have moved from the laboratory to the clinic and then to patients in record times; a matter of months rather than years or decades. Regulatory agencies have reviewed marketing applications with unprecedented speed and efficiency and international organizations have taken measures in an effort to ensure equitable access to medicines and vaccines in all countries.

In times such as these, 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 that 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 year's publication will be especially 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
February 2021

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Chapter 21

SOUTH AFRICA

Tyron Grant, Dirk Hanekom, Chyreene Truluck and Patrick O'Brien[1]

I INTRODUCTION

The South African Pharmaceutical sector is primarily regulated by The Medicines and Related Substances Act 101 of 1965 (Medicines Act).

A number of regulations to the Medicines Act have been published. The General Regulations to the Medicines and Related Substances Act, published under Government Notice 859 in Government Gazette 41064 of 25 August 2017 (General Regulations) deal with general issues including the supply and registration of medicines and the requirements for various permits and authorisations, such as clinical trials. There are also regulations that deal with specific issues including: (1) the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances published under Government Notice R1102 in Government Gazette 28214 of 11 November 2005 (Transparent Pricing Regulations); (2) Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices (IVDs) published under Government Notice 1515 in Government Gazette 40480 of 9 December 2016 (Medical Devices Regulations); and (3) Regulations Relating to the Period and Manner of Appeal Against Decisions of the Medicines Control Council published under Government Notice R906 in Government Gazette 14826 of 28 May 1993 (Appeal Regulations).

In addition, a number of Notices have been published in the Government Gazette relating to certain administrative aspects under the Medicines Act.

The Medicines Act is administered by the South African Health Products Regulatory Authority (SAHPRA), which took over administration of the Medicines Act from its predecessor, the Medicines Control Council (MCC). The MCC, and later the SAHPRA, have issued a number of guidelines relating to all aspects of approval of medicines.[2]

II THE REGULATORY REGIME

i Classification

The Medicines Act provides for the establishment of the SAHPRA, which oversees the registration of medicines, medical devices, and in vitro diagnostic medical devices (IVDs).

1 Tyron Grant is a partner, Dirk Hanekom is a partner, Chyreene Truluck is a partner and Patrick O'Brien is a candidate attorney at Spoor & Fisher.

2 The guidelines are available at www.sahpra.org.za/guidelines.

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The definition of 'medicines'[3] provided in the Medicines Act includes veterinary medicine, as well as complementary medicines.[4]

Medical devices include any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances (according to the Hazardous Substances Act No. 15 of 1973), which does not achieve its primary intended action by pharmacological, immunological or metabolic means. In terms of the Medicines Act, medical devices include devices for animal use.

Foodstuffs and cosmetics are regulated under the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (FCD Act). The definition of 'foodstuff'[5] provided in the FCD Act is fairly broad, and includes all products manufactured for human consumption, but excluding 'medicines' as defined in the Medicines Act.

Borderline cases frequently arise at the intersection of foods and complementary medicines, as well as complementary medicines and traditional Western medicines. The two main factors that affect the classification of such products are the presence or concentration of certain regulated ingredients and the nature of the claim or claims made in any packaging, labelling or advertising material.

The SAHPRA has issued a Guideline to assist manufacturers, importers, distributors and wholesalers of medical devices and IVDs in the classification of medical devices and IVDs.[6]

ii Non-clinical studies

The Medicines Act provides for access to unregistered medicines for non-clinical studies and clinical trials.[7] In terms of the relevant section, the SAHPRA may authorise the sale of an unregistered medicine to a specific person or institution for this purpose.

The General Regulations to the Medicines Act set out the requirements for the conduct of clinical trials and investigations for medicines. In terms of the General Regulations, the definition of 'clinical trial' includes studies involving animal subjects and the General

3 'Medicine' means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or restoring, correcting or modifying any somatic or psychic or organic function in humans; and includes any veterinary medicine.

4 'Complementary medicine' means any substance or mixture of substances that originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by the SAHPRA; is used or purporting to be suitable for use or manufactured or sold for use: in maintaining, complementing or assisting the physical or mental state; or to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human being or animal; and is used: as a health supplement; or in accordance with those disciplines as determined by the SAHPRA.

5 'Foodstuff' means any article or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)) 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.

6 'Classification of Medical Devices and IVDs', November 2019, www.sahpra.org.za.

7 Section 21(1) of the Medicines and Related Substances Act 101 of 1965.

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Regulations provide that anyone desiring to initiate or conduct such trials must apply to the SAHPRA for authorisation to conduct such a study.[8] There is little distinction between the relevant documentation required for approval of non-clinical studies and clinical trials.

One of the requirements for obtaining approval for conducting non-clinical studies is the submission of an approval by an Animal Ethics Committee for the study, where it involves research on animals.[9] The Animal Ethics Committee must conform to a South African National Standard for the care and use of animals for scientific purposes, developed and published in 2008 by the South African Bureau of Standards.[10] This standard aims to ensure the ethical and humane care of animals used for scientific purposes and encompasses all aspects of care, use of, or interaction with animals for scientific purposes, including field trials, product testing, diagnosis and the production of biological substances. It also details the terms of reference, membership and operation of institutional Animal Ethics Committees. In particular, Animal Ethics Committees must ensure that all scientific studies that involve the use of animals comply with relevant legislation. One such example is the Animals Protection Act 71 of 1962, which provides that it is a criminal offence to administer a poisonous or injurious drug or substance to any animal without reasonable cause.[11]

iii Clinical trials

As with non-clinical studies, the use of unregistered medicines for clinical trials may be authorised by the SAHPRA in terms of the Medicines Act.[12] Similarly, the requirements for the conduct of clinical trials and investigations for medicines are governed by the General Regulations to the Medicines Act and anyone desiring to initiate or conduct such trials must apply to the SAHPRA for authorisation to conduct such a trial by submitting the required fee, together with the stipulated information.[13]

When conducting clinical trials, it is a requirement that the investigators responsible for the sites where the trial is to be conducted are appropriately qualified and competent persons, registered with the relevant statutory health council, and resident in South Africa.[14] Further, when applying for authorisation, proof of current training in Good Clinical Practice of all investigators involved in the study is required[15] and a signed declaration by the applicant and all investigators indicating that they will comply with Good Clinical Practice as determined by the SAHPRA in the conduct of the trial must be furnished.[16] In this regard, the SAHPRA relies on the South African Good Clinical Practice Guidelines (GCP Guidelines)[17] as providing clearly articulated standards of Good Clinical Practice that address the South African realities and contexts, thereby ensuring that clinical trials involving South African human participants

8 Regulation 30(1) of the General Regulations, Government Notice 859 of August 2017.

9 Regulation 30(2)(k)(ii) of the General Regulations, Government Notice 859 of August 2017.

10 SANS 10386:2008 The Care and Use of Animals for Scientific Purposes. South African Bureau of Standards, 2008.

11 Section 2(n) of the Animals Protection Act 71 of 1962.

12 Section 21(1) of the Medicines and Related Substances Act 101 of 1965.

13 Regulation 30(1) and (2) of the General Regulations, Government Notice 859 of August 2017.

14 Regulation 30(2)(d) of the General Regulations, Government Notice 859 of August 2017.

15 Regulation 30(2)(f) of the General Regulations, Government Notice 859 of August 2017.

16 Regulation 30(2)(i) of the General Regulations, Government Notice 859 of August 2017.

17 Department of Health. *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa* (second edition). Pretoria, South Africa: Department of Health, 2006.

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are designed and conducted according to local requirements while at the same time aligning with sound scientific and ethical standards within the accepted international framework for good clinical practice.

Prior approval for the clinical trial must be obtained from any health research ethics committee registered with the National Health Research Ethics Council in terms of the National Health Act 61 of 2003 (Health Act).[18] The Health Act provides for the establishment of a National Health Research Ethics Council, which is a statutory body empowered to set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials.[19] Further, in terms of the Health Act, every institution, health agency and health establishment at which health research is conducted must establish or have access to a health research ethics committee registered with the National Health Research Ethics Council.[20] An underlying principle of health research ethics is that of prior informed consent, entrenched in the Health Act, which requires that research or experimentation on a living person may only be conducted with the written consent of that person after informing them of the objects of the research or experimentation and any possible consequences on his or her health.[21] Prior informed consent is also a requirement for an application for conducting a clinical trial in terms of the General Regulations to the Medicines Act, which stipulate that participant information and informed consent documents must be provided in the case of human trials.[22] The South African Good Clinical Practice Guidelines, referred to above, extensively cover the topic of informed consent as it pertains to clinical trials and detail the specific requirements in this regard.

In the case of clinical trials involving human participants, the applicant is also required to submit proof of current, relevant and appropriate study insurance for all participants and professional indemnity insurance for all investigators.[23] The SAHPRA has issued a guideline on Liability Insurance for Clinical Trials that clarifies the requirements of insurance for those who conduct clinical trials involving human participants.[24] In terms of this guideline, evidence of comprehensive no fault insurance for serious injury and harm or death should be provided by the sponsor, who should take responsibility of ensuring that participants are fully compensated. In addition, the sponsor must provide indemnification for all investigators and trial sites involved in their clinical studies in compliance with the protocol requirements. In cases where the investigators or site staff were negligent or did not comply with the protocol requirements, personal malpractice insurance would apply. The guideline also details the specific requirements for compensation and insurance in clinical trials involving humans.

In terms of reporting obligations on a person authorised to conduct a clinical trial by the SAHPRA, such person is required to submit progress reports to the SAHPRA every six months from the date of approval of the clinical trial application and 30 days after completion or termination of the clinical trial. In addition, a development safety update report must be submitted annually and a final safety report submitted 30 days after the completion or termination of the clinical trial. A final study report is required to be submitted

18 Regulation 30(2)(k)(i) of the General Regulations, Government Notice 859 of August 2017.

19 Section 72(6)(c) of the National Health Act 61 of 2003.

20 Section 73 of the National Health Act 61 of 2003.

21 Section 71(1) of the National Health Act 61 of 2003.

22 Regulation 30(2)(j) of the General Regulations, Government Notice 859 of August 2017.

23 Regulation 30(2)(g) of the General Regulations, Government Notice 859 of August 2017.

24 SAHPRA, Guideline on Liability Insurance for Clinical Trials, November 2019.

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within 180 days of completion or termination of the clinical trial.[25,26] Further, the principal investigator is required to inform the SAHPRA of any suspected adverse events or safety concerns occurring as a result of the use of any medicine during the conduct of a trial.[27] The SAHPRA has issued a guideline on Safety Reporting During Clinical Trials in South Africa. The guideline is intended to assist sponsors in the reporting of adverse drug reactions and serious adverse events occurring during clinical trials that may be related to the investigational product or the conduct of the trial and provide a framework for the minimum requirements for the information required.[28]

iv Named-patient and compassionate use procedures

Section 21 of the Medicines Act is worded broadly enough to provide for the use of unregistered medicines in non-clinical studies and clinical trials, as well as for compassionate use. The General Regulations to the Medicines Act also govern authorisation for unregistered medicines other than a clinical trial and set out the requirements for an application for such authorisation.[29]

The application process for such authorisation has been simplified through the introduction of an online submission form that is completed by the applicant and the decision of the SAHPRA is provided to the applicant via electronic mail, typically within 1 or 2 working days.[30]

The application must be made by a treating medical practitioner by submitting the online application form, together with (1) a product brochure containing the relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human or animal pharmacological and clinical data; (2) a witnessed informed consent document, where applicable; (3) details of registration or pending registration of the medicine with any other regulatory authority, if available; (4) evidence of compliance of the manufacturer of the medicine with Good Manufacturing Practice standards; and (5) reasons why a South African registered medicine cannot be used.[31]

The person under whose supervision the unregistered medicine or substance is prescribed must submit any adverse event report to the SAHPRA and must also provide the SAHPRA with progress reports after six months from commencing use of the unregistered medicine, as well as a progress report 30 days after the completion or termination of the use of the medicine.[32]

Authorisation typically lasts for six months, after which reauthorisation may be applied for, online.

A different process applies to complementary medicines, medical devices and veterinary medicines, although the principles are the same.

25 Regulation 30(6) of the General Regulations, Government Notice 859 of August 2017.

26 The six-monthly progress report form template and development safety update report template are available from the SAHPRA (www.sahpra.org.za/clinical-trials-application-and-report-forms).

27 Regulation 30(7) of the General Regulations, Government Notice 859 of August 2017.

28 SAHPRA. Guideline on Safety Reporting During Clinical Trials, November 2019.

29 Regulation 29 of the General Regulations, Government Notice 859 of August 2017.

30 www.sahpra.org.za/unregistered-products/.

31 Regulation 29(2) of the General Regulations, Government Notice 859 of August 2017.

32 Regulation 29(3) of the General Regulations, Government Notice 859 of August 2017.

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v Pre-market clearance

In terms of the Medicines Act, no person may sell any medicine, medical device or IVD unless it complies with the relevant prescribed requirements.[33] The prescribed requirements include a requirement that the medicine, medical device or IVD must be registered with the SAHPRA.[34]

Medicines

Any person[35] residing in South Africa may make an application for the registration of a medicine.[36] The application for registration must be submitted for review and approval by the SAHPRA and must be accompanied by: a screening form, a proposed label for use on the medicine, a copy of the manufacturing licence together with the current Good Manufacturing Practice certificate from the regulatory authority of the country where the medicine is manufactured (if applicable), a certified copy of a permit to manufacture specified Schedule 5, Schedule 6, Schedule 7 and Schedule 8 substances, all available data on the safety, efficacy and quality of the medicine, proof of the existence of a manufacturing site licence; and the applicable application fee.[37]

An application for registration of a medicine is required to contain the particulars of the applicant and the prospective holder of the certificate of registration and particulars of the medicine.[38] Separate applications are required for each individual dosage form and strength of a medicine.[39] If the medicine has been registered by a regulatory body outside of South Africa, the applicant is required to submit a copy of the certificate of registration, professional information relating to the medicine and any conditions relating to the registration.[40]

Medical devices

Any person[41] residing or doing business in South Africa may make an application for the registration of a medical device or IVD.[42] The application for registration must be submitted for review and approval by the SAHPRA and must be accompanied by: a complete application form, a proposed label for use on the medical device or IVD, instructions for use, a copy of the manufacturer licence or distributor licence together with a conformity assessment certificate issued by a Conformity Assessment Body, and the applicable application fee.[43]

An application for registration of a medical device or IVD is required to contain the particulars of the prospective holder of the certificate of registration and particulars of the

33 Section 19(1) of the Medicines and Related Substances Act 101 of 1965.
34 Section 15 of the Medicines and Related Substances Act 101 of 1965.
35 A 'person' means both a natural and a legal person.
36 Regulation 16(1) of the General Regulations, Government Notice 859 of August 2017.
37 Regulation 16(2) of the General Regulations, Government Notice 859 of August 2017.
38 Regulation 16(5) of the General Regulations, Government Notice 859 of August 2017.
39 Regulation 16(7) of the General Regulations, Government Notice 859 of August 2017.
40 Regulation 16(8) of the General Regulations, Government Notice 859 of August 2017.
41 A 'person' means both a natural and a legal person.
42 Regulation 8 (1) of the Regulations Relating to Medical Devices and In vitro Diagnostic Medical Devices (IVDs), Government Notice 1515 of December 2016.
43 Regulation 8 (3) of the Regulations Relating to Medical Devices and In vitro Diagnostic Medical Devices (IVDs), Government Notice 1515 of December 2016.

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medical device or IVD.[44] A medical device or IVD, must comply with the Essential Principles for Safely and Performance of Medical Devices, which includes requirements for quality, safety and performance.[45] Separate applications are required for each individual medical device or IVD or modification thereof.[46] If the medical device or IVD has been registered by a regulatory body outside of South Africa, the applicant is required to submit a copy of the certificate of registration or premarket approval, instructions for use and any conditions relating to the registration.[47]

vi Regulatory incentives

There is no link between the regulatory regime and patents in South Africa.

South African law does not make provision for the extension of the term of a patent, or patent linkage, in any way. In fact, Section 69A(1) of the Patents Act No. 57 of 1978 (Patents Act) provides that, in certain circumstances, actions taken towards obtaining, development and submission of information for regulatory approval will not be considered an act of patent infringement.[48] However, this section is followed by Section 69A(2), which provides that stockpiling is prohibited and not covered by the provisions of Subsection (1).[49]

There are no provisions in the Patents Act or the Medicines Act that provide for regulatory data exclusivity.

Although the Medicines Act provides for the 'Preservation of Secrecy' under Section 34 thereof, other sections of the Medicines Acts and the Patents Act provide for alternative measures for the supply of more affordable medicines, and to enable and encourage early registration of generic pharmaceutical products.

Most notably, Section 15C of the Medicines Act provides for parallel importation of medicines into South Africa,[50] while Section 69A of the Patents Act provides that certain acts

44 Regulation 8 (5) of the Regulations Relating to Medical Devices and In vitro Diagnostic Medical Devices (IVDs), Government Notice 1515 of December 2016.

45 Regulation 8 (6) of the Regulations Relating to Medical Devices and In vitro Diagnostic Medical Devices (IVDs), Government Notice 1515 of December 2016.

46 Regulation 8 (8) of the Regulations Relating to Medical Devices and In vitro Diagnostic Medical Devices (IVDs), Government Notice 1515 of December 2016.

47 Regulation 8 (9) of the Regulations Relating to Medical Devices and In vitro Diagnostic Medical Devices (IVDs), Government Notice 1515 of December 2016.

48 Section 69A(1) of the Patents Act 57 of 1978, states 'it shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture production, distribution, use or sale of any product.'

49 Section 69A(2) of the Patents Act 57 of 1978, states 'it shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection.'

50 The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may: (1) notwithstanding anything to the contrary contained in the Patents Act 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent; (2) prescribe the conditions on which any medicine that is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration

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on a non-commercial scale and performed solely for the purposes reasonably related to the obtaining, development and submission of regulatory information will not be considered acts of infringement. The requirements for valid parallel importation are expanded on in a guidelines document issued by the SAHPRA.[51]

South African law also does not make any special provision relating to products for rare diseases, or products for special paediatric use.

vii Post-approval controls

The General Regulations of the Medicines Act state that any person, holder of a certificate of registration or licensee in respect of a medicine or scheduled substance must inform the SAHPRA of any new or existing quality, safety or effectiveness concerns related to any medicine or scheduled substance, including but not limited to adverse drug reactions.[52] The person, certificate holder or licensee must also maintain and provide access to case reports relating to any quality, safety or effectiveness concerns, if so required.[53]

The Medicines Act and the General Regulations also place an obligation on healthcare providers, veterinarians or any other persons to report any suspected adverse drug reactions or any safety, quality or effectiveness concerns, occurring as a result of the use of any medicine or scheduled substance.

In addition to the General Regulations, the SAHPRA has also published specific guidelines that are to be used to report any quality, safety or effectiveness concerns or any adverse effects in relation to a medicine, scheduled substance, medical device or IVD.

viii Manufacturing controls

The Medicines Act provides for the licensing of manufacturers, wholesalers, distributors, importers and exporters, and for exemptions from the regulation and control of the manufacture of medicines, medical devices and IVDs.[54]

Manufacturers of unregistered medicinal products, such as investigational medicinal products, are also controlled in accordance with the relevant provisions of the Medicines Act and the regulations.

In addition to the relevant licence from the SAHPRA, an applicant will require a site licence from the National Department of Health, and a licence as a Manufacturing Pharmacy from the South African Pharmacy Council (SAPC).

In terms of the Medicines Act, 'manufacture' means all operations including purchasing of material, processing, production, packaging, releasing, storage and shipment of medicines and related substances in accordance with quality assurance and related controls, and 'manufacturer' means a person manufacturing a medicine and includes a manufacturing pharmacy.

certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the Authority in the prescribed manner, may be imported; (3) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (2).

51 Guideline for Parallel Importation of Medicines in South Africa, June 2003, www.sahpra.org.za.

52 Regulation 40(1) of the General Regulations, Government Notice 859 of August 2017.

53 Regulation 40(2) of the General Regulations, Government Notice 859 of August 2017.

54 Section 22C of the Medicines and Related Substances Act 101 of 1965.

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The application for a manufacturer's licence should include the qualification of staff to manufacture, store, distribute and sell medicines, scheduled substances or medical devices and documentary proof of the ability to comply with good manufacturing practices (GMP) as determined by the SAHPRA.[55]

The application should include, as proof of compliance with GMP, a Site Master File, which must contain specific and factual information about the production or control of the pharmaceutical manufacturing operations to be carried out by the applicant.

The application should include:

a a copy of the local area plans of the location of the business premises indicating all adjacent properties and the nature of the business being carried out on such premises;

b a floor plan of the building in which the business premises are situated;

c a plan of the actual layout of the business premises;

d an inventory of equipment to be used in conducting the business; and

e a manual of procedures and practices to be implemented to ensure the safety, efficacy and quality of medicines or scheduled substances or medical devices to be manufactured or distributed and sold.

ix Advertising and promotion

The advertising of medicines is primarily regulated by the Medicines Act, and the regulations made thereunder.

The medicines and medical device industry is further self-regulated under the South African Code of Marketing Practice for Health Products (Marketing Code) of the Marketing Code Authority, as well as the Medical Device Code of Ethical Marketing and Business Practice published by the South African Medical Technology Industry Association (SAMED).

In addition, the Consumer Protection Act[56] (CPA) also applies to the advertising and marketing of medicines and related products to the consumer. Finally, the Code of Advertising Practice of the Advertising Regulatory Board (ARB) is a self-regulatory code that regulates advertising in general. The main thrust of the ARB code is that advertising may not be misleading in any way.

Schedule 0 and 1 medicines, known as over the counter (OTC) medicines, can be advertised to the general public. Medicines in Schedules 2 to 6 require a prescription from a healthcare provider and may not be advertised to the general public and can only be advertised in relevant publications directed at healthcare professionals and administrative personnel.

x Distributors and wholesalers

The Medicines Act provides for licensing under Section 22C thereof, including the licensing of wholesalers and of medicines, medical devices and IVDs.

Further, the definition of 'manufacture' provided in the regulations to the Medicines Act includes the purchasing of material, processing, production, packaging, releasing, storage and shipment of medicines and related substances in accordance with quality assurance and related controls. 'Manufacturer' means any person manufacturing a medicine, and

55 South African Guide to Good Manufacturing Practice, December 2017, www.sahpra.org.za.

56 Consumer Protection Act 68 of 2008.

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includes a manufacturing pharmacy. 'Wholesaler' includes a wholesale pharmacy and means a person who holds, stores, delivers or purchases medicines or scheduled substances from a manufacturer and sells them in terms of Section 22H of the Medicines Act.

In terms of Section 22H, a wholesaler is prohibited from purchasing medicines, scheduled substances, medical devices or IVDs from any source other than the original manufacturer or primary importer of the finished product.

In addition to the general GMP guidelines for manufactures, the SAHPRA has provided guidance in two further guideline documents relating specifically to wholesalers.[57,58]

xi Classification of products

In terms of the General Regulations made under the Medicines Act, medicines in South Africa are classified into four categories:[59]

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

b Category B: medicines intended for use in humans or animals, which cannot be administered in the normal course without further manipulation;

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

d Category D: complementary medicines intended for use in humans or animals that are ready for administration without the need for any manipulation, including packaged preparations where only a vehicle is added.

Medicines are further classified into sub-classes according to Annexures 1 and 2 appended to the General Regulations[60] made under the Medicines Act.

The Medicines Act further classifies medicines into schedules that effectively impacts on the advertising and dispensing thereof.

The scheduling of medicines and products containing substances already listed in the schedules, as well as new chemical entities not yet provided for in the schedules, forms part of the medicine registration process. More information on the scheduling of medicines in South Africa is provided in a scheduling guidelines document issued by the SAHPRA.[61]

57 South African Guide to Good Wholesaling Practice for Wholesalers, July 2016, www.saphra.org.za.

58 Guideline for the Exportation of Medicinal Products by Wholesalers, May 2016, www.sahpra.org.za.

59 Regulation 9 of the General Regulations, Government Notice 859 of August 2017.

60 General Regulations, Government Notice 859 of August 2017.

61 Guideline to the Scheduling of Medicines, November 2019, www.sahpra.org.za.

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xii Imports and exports

The Medicines Act only allows a person[62] who has been licenced in terms of the Act to import registered medicines, unregistered medicines and scheduled substances into the Republic of South Africa.[63] Additionally, medicines and medical substances may only be imported through the Cape Town, Port Elizabeth and Durban international airports and harbours and through the Johannesburg international airport.[64]

The SAHPRA may issue licences for either the manufacture, import or export of a medicine or scheduled substance or for any combination of the aforementioned. The application for a licence is submitted to the Chief Executive Officer of the SAHPRA and must include: (1) details of the owner of the business; (2) proof of registration of the responsible pharmacist with the South African Pharmacy Council; and (3) details of the qualifications of the key personnel responsible for manufacture, storage, distribution and sale of the medicine or scheduled substances. The applicant must also show the ability to comply with good manufacturing, wholesaling or distribution practices as determined by the SAHPRA.[65] Additionally, the applicant must pay the prescribed fee, provide any further information as may be required and specify the medicines or scheduled substances that it proposes to import or export.[66]

It is incumbent on the applicant for a licence to appoint a responsible pharmacist who will control the importation, exportation, manufacturing, wholesaling and distribution of the medicine or scheduled substance. The applicant is also required to appoint and designate a natural person who resides in South Africa as the person responsible for compliance with the Medicines Act.[67] A licence is valid for a period of five years, subject to the payment of annual renewal fees.

In addition to the above, an applicant wanting to import or export any specified Schedule 5 to 8 substance is required to obtain a permit from the Director-General: Health to do so.[68] A permit to import or export any Schedule 5 to 8 substance is only valid for a period of six months, subject to the applicant meeting certain conditions.[69] Further, should an applicant wish to import a Schedule 5 to 8 substance, they are also required to submit a certified copy of a permit for exportation issued by the country from which the substance is to be exported.[70]

Specific provisions to ensure the supply of affordable medicines in South Africa were introduced into the Medicines Act in 2011.[71] These measures were introduced to ensure equitable access to medicines for all South Africans. These provisions allow the Minister of

62 A 'person' means a natural or a juristic person.

63 Regulation 6(2) of the General Regulations, Government Notice 859 of August 2017.

64 Regulation 6(1) of the General Regulations, Government Notice 859 of August 2017.

65 South African Guide to Good Manufacturing Practice, December 2017, www.sahpra.org.za.

66 Regulation 23(1) of the General Regulations, Government Notice 859 of August 2017.

67 Regulation 23(2) of the General Regulations, Government Notice 859 of August 2017.

68 Section 22A(11) of the Medicines and Related Substances Act 101 of 1965.

69 Regulation 27 of the General Regulations, Government Notice 859 of August 2017.

70 Regulation 27(2) of the General Regulations, Government Notice 859 of August 2017.

71 Section 15C of the Medicines and Related Substances Act 101 of 1965.

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Health to prescribe that certain rights of an owner of a patented medicine, which is registered in South Africa, are limited and do not extend to certain acts of infringement by a third party when it comes to providing access to affordable medicines.[72]

Additionally, the amendment to the Medicines Act also allows the Minister, in certain instances, to prescribe conditions for the parallel importation of medicines into South Africa.[73]

xiii Controlled substances

South Africa is a signatory to the Single Convention on Narcotic Drugs of 1961 (as amended in 1972); the Convention on Psychotropic Substances of 1971; and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. These conventions place an obligation on the signatories to ensure that applicable control measures are put in place to ensure the availability of narcotic drugs and psychotropic substances, including precursors of such drugs and substances, for medical and scientific purposes, while at the same time preventing their diversion into illicit channels.

Consequent to its accession to these conventions, South Africa made relevant amendments to the Medicines Act and it enacted the Drugs and Drug Trafficking Act (1992). The provisions of the Drugs and Drug Trafficking Act apply in addition to, and not in substitution for the provisions of the Medicines Act.

In terms of the Medicines Act, the substances listed in Schedules 5 to 8 of the Act, which include narcotic drugs and psychotropic substances, are regulated more strictly than other scheduled drugs and substances. The Medicines Act provides that the importation, exportation, acquisition, use, possession, manufacture and supply of a controlled substance requires a permit issued by the Director General: Health to regulate the movement and trade in these substances.[74] Before any controlled substance is imported into South Africa, the applicant must submit a copy of the permit for exportation issued by the country from which the substance is to be exported. Additionally, the holder of a permit is required to submit information relating to the quantity of the substance held in stock, acquired, used, imported or produced in a given year to the Chief Executive Officer of the SAHPRA.[75]

xiv Enforcement

There are a large number of regulatory requirements as well as industry codes of practice applicable to medicines and medical devices, each with its own enforcement procedures. The most important legislative regulations include the Health Act, the Medicines Act and the Health Professions Act 56 of 1974 (Health Professions Act). Under the Medicines Act, inspectors may at all reasonable times enter any place or premises relating to medicines or medical devices under the Medicines Act, or where inspectors suspect that an offence has been committed; may inspect any medicine or medical device; may seize any such medicine or

72 Section 15C(a) of the Medicines and Related Substances Act 101 of 1965, and Regulation 5 of the General Regulations, Government Notice 859 of August 2017.

73 Section 15C(b) of the Medicines and Related Substances Act 101 of 1965, and Regulation 5 of the General Regulations, Government Notice 859 of August 2017.

74 Section 22A(12) of the Medicines and Related Substances Act 101 of 1965.

75 Regulation 28 of the General Regulations, Government Notice 859 of August 2017.

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medical device as evidence of a contravention; and may take so many samples as necessary for the purpose of testing and analysis.[76] Any person convicted of a offence under the Medicines Act is liable to a fine or imprisonment.[77]

Similarly, a health officer and an inspector under the Health Act may enter any premises or health establishment at any reasonable time to inspect it and ensure compliance with the Health Act, and may take samples of any substance or photographs relevant to the inspection.[78] Search and seizures may also be conducted with a warrant. The Office of Health Standards Compliance may, in respect of non-compliance with a compliance notice issued by an inspector or health officer, issue a written warning, require a written response, recommend appropriate action to the relevant authority, revoke compliance certificates, impose fines or refer the matter to the National Prosecuting Authority for prosecution.[79] Any person convicted of an offence is liable to a fine, to imprisonment or to both a fine and imprisonment.[80]

Health professions and healthcare professionals are regulated by the Health Professions Act. The Health Professions Act empowers the Health Professions Council of South Africa and subordinate professional boards to institute an enquiry into any complaint or allegation against a healthcare professional registered under the Act.[81] If found guilty of improper or disgraceful conduct, a healthcare professional is liable to a number of penalties, including a caution, suspension, removal of his or her name from the register, a fine, or a compulsory period of professional service.[82]

III PRICING AND REIMBURSEMENT

The Medicines Act was amended in 1997 to ensure a transparent pricing system and to establish a Pricing Committee tasked with overseeing the pricing of medicines and scheduled substances.[83] The Regulations made in terms of Section 22G(2) of the Medicines Act establish a single exit price[84] which is the only price at which manufacturers are permitted to sell medicines and scheduled substances to any person other than the state. According to the Medicines Act, no pharmacist, wholesaler, distributor or anyone permitted to sell medication may sell a medicine at a price higher than the single exit price. A dispensing fee may be charged; however, this is also regulated.

76 Section 28(1) of the Medicines and Related Substances Act 101 of 1965.

77 Section 30(1) of the Medicines and Related Substances Act 101 of 1965.

78 Section 82(1) of the National Health Act 61 of 2003.

79 Section 82A of the National Health Act 61 of 2003.

80 Section 89 of the National Health Act 61 of 2003.

81 Section 41 of the Health Professions Act 56 of 1974.

82 Section 42 of the Health Professions Act 56 of 1974.

83 Section 22G was inserted by Section 14 of the Medicines and Related Substances Control Amendment Act 90 of 1997 and was later amended by Section 8 of the Medicines and Related Substances Amendment Act 59 of 2002.

84 The Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances define the 'single exit price' as the price set by the manufacturer or importer of a medicine or scheduled substance in terms of these regulations combined with the logistics fee and VAT and is the price of the lowest unit of the medicine or scheduled substance within a pack multiplied by the number of units in the pack (where 'VAT' is the value added tax as contemplated in the Value Added Tax Act 89 of 1991).

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The single exit price is made up of the price determined by the manufacturer or importer, a logistics fee and VAT. In terms of the Regulations, the manufacturer or wholesaler must publish a schedule specifying the single exit price of a medicine or scheduled substance, as well as the logistics fee, together with its proprietary name, generic or approved name, quantity of each active ingredient, as well as the therapeutic category, schedule and pharmacological class of the medicine or scheduled substance.[85]

The logistics fee is determined by agreement between a logistic services provider and the manufacturer or importer, provided that it must be less than the maximum logistics fee set by the Pricing Committee.[86]

The Regulations further restrict any increase of the single exit price, both in terms of frequency and quantum.[87]

Retailers must ensure that the single exit price appears clearly and legibly on the medicine packaging and display a notice indicating the maximum fee structure used to determine the dispensing fee. In addition, at the time of the sale of a medicine to a user, the user must be provided with an invoice that clearly shows both the single exit price of the medicine and the dispensing fee.[88]

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Remedies for administrative decisions in South Africa are governed by the Promotion of Administrative Justice Act 3 of 2000 (PAJA). A decision (or failure to take a decision) by any organ of state, or natural or juristic person exercising a public power or function, that adversely affects the rights of any person and that has a direct, external legal effect, is subject to review under a number of circumstances. The grounds for review include that the administrator was not authorised, a compulsory and material requirement was not complied with, the action was procedurally unfair, the action was materially influenced by an error in law, the action was taken for an ulterior purpose, or the action was unlawful or unconstitutional.[89] Judicial review proceedings must be brought without unreasonable delay and no later than 180 days after the administrative action or after an internal remedy has first been exhausted, where provided for in a relevant law.[90] The court or tribunal in judicial review proceedings may give an order that is just and equitable, including an interdict, setting aside the administrative action, declaring the rights of the parties and granting other temporary relief.[91]

Under the Medicines Act and its General Regulations, any person aggrieved by a decision of the Director-General (D-G) may within 30 days from the date of receiving a written decision of the D-G make written representations regarding that decision to the

85 Regulation 3 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, Government Notice R1102 of 2005.

86 Regulation 5(2)(f) and Regulation 5(2)(g) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, Government Notice R1102 of 2005.

87 Regulations 7, 8 and 9 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, Government Notice R1102 of 2005.

88 Regulation 4 and Regulation 10(3) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances, Government Notice R1102 of 2005.

89 Section 6(2) of the Promotion of Administrative Justice Act 3 of 2000.

90 Section 7(1) of the Promotion of Administrative Justice Act 3 of 2000.

91 Section 8(1) of the Promotion of Administrative Justice Act 3 of 2000.

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Minister.[92] The Minister may confirm, set aside or vary the decision of the D-G. A decision of the SAHPRA may be appealed against by an aggrieved person within 30 days of the decision by notice to the Chief Executive Officer (CEO) of the SAHPRA. The CEO must meet with the appellant to try to resolve the matter, failing which the Minister must be requested to convene an appeal committee.[93] A decision of the appeal committee may be subject to judicial review by the High Court if a party is aggrieved by that decision.[94]

Appeal and review procedures under various other pieces of relevant legislation are also provided for,[95] as well as for national industry organisations in respective codes of practice.[96]

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

Financial relationships between prescribers and payors are regulated under the Health Professions Act and the Medicines Act,[97] as well as under codes of practice of national industry organisations. Under the Health Professions Act, a medical practitioner may generally not manufacture, sell, advertise or promote medicines or medical devices.[98] Further, a practitioner may not advocate the preferential use or prescription of any medicine or medical device that is not clinically appropriate or most cost-effective.[99] A practitioner may, however, own shares in a listed company, or manufacture or market medicines in the course of employment by a pharmaceutical entity, subject to the provision that a notice is displayed in the practitioner's waiting room and that a patient is informed of the financial interest in a listed company or the employment by a pharmaceutical entity that manufactures and markets a medicine or medical device prescribed to the patient.[100]

Under the Medicines Act, no person may supply any medicine or medical device in terms of a bonus, rebate or other incentive system.[101]

Industry codes provide in general that there should be no undue enrichment of healthcare professionals, and that no gifts, rebates, discounts, kickbacks or other financial advantages should be offered to healthcare professions as an enticement to prescribe, lease, supply, stock, dispense, administer or buy any medicines or medical devices.[102]

92 Section 24 of the Medicines and Related Substances Act 101 of 1965, read with Regulation 47 of the General Regulations, Government Notice 859 of August 2017.

93 Section 24A of the Medicines and Related Substances Act 101 of 1965, read with Regulation 48 of the General Regulations, Government Notice 859 of August 2017.

94 Section 24A of the Medicines and Related Substances Act 101 of 1965.

95 See, for example, Sections 100, 101 and 115 of the Consumer Protection Act and Section 88A of the National Health Act 61 of 2003.

96 See, for example, the Advertising Regulatory Board Code Procedural Guide; chapter 16 of the Marketing Code Authority's 'The South African Code of Marketing Practice for Health Products' Code and Guideline, Version 13, 23 July 2020 (Marketing Code); and part 2 of the South African Medical Technology Industry Association Medical Device Code of Ethical Marketing and Business Practice, Version 6 (SAMED Code).

97 The Prevention and Combating of Corrupt Activities Act 12 of 2004 additionally provides general laws aimed at the prevention and combating of corruption.

98 Ethical Rules of Conduct for Practitioners Registered under the Health Professions Act 56 of 1974.

99 ibid.

100 ibid.

101 Section 18A of the Medicines and Related Substances Act 101 of 1965.

102 See Chapter 7 of the Marketing Code and Part 1, Chapter 3 of the SAMED Code.

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VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Personal injury claims fall within the common law of delict in general, for which liability follows culpable conduct that is wrongful and that causes damage. Compensation may be sought from the courts in this regard, and the specific liability and compensation systems discussed below do not exclude the jurisdiction of the courts. Specific liability and compensation systems for medicines and medical devices is provided for under the Health Act and the GCP Guidelines. Regulations under the Health Act specify that research involving human participants must make provision for compensation for research-related injury, for more than minimal risk research, and participants must be informed of the potential harms and risks of harm posed by the research.[103]

All participants in clinical trials must be covered by comprehensive insurance for injury and damage.[104] A sponsor is liable to pay compensation for bodily injury, including death when, on a balance of probabilities, the injury was caused to the participant by the medical product under the trial. Compensation is not payable for temporary pain or less serious complaints. Compensation is payable irrespective of whether or not there was negligence by the sponsor or the fact that the participant consented to the trial. Certain exclusions in respect of compensation are provided for in the GCP Guidelines.[105]

General product liability, which is also applicable to medicines and medical devices, is provided for in the CPA. A producer, importer, distributor or retailer of any goods is liable for any harm (including illness, injury or death) resulting from the supplying of unsafe goods, a product failure or hazard, or inadequate instructions or warnings, irrespective of whether or not the producer, importer, distributor or retailer was negligent.[106] Provision is also made for vicarious liability of an employer or principal for liable conduct of an employee or agent acting within the course of his or her employment or mandate.[107] The CPA also further provides for restrictions on risk and limiting supplier liability.[108]

103 Regulations Relating to Research with Human Participants, Government Notice R719 of 2014.

104 Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (second edition), Pretoria: Department of Health, 2006.

105 id., Chapter 4.11.

106 Section 61 of the Consumer Protection Act 68 of 2008.

107 Section 113 of the Consumer Protection Act 68 of 2008.

108 See Sections 49, 51 and 58 of the Consumer Protection Act 68 of 2008.

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VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

South African public competition law is governed by the Competition Act 89 of 1998 (Competition Act). The Competition Act does not have specific provisions relating to medicines or medical devices. However, provisions that are of particular relevance to the pharmaceutical industry include prohibitions against dominant firms engaging in excessive pricing,[109] exclusionary conduct[110] and price discrimination.[111]

Around 2017, the South African Competition Commission identified the healthcare sector, and in particular pharmaceuticals, as an important sector for the enforcement of anticompetitive behaviour because of the potentially significant impact such behaviour would have on consumers, in particular the poor and vulnerable.[112] The Competition Commission launched investigations in 2017 against five dominant pharmaceutical companies for alleged anticompetitive behaviour, in particular the three prohibitions mentioned above, relating to cancer drugs. The investigations into two of the companies were dropped by the Competition Commission in late 2017 and at least two of the other three investigations are still ongoing. If these investigations are referred to the Competition Tribunal, they will form pivotal cases regarding deterrence of generic entry and assessing anticompetitive behaviour in respect of patent law abuse in the pharmaceutical industry in South Africa.[113]

Although not explicitly prohibited, the Competition Commission considered the factors of 'patent ever-greening' and 'patent thicketing' strategies in the above-mentioned investigations into anticompetitive behaviour, particularly engagement in exclusionary conduct.[114] The Competition Commission has since broadened its study in South Africa to investigate all pharmaceutical drugs whose prices are potentially excessive.[115]

The Competition Commission is of the view that the relevant market, in assessing the dominance of a pharmaceutical company, is determined by considering the specific active pharmaceutical ingredient (API), and not all medicines that may be used to treat the relevant

109 In terms of Section 8(1)(a) of the Competition Act 89 of 1998, it is prohibited for a dominant firm to charge an excessive price to the detriment of consumers or customers.

110 In terms of Section 8(1)(c) and (d) of the Competition Act 89 of 1998, it is prohibited for a dominant firm to engage in an exclusionary act if the anticompetitive effect of that act outweighs its technological, efficiency or pro-competitive gain. According to Section 1(1) of the Competition Act 89 of 1998, an exclusionary act is one that impedes or prevents a firm from entering into, participating in or expanding within a market.

111 Price discrimination by a dominant firm as a seller is prohibited in terms of Section 9 of the Competition Act 89 of 1998.

112 www.gov.za/speeches/media-statement-commissioner-investigation-manufacturers-cancer-drugs-13-jun-2017-0000.

113 Excessive Pricing in Pharmaceutical Markets – Note by South Africa, prepared for the 130th OECD Competition Committee meeting on 27-28 November 2018. Available at: https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf.

114 www.gov.za/speeches/media-statement-commissioner-investigation-manufacturers-cancer-drugs-13-jun-2017-0000. Patent ever-greening is a strategy to attempt to extend patent protection of a first-generation patent that is about to expire by obtaining second-generation patent protection for a minor change. The patent thicketing strategy prevents or delays entry of a generic alternative by limiting the processes for producing the product, as well as the number of forms of the active ingredient.

115 Excessive Pricing in Pharmaceutical Markets – Note by South Africa, prepared for the 130th OECD Competition Committee meeting on 27-28 November 2018. Available at: https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf.

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disease or disorder.[116] Accordingly, it is not unlikely that in many cases a pharmaceutical company may be considered dominant in respect of a specific API. It is noteworthy that dominance in itself is not wrongful, only the abuse thereof.

The South African competition authorities have not decided on the issue of 'pay for delay' agreements, but it is likely that that such agreements will be held to be anticompetitive, and in particular engaging in exclusionary conduct. The Competition Tribunal recently approved of a settlement agreement in an analogous case, involving plant breeders' rights, wherein an attempt to extend protection, by contract, of a plant breeders' right that had expired was found to be anticompetitive in that a dominant company was engaging in exclusionary behaviour.[117]

ii Transactional issues

In terms of Section 22H of the Medicines Act, no wholesaler shall purchase medicines and medical devices from any source other than from the original manufacturer or from the primary importer of the finished product, although exemption from this provision may be applied for from the Director-General. Further, wholesalers may only sell medicines into the retail sector.[118]

Section 15C of the Medicines Act was inserted to ensure the supply of more affordable medicines and provides the Minister of Health with a discretion to determine that the rights with regard to any medicine under a patent granted in South Africa shall not extend to acts in respect of such medicine that have been put onto the market by the owner of the medicine, or with his or her consent.[119]

In addition, Section 15C(b) provides that the Minister of Health may prescribe the conditions on which any medicine that is identical in composition meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in South Africa, but that is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and that originates from any site of manufacture of the original manufacturer as approved by the SAHPRA, may be imported.[120] The applicant for import must provide an undertaking to ensure the continued safety, efficacy and quality of the medicine.

116 www.gov.za/speeches/media-statement-commissioner-investigation-manufacturers-cancer-drugs-13-jun-2017-0000.

117 *Competition Commission v. Wesgrow Potatoes (Pty) Ltd and Another* [2020] ZACT 3 (15 January 2020).

118 The Medicines and Related Substances Act 101 of 1965 defines 'sell' rather broadly as 'sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise'.

119 Section 15C was inserted into the Medicines and Related Substances Act 101 of 1965 by Section 10 of the Medicines and Related Substances Control Amendment Act 90 of 1997.

120 The procedure to be followed in terms of Section 15C(b) is set out in Regulation 5 of the General Regulations, Government Notice 859 of August 2017, and requires documentary proof: (1) that the medicine is under patent in South Africa; (2) that the medicine is registered in the country of export by a regulatory authority recognised by the SAHPRA; (3) regarding the lowest price at which the medicine is sold in South Africa; (4) regarding the price at which the medicine will be sold in South Africa; and (5) that the person desiring to import the medicine is able to comply with good manufacturing and distribution practices as determined by the SAHPRA.

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VIII CURRENT DEVELOPMENTS

The world has been gripped by the covid-19 pandemic and the response to the pandemic by the SAHPRA has included the following initiatives aimed at minimising the potential negative impact of the pandemic on the availability of medicines and medical devices in South Africa:

a communication with manufacturers, wholesalers, pharmacists and healthcare providers to identify and respond to medicine or medical device shortages;

b a mandatory process for notifying the SAHPRA of any anticipated disruptions in supply, any shortages of products experienced, and any planned withdrawals of products from the market by manufacturers or suppliers;

c actively monitoring the potential impact of the covid-19 pandemic and responding to any disruptions or shortages;

d ensuring the uninterrupted supply of medicines, medical devices, in vitro diagnostics and medical equipment, particularly those used to manage covid-19 as well as other priority diseases;

e being part of a collaborative network of regulators around the world who are communicating regularly to ensure availability of safe, efficacious and quality medicines and medical devices required to manage patients affected by covid-19;

f when a vaccine or medicine is developed to prevent or treat covid-19, the SAHPRA has undertaken to take appropriate action to ensure availability, including fast-tracking through a priority review process; Special Access Program for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed or are unavailable; and expedited review of clinical trials for new vaccines, new or repurposed antivirals, or supportive therapies; and

g a commitment to expedite review of covid-19-related clinical trial applications, with the review timeline being between 7 and 10 working days.

South Africa joined with India in petitioning the World Trade Organization to temporarily suspend intellectual property rights so that covid-19 vaccines and other new technologies are accessible for poor countries. However, this was opposed by a number of high-income countries, which objected that such a move would stifle innovation when it is needed most.

In 2019, South Africa joined a growing number of countries in moving to allow certain cannabinoids to be unscheduled. On 23 May 2019, the Minister of Health issued a Notice that excludes certain preparations containing cannabidiol (CBD) from the Schedules to the Medicines Act.

Preparations that are specifically excluded are those that contain a maximum daily dose of 20mg CBD with an accepted low risk claim or health claim which refers to (1) general health enhancement without any reference to specific diseases; (2) health maintenance; or (3) relief of minor symptoms (not related to a disease or disorder). In addition, preparations containing CBD that consist of processed products made from cannabis raw plant material and processed products, where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product, and which contain no more than 0.001

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per cent of tetrahydrocannabinol (THC) and not more than 0.0075 per cent total cannabidiol (CBD) are also excluded from the Schedules to the Medicines Act. The Schedules to the Medicines Act were amended to this effect on 22 May 2020.[121]

121 Government Notice No. 586, Government Gazette No. 43347, 22 May 2020.

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Appendix 1

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