The Life Sciences Law Review

Fourth Edition

Editor
Richard Kingham

Law Business Research

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EDITOR'S PREFACE

The fourth edition of *The Life Sciences Law Review* provides an overview of legal issues of interest to pharmaceutical, biotechnology and medical device companies in more than 30 jurisdictions. As before, each chapter contains information on legal requirements relating to the key stages in the life cycle of a regulated product, from discovery, through the clinical development process, registration, manufacturing and promotion, plus other issues of special interest, such as pricing and reimbursement, special liability regimes, competition and commercial transactions in the context of the medical products business. Each of the chapters has been prepared by a recognised expert in the relevant jurisdiction, and the resulting work product will assist industry lawyers, regulatory affairs staff and others who need to have an understanding of the issues in each major market.

There is also a chapter on international harmonisation, which plays an increasingly important role in the regulation of pharmaceuticals and medical devices. In particular, the guidelines adopted by the International Conference on Harmonisation have been incorporated into the national requirements for pharmaceuticals in the European Union, United States, Japan and most other developed countries, and are increasingly influential in developing countries. Readers may find it useful to review this chapter before consulting the national chapters, because it is often key to understanding many local requirements.

Once again, I wish to thank all of the lawyers who contributed to this reference work. It is a pleasure to be associated with them.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2016

Chapter 3

AUSTRALIA

Bernard O'Shea[1]

I INTRODUCTION

The Australian biotechnology and pharmaceutical industry is subject to regulation by the state and Commonwealth governments.

Commonwealth legislation in the main regulates the manufacture and supply of therapeutic goods, and also provides a regime for reimbursement. Primary regulation is through the Therapeutic Goods Act 1989 (the TG Act) and its associated regulations, the Therapeutic Goods Regulations 1990 (the TG Regulations) and the Therapeutic Goods (Medical Devices) Regulations 2002 (the Devices Regulations). Pricing and reimbursement is provided under the National Health Act 1953 (the NH Act).

There are still areas where state and territory legislation 'overlaps' with the Commonwealth legislation. For example, human tissue legislation in each state and territory predates the Commonwealth TG Act and the new biologicals regime applicable to such human tissue products. As such, products that have met the Commonwealth requirements and are registered therapeutic goods may still have to satisfy additional state or territory-based restrictions.

State and territory legislation traditionally regulated the professions involved in the supply of therapeutic goods, such as doctors and pharmacists. Since 2010, a single national registration and accreditation scheme has been in place for the health professions, through legislation passed by each Australian state and territory. This single regime simplifies a number of issues in relation to prescribing and dispensing.

Privacy laws are in place at both the Commonwealth and state levels.

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1 Bernard O'Shea is a partner at Norton Rose Fulbright. The author would like to thank Kate Sherburn for her assistance in the preparation and updating of this chapter.

II THE REGULATORY REGIME

To be supplied in Australia, therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA). For this to occur, the sponsor of a medicine needs to apply to the TGA for registration. The definition of 'sponsor' is slightly unusual, as it basically means the person who imports, exports or manufactures the therapeutic goods, or who has therapeutic goods imported or manufactured on their behalf. The TG Act then imposes all relevant obligations on this person.

i Classification

In broad terms the TG Act has three categories of products with different regulatory pathways: biologicals, non-biologicals and medical devices. In addition there is a defined subcategory of products (both non-biologicals and devices) that is subject to listing (as opposed to registration), a less demanding process that typically does not require demonstration of efficacy, only safety.

The TGA typically does not seek to regulate foods, cosmetics, chemicals or general consumer products. However, if claims in the nature of therapeutic claims are made in respect of such products, it is possible for such products to come within the regulatory framework of the TG Act. Thus, for example, in some areas there are extensive rules or guidelines in relation to the claims that can be made in respect of a product before it falls within or outside the TG Act.

The fringes of each of these categories tend to be in a state of flux, with various areas of contention emerging from time to time. The area of nutraceuticals (food that reportedly provides health and medical benefits) and enhanced foods remains in focus, and various non-intrusive devices are contentious, for example, laser-based hair removers and 'fat blasters'.

The medical devices regulatory framework is modelled on that applicable in the European Union.

ii Non-clinical studies

Use of animals

Each Australian state has its own laws that govern the use of animals in product testing, research and teaching. In some states an institution must be licensed to conduct research using animals. Despite these differences the common framework of principles and regulations is found in the Australian Code for the Care and Use of Animals for Scientific Purposes[2] (the Code). All states are required to comply with the Code and some states have incorporated the Code into their own legislation.

2 www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ea28_code_care_use_animals_130728.pdf.

The purpose of the Code is 'to promote the ethical, humane and responsible care and use of animals for scientific purposes'.[3] The Code was updated in July 2013, mainly to provide greater clarification on the distinction between provisions which are mandatory and those which are recommendations.

Embryos

In Australia, the use of human embryos is strictly regulated by legislation at the Commonwealth level and in each state and territory, with the exception of the Northern Territory, which is in the process of drafting its legislation and has been for some time.

At the Commonwealth level, the relevant legislation is the Research Involving Human Embryos Act 2002 (Cth). It provides that in respect of excess embryos created by assisted reproductive technology (ART), a person may not use the embryo unless the use is authorised by licence or the use is one of a number of exempt uses (for example, storage of the excess embryo). Similarly, for other embryos a licence must also be obtained for use. Licences are sought by application to the Embryo Research Licensing Committee (the Committee) of the National Health and Medical Research Council (NHMRC). The Committee must consider certain factors in deciding whether to grant a licence and the use of embryos is generally restricted to uses that would result in development of the embryo for no more than 14 days.

IVF regulation

IVF in Australia is somewhat unusual, as the TGA and the states have effectively ceded oversight to the Fertility Society of Australia, a body largely comprised of IVF practitioners. The primary legislation in this space is still the TG Act, however, the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 provides that reproductive tissue for use in ART is declared not to be a therapeutic good. While 'reproductive tissue' is not defined, the guidelines to this order indicate that it is the intention that any tissue that is used for ART would fall within 'reproductive tissue'.

Stem cells

As to the use of stem cells (embryonic or non-embryonic) after they have been derived, there is no specific applicable legislation over and above the TG Act.[4] Rather, the approval of a human research ethics committee and compliance with relevant NHMRC guidelines is required to use stem cells.[5]

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3 www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ea28_code_care_use_animals_130728.pdf.

4 www.nhmrc.gov.au/health-ethics/human-embryos-and-cloning/stem-cells-cloning-and-related-issues/stem-cell-research.

5 Ibid.

Gene technology

The Gene Technology Act 2000 (the GT Act) regulates dealings with genetically modified organisms (GMOs). Gene technology is defined as any technique for the modification of genes or other genetic material. However, it does not include sexual reproduction, homologous recombination or any other technique specified in the regulations.

Generally, dealings with GMOs are prohibited and penalties will apply if unlawful dealings with GMOs cause or are likely to cause significant damage to the environment or threaten the health and safety of persons. The GT Act provides several ways in which dealings with GMOs will be permitted, including when:

a a licence is granted for the dealing by the Gene Technology Regulator, the body responsible for administering the licensing system;

b the dealing is specified in an emergency dealing determination by the Minister of Health and the dealing is able to adequately address any imminent threat to the health and safety of the people or the environment;

c the dealing is a notifiable low-risk dealing, meaning that it would involve little or minimal risk to the health and safety of people and to the environment;

d the dealing is an exempt dealing as specified in the regulations; or

e the dealing is included in the GMO Register by being authorised under a GMO licence or is genetically modified only because it is declared in the regulations as being a GMO.

The Office of the Gene Technology Regulator has been established within the Australian government Department of Health to provide administrative support to the Gene Technology Regulator. In addition to the Gene Technology Regulator, the GT Act establishes the Gene Technology Technical Advisory Committee, the Gene Technology Ethics and Community Consultative Committee and the Legislative and Governance Forum on Gene Technology (formerly the Gene Technology Ministerial Council).

iii Clinical trials

There are two schemes under which clinical trials involving therapeutic goods in humans may be conducted in Australia. The Clinical Trial Exemption Scheme (the CTX Scheme) and the Clinical Trial Notification Scheme (the CTN Scheme). These schemes are used for clinical trials involving any product not entered on the ARTG or the use of a registered or listed product in a clinical trial beyond the conditions of its marketing approval.

There is no requirement that clinical trials be performed in Australia before a therapeutic good may be entered in the ARTG.

Under the CTX Scheme the sponsor submits an application, including proposed usage guidelines, to the TGA for approval. A sponsor may not commence a CTX trial until written advice is received from the TGA. Additionally, approval must be obtained from a properly constituted Human Research Ethics Committee (HREC), relevant to the institution at which the trial is proposed to be conducted. The sponsor must also notify the TGA on commencement of each new trial to which the approval applies, including new sites for an ongoing trial.

The CTN Scheme is a notification scheme where primary responsibility falls to the relevant ethics committee. All documentation and material in relation to the

proposed trial is submitted directly to an HREC, usually the HREC at the institution where the trial is proposed to be conducted. The HREC is responsible for approving the trial protocol, assessing the scientific validity of the trial, the safety and efficacy of the trial medication or device and acceptability of the trial design. The institution at which the trial will be conducted provides final approval for the trial. Importantly, under the CTN arrangements the TGA does not review the proposed trial. A CTN trial may not commence until the trial is notified to the TGA and the notification fee paid.

The choice of which scheme to adopt is the sponsor's and the HREC's. The key factor for an HREC to consider is whether it has access to appropriate scientific and technical expertise to assess the potential safety of the trial product. For this reason most Phase 1 trials are done under the CTX Scheme.

The sponsor of any clinical trial must be a locally incorporated body.

Essentially all clinical trials need to be compliant with the NHMRC's National Statement on Ethical Conduct in Human Research.[6] It is these guidelines to which HREC's have regard when considering the appropriateness of a clinical trial.

The pharmaceutical industry, together with various states, has developed a suite of standard form clinical trial agreements.[7] Because most clinical trials are undertaken in public hospitals the states or territories, as the operators of those hospitals, play an important role in the clinical trial approval process, including in particular being interested in the form of the clinical trial agreement, and the insurance that is put in place to protect participants.

In most states or territories a sponsor is required to have a minimum of A$10 million insurance, although New South Wales and the Australian Capital Territory require A$20 million. Industry is currently campaigning for the insurance minimum to return to A$10 million in New South Wales. Additionally, in accordance with the Medicines Australia Guidelines, all pharmaceutical companies that are members of Medicines Australia, must in respect of clinical trials involving drugs commit to the Voluntary Compensation Guidelines[8] (Compensation Guidelines). In practice those guidelines are followed for all company sponsored clinical trials.

There are no special rules for investigator-initiated studies that need to comply with the same regime as for company-sponsored trials, although typically no separate insurance is required by the investigator's institution.

It is not usual for trial participants to be remunerated for their participation in clinical trials, although there may be some limited reimbursement of actual travel and other minor out-of-pocket expenses involved in their participation.

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6 www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf.

7 Available at https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/.

8 http://medicinesaustralia.com.au/files/2010/09/Clnical-Trials-Compensation-Guidelines.pdf.

iv Named-patient and compassionate use procedures

The Special Access Scheme (SAS) under the TG Act permits a medical practitioner to treat a person with medication that is otherwise unapproved (an SAS drug) pursuant to the TG Act, utilising one of two mechanisms.

A medical practitioner may treat a person (a Category A patient) with an SAS drug without the approval of the TGA, provided certain conditions are satisfied. The medical practitioner must notify the TGA within 28 days. The person treated must be 'seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'. Finally, informed consent to the medicine being given is required from the person, or guardian of the person.

The SAS also permits a medical practitioner to treat a person (a Category B patient) with an SAS drug, on approval by the TGA or a delegate outside the TGA such as the ethics committee of an institution. Category B patients are patients that do not fall within the definition of Category A patients. The TGA must be provided with certain patient details including clinical justification for the treatment. Approval for the supply of an SAS drug to a Category B patient is on a patient-by-patient basis.

Importantly, a pharmaceutical company is unable to supply an SAS drug until a medical practitioner requires it for a Category A patient or approval has been obtained from the TGA for administration to a Category B patient. If an SAS drug is supplied pursuant to the SAS, the pharmaceutical company is required to provide the TGA with reports every six months detailing the supplies made and is required to monitor supplies. A pharmaceutical company, as sponsor of an SAS drug, is under no obligation to supply it to a particular patient.

Careful attention needs to be paid to the obtaining of requisite approvals by companies to import drugs subject to these SAS schemes. SAS supply will not usually be able to be continued once a registered product with essentially the same indication is approved.

In addition, individuals can legally import most therapeutic goods for personal use under the Personal Importation Scheme. Under this scheme, an individual arranges for a therapeutic good to be sent to them from an overseas supplier or family or friend, and the goods can only be used by that individual or a member of his or her immediate family. The goods cannot be sold or supplied to any other person. A three-month supply (at the maximum dose recommended by the manufacturer) can be imported at one time, provided the goods are not restricted under Australian Customs or quarantine rules, the goods are not injections that contain material of human or animal origin (except insulin) and if the goods are Schedule 4 or 8 on the Poisons Standard, the individual must hold a prescription from an Australian registered medical practitioner.

Recently, a number of third parties have become actively involved in the facilitation of the use of this exemption, most typically where the product has not been registered here or where it can be sourced significantly more cheaply in another market.

v Pre-market clearance

To be supplied in Australia, therapeutic goods must be included in the ARTG by the TGA. For this to occur, the sponsor of a medicine must apply to the TGA for registration or listing. The TGA provides that '[t]he sponsor must be a resident of Australia or be an incorporated body in Australia and conducting business in Australia'.[9]

Medicines and biologicals

Applications for registration are governed by Sections 23 and 24 of the TG Act. The process for registration involves evaluation by the Prescription Medicines Authorisation Branch (PMAB) of the TGA, and may also involve a referral to the Advisory Committee on Prescription Medicines (ACPM) for advice and recommendations about the acceptability of applications for registration. The Australian Regulatory Guidelines for Prescription Medicines (ARGPM) (a series of web pages that includes information about the prescription medicine registration process) notes that the PMAB is not obliged to refer applications to the ACPM,[10] however, it tends to do so for major applications.

Particular routes of evaluation, with different time frames and fees, apply depending on the category of application.[11] For new dosage forms, new strengths, new generic products, extensions of indications and amendments to the product information, a Category 1 application, which is provided under Regulations 16C(3)(b) and 16D(3)(b) of the TG Regulations, is the typical route.

For medicines that have previously been approved in two acceptable countries there is an alternative Category 2 evaluation process provided under Regulations 16C(4) and (5) and 16D(4) and (5) of the TG Regulations. This is an expedited application. The formulation, directions for use and indications of the product proposed to be registered in Australia must be identical to the products registered in the acceptable countries. Acceptable countries are currently Canada, Sweden, the Netherlands, the United Kingdom and the United States.

There is no formal priority evaluation system. The ARGPM provides that if the TGA considers an application to be a 'significant therapeutic advance or of critical importance, the TGA will, wherever possible, work with the relevant applicant with a view to facilitate early access to the new product.'[12]

Fees for the application for registration and evaluation of a 'new chemical entity' as at 1 January 2016 are A$45,100 and A$181,000, respectively.[13]

Complementary medicines include medicinal products containing herbs, vitamins, minerals, nutritional supplements, homeopathic medicines and certain aromatherapy products that consist wholly or principally of one or more designated active ingredients that have a traditional use. Complementary medicines are regulated

9 www.tga.gov.au/role-sponsor.

10 www.tga.gov.au/prescription-medicines-registration-process.

11 Therapeutic Goods Regulations 1990.

12 www.tga.gov.au/prescription-medicines-registration-process.

13 Information on fees is available at https://www.tga.gov.au/summary-fees-and-charges-1-january-2016.

as medicines under the TG Act and the types of active ingredients that may be used in complementary medicines are set out in the TG Act and the TG Regulations. The TGA has developed the Australian Regulatory Guidelines for Complementary Medicines[14] in consultation with the industry.

Generics and biosimilars

In order for a product to be treated as generic medicine it must demonstrate bio-equivalence to the originator product. This is important from both a simplified regulatory perspective, but also from that of reimbursement, as it allows for generic substitution.

The ARGPM sets out guidance for the evaluation of biosimilars.[15] This guideline is continually updated as the TGA's understanding of biosimilars evolves, with the most recent version being published in December 2015. Applications to register biosimilars are managed through the Prescription Medicines Registration Process. The biosimilar registration process involves an abridged submission with a comparability study. If upon evaluation, the TGA considers the biosimilar is not sufficiently comparable to the originator product, the sponsor may elect to resubmit with a full data set as a novel biological medicine. Until the WHO Programme on International Nonproprietary Names determines a naming convention for the active ingredients of all biological medicines, including biosimilars, the TGA has stated that active ingredients of biosimilars will use the Australian Biological Name (ABN) without a specific biosimilar identifier suffix. As a biosimilar is not identical to its reference product, it must be possible to distinguish between the two; thus the use of the active ingredient ABN in the trade name of a biosimilar is not acceptable.

Devices

Medical devices generally must be included in the ARTG in order to be imported into, exported from, or supplied in Australia. A sponsor can apply to include a medical device in the ARTG if the device complies with the Essential Principles,[16] which set out the requirements relating to the safety and performance characteristics of medical devices, and appropriate conformity assessment procedures have been applied to the device.[17] There are three slightly different processes for including medical devices in the ARTG for either Class I medical devices (as defined in the Devices Regulations), export-only medical devices and medical devices other than Class I. While the presence of a CE marking is not a requirement of the Australian medical device regime, Australia's regime is more closely aligned with the European regulatory regime than the 510(k) process in the United States.

14 www.tga.gov.au/publication/australian-regulatory-guidelines-complementary-medicines-argcm.

15 www.tga.gov.au/publication/evaluation-biosimilars.

16 Set out in Schedule 1 of the Devices Regulations.

17 www.tga.gov.au/sites/default/files/devices-argmd-01.pdf.

Drug device combinations, such as systems (components, including at least one medical device, that are intended to be used in combination as a unit, such as a complete patient monitoring system) and procedure packs (components that are packaged together, including at least one medical device, that are intended to be used in a medical, surgical or diagnostic procedure, such as a first-aid kit) are regulated as medical devices. However, an article that administers a medicine in such a way that the medicine and the article form a single product that is intended for use only in that combination, are not regulated as devices (such as a tube of cream with a specifically designed applicator, or a syringe pre-filled with a medicine).

vi Regulatory incentives

The Patents Act 1990 (Cth) (the Patents Act) provides that a patent extension for a period of up to five years can be obtained for pharmaceutical substances. Only one extension is permissible and the regime does not apply to medical devices.

There is also a data exclusivity regime in respect of products that have not previously been incorporated in the ARTG. The regime provides protection for non-public data for a period of up to five years. It does not provide any in-market exclusivity, but this means a generic product must have an application that can be sustained on its own data.

There are significant difficulties with the operation of the data exclusivity regime including that there is no mechanism to obtain confirmation that the protection is applicable either from the perspective of the person lodging data or a third party. Further, a strict view appears to be taken in relation to what constitutes non-public information.

Under the European Medicines Agency (EMA) policy whereby the EMA proactively publishes the clinical reports submitted as part of marketing authorisation applications for human medicines, information would be published that would otherwise fall within the data exclusivity regime. Once such information is published, however, it would be considered public and hence outside of the regimes protection.

There are very few concessions or incentives available to prospective sponsors in relation to their products. The only formal one available concerns orphan products, and there the incentive is the waiver of TGA application fees. An orphan product is a medicine, vaccine or in vivo diagnostic agent that is intended to treat, prevent or diagnose a rare disease or that is not commercially viable to supply to treat, prevent or diagnose another disease or condition. There is scope to undertake literature-based submissions in some limited cases, which can be of assistance for line extensions and sometimes orphan products.

In July 2015, the TGA introduced a new annual charge exemption (ACE) scheme. Under this scheme, sponsors can apply for a waiver of the annual charge if a public health risk would arise if the entry is removed from the ARTG and if the product would become financially unviable if an annual charge was paid. The product must have A$0 turnover in the previous financial year to be eligible for the ACE scheme. Once an ACE entry commences turnover, it will incur an annual charge each year until cancelled from the ARTG. New entries on the ARTG automatically qualify for an ACE, without an application, until the entry first generates turnover. This scheme replaces the previous low-value turnover scheme.

vii Post-approval controls

The post-approval controls applicable in Australia in large measure reflect those applicable in Europe and the United States.

Typically a sponsor is required to have a nominated person who can receive medical and regulatory questions about products. The person must be someone familiar with the regulatory requirements in Australia, in particular, the pharmacovigilance requirements, but they do not need to be resident in Australia. In respect of implantable devices, ongoing registers are required to be maintained. Following a review on eight European notified bodies performing conformity assessment, the TGA is auditing all ARTG applications supported by certification from the notified bodies and is monitoring the possible future adoption of stronger controls around high-risk medical devices in Europe, such as the introduction of new bodies responsible for conformity assessment of high-risk medical devices.

As part of product approval, sponsors must submit a risk management plan, which consists of a set of pharmacovigilance activities and interventions designed to identify and manage safety concerns relating to their products. Sponsors are also required to submit regular periodic safety update reports, which consist of a detailed analysis of emerging information on the risks of the product, not only in Australia but globally. In addition, sponsors must alert the TGA of any international concerns relating to the safety and effectiveness of the product.

The transfer of ownership of product approvals is a simple and straightforward process, although transfers can only take place when all regulatory issues are in order.

There are multiple reasons that could lead to the suspension or revocation of product approvals, such as the failure to manufacture products in accordance with good manufacturing practice (GMP), promotion for unregistered indications, misleading information and failure to respond to various regulatory requests. Some of these sanctions may be applicable only in respect of a given product, but some may be applicable to all products or registrations held by a sponsor even though the non-compliance relates to only one.

The TGA has its own comprehensive system for monitoring approved products that are on the market.

The TGA has problem-reporting systems for reporting medicine defects and adverse reactions to medicine. Under these systems sponsors, health professionals, patients and consumers can all report their safety concerns to the TGA. In addition to receiving reports from others, the TGA laboratory undertakes their own random and targeted sampling of approved products. Where a problem has been identified, there is a range of regulatory actions available to the TGA, from continuing to monitor the product to withdrawing the product from the market. Other actions the TGA can take include informing health-care professionals and consumers about the risks of the product, reassessing the benefit-risk profile, requiring changes to the product, restricting access to the product, recalling the product and removing the product from the ARTG.

The TGA now regularly publishes product adverse event reports in the interests of transparency, a move generally not welcomed by sponsors.[18]

In addition to the registration, evaluation and variation fees, annual charges also apply to products on the ARTG. If these charges are not paid within 28 days after they become payable, the registration or listing of goods on the ARTG can be immediately cancelled.

viii Manufacturing controls

The manufacture of therapeutic goods must be carried out at a satisfactory level of compliance with the standard of GMP, and at the facility recorded as part of the particular drug's ARTG registration or listing.

The TGA has the right to undertake audits of overseas GMP facilities to validate their status, either prior to granting an initial GMP clearance or at any time following the issue of GMP clearance, but typically relies upon the GMP certifications by comparable authorities.

Transfer of ownership of manufacturing facilities is straightforward, but might well be an event that triggers an audit, particularly if the transferee is not an entity that has previously been audited by the TGA. Where a GMP clearance needs to be changed or renewed, a new application with all required documentation must be submitted, and applicable fees paid.

ix Advertising and promotion

In Australia, advertising or promotion to consumers of prescription products is not permitted. Advertising of medical devices is permitted, subject to the relevant Codes (see further below). While the TG Act deals with the promotion of products, in practice promotion of products, whether to consumers or health-care professionals, is governed by a number of self-regulatory codes that are administered by relevant industry bodies. The four main codes are: the Medicines Australia Code of Conduct (MA Code), covering the ethical pharmaceutical companies; the Generic and Biosimilar Medicines Industry Association Code, covering generic suppliers; the Medical Technology Association of Australia Code, covering the medical devices sector; and the Australian Self Medication Industry Code, covering the self-medication sector. Membership of each of the sponsoring bodies and hence applicability of the relevant code is effectively voluntary, meaning that there are some product sponsors that are not subject to any code. Regulatory conditions may also mandate code compliance. It is typically a condition of registration of therapeutic goods that the promotion of all prescription products comply with the requirements of the MA Code, whether or not the sponsor is a member of Medicines Australia.

Additionally, there is the Therapeutic Goods Advertising Code (TGAC), which regulates certain categories of permissible advertisements, and in some cases requires pre-approval of advertisements. For example, all forms of advertisements to consumers may only refer to restricted representations if prior approval has been obtained by the TGA for such a reference. Restricted representations are references to a serious disease,

18 These are available at www.tga.gov.au/daen/daen-entry.aspx.

ailment or defect that is generally accepted to be not appropriate to be diagnosed and treated without consulting a suitably qualified health professional, or which is beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified health professional. The list of restricted representations is specified in the TGAC, and includes cardiovascular diseases, infectious diseases and renal diseases. The requirements in relation to restricted representations are in addition to any requirements set out in the applicable industry code.

The TGAC is established under the TG Act and breach of the TGAC enables the TGA to exercise certain powers and impose penalties. This structure has thrown up some difficulties in the past, and in May 2013, the TGA released a Consultation Regulation Impact Statement (RIS) detailing options for reforming the advertising regulatory framework for comment. Following on from this, in October 2014 the Australian government announced a review of the regulation of medicines and medical devices. The second report stemming from this review, addressing the regulatory frameworks for complementary medicines and the advertising of therapeutic goods was delivered in July 2015. The TGA is considering possible regulatory changes arising from the review. See Section VIII, *infra* for further information.

In most cases the TGA tends to defer to the operation of the relevant code rather than itself exercise the statutory rights it has in relation to an allegedly offending advertisement or communication.

Most of the Codes are complaint-driven, with the majority of complaints traditionally being initiated by competitors. However, there is a growing trend of consumer or consumer-advocate-led complaints, and the TGA itself initiates complaints from time to time.

While advertising prescription products to consumers is prohibited, there is some scope for communications of an educational nature, however this can be quite problematical, as the consequences if such communications are considered advertising are severe.

Each of the above Codes also deals with interactions with health-care professionals. In this regard the Medicines Australia Code is typically the most prescriptive, and has recently become more so, particularly in relation to the transparency of such interactions. See Section VIII, *infra* for further information. The Medicines Australia Code is also the Code with the highest penalties. The majority of complaints under that Code typically relate to promotion to health-care professionals.

ASMI became the first health-care industry body to release social media guidelines in late 2013.[19] These guidelines apply to non-prescription medicines and provide guidance as to what is and is not acceptable social media content in the highly regulated health-care space. It is expected other industry bodies will release social media policies and guidelines in the not-too-distant future.

19 www.asmi.com.au/media/7996/social_media_guideline_document_-_final_final_for_publishing.pdf.

x Distributors and wholesalers

Typically distributors and wholesalers require minimal permits to operate. Those permits are usually issued by the state authorities and are generally warehousing or wholesaling permits. There are, however, some special categories of products and precursor chemicals that mandate higher levels of scrutiny or security. These tend to be in the area of certain narcotics or narcotic-related substances.

Additionally, for those wholesalers who operate in relation to prescription products being supplied through the Pharmaceutical Benefits Scheme (PBS) (see Section III, *infra*), there is the possibility of accessing an additional fee as part of the community service obligation. This requires certain additional obligations to be met and an agreement to be entered into with the Commonwealth in relation to the performance of those obligations and reporting thereon.

The distribution of prescription pharmaceuticals is controlled by a few (mostly Australia-wide) wholesalers, with some companies having direct distribution models. Distribution of medical devices is much more fragmented.

xi Classification of products

In respect of medicinal products, the key regulatory document that categorises products (i.e., as prescription or over-the-counter) is the Poisons Standard, also known as the Standard for the Uniform Scheduling of Medicinal Products. This document, which is now organised at the Commonwealth level and adopted by each state and territory as part of its poisons and controlled substances legislation, divides all products into nine different schedules. The most relevant schedules from the perspective of human therapeutic application are:

a Schedule 2 – pharmacy medicines;
b Schedule 3 – pharmacy-only medicines, typically behind the counter;
c Schedule 4 – prescription medicines;
d Schedule 8 – controlled drugs; and
e Schedule 9 – prohibited substances.

However, the Poisons Standard is only partially definitive in terms of the categorisation of the products for the purposes of the regulatory framework. As noted the claims that are made in respect of products may also influence the category into which the products are put. Thus, if a substance that is not scheduled is the subject of claims of a therapeutic nature, including claims to be useful or active, it may well be required to be registered as a therapeutic good, where it will need to demonstrate both safety and efficacy.

The main consequences of being in the different schedules are usually that Schedule 2 and 3 substances can be promoted to a greater or lesser extent, Schedule 4 substances may not be promoted to the general public, and Schedule 8 substances are subject to additional restrictions, commonly on who can prescribe them and additional controls around the distribution chain. Most Schedule 2 and 3 substances are only required to be listed under the TG Act and hence only need to demonstrate safety.

Under the TG Act, the Secretary to the Department of Health, or a delegate, can make scheduling decisions. Further, the delegate can make such decisions simply on the delegate's own initiative. These decisions can be made swiftly, and can have

profound commercial and legal consequences. Interested persons need to be alert to proposed changes to ensure they can provide input, because if they are not involved at the start of a review, the ability to be involved at later stages is effectively discretionary. Scheduling decisions cannot be the subject of an appeal in the Federal Court under the Administrative Decisions (Judicial Review) Act 1977 (ADJR), and are not 'initial decisions', and therefore are also not reviewable by the Administrative Appeals Tribunal (AAT). As such, final scheduling decisions are all but unreviewable. Applications can be made for amendment of the Poisons Standard, and poisons can be rescheduled within the Poisons Standard.

Medical devices are classified in accordance with Division 3.1 of Part 3 and Schedule 2 and 2A of the Devices Regulations. Medical devices other than IVD (in vitro diagnostic) medical devices are classified as either Class I, IIa, IIb, III or AIMD (active implantable medical device). IVD medical devices and in-house IVD medical devices are classified as either Class 1, 2, 3 or 4.

xii Imports and exports

For therapeutic goods manufactured overseas and imported into Australia, the overseas manufacturer must comply with a standard of good manufacturing practice equivalent to that required of an Australian manufacturer (i.e., GMP). The standard of manufacture and quality control of such drugs is taken into consideration for the purposes of drug registration or listing unless the drug is exempt.

A sponsor applying for the registration of a drug manufactured outside Australia must provide the TGA with an acceptable form of evidence to show that the manufacture of the drug is in accordance with GMP.[20]

Sponsors of goods manufactured outside Australia are requested on a periodic basis to provide evidence that the standard of manufacture continues to be that acceptable to the TGA. Importantly, the TGA may cancel the registration or listing of a drug if it does not conform to a standard applicable to the drug such as the standard for GMP in Australia.

The regulatory framework makes no distinction between products for local consumption and those for export.

Medical devices generally must be included in the ARTG in order to import them into or export them from Australia. The process for including devices in the ARTG varies depending on whether the medical device is a Class I device, a device other than a Class I device, or an export-only device.

Narcotic substances are subject to a range of special permits and requirements, but generally there is little overhead involved in such activities beyond that associated with the TG Act.

20 See the Australian Regulatory Guidelines GMP Clearance for Overseas Manufacturers – (www.tga.gov.au/sites/default/files/manuf-overseas-medicines-gmp-clearance-17.pdf).

xiii Controlled substances

Australia is a signatory to the Single Convention on Narcotic Drugs of 1961. The obligations of this Convention are to a large extent embodied in legislation at the Commonwealth level, namely the Narcotic Drugs Act 1967 (Cth)[21], supported by a range of other Commonwealth legislation in relation to import and export, as well as legislation at the state and territory level in respect of poisons, drugs and controlled substances.

Additionally, the Commonwealth and various states and territories have increasingly sought to regulate precursor chemicals, especially in circumstances where those chemicals might be used for both legitimate pharmaceutical purposes as well as for illegitimate purposes, for example pseudoephedrine and some of the precursor chemicals for that.

In 2014, the Drugs, Poisons and Controlled Substances (Poppy Cultivation and Processing) Regulations 2014 were introduced in Victoria in relation to poppy growing and processing. The Controlled Substances (Poppy Cultivation) Amendment Bill 2015 has also recently been passed in South Australia that will enable South Australian farmers to apply for licences to cultivate and process poppies. This Bill is currently awaiting assent.

In addition, the Victorian government plans to legalise medicinal cannabis as part of a state-based cannabis cultivation trial. This will require the support of the federal government, which is a signatory to an international convention on narcotic drugs, however, the current Federal Health Minister has indicated that she will amend the Narcotic Drugs Act to allow the growing of cannabis for medical purposes. Medicinal cannabis will be prescribed by a specialist and sold at pharmacies. It is proposed that children with severe epilepsy would be the first to be treated with medicinal cannabis, from 2017. The Access to Medicinal Cannabis Bill was introduced into the Victorian Parliament in December 2015.

xiv Enforcement

Pursuant to the regulatory framework, the TGA is primarily responsible for all formal and informal enforcement actions and for inspections relevant to the regulatory framework. In this regard, the TGA has a raft of enforcement mechanisms at its disposal such as the ability to bring prosecutions, issue infringement notices, accept court-enforceable undertakings and seek warrants. Under the Personal Liability for Corporate Fault Reform Act 2012 (Cth), provisions of the TG Act concerning personal liability of executive officers were amended, primarily removing a blanket provision under which executive officers can be liable for all offences of their company under the TG Act.

On a day-to-day basis the industry codes of conduct are most often used, typically because it is the marketing and promotion of products that gives rise to the greatest number of issues.

Additionally, the Australian Competition and Consumer Commission (ACCC), primarily the antitrust regulator, also has powers that partially overlap with a number

21 www.comlaw.gov.au/Details/C2011C00300.

of the Codes and the TGA's powers. This overlap concerns misleading and deceptive conduct, product recall obligations and consumer rights and remedies. Additionally the Competition and Consumer Act 2010 (Cth) (CCA), under which the Australian Consumer Law (ACL) operates, provides remedies for private litigants and particularly as between competitors there can be a tactical and substantive issue as to whether provisions of those laws are used rather than having resort to the complaint mechanisms under an industry code, or indeed seeking to refer the matter to the TGA.

In 2015, the ACCC commenced proceedings against a pharmaceutical company, alleging misleading conduct in contravention of the ACL by representing that its specific pain products (back pain, period pain, migraine pain, tension headache) were each formulated to treat that specific type of pain, when the products were in fact identical. The Federal Court found that the pharmaceutical company had made misleading representations. The Court ordered that the pharmaceutical company remove the specific pain products from shelves, publish website and newspaper corrective notices, implement a consumer protection compliance programme as well as pay the ACCC's costs. A hearing on penalty has yet to be held.

xv Recalls

A recall of therapeutic goods can be initiated by a supplier or mandated by the government. Recalls of therapeutic goods must comply with provisions of the CCA, as well as specific guidance provided by the ACCC in the Consumer Product Safety Recall Guidelines.[22] In addition, the TGA has published detailed recall procedures in the Uniform Recall Procedure for Therapeutic Goods (URPTG).[23] While the URPTG is not directly enforceable, not following it would almost certainly invite some form of enforcement action or prosecution under the ACL or the TG Act by the ACCC or TGA respectively.

The URPTG applies to all recalls of therapeutic goods, regardless of whether they are safety related. Under the URPTG, sponsors are responsible for maintaining adequate records to facilitate a recall should it become necessary. Sponsors must also establish recall procedures and take prime responsibility for implementing any recall required following liaison with the Australian Recall Co-ordinator.

A compulsory recall notice under the ACL may only be issued if it appears that the sponsor has not taken satisfactory action to prevent the goods from injuring someone. A sponsor that complies with the URPTG is likely to be seen as having taken satisfactory action, and will therefore likely avoid a compulsory recall notice being issued.

The ACCC has a range of compliance and enforcement options, one of which is criminal prosecution. The ACL introduces strict liability offences relating to the recall of consumer goods. Failure to comply with a recall order, or supplying goods of the kind to which a recall notice relates, carries the maximum penalty of A$1.1 million for a body

22 Available at www.recalls.gov.au/content/item.phtml?itemId=1000106&nodeId=4d50ec7b656f76ef1ede7b46a79e464e&fn=Consumer%20Product%20Safety%20Recall%20Guidelines.pdf.

23 Available at www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg.

corporate, or A$220,000 for an individual. Other offences such as failure to comply with notification requirements carry the penalty of A$16,650 for a body corporate and A$3,330 for an individual. The ACL only applies to recalls that are safety related.

Each recall is a unique exercise, and the requirements for recall vary depending on the deficiency of the therapeutic good and the risk that the deficiency poses to public safety.

III PRICING AND REIMBURSEMENT

Australia has two main payor components of its national health system: Medicare, which provides universal hospital care cover for all Australians; and the PBS, which pays for a variety of prescription products.

Under the Medicare system a wide variety of medical procedures are reimbursed by the Commonwealth, and a number of these include activities that involve the use of medical devices including diagnostics, providing a *de facto* reimbursement scheme for the use of those devices. A formal scheme specifically for the reimbursement for medical devices has previously been contemplated but seems to have been set aside at this stage.

The PBS, however, provides a subsidy in respect of prescription items used typically outside of a hospital setting.

While the PBS is a voluntary scheme, that is, products do not have to be supplied through the PBS, there are very few products that have been commercially successful without being reimbursed through the PBS.

Obtaining reimbursement through the PBS is potentially a complex and drawn-out process. This is particularly so for newer and innovative products, especially those seeking to attract a price premium over their reference product. There continues to be significant pressure and regulatory and policy emphasis on decreasing the expenditure through the PBS and this has led to a multitude of changes, both formal and informal, to either decrease prices or make it difficult to obtain admission or additional pricing. See further information under Section VIII, *infra*.

While there is an opportunity once per year to request a price increase, once a product is PBS-listed, its price is expected to remain fairly stable until a generic product is introduced. In accordance with the NH Act, a one-off statutory price reduction of 16 per cent is applied to existing PBS-listed products when the first generic product is listed on the PBS.

The PBS price disclosure arrangements require suppliers of certain PBS-listed brands of medicines to provide information in relation to supply of their brands, which is then used to work out the price at which the brands are sold. Under arrangements in the Act and the National Health (Pharmaceutical Benefits) Regulations 1960, the price the Government pays for the PBS-listed medicines will move closer to the price at which they are supplied in the market. There are six monthly data collection periods and two regular reduction days each year, which are intended to streamline price disclosure processes and allow PBS prices to be adjusted to market prices more quickly. The third reduction, which occurred on 1 October 2015, resulted in average price cuts of approximately 20 per cent for around 70 drugs in almost 230 dosages and presentations.

Amendments were made during 2015, expanding the early supply provisions for PBS prescriptions and removing the originator brand from price disclosure calculations. See further information under Section VIII, *infra*.

The PBS is established under the NH Act. However, important parts of the scheme are outside this framework leading to difficulty in understanding the overall scheme. This has led to a variety of reforms in recent times to make the processes more transparent. The Pharmaceutical Benefits Pricing Authority was abolished in 2014 as part of a streamlined pricing process. The new process is intended to reach pricing agreements faster, once approved by the Pharmaceutical Benefits Advisory Committee. Under the new process, final decisions on price are still made by the Minister.

In order to minimise the Commonwealth government's exposure to risks associated with the listing of a new medicine on the PBS, deeds of agreement are entered into between the government and responsible persons (being pharmaceutical companies or sponsors). These deeds of agreement are designed to provide certainty for government outlays and to maintain the appropriateness and cost-effectiveness of PBS medicines.[24] The Commonwealth has also recently sought damages over its perceived overpayment under the PBS in relation to an invalid patent. See further information under Section VIII, *infra*.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

i Internal review processes

The TG Act provides a mechanism for internal review of a variety of decisions. These include decisions on whether to register and list therapeutic goods, or to suspend or cancel a medical device from the ARTG. Internal review can be requested by a person 'whose interests are affected by an initial decision'. Following a request, the Minister of Health must reconsider the initial decision and may confirm or revoke the initial decision, or revoke the initial decision and make a substitute decision.

Alternatively, the Minister of Health may in some circumstances remit the matter to an authorised delegate to make a fresh decision.

If an applicant is dissatisfied with the decision made under the internal review process, they may be able to seek administrative or judicial review in accordance with other Commonwealth legislation.

ii Administrative review

A person may apply for review of a decision made under Section 60 of the TG Act in the AAT. The AAT is a Commonwealth body that reviews decisions on the 'merits' (i.e., based on the evidence and according to what the preferable decision is). Specific requirements as to when review will be available in the AAT are set out in the Administrative Appeals Tribunal Act 1975 and the TG Act.

24 A *pro forma* deed of agreement is available at www.pbs.gov.au/industry/listing/elements/deeds-agreement/Attachment_B_Basic_deed_example.pdf.

iii Judicial review

Under the ADJR, it is possible for a person to seek judicial review of a decision. This court process is different to an administrative review, as the court will not consider specifically whether a decision was preferable. Rather, the focus is on whether a decision was made within the powers conferred on the decision-maker and made following due process. Examples of grounds for judicial review under the ADJR include where the decision was an improper exercise of power (e.g., it took into account irrelevant considerations), was not authorised by the relevant enactment, or involved an error of law. Nearly all administrative decisions are amenable to judicial review (subject to there being a recognised ground for review), but only specified decisions are subject to administrative review.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

Several of the industry codes seek to constrain or deal with the financial relationships between prescribers and pharmaceutical or device companies, and to a lesser extent relationships between pharmaceutical companies and payors.

The codes differ significantly in the scope and detail of the restrictions they impose, partly owing to the fact that the normal promotion by their members is somewhat different, with Medicines Australia members being primarily concerned with promotions to doctors, generic companies being concerned with promotion to pharmacies and device companies being concerned with promotion to specialist groups, in particular, surgeons.

In recent years there has been an increased focus on the transparency of relationships between pharmaceutical companies and prescribers, with the recent introduction of educational events reporting, focused on reporting of costs and numbers attending and the introduction of the reporting of all relevant transfers of value to individual health-care professionals. See further information in relation to the Medicines Australia Code of Conduct transparency requirements in Section VIII, *infra*.

There is no specific legislation dealing with interactions with payors, although at Commonwealth and state level, there are various provisions dealing with the proper conduct of their procurement processes relating to bribery and kickbacks. There has been a focus on tightening the processes around procurements, particularly in the health space. The Western Australian Corruption and Crime Commission published a report on fraud and corruption in WA Health, and recommended that compliance and audit strategies be developed.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

There are no bespoke liability or compensation systems applicable specifically to medicines or medical devices. Rather, product liability claims are typically made on the basis of the common law and relevant statutory provisions. As noted, the sponsor of a

clinical trial is required to hold clinical trial insurance of at least A$10 million, and in at least two states this is A$20 million, and in addition is in practice required to commit to abide by the Compensation Guidelines.

The various states and territories of Australia have implemented frameworks to facilitate class actions, which might often be used in the context of product liability claims regarding medicines or medical devices. However, the utility of such schemes, on the basis of some recent decisions, has been the subject of some recent speculation.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

The ACCC is the primary regulator in this space.

There are no rules specific to medicines or medical devices and the ACCC has not taken any great interest in the settlement of patent disputes or pay-for-delay agreements to date, in contrast to the position of some of its foreign counterparts.

In 2014, the ACCC instituted proceedings against a pharmaceutical company for alleged misuse of market power and exclusive dealing in contravention of the Australian Consumer Law. This was the ACCC's first allegation of misuse of market power in the health sector in some time, however in this case, the Federal Court dismissed the ACCC's case against the pharmaceutical company, with the court finding that the actions taken by the pharmaceutical company were not done for an anticompetitive purpose, but rather in recognition of the commercial challenges the company would face as it moved beyond the expiry of its patent. The ACCC appealed this decision and the appeal has now been heard. Judgment has been reserved. The ACCC has developed a reasonably well-understood basis for evaluating mergers in this sector, which focuses on markets at a product substitutable level. This means that mergers may be considered across a multitude of discrete product markets. This approach has been largely consistent with that taken by the ACCC's peer organisations overseas.

Particularly in the case of PBS-listed products and the tightly organised distribution chain, care is required in relation to exclusivity and discounting or incentive arrangements to ensure that they comply with the requirements of competition laws.

ii Transactional issues

The process of transferring marketing authorisations is straightforward, although the TGA will require the registration to be fully up to date before it will accept the transfer.

An issue that is often overlooked by foreign acquirers is the potential for stamp duty to be applicable to consideration paid for business transfers, marketing authorisation transfers and business intellectual property associated with the same. Such stamp duty can be at a rate as high as 5.5 per cent and can be an unwelcome addition to purchase price consideration if not anticipated and planned for.

Other issues to be noted in the context of transactions are:

a if there is to be a change in where the active ingredients in products are manufactured, this may take some time to process, and special attention must be

paid to the consequences of this, particularly if there is an obligation to ensure continuity of supply, which may be a condition of PBS listing, with possibly very severe consequences if it is breached; and

b because the current regulatory regime is relatively new (in force for less than 20 years) it is possible that some products subject to a transaction may be grandfathered into the current regime and hence not have undergone the full evaluation process. It is open to the regulator at any time to require such process to be performed, and if the transaction involves such products this needs to be allowed for.

VIII CURRENT DEVELOPMENTS

i PBS reform

In May 2015, the Australian government announced the PBS Access and Sustainability Package. This package establishes pharmacy funding, medicines pricing arrangements and a range of sector improvements to ensure ongoing access to innovative medicines through a sustainable PBS that have been established following consultations with a wide range of stakeholders. This package includes the introduction of a one-off statutory price reduction of 5 per cent to apply to F1 drugs (mainly single brand patent-protected drugs) once they have been listed on the PBS for at least five years. The first F1 5 per cent reduction day will be on 1 April 2016. This change appeared to have bipartisan support, and as such, could have resulted in a much greater price reduction than 5 per cent.

ii Medicines Australia Code of Conduct and transparency

There has been a push from multiple quarters regarding the transparency of relationships between the pharmaceutical industry and health-care professionals.

From 1 October 2015, Medicines Australia's 18th Edition of the MA Code introduced a new reporting regime, which requires reporting of transfers of value, which includes fees paid to health-care professionals (or their employers or a third-party organisation) for consulting services, attendance at an advisory board meeting or speaking at an educational meeting, airfares for travel, accommodation provided or registration fees paid to enable attendance at an educational meeting.

The transparency reporting requirements are being phased in over a period of 18 months. These changes involve moving from reporting in an aggregated manner to reporting transfers of value to health-care professionals individually. Such reports must be available on the company's own website for a period of at least three years, and Medicines Australia provides hyperlinks to each company's report on its own website.

For transfers of value provided until 30 September 2016, companies must obtain informed consent from each health-care professional to whom it provides a transfer of value, before the transfer of value is provided. If the health-care professional refuses consent, the amount attributable to such transfers must be reported on an aggregate basis. For transfers of value provided from 1 October 2016, companies must not make a transfer of value to a health-care professional unless they have taken appropriate steps to give notice of this disclosure obligation, so that the health-care professional would

reasonably expect the disclosure. From this time, there will be no option to report in the aggregate; if the health-care professional explicitly refuses consent, the transfer of value cannot be provided.

Medicines Australia has announced that it will undertake a communications campaign with health-care professionals in order to create the reasonable expectation of disclosures.

These transparency reporting requirements do not apply to the whole industry, as only Medicines Australia member companies are required to comply with the MA Code. In addition, a notable exception is that payments in relation to research and clinical trials are not required to be reported.

iii Release of regulatory data by the TGA

In May 2014 the TGA released its approach to disclosure of commercially confidential information.[25] The overarching position of the TGA is that trade secrets and commercial confidences will not normally be released for as long as they retain their quality of confidentiality, unless there is an overriding public interest reason for doing so (such as to keep the public informed about the safety and safe use of therapeutic goods). As the paper on commercially confidential information has only recently been released, it is yet to be seen how the TGA will interpret and use the 'public interest' exception; however, to date it does not appear that the 'public interest' exception has resulted in the regular release of data.

This approach leaves it open for the TGA to follow the EMA's proactive disclosure policy, under which clinical reports submitted as part of marketing authorisation applications will be released by the EMA. Australia does tend to follow significant changes in this area that have been made by the EMA, however, this would be an abrupt change from established practice and expectations.

The TGA, now pursuant to government policy, publishes any documents that are released by the TGA in response to a freedom of information request on the TGA website, unless the document falls within any of the specified exemptions.[26]

iv Patent actions – damages

Until recently, there has been a fairly settled formula in relation to pharmaceutical product patent litigation in Australia whereby, at the first sign of infringement of generic activity, the patent holder would seek and obtain an interim injunction. That position would then remain until the expiry of the patent, with perhaps the possibility of some early entry arrangement. However, with the introduction of the patent certificate regime included in the TG Act[27] and additional objections made by generic companies, it is

25 www.tga.gov.au/publication/tga-approach-disclosure-commercially-confidential-information-cci.

26 Available at www.tga.gov.au/documents-released-under-section-11c-freedom-information-act-1982.

27 See Section 26B.

becoming increasingly common for the obtaining of an injunction on an interim basis to be followed by a formal hearing, and then by claims for damages by the generic company if the patent is not upheld.

In addition, the Commonwealth is now seeking to rely on the usual undertaking as to damages given when seeking an injunction to pursue at least two originator companies for damages in circumstances when the basis for the original injunction was ultimately not upheld. Such damages are essentially claimed on the basis of delayed price reductions.

v Patent actions – gene patents

The High Court of Australia recently unanimously invalidated a patent that related to the BRCA1 gene. The location of the BRCA1 gene was located, as were mutations that increased the susceptibility of the patient to breast and ovarian cancer. The patent granted the patent owner the sole right to isolate the BRCA1 gene for the purposes of genetic testing. The High Court determined that the BRCA1 gene was not patentable subject matter.

This decision has cast significant doubt on the validity of gene patents in general, although the work of the Human Genome Project has largely rendered such patents obsolete. However, products produced from isolated genetic materials may still be patentable.

The High Court passed the onus of determining patentability of isolated genes to the legislature. Accordingly, the Commonwealth Parliament will need to consider whether to legislate to enable the protection of isolated genes. The Commonwealth Parliament has previously declined opportunities to expressly exclude these products as patentable subject matter against the backdrop of the continued granting of patents by the Patent Office. However, the current prime minister has previously given strong commentary against gene patents[28] and with the public outcry regarding the claims in dispute, it seems unlikely that the Commonwealth will legislate specifically in favour of gene patenting. It is unclear the extent to which this decision will have an impact upon inventions other than isolated DNA. Given the majority of the High Court focused heavily on policy considerations, it is possible that the scope of the decision may prove not to be confined to isolated DNA.

vi Health care at home

Partly as a means of reducing the burden on hospitals and partly for efficiency reasons, there is a great deal of activity surrounding the delivery of health care at home. This could have an impact on the sector in a number of ways because it affects who can deliver those services, prescribing and dispensing and how such activities are paid for.

Nurse practitioners and eligible midwives are now able to prescribe drugs and some other non-medical health professionals, including pharmacists, are authorised to prescribe certain drugs. This is particularly important in rural areas.

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28 See www.theage.com.au/it-pro/humanity-fights-for-ownership-of-its-soul-20101102-17c9d.html.

It has recently been announced that Victorian pharmacists will be permitted to deliver vaccinations and medication management with general practitioners under the Pharmacist Chronic Disease Management pilot programme. This follows a successful pilot in Queensland. The Victorian programme will allow pharmacies to provide flu vaccinations from 2016 and pertussis vaccinations for eligible adults in 2017.

vii State-to-federal transfer of health services

Traditionally the hospital systems have been run by the states and at first instance funded by them. The Commonwealth then provides grants for the operation of the hospitals. This system has long been regarded as inefficient, and only gives the Commonwealth the indirect means to control or reduce costs in the health sector. Additionally, from the perspective of those providers of medicines, particularly where reimbursement was being sought, it has meant that the Commonwealth does not fully appreciate savings that might be made in the hospital sector, because it does pay for them directly. Thus, medicines that might substantially reduce the time patients spend in hospital find it difficult to attract additional reimbursement reflective of that saving. From mid-2014, Commonwealth funding for public hospitals has been determined by the number and kinds of services the hospital provides, based on price for each type of service that has been independently determined. Such activity-based funding provides incentives for more efficient treatment of patients.

The Commonwealth and states are slowly moving to a single scheme where the Commonwealth will have much greater funding control.

viii Labelling reforms

The TGA has released its draft Therapeutic Goods Order No. 79 setting out proposed new standards for the labelling of medicines. While the ostensible purpose of this draft order is to make labelling clearer, some of the changes could affect the utility of trademarks and brand names in the promotion of products if the draft order is adopted unamended. The key proposals set out in the draft order are:

a standardisation of packaging, such as mandatory font sizes, colouring and rules around the prominence of active ingredients;
b the introduction of a medicine information panel for non-prescription medicines;
c requirements around blister strip labelling;
d reduction in the labelling requirements for small containers; and
e the introduction of new mandatory labelling requirements for pregnancy and allergen warnings, particular ingredients and expiry dates.

Consultation on the draft order has now closed and the TGA will present a finalised draft order to the government for its consideration. A transition period of three to four years for compliance with the new standards is currently contemplated.

ix Industry agreements

The Medicines Australia MOU, which was in its first iteration, expired on 30 June 2014. While it was thought it may be renewed and broadened, this has not eventuated.

The Sixth Community Pharmacy Agreement commenced on 1 July 2015 and provides a range of measures between pharmacies and the Commonwealth. The Agreement encompasses pharmacy remuneration for dispensing PBS subsidised medicines, wholesaler remuneration, the Pharmacy Location Rules and Professional Programs and Services. The Sixth Community Pharmacy Agreement will expire in 2020.[29]

x Privacy reforms

The Commonwealth Privacy Laws were amended with effect from 12 March 2014. While not specifically directed at the life sciences sector, the introduction of fines and the tightening-up of requirements around the export of personal data are relevant, the latter especially in relation to pharmacovigilance activities.

Of particular relevance are the requirements around cross-border disclosure of personal information, which would catch the transfer of information in a global IT system. Further, the collection and use of health information is subject to more stringent requirements that must be complied with. While the Privacy Laws do potentially create a number of issues, these issues can all be dealt with by the correct documentation.

Any collection and reporting of information in accordance with the transparency requirements (see subsection ii, *supra*) will also need to be considered in relation to the Privacy Laws.

The Office of the Australian Information Commissioner (OAIC) released a series of new draft health privacy guidance resources for health services providers. Currently, the Australian Privacy Principles (APP) Guidelines, also published by the OAIC, are the current guidelines in relation to health information. These APP Guidelines are not specific to health information, and as such, do not provide much insight into the treatment of health information. The draft health privacy guidelines are much more detailed and contain useful guidance to health service providers on their use and treatment of health information. The OAIC sought public comment on the draft health privacy guidelines. The OAIC has yet to release any further public comment on the draft guidelines.

In addition, the Attorney General's department has released an exposure draft of the Australian government's mandatory data breach notification bill. The Privacy Amendment (Notification of Serious Data Breaches) Bill 2015 proposes to amend the Privacy Act to introduce an obligation for organisations and Commonwealth government agencies that are subject to the Privacy Act to notify the Australian Information Commissioner and affected members of the public of the occurrence of a data breach in certain circumstances. Public comments are currently being sought on the exposure draft. It seems likely that the Bill will be passed in 2016, at least in some form.

29 www.guild.org.au/docs/default-source/public-documents/tab---the-guild/Community-Pharmacy-Agreements/6cpa---final-24-may-201558b59133c06d6d6b9691ff000026bd16.pdf?sfvrsn=2.

xi Statements by non-sponsors

Issues arise around the ability of non-sponsors of medicines to say anything about products with little or no recourse, notwithstanding the potential for significant adverse health consequences on the community. It remains to be seen whether some specific regulatory response will emerge to what is essentially negative advertising. The latest issue was around the use of statins. After complaints and an internal review, the non-sponsor apologised for its statements and removed them from its website, however, no further action was taken. The previous issue was around vaccination.

xii Trans-Pacific Partnership Agreement (TPP)

The TPP was finally entered into in October 2015 and, as predicted, touches on a number of areas of particular interest to the sector. The TPP consists of 30 chapters, and thousands of pages. It has been reported that the TPP has no impact on the Pharmaceutical Benefits Scheme or on the accessibility and affordability of medicines in Australia.

The final negotiations of the TPP focused on pharmaceuticals, with significant disagreement between Australia and the United States on how long pharmaceutical companies could retain intellectual property rights over their products. The United States were pushing for the exclusive period of 12 years to use clinical data behind the approval of a new biological drug, but Australia refused to increase beyond a five-year period. A major concern of the generics industry has been that an increase in data exclusivity would result in further delaying the entry of generic competition. The final agreement offers at least five years' protection for biologic drugs, plus some time for other measures. It is unclear exactly what this would entail, however the Australian Government has provided repeated assurances that there will be essentially no change from the current position in Australia.

The TPP Agreement will be tabled in Parliament before being reviewed by the Joint Standing Committee on Treaties.

xiii Simplification of Medicines and Medical Devices Regulation – review

In October 2014, the government announced an independent review of the regulation of medicines and medical devices to be led by Emeritus Professor Lloyd Sansom AO, following a statement by the Prime Minister that Australia's current system of medicines regulation was a 'thicket of complexity, bureaucracy and corporate and institutional self-interest' and that 'if a drug that is proven to be safe abroad is needed here, it should be available'.

The purpose of the review was to identify regulation that could be removed without undermining the safety or quality of therapeutic goods available in Australia and identify opportunities to enhance the regulatory framework. The PBS is off limits for the review.

The Panel reported in two stages. The government is currently considering the first report, which covers recommendations on the regulatory frameworks for medicines and medical devices. The second report, addressing the regulatory frameworks for complementary medicines and the advertising of therapeutic goods was delivered in July 2015 and is also being considered by the government. The TGA is considering possible regulatory changes arising from the review.

Recommendations from the report include expanding the pathways by which sponsors can seek marketing approval for a medicine or medical device, including making provision for utilised assessments conducted by comparable overseas regulators, improving transparency and predictability of processes and decisions, enhancing post-market monitoring of medicines and medical devices and enhancing and streamlining the advertising framework.

xiv Rescheduling of codeine

In October 2015 the TGA published an interim decision on a proposal to up-schedule codeine, recommending that all over-the-counter medicines containing codeine be rescheduled to become prescription-only medicines. In November, the Department of Health's medicines scheduling delegate decided to defer making a final decision until 2016 because of the large number of submissions received; the majority are opposed to the proposal. The delegate now has the option to seek further advice, including from the Advisory Committee on Medicines Scheduling, and will not make a final decision before June 2016. Should the final decision require an implementation date, such implementation would not be before 2017.

xv Genetic testing – devices reform

Following a consultation paper on proposed amendments to the regulatory framework for in vitro diagnostic medical devices, the TGA has finalised a regulation impact statement recommending amendments to the framework. One recommendation was to ensure that tests that determine predisposition or susceptibility to a disease (that were defined as 'other therapeutic goods'), such as genetic tests, are included within the definition of a medical device and are required to be included in the ARTG.

Following this recommendation, the Therapeutic Goods (Articles that are Medical Devices) Specification 2014 was introduced, however, this Specification does not seem to adequately implement the recommendation. The language used in the Specification does not align with the definition of a sponsor, and while the tests themselves may be regulated, the interpretation and advice based on such tests are not.

xvi Patent box regime

Industry has been calling for the introduction of UK-style 'patent box' rules in Australia. The patent box rules provide companies concessional tax treatment on profits gained within the jurisdiction where certain types of patented technology are developed. While the government had indicated that it was interested in this regime, it was not included in the government's Innovation Plans Agenda and seems to have been deferred at this stage.

xvii Employee share reforms

From 1 July 2015, changes were made to the tax rules for employee share schemes to make them more attractive to employers and employees. These changes reverse certain tax changes made in 2009 that effectively stopped the use of employee share option plans in Australia. The main changes involve when options are taxed (employees will be able to defer paying tax until the options are exercised and converted into shares), increasing the maximum ownership limit to 10 per cent of the total shares (up from 5 per cent),

increasing the deferral period to 15 years (up from seven years) for tax deferred schemes, allowing a tax refund in circumstances where an employee acquires rights but chooses not to exercise them, and more favourable treatment for start-ups. Under the new rules, if shares are acquired in a start-up at a discount of up to 15 per cent (relative to market value), then the discount is exempt from income tax. The shares will only be subject to capital gains tax on disposal.

xviii Human tissue reforms

In all jurisdictions, there is a general prohibition on trading in human tissue. While the human tissue legislation in some jurisdictions contained exemptions, allowing for trading in tissue in certain circumstances, some jurisdictions, namely the Northern Territory, Queensland, Victoria and Western Australia required some form of approval to trade in tissue. The introduction of the Health Legislation Amendment Act 2014 (QLD) means that, from 2015, approval or consent is no longer required in Queensland for the sale or supply of tissue, provided the tissue has been subjected to processing or treatment, the trading of tissue is for a therapeutic, medical or scientific purpose, and the product is on the ARTG. The human tissue legislation in each jurisdiction was originally introduced to prevent simple trading in tissue (e.g., selling a kidney). The change in Queensland reflects acknowledgement that the existing human tissue legislation did not adequately deal with the changing nature of products containing human tissue, and it is likely that the other jurisdictions that still require approval for any trade in tissue will follow Queensland's lead and introduce a similar exemption.

xix Vaccines push

There has been a recent push to try to increase the uptake of childhood vaccinations, which are free in Australia. The federal government has introduced a 'No Jab, No Pay' policy, which means from 1 January 2016, people will not be eligible for the Family Tax Benefit (Part A), Child Care Benefit or the Child Care Rebate unless their children are up-to-date with their immunisations. Children not up-to-date will be required to follow a catch-up schedule. This excludes people who fall within a valid exemption category (e.g., allergies to vaccines), however 'vaccination objections' (previously called 'conscientious objections') will no longer be a valid exemption category.

The Victorian Government has also recently introduced legislation aimed at increasing vaccination rates, called 'No Jab, No Play'. From 1 January 2016, the legislation requires all children enrolling in early childhood education and care services (including kindergarten, long day care, occasional care and family day care) to be up-to-date with their vaccinations, have an approved exemption or be on a vaccination catch-up programme. As with the 'No Jab, No Pay' policy, conscientious objection is not an exemption under the No Jab, No Play legislation.

Chapter 7

CANADA

Jill Daley, Randy Sutton and Kristin Wall[1]

I INTRODUCTION

The life sciences sector is highly regulated in Canada. Food, drugs, cosmetics, medical devices and natural health products are federally regulated under the Food and Drugs Act[2] (FDA) and the regulations thereto, the Food and Drug Regulations[3] (FDR), the Cosmetic Regulations[4], the Medical Devices Regulations[5] (MDR) and the Natural Health Products Regulations[6] (NHPR), respectively.

Health Canada is the federal government department responsible for maintaining and improving the health of Canadians. The key branches of Health Canada are the Therapeutic Products Directorate, the Biologics and Genetic Therapies Directorate, the Medical Devices Bureau, the Natural and Non-Prescription Health Products Directorate, the Marketed Health Products Directorate and the Health Protection and Food Branch Inspectorate (which has an enforcement and inspection mandate concerning compliance with the FDA and its related regulations). The Canadian Food Inspection Agency (CFIA), under the authority of the Canadian Food Inspection Agency Act and the Safe Foods for Canadians Act, is responsible for the administration and enforcement of the FDA as it relates to food products.

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1 Jill Daley, Randy Sutton and Kristin Wall are partners at Norton Rose Fulbright Canada LLP, and the authors would like to thank Karen Sie, associate, for her assistance in preparing this chapter.

2 Food and Drugs Act, R.S.C., 1985, c.F-27.

3 Food and Drug Regulations, C.R.C., c.870.

4 Cosmetic Regulations, C.R.C., c.8.

5 Medical Devices Regulations, SOR/98-282.

6 Natural Health Product Regulations, SOR/2003-196.

Drugs, medical devices, natural health products (NHP) and certain foods are subject to a high degree of regulation in Canada including requirements to establish safety and efficacy, to obtain regulatory clearance prior to sale and to observe good manufacturing practices. Patented medicines are subject to price regulation through the Patented Medicine Prices Review Board (PMPRB), which derives its powers and jurisdiction from the Patent Act.[7]

Food is subject to less direct regulatory oversight in comparison with drugs; however, Canadian food legislation prohibits the advertising or sale of unsafe or adulterated foods, regulates health claims, sets standards for specific food products, mandates standards of purity and quality, and imposes packaging and labelling requirements on food products.

Protection of intellectual property rights is effected through the Patent Act (administered by the Commissioner of Patents) and the Trade-marks Act[8] (administered through the Registrar of Trademarks). The Patent Act grants a 20-year term of protection against the manufacture, use, sale, import or export of a patented invention without the patentee's permission. The Trade-marks Act provides a registration framework for brand names, designs, logos and, in certain cases, product appearance (a 'distinguishing guise').

II THE REGULATORY REGIME

i Classification

The classification of a product under the applicable regulatory framework normally involves compositional, structural and contextual analyses.

For example, an assessment of whether a product is a drug or device typically involves consideration of the definitions of a 'drug' and 'device' in a contextual manner, an assessment of how the product achieves its therapeutic function (its principle mechanism of action), and how its composition and characteristics are represented and perceived in the marketplace.[9] Drug products and devices differ in their therapeutic effect and in how this effect is achieved. For example, drugs are used to restore, correct or modify organic functions, whereas a device is typically used to restore, correct or modify a body function or structure (i.e., devices exert a physical effect on the body).

Similarly, personal care products may have the characteristics of both a cosmetic and a drug. In classifying such products as either a cosmetic or a drug, Health Canada has identified two main factors to guide the analysis: (1) the representations made in respect of the product (i.e., proposed claims that describe the function, use or attributes of the product); and (2) the composition of the product and whether the ingredients or components of the product render that product a drug or a cosmetic. The intended purposes of the product weigh most heavily in the classification analysis.[10] Classification

7 Patent Act, R.S.C., 1985, c.P-4.

8 Trade-marks Act, R.S.C., 1985, c.T-13.

9 Guidance Document: Factors Influencing the Classification of Products at the Drug-Device Interface, Health Canada, 4 March 2013.

10 Guidance Document: Classification of Products at the Cosmetic-Drug Interface, Health Canada, 2008.

issues could also arise for medical devices that also have the characteristics of either a cosmetic or a drug, or be considered a combination product. Health Canada's policy concerning drug or medical device combination products assists in the resolution of classification issues for such combination products. Combination products are those where the drug and device components are combined into a singular product. Combination products are regulated under the regulatory framework associated with the 'principal mechanism of action' of the product; however, all of the standards of safety, efficacy and quality of all applicable regulatory frameworks must still be met.[11]

ii Non-clinical studies

The Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP) apply to non-clinical animal or in vitro studies in Canada and are administered by the Standards Council of Canada (SCC).[12] The SCC serves as the monitoring authority for the GLP programme. The GLP requirements encompass all aspects of work conducted in a laboratory, from the planning of a study to the experimental procedures and reporting of results. All laboratories conducting animal or in vitro studies must comply with the GLP requirements and are inspected by the SCC.

The Canadian Council on Animal Care (CCAC) is a quasi-regulatory body that oversees the ethical use of animals for science in Canada. The CCAC sets standards by way of published guideline documents and policy statements. An institution conducting animal research must be accredited by the CCAC to receive research funding from the federal government. In the majority of institutions where animals are used in non-clinical studies, a study protocol must be submitted to and approved by the institution's research ethics board or animal care committee to ensure that the proposal meets the humane and welfare standards.

iii Clinical trials

Clinical trials are regulated under the FDR. Phase I to III clinical trials, including investigator-initiated studies, must comply with the requirements of Division 5 of the FDR. Research Ethics Board (REB) approval of the research protocol and an informed consent form for each clinical site must be obtained before the clinical trial begins. Canada's three federal funding agencies[13] have developed a joint policy governing the ethical conduct of research involving humans.[14] To be eligible to receive and administer

11 Health Canada Policy: Drug/Medical Device Combination Products, 1 March 2006.

12 The Standards Council of Canada is a federal Crown corporation established to foster and promote voluntary standardisation in Canada.

13 The Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC).

14 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.

research funds from the agencies, institutions must agree to comply with the joint policy and ensure that research conducted under their auspices adheres to the policy. Such adherence is a condition of funding.

A clinical trial application (CTA) must be filed with Health Canada. The CTA includes information on the trial protocol, informed consent documents, information on the perceived benefits and risks of the drug, and the investigator's brochure on the effects of the drug to be used in the trial. The CTA will be reviewed by the appropriate directorate at Health Canada and the sponsor will be provided with a notification within 30 days. If there are no deficiencies found, a 'no objection letter' will be issued.

Health Canada publishes a drug clinical trial database, which is a public listing of specific information on phase I, II and III clinical trials authorised by Health Canada from April 2013 onwards. The information in the database is provided by the sponsor of the clinical trial.

Each clinical trial participant must give voluntary, informed and ongoing consent to be in the study. The sponsor must provide full disclosure of information for making an informed decision to participate in the research project. Other than in exceptional cases, informed consent must be obtained from the participants, in the form of a signed statement, before engaging in any research in the clinical trial. Good clinical practice guidelines are defined under both the International Conference on Harmonisation and the FDR. Sponsors must report all serious, unexpected, drug-related adverse events associated with the clinical trial to Health Canada and to the REB.

iv Named-patient and compassionate use procedures

Canada's Special Access Programme (SAP)[15] allows patients access to drugs that are not approved for sale in Canada. The framework of the SAP, provided under the FDR, was established to provide compassionate access to drugs for patients with serious or life-threatening conditions, or to provide drugs on an emergency basis when conventional therapies are unsuitable, unavailable or have failed. The types of drug that may be authorised under the SAP range from pharmaceutical and biologic to radiopharmaceutical drugs.

A SAP request is made to Health Canada by a medical practitioner; it is the responsibility of the medical practitioner to ensure that the decision to use the drug is supported by credible evidence and that the patient is aware and informed of the risks involved with using a drug not approved for use in Canada.

If the SAP request is granted by Health Canada, the manufacturer is responsible for deciding whether to fulfil the request. The manufacturer can determine the conditions, including cost, under which the request will be fulfilled. The requesting medical practitioner is required to report on the results of using the drug, including any adverse drug reaction experienced.

15 Guidance for Industry and Practitioners – Special Access Programme (SAP) for drugs, Health Canada, 2008.

The provisions of the FDR authorising the SAP were amended in October 2013 to remove access to certain types of illicit drugs under the programme. In particular, heroin and certain types of cocaine are no longer accessible through a SAP request.

The SAP process does not involve a comprehensive evaluation of the safety, efficacy and quality of the drug. It does not constitute an approval of the drug, a mechanism for early use of the drug or a mechanism to expedite the drug approval process in Canada.

v Pre-market clearance

Drugs, natural health products and medical devices are federally regulated under the FDA, FDR, NHPR and MDR.

Drug approval

A new drug must receive Health Canada approval through the filing of a new drug submission (NDS). The NDS contains information and data about the drug's safety, effectiveness and quality, along with pre-clinical and clinical study data, details on the production of the drug, packaging and labelling, therapeutic claims and side effects. Upon completion of its review, and where the directorate within Health Canada is satisfied that the benefits of the drug outweigh the risks, a notice of compliance (NOC) and a drug identification number (DIN) will be issued. The NOC and DIN indicate approval and permission to market the drug in Canada.

If a drug is not approved, the applicant is given the opportunity to provide additional information and re-submit its NDS, or appeal the decision.

Applicants seeking approval for old drugs[16] need only file a DIN application.

Priority review

A priority review process is available for certain drugs. These include promising drugs for the treatment of life-threatening or severely debilitating conditions, diseases for which there is currently no existing therapy, or new drugs that significantly improve existing therapies.

Abridged review

Applicants seeking Health Canada approval for subsequent entry generic drugs are permitted to submit an abbreviated new drug submission (ANDS). The ANDS allows the generic manufacturer to rely on the innovator's NDS, including the pre-clinical and clinical data in respect of safety and efficacy of the drug. The generic manufacturer need only establish bioavailability and bioequivalence with the innovator's drug to be issued a NOC and DIN.

16 'Old drugs' refer to those drugs that fall under Division 1 of the FDR and have been on the market for a number of years.Often those drugs are available without a prescription (i.e., acetaminophen).

Natural health product approval

The NHPR apply to the sale, manufacture, packaging, labelling and importation for sale of NHPs, as well as the distribution and storage of NHPs. Pursuant to the NHPR, all NHPs sold in Canada must have a product licence. An applicant must submit a NHP licence application to Health Canada, which includes detailed information about the product, its medicinal and non-medicinal ingredients, source, dose, potency and its recommended uses. An approved NHP will receive a Natural Product Number (NPN) or a Homeopathic Medicine Number (DIN-HM) for homeopathic products that may contain or be manufactured from substances that are not otherwise regulated under the NHPR (e.g., substances listed in Schedule D of the FDA). The NPN and DIN-HM serve as notification to the public that the NHP has been reviewed by Health Canada and determined to be safe, effective and of high quality.

Medical device approval

In Canada, the regulation of medical devices is limited to devices intended for use in the treatment of humans. With the exception of medical devices categorised as Class I (i.e., those in the low risk category), Class II to IV medical devices marketed in Canada require a medical device licence. This licence is issued by Health Canada to the device manufacturer once compliance with the MDR has been established. The MDR apply to the sale and advertising of a medical device and the importation of a medical device for sale or for use on patients.

vi Regulatory incentives

The Patented Medicines (Notice of Compliance) Regulations

The Patented Medicines (Notice of Compliance) Regulations[17] (PM(NOC) Regulations), made under the Patent Act, provide a linkage between the drug approval process and patent protection for drugs. They prohibit the issuance of a NOC by the Minister of Health (Minister) where a generic drug is alleged to infringe the patent of the Canadian reference product (an innovative drug) subject to certain processes.

Under the PM(NOC) Regulations, the Minister of Health is required to keep a Patent Register: a list of all patents that the manufacturer has applied to have listed in relation to those approved drugs. In order for a patent to be listed, certain substantive and temporal eligibility requirements must be met. For example, from a substantive perspective the patent must contain at least one eligible claim for the medicinal ingredient, dosage form, formulation or use of the medicinal ingredient in order to be listed on the Patent Register against the drug product. If a generic manufacturer seeks approval for a drug relying on an innovative drug with listed patents, the manufacturer must address these patents before receiving regulatory approval.

When a sponsor files a submission for a generic drug where there are associated patents listed on the Patent Register, the applicant must either accept that they will not be issued an NOC until the expiration of a listed patent or file a statement alleging that

17 Patented Medicines (Notice of Compliance) Regulations, SOR/93-133.

the person who filed the patent is not the owner of the patent, that the patent is invalid, expired, or that the generic drug does not infringe the existing patent. This statement is called a notice of allegation (NOA).

The NOA is required to be served on the person who filed the patent, who may, within 45 days, initiate court proceedings seeking to prohibit the Minister of Health from issuing a NOC to the generic manufacturer. Upon initiating this application process, the Minister of Health is prohibited from issuing a NOC for a maximum period of 24 months, or the conclusion of the litigation, whichever comes earlier. The court will make a determination as to whether the allegations in the NOA are justified. If the court decides the allegations were justified, the generic manufacturer will be issued its NOC and can come to market immediately. On the other hand, if the court decides that the allegations were not justified, the NOC will not be issued and the generic manufacturer will need to wait until the patent expires before being granted its NOC.

Decisions under the PM(NOC) Regulations are not final determinations of patent rights. Innovative drug manufacturers are still able to sue for patent infringement once the generic comes to market, and generics are able to seek a declaration of invalidity.

Data protection

Under the FDR, innovative drug[18] manufacturers are given a form of market exclusivity by way of data protection. Data protection prevents, for a period of eight years after the innovator receives its NOC, a subsequent manufacturer from obtaining approval by relying on the innovator's undisclosed pre-clinical and clinical test data submitted to Health Canada. A further six months of exclusivity is granted based on paediatric studies, if certain criteria are met.

While the competitor cannot actually obtain its NOC for eight or eight and a half years, the submission, relying on the innovator's data, may be filed with Health Canada after six years from the date the innovator obtained its approval.

vii Post-approval controls

The FDA was amended with the passage of Bill C-17, an Act to Amend the Food and Drugs Act, in November 2014. The amendments aim to better address patient safety and to strengthen Health Canada's enforcement powers over drugs and medical devices. To this end, the amendments grant Health Canada new authority to, among other things, order a recall of a product, order changes to the labelling or packaging of the drug, conduct assessments of the drug and order the provision of any information deemed necessary, including confidential business information, where the product may present a serious risk of injury to Canadians. Regulations and guidance documents regarding Health Canada's enforcement powers have been proposed but are not yet finalised.

After marketing authorisation is granted, Health Canada remains involved in post-market surveillance, inspections and investigations in respect of the safety and

18 An 'innovative drug' is defined under the FDR as a drug that contains a medicinal ingredient not previously approved in a drug by the Minister of Health, and is not a variation of a previously approved drug, such as an ester, salt, enantiomer, solvate or polymorph.

efficacy of the drug. The Minister also has the ability to issue warnings to the public or health professionals, seize products, suspend or cancel a notice of compliance or drug identification number, require the submission of further evidence of safety or efficacy, or to refuse imports.

Notice of compliance with conditions

Health Canada may grant marketing approval of a drug with conditions (NOC/c).[19] The primary condition is that the sponsor will undertake to conduct additional studies to show the clinical benefit of the drug. The NOC/c allows drugs to come to market earlier and may be issued to eligible and potentially life-saving drugs. The drugs must have been shown to have promising clinical effectiveness in clinical trials. With the issuance of a NOC/c, Health Canada conducts enhanced post-market surveillance on the drug. Along with conducting further studies, these post-market surveillance measures typically include an undertaking for increased monitoring of the drug and reporting to Health Canada, the provision of educational material and restrictions on advertising and labelling of the drug.

Adverse event reporting

The FDR requires that manufacturers report adverse reactions to Health Canada. The means of adverse reporting will depend on the type of health product; however, the majority of reporting is provided to the Canada Vigilance National Office.

The Canada Vigilance Program, Canada's post-market surveillance programme, allows manufacturers, consumers, patients and health professionals to report suspected adverse reactions or side effects to health products, including prescription and non-prescription drugs, biologics, natural health products and radiopharmaceuticals. MedEffect is an online portal maintained by the Marketed Health Products Directorate at Health Canada that allows patients, health-care professionals and consumers to report easily adverse drug reactions and side effects.

Reporting of adverse effects related to medical devices can be done by the consumer or health professional directly to Health Canada (via a Medical Device Problem Report).

The new amendments to the FDA require mandatory reporting by a prescribed health-care institution of serious adverse reactions involving a therapeutic product or medical device. However, this will only be effective when the relevant health-care institutions have been 'prescribed' in regulation, which has not yet occurred.

viii Manufacturing controls

Drug products

Any party seeking to fabricate, package, label, distribute, wholesale, test or import drugs is required to obtain a drug establishment licence (DEL) before doing so. A DEL

19 Guidance Document: Notice of Compliance with conditions (NOC/c), Health Canada, 30 June 2011.

applicant must demonstrate compliance with good manufacturing practices (GMP). The applicant's site will be subject to inspections by the regulatory authority, including a GMP inspection, laboratory analysis and a controlled substances inspection.

Medical devices

Persons wishing to import or sell a medical device in Canada must hold a medical device establishment licence (MDEL). Any manufacturer of a Class I device must hold an MDEL unless they import or distribute solely through a person who holds an MDEL. Retailers, health-care facilities and manufacturers importing or selling their own Class II, III and IV devices are exempt from this requirement.

ix Advertising and promotion

Health Canada has enforcement oversight of the advertising of food, drugs, NHPs and medical devices in Canada. It is an offence under the FDA to advertise, package, label or sell a food, drug or device in a manner that is 'false, misleading or deceptive or is likely to create an erroneous impression regarding the character, value, quantity, composition, merit or safety' of the product. Misleading advertising or deceptive marketing is also prohibited under Canada's Competition Act [20] and various provincial consumer protection statutes.

The advertising of approved drug products, NHPs, or medical devices is limited to the terms of marketing authorisation. Under the FDR, advertisements to the public for prescription drugs may only contain the drug name, price and quantity of the drug. Similarly, the advertisement to the public of any food, drug, cosmetic or device as a treatment, preventative or cure for any disease or disorder referenced in Schedule A of the FDA (such as cancer, congestive heart failure or other serious diseases) is prohibited under the FDA. Drugs and NHPs sold over the counter are exempt from the prohibition with respect to preventative claims relating to Schedule A diseases.[21] 'Disease awareness' advertising is permitted in Canada provided the advertisement is not branded with product names or the manufacturers' names and logos.

Advertising preclearance agencies work with Health Canada to ensure the advertising of health products comply with the regulatory requirements. The Pharmaceutical Advertising Advisory Board (PAAB) is an agency that conducts preclearance for the advertising of drug products directed at health-care professionals. Advertising Standards Canada (ASC) is an advertising preclearance agency that reviews advertising material for non-prescription drugs and NHPs targeted at consumers. The ASC also reviews direct-to-consumer advertising and information for prescription drug products. Both PAAB and the ASC have advertising codes that provide guidance of what is acceptable in terms of compliance with regulatory regimes. These serve as guidance for industry and do not have the force of law.

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20 Competition Act, R.S.C., 1985, c.C-34.

21 See also: Guidance Document: Consumer Advertising Guidelines for Marketed Health Products (for Non-prescription Drugs including Natural Health Products), Health Canada, 18 October 2006.

x Distributors and wholesalers

Distributors and wholesalers are required to have a valid DEL. Further details of the requirements for a DEL are discussed above (see Section II.viii, *supra*).

xi Classification of products

Health Canada has established a broad set of principles and factors to be considered when deciding whether a drug is to be marketed as a prescription or non-prescription product.[22] Drug products are first classified as either prescription or non-prescription at the federal level. Following the federal classification, the provinces and territories can further restrict the conditions of sale with respect to drug products, but cannot be less stringent than the federal requirements. Most provincial restrictions follow the schedule of drug products as recommended by the National Association of Pharmacy Regulatory Authorities (NAPRA), which consist of four categories (Schedule I – III and Unscheduled), each with specific conditions for sale.[23] For example, Schedule I drugs requires a prescription and its sale is controlled in a regulated environment as defined by provincial pharmacy legislation; Unscheduled drugs, on the other hand, may be sold without prescription or professional supervision from any retail outlet.

In accordance with the FDR and the Controlled Drug and Substances Act (CDSA)[24] drugs may be classified and regulated as follows:[25]

a Prescription Drug List (prescription drugs)[26];
b Schedule G (controlled drugs, CDSA III, CDSA IV);
c Schedule D (biological products);
d Narcotic (CDSA I);
e Narcotic (CDSA II); and
f Targeted (CDSA IV).

Drugs that are not included in one of the above schedules are classified and regulated as either NHP, including homeopathic drugs, or non-prescription (over-the-counter) drugs.

xii Imports and exports

The import and export of health products including drugs and medical devices is regulated under the FDA and its regulations. An importer of a drug or medical device is required to obtain a DEL and meet GMP requirements (see Section II.viii, *supra*).

22 Guidance Document: Determining Prescription Status for Human and Veterinary Drugs, Health Canada, 20 June 2013.

23 Health Canada, Prescription Drug List Question & Answer.

24 Controlled Drugs and Substances Act, S.C., 1996, c.19.

25 Health Canada, Drug Product Database, Terminology.

26 See FDA Section 29.1, which gives the Minister of Health the power to establish a list that sets out prescription drugs.The Prescription Drug List came into effect on 19 December 2013 and replaces the former Schedule F to the Food and Drug Regulations.

Drugs that are imported into Canada must meet Canadian market authorisation requirements, which include labelling, as well as meeting DEL and GMP requirements mentioned above.

If a drug is manufactured in Canada for export only, but is not for sale or consumption within Canada, then Canadian licensing requirements need not be met. When being exported, an export certificate may be sought on the basis of an attestation by the fabricator that the drug is not manufactured or sold for consumption in Canada and that its package and contents do not contravene the known laws or requirements of the country to which it is being exported.

Drugs and devices may also be exempt from meeting Canadian licensing requirements if being manufactured for the purpose of exporting to a country under the General Council Decision of the World Trade Organization for access to medicines for public-health purposes (known as the Doha Decision).

xiii Controlled substances

Controlled substances are those that are defined by statute as having a higher-than-average potential for abuse or addiction. Controlled substances are categorised by schedule, where each schedule is associated with the usefulness of the drug in medical therapy, the dependence potential and the abuse liability of the drug.

The legislation governing controlled substances is the CDSA and Schedule G to the FDR. The CDSA contains restrictions in respect of possession, import, export, production and distribution of controlled substances.

The FDR specify the circumstances under which activities involving controlled drugs are permitted, and the requirements for the issuing of licences in respect of import, export, sale, manufacture, production or distribution and prescriptions of controlled substances.

Only 'licensed dealers' are permitted to produce, make, assemble, import, export, sell, provide, transport or advertise a controlled drug. Typically, licensed dealers include drug manufacturers, wholesalers, pharmacists and practitioners. It is an offence to possess a controlled substance except as authorised by the FDR (i.e., holding a dealer licence).

The requirements for obtaining a dealer's licence are set out in the FDR. A detailed application must be made to the Minister of Health to obtain the licence. Among other things, the application must include information about security measures at the licensed premises and proper record keeping of the controlled substance.

The CDSA prohibits the import or export of controlled substances unless authorised by the FDR. In addition to requiring a dealer licence, a permit to import or export the controlled substance must be obtained by application to the Minister of Health. The permit places further restrictions on the handling of the controlled substance. For example, the permit will only apply to a single complete shipment and to the amount of the controlled substance listed on the permit.

xiv Enforcement

Health Canada has significant powers of investigation, inspection, detention and seizure to investigate and prosecute violations of regulatory requirements for drugs and medical devices. While such issues are often resolved administratively without the need to resort

to formal prosecution, prosecution remains an available enforcement option. The FDA provides penalties for violations of the FDA and its related regulations including fines and imprisonment. Other federal regulators, including the Canada Border Services Agency and the Canadian Competition Bureau (headed by the Commissioner of Competition (the Commissioner)), share overlapping enforcement responsibility with Health Canada and derive their powers from legislation other than the FDA.

Recent amendments to the FDA impose significantly stricter penalties associated with violators of the provisions of the FDA and regulations in respect of 'therapeutic products'.[27] These penalties include fines of up to C$5 million or imprisonment for a term of up to two years, or both, and unlimited fines and imprisonment of up to five years for those found to have wilfully provided false or misleading information to the Minister, or to have knowingly or recklessly caused serious risk of injury to human health by contravening any provision of the FDA, FDR or MDR.

Misleading or deceptive advertising or marketing may be prosecuted as a criminal offence or challenged civilly as 'reviewable conduct' under the Competition Act. A court of competent jurisdiction has the discretion to order criminal fines or imprisonment for a term not exceeding 14 years (or both). For civil prosecutions, fines, in the form of administrative monetary penalties, range from maximums of C$750,000 for individuals to C$10 million for a corporation, each in the case of a first-time offence, with increasing fines for subsequent offences, may be imposed either by a court or by the Competition Tribunal. An order may also be made requiring compensation to be provided to those affected by the conduct. The Commissioner will generally pursue civil remedies unless there is clear and compelling evidence that the accused knowingly or recklessly made a false or misleading representation to the public; and the Commissioner is satisfied that criminal prosecution would be in the public interest. The Competition Act also provides a right of action for any person who has suffered loss or damage arising from a breach of the criminal provisions of the Act, including the criminal provisions relating to false or misleading advertising.

III PRICING AND REIMBURSEMENT

The regulation of drug prices in Canada is governed by a combination of the PMPRB and provincial or territorial public drug plans. Health Canada is not involved in regulating the price of medicines or medical devices in Canada.

While there is universal coverage for medically necessary services in Canada, there is no universal drug benefits plan in Canada. Each provincial or territorial government provides coverage to specific subgroups of the population. Each public drug plan develops a formulary specifying the drugs that are eligible for coverage and the conditions for reimbursement. The provinces and territories, including most recently

27 'Therapeutic product' means a drug or device or any combination of drugs and devices, but does not include a natural health product.

Quebec, participate in the Pan-Canadian Pharmaceutical Alliance (pCPA)[28], which is aimed at facilitating multi-jurisdictional negotiations on pricing and reimbursement of brand name and generic drugs for listing on the provincial formularies.

The price of patented medicines is regulated by the PMPRB. The PMPRB is an independent quasi-judicial federal body created under the Patent Act that reviews the factory-gate pricing of patented medicines to ensure that the prices of patented medicines sold in Canada are not excessive. Patentees are required to submit pricing information in respect of a patented drug product when it is first offered for sale in Canada and semi-annually thereafter. To determine whether a product's average price is excessive, the PMPRB may consider factors including the maximum Canadian price of other products in the same therapeutic class and the prices of the same patented drug in seven other industrialised countries.[29] If the price of a patented medicine is found to be excessive, the PMPRB can order a price reduction of the product or other fines or penalties, such as repayment of revenues found to be excessive.[30]

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

In general, parties aggrieved by decisions of Canadian federal agencies (such as Health Canada) exercising authority under a federal statute may challenge such decisions by seeking judicial review of the decision before Canada's Federal Court. Provincial bodies are subject to similar judicial review before provincial courts. The remedies available to a reviewing court include the ability of the court to quash decisions of such administrative agencies for serious errors of jurisdiction, law, fact or fairness. Administrative reviews or appeals before the agency that made the decision may also be provided under the agency's empowering statute and, generally, should be exhausted before seeking judicial review.

If a reviewing court determines it is necessary to intervene in respect of a decision rendered by an administrative agency, the reviewing court will frequently send the decision back to the agency that made to the decision with instructions as to how to either correct the error in the proceeding or correct the interpretation of law that gave

28 The pCPA was formerly known as the pan-Canadian Pricing Alliance.The new name collectively references both the pan-Canadian Pricing Alliance and Generic Value Price Initiative.

29 Section 85 of the Patent Act specifies the factors to be considered in determining whether the price is excessive.These factors include the sale price for the medicine in the relevant market; the price of other drugs from the same therapeutic class in the relevant market, the price of the same medicine or other medicines in the same therapeutic class in the seven specific foreign comparator countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States); and changes in the consumer price index.

30 The PMPRB may negotiate a voluntary compliance undertaking with the patentee regarding the excess price or may order a price reduction or retroactive payment of excess revenues, or both.

rise to the decision. In cases where a decision was based on the exercise of discretion, Canadian courts will not usually intervene except in cases where the decision was made in bad faith, for an improper purpose or on the basis of irrelevant considerations.

As a general principle, discretionary power exercised by an administrative decision-maker must be exercised in good faith and used to promote the policies and objects of the empowering legislation. In cases involving health and safety or matters requiring technical expertise, the court will often defer to the expertise of the decision-maker.[31]

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

The provision of gifts, donations or reimbursements is regulated under the various codes of conduct or ethical codes of drug manufacturers and health-care professionals. The regulatory bodies for health-care professionals such as the Canadian Medical Association and the Royal College of Physicians and Surgeons of Canada have ethical guidelines that their members must adhere to, as do the provincial 'colleges' that oversee the regulated health-care professions. Professional misconduct may be found where a conflict of interest exists between the professional and a pharmaceutical company. Manufacturers that are members of Canada's Research-Based Pharmaceutical Companies (Rx&D)[32], the industry association for innovative pharmaceutical manufacturers, are bound by its Code of Ethical Practices, which prohibits the provision of gifts, promotional aids, rewards or any other item intended for personal or family benefit, or that provides a pecuniary advantage to health professionals and their staff. The Rx&D Code also includes Guidelines for Transparency in Stakeholder Funding.

Some provinces restrict the permissibility of discounts and rebates; for example, British Columbia, Ontario and Quebec have legislation that governs the provision of rebates by pharmaceutical manufacturers to pharmacies or wholesalers, and the extent to which manufacturers may provide other benefits or other payments to pharmacies.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Canada's product liability framework for drugs and medical devices is generally based on a tort compensation system. Increasingly, product liability cases take the form of a class action proceeding – a case in which a representative plaintiff brings the claim on behalf of two or more similarly affected persons.

In recent years, there have been several notable class actions related to health-care products. *Andersen v. St Jude Medical, Inc*[33] was the first certified, national product liability medical device class action to proceed to trial in 2010; it was dismissed. In

31 See, for example, *Apotex v. Canada* (1993), 59 F.T.R.85 (T.D.); *Reddy-Cheminor, Inc. v. Canada (Attorney General)*, 2004 FCA 102.

32 Rx&D has changed its name to 'Innovative Medicines Canada' effective 4 January 2016.

33 *Andersen v. St Jude Medical*, Inc, 2012 ONSC 3660.

2015, the British Columbia Court of Appeal dismissed a proposed class action in *Low v. Pfizer Canada Inc*. The proposed class action was brought by consumers of VIAGRA® and alleged that the manufacturer had unlawfully abused the patent system resulting in high prices for the drug product.[34] The Court of Appeal held that the patent regulatory regime is a complete code and excludes parallel civic actions by consumers that are based on findings in the patent regime.

In some provinces, subrogation claims may also be advanced in the context of product liability actions by provincial health authorities to recover health-care costs from the person who caused the injury. While alternative compensation programmes have existed in Canada, for example, compensation programmes for individuals with transfusion-related HIV or Hepatitis C, the traditional tort-based liability system remains the primary compensation model for Canada.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

A 'pay for delay' agreement (also known as a reverse-payment settlement) is an agreement whereby an innovative manufacturer and potential competitors agree to delay the entry of a generic into the marketplace. Although the Commissioner has expressed the preliminary views of the Competition Bureau on 'pay for delay' agreements and how the Competition Act may apply, this is an issue that has yet to be dealt with in Canada. It is possible these could be challenged under either the existing conspiracy provisions or the civil review provision of the Competition Act, which provides that, on application by the Commissioner, an order may be made by the Competition Tribunal prohibiting any person from doing anything under the agreement or requiring any person to take any other action where an existing or proposed agreement or arrangement between competitors presents or lessens, or is likely to prevent or lessen, competition substantially in a market.

Companies, such as pharmaceutical manufacturers, that have commercial agreements in Canada with competitors or potential competitors (such as a generic manufacturer) must ensure that the agreements do not violate the Competition Act, particularly if the parties to the agreement have market power.

ii Transactional issues

The high degree of regulation in the life sciences sector adds complexity to commercial transactions. Regulatory transaction approval or notification may be required in the event of a change of control. Competition issues (briefly outlined above) also bear close review.

Post-closing issues for a commercial transaction relating to either drugs or medical devices are often complicated to the extent that pre-closing due diligence identifies changes necessary to commercial operations in the acquired company.

34 *Low v. Pfizer Canada Inc.*, 2015 BCCA 506 .

VIII CURRENT DEVELOPMENTS

Health Canada's legislative renewal initiative in the life sciences sector will continue across various regulated products. In April 2014, Health Canada announced its Regulatory Transparency and Openness Framework: a plan for improving access to timely, useful and relevant health and safety information for Canadians. In 2015, Health Canada had successfully completed the targeted 15 initiatives to improve transparency, including in key areas such as drug safety and inspections, food and nutrition, consumer products and stakeholder engagement. Notable initiatives include the development of the Drug and Health Product Register, Good Manufacturing Processes inspection summaries and Inspection Tracker, health products advertising complaints listing and the listing of submissions under review for new active substances, pharmaceuticals and biologics. The second phase of the Regulatory Transparency and Openness Framework was announced in June 2015 and includes a three-year plan to further expand the information available in the Drug and Health Product Register and enhance the Drug and Health Product Inspection Database to include more information on Health Canada inspection activities. With the changes to the FDA (see Sections II.vii, and xiv, *supra*), Health Canada's Transparency and Openness Framework and strengthened enforcement powers over drugs and medical devices, a more active approach against contraventions of the FDA and its regulations is expected.

In terms of regulatory requirements relating to food, new food and nutrition labelling regulations have been proposed. The changes to food labelling in Canada aim to ensure that food labels are consistent and easily understood by consumers making purchasing decisions. The proposed changes reflect a modernisation goal – ensuring that serving size reference amounts reflect current consumption patterns, that upper limits for vitamins and minerals reflect current scientific data and that nutrients of public health concern are considered in the context of Canada's food labelling requirements.

The Minister of Health announced an intention to adopt an orphan drug framework for Canada in 2014. To accomplish this, amendments to the FDR for the approval of drugs for rare diseases (orphan drugs) are expected in the near future. It is anticipated that the proposed amendments will work to expedite approval for these products and will promote greater access for Canadians to drugs that treat rare diseases in small patient populations because of an anticipated priority review process and a reduction in submission fees for these products.

The Comprehensive Economic Trade Agreement (CETA) between Canada and the European Union was finalised and published in September 2014. The text of the agreement is currently undergoing legal review and translation into all official languages of the EU countries, after which it will be presented for approval by the Council and European Parliament. For Canada, CETA will mean changes to certain elements of the intellectual property system. Specifically, an effective right of appeal for innovative drug manufacturers under the PM(NOC) Regulations and the potential for a maximum two-year patent term extension under certain circumstances to compensate for delays caused by regulatory approval.

In November 2015, the text of the Trans-Pacific Partnership (TPP) was released to the public. The TPP is a multilateral free-trade agreement covering the Pacific region, entered into between 12 nations: Australia, Brunei, Canada, Chile, Japan, Malaysia,

Mexico, New Zealand, Peru, Singapore, Vietnam and the United States. Chapter 18 of the TPP includes provisions respecting intellectual property. For Canada, the provisions regarding patents are largely consistent with current Canadian law. The TPP includes obligations for patent term extension for regulatory delays, but will have the necessary flexibility to allow Canada to retain its export exception and two-year patent term restoration cap, in line with the agreed upon terms in CETA.

In December 2015, the Federal Court denied the first application under the PM(NOC) Regulations regarding a Subsequent Entry Biologic (SEB, also known as biosimilars or follow-on biologics).[35] In this case, Amgen Canada Inc. and Amgen Inc., the manufacturer of NEUPOGEN® (filgrastim), a biologic for the treatment of neutropenia, brought an application under the PM(NOC) Regulations to prohibit the Minister from granting regulatory approval for Apotex's SEB of filgrastim until the expiration of the patent associated with NEUPOGEN®. The Federal Court dismissed the application and held that Amgen had failed to show that Apotex's obviousness allegation regarding its patent was not justified. The appeal of this decision is currently pending.

In December 2015, Health Canada released a draft revised guidance document regarding regulatory approval submission requirements for SEBs, updating the current guidance that was released in 2010. Health Canada is now seeking consultation on the draft guidance document that sets out further specifications on the selection of reference innovator products, clinical and non-clinical study requirements and post-market requirements for SEBs before finalising the guidance document. SEBs are expected to enter the Canadian market in increasing numbers and are likely to face continued challenges including regulatory approval, patent infringement and litigation under the PM(NOC) Regulations.

The Marihuana for Medical Purposes Regulations (MMPR), which came into force in 2013, replaced the previous regulatory regime. The MMPR create conditions for a commercial industry that is responsible for the production and distribution of marijuana for medical purposes. Under the MMPR regulatory scheme, medical marijuana, in the form of dried marijuana, may only be obtained from a licensed producer pursuant to a medical document from a health-care practitioner.

The constitutionality of the MMPR has been challenged under the Canadian Charter of Rights and Freedoms. 'Designated persons' who were licensed to grow marijuana for medical purposes under the previous regulations are no longer authorised to do so under the MMPR. The plaintiffs argue that the requirement to purchase medical marijuana from licensed producers is unaffordable compared with self-cultivation, affecting their right to life, liberty and security of the person under Section 7 of the Charter. Pursuant to a Federal Court order in March 2014, certain individuals who were previously authorised to possess and produce marijuana, and who meet the terms of the Federal Court order, will be able to continue to do so on an interim basis pending the final decision of the Court.

With the trend toward the globalisation of commercial operations in the life sciences sector, increasing activity in the area of commercial transactions is expected.

35 *Amgen Canada Inc. v. Apotex Inc.*, 2015 FC 1261.

Chapter 30

SOUTH AFRICA

Andrew Parsons, Allison Williams,
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I INTRODUCTION

The life sciences industry is regulated by the Medicines Control Council (MCC), a body established by the Medicines and Related Substances Act No. 101 of 1965 (Act 101) to oversee the registration, manufacture, production, importation, exportation, sale, marketing, licensing, disposal and regulation of medicines medical devices and IVD (in vitro diagnostic medical devices).[2]

Act 101 is supplemented by other laws, guidelines and ethical codes that play roles in specific areas in the sector.

II THE REGULATORY REGIME

i Classification

Act 101 as amended[3] defines medicine as any substance suitable for use in the diagnosis, treatment, mitigation, modification or prevention of disease, or the symptoms thereof, or restoring, correcting or modifying any somatic, psychic or organic function in a person and includes veterinary medicine.[4]

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1 Andrew Parsons, Allison Williams, Liesel Kok and Rosalind Lake are directors at Norton Rose Fulbright South Africa Inc. The authors would also like to thank directors Maria Philippides, Donald Dinnie and Sandra Sithole for their assistance in the preparation of this chapter.

2 Medicines and Related Substances Amendment Act 14 of 2015.

3 Medicines and Related Substances Amendment Act 14 of 2015 Section 1 (g) – amendment to definition of 'medicine'.

4 Section 1 of Act 101.

A medical device is defined[5] as:

> *any instrument, appliance, material, apparatus, implant [in vitro], reagent [or calibrator] for in vitro use, software, material or other similar related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act 1973 intended by the manufacturer to be used, alone or in combination, for humans and animals for one or more of the same purposes as medicines (described above) as well as supporting ir sustaining life; disinfection of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; the prevention of pregnancy and which does not achieve its purpose through pharmacological, immunological or metabolic means in or on the human or animal body, but which may be assisted in its intended function by such means.*

The Foodstuffs, Cosmetics and Disinfectants Act[6] regulates the sale, manufacture, importation and exportation of foodstuffs and cosmetics.[7]

Act 101 was amended[8] to create a new medicines regulatory authority, the South African Health Product's Regulatory Authority (SAHPRA), which will replace the MCC and widen the regulatory landscape to cover medical devices[9] more effectively, and to bring certain foodstuffs and cosmetics within the scope of the territory previously covered by Act 101. The Medicines and related Substances Act 4 of 2015 has been promulgated and provides further clarification on proposed object and functions of SAHPRA. SAHPRA will replace the MCC on a date to be determined by the Minister of Health.[10] In the interim, the MCC remains the primary regulator in the sector.

ii Non-clinical studies

In terms of the National Health Act 61 of 2003 (NHA), the National Health Research Ethics Council has been empowered to set standards for conducting research on animals and humans.[11] The General Regulations published under Act 101 include animals in the definition of 'clinical trial', insofar as it pertains to the investigation of medicines intended for use in either humans or animals and involving research on animals. Persons wishing to conduct clinical trials in respect of medicines for use in animals, or involving

5 The Medicines and Related Substances Amendment Act of 2015 in Section 1(h) amended the definition of 'medical device'.

6 Foodstuffs, Cosmetics and Disinfectants Act of 1972.

7 The sale, marketing and importation of all medicines, medical devices and complementary medicines will also be regulated by the provisions of the Consumer Protection Act, 2008 (CPA).

8 Medicines and Related Substances Amendment Act 72 of 2008.

9 Separate draft regulations were subsequently published in 2014 to comprehensively regulate medical devices – 'Regulations relating to medical devices and in vitro diagnostic medical devices (IVDs)' (draft device regulations) published under Section 35 of Act 101.

10 Medicines and Related Substances Amendment Act 14 of 2015 – Section 26 – Transitional provisions.

11 Section 72(6) of the NHA 2003.

animal subjects, are now required to apply to the MCC for authorisation to conduct such clinical trials. The relevant documentary requirements for MCC approval are similar to those applicable to clinical trials involving human subjects.[12]

The South African Medical Research Council (SAMRC) has published the Guidelines on Ethics for Medical Research: Use of Animals in Research and Training,[13] which provides for formal ethical review of animal research protocols by a specially constituted ethical committee for research on animals.

A national standard for the care and use of animals for scientific purposes was published by the South African Bureau of Standards in 2008.[14] This standardisation document encompasses all aspects of the care and use of animals for scientific purposes including in medicine and research, product testing and diagnosis. It serves as a guide to researchers and institutions in promoting animal welfare in health research.

The Animals Protection Act 1962[15] makes it a criminal offence for a person to administer any poisonous or injurious drug or substance to an animal without reasonable cause.[16]

iii Clinical trials

The framework for conducting health research on humans consists of:

a legislation, consisting primarily of the NHA, Act 101[17] and various regulations published in terms of these statutes;

b ethical guidelines published by the Department of Health and statutory bodies to establish the substantive and procedural norms for conducting research; and

c statutory bodies such as the MCC, institutional research ethics committees (RECs), the National Health Research Ethics Council (NHREC) and the SAMRC (see the description of each above and below). These are entrusted with monitoring and enforcing the legislation and the guidelines pertaining to research on humans and clinical trials involving humans.

The NHA stipulates that research or experimentation on living persons may only be conducted with the written consent of those persons and in the manner prescribed by regulation.[18] Regulations relating to research on human participants have recently been

12 Regulation 34 published under Section 35 of the Medicines and Related Substances Act 1965 as amended with effect from 15 November 2013. See also footnote 19, *infra*.

13 South African Medical Research Council. Guidelines on Ethics for Medical Research: Use of Animals in Research and Training. Cape Town: South African Medical Research Council, 2004.

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

15 Act 71 of 1962.

16 Section 2(1)(n) of the Animals Protection Act 1962.

17 Act 101 of 1965.

18 Section 71(1) of the NHA 2003.

brought into effect.[19] These regulations affirm the general principles relating to health research on humans (such as consent and independent ethical review requirements) and stipulate researchers' specific obligations when conducting research on various categories of human participants. Additional requirements apply to research on vulnerable participants such as children and prisoners. Ministerial consent is required for non-therapeutic research on minors.

The overarching consideration for the acceptance of health research under the proposed regulations is that it must be relevant and responsive to the overall health and development needs of South Africa, including the individual needs of those who form the subject of the research.

The regulatory framework for clinical trials in South Africa is supplemented by a number of influential guideline documents. The following are the most relevant:

a the Department of Health's Ethics in Health Research: Principles, Structures and Processes;[20]

b the Department of Health's Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa;[21] and

c the South African Medical Research Council's Guidelines on Ethics for Medical Research: General Principles.[22]

The sponsor or principal investigator of the trial must comply with the Department of Health's Guidelines.[23]

The NHREC established under the NHA sets norms and standards for the functioning of health research ethics committees in South Africa.

Before a clinical trial of a medicine or medical device can start, regulatory approval must be obtained from the MCC. The form and content of applications for approval are contained in regulations published under Act 101.[24] Once approved, trial information must be recorded in the South African National Clinical Trials Register and assigned a unique number.

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19 'Regulations relating to research with human participants' published in Government Gazette No. 38000 on 19 September 2014.

20 Department of Health. Ethics in Health Research: Principles, Structures and Processes. Pretoria: Department of Health, 2004.

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

22 South African Medical Research Council. Guidelines on Ethics for Medical Research: General Principles. Cape Town: South African Medical Research Council, 2004 (fourth edition).

23 Regulation 2 of the Regulations relating to research with human participants' published in Government Gazette No. 38000 on 19 September 2014 read together with Section 1.4 of the Department of Health Guidelines.

24 The existing General Regulation 34 and the draft device regulations, both published under Section 35 of Act 101, set out various documentary requirements for obtaining approvals from the MCC for clinical trials of medicines and medical devices respectively.

All clinical trials to be conducted in South Africa must apply for and receive ethical approval from an accredited REC. The RECs throughout South Africa are required, in compliance with the NHA, to register with the NHREC and to abide by its norms and standards.

The principal investigator must be appropriately qualified and approved by the MCC and resident in South Africa. The principal investigator is responsible for obtaining informed consent from each participant in a clinical trial. This involves sharing information followed by the completion of a written informed consent document that has been approved by an REC.

There is a continuous reporting obligation on the principal investigator to submit progress reports to the MCC, REC and the sponsor, if applicable. Regulations under Act 101 require the principal investigator to submit progress reports to the MCC every six months and to provide a final report 30 days after completion or termination of the clinical trial.[25] Serious adverse events defined in the protocol must be reported to the REC and MCC.

In March 2012, a series of regulations under the NHA relating to: the establishment of stem cell banks and tissue banks; the general control of dead human bodies, tissue, blood, blood products and gametes; and the import and export of blood products and human tissue including stem cells were published. These regulations are currently in force. In the Guidelines for Registration of Medicines,[26] the MCC defines Biological medicine as: 'A medicine where the active ingredient and/or key excipients have been derived from living organisms or tissues, or manufactured using a biological process. Biological medicines can be defined largely by reference to their method of manufacture (the biological process).'[27]

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25 General Regulation 34(6) and the recently proposed Regulation 22 of the draft device regulations published under Act 101 of 1965.

26 MCC's Guidelines for the Registration of Medicines : General Informations – Pretoria, August 2012

27 These include *inter alia* medicines prepared from the following substrates:

a microbial cultures (fermentation);

b plant or animal cell cultures (including this resulting from recombinant DNA or Hybridoma techniques);

c extraction from biological tissues; and

d propagation of live agents in embryos or animals.

The living substrate may be genetically modified in a number of ways to provide the required active ingredient, including recombinant DNA technology or hybridoma techniques.

Biomedical medicines include, but may not be limited to, the following:

a plasma derived products (e.g., clotting factors, immunosera, etc.);

b vaccines;

c biotechnology – derived medicinal products (rDNA products) (e.g., R Hu-antihemophilic factors, hormones, cytokines, enzymes, monoclonal antibodies, erythropoietins); and

d human gene therapy.

Stem cell therapy is classified as biomedical medicine and the same registration process that applies to the registration of medicines and medical devices is applicable to stem cell therapy and research.

iv Named-patient and compassionate use procedures

Act 101 permits the MCC to authorise the sale of unregistered orthodox medicine, complementary medicine and veterinary medicine or devices for certain purposes. Section 21 of that Act gives the MCC broad authority to consider named-patient use, the distribution of donated[28] medicines and medical devices, as well as the supply of unregistered medicines and medical devices, for compassionate use.[29] The MCC has discretion to determine the requirements and terms under which the medicines or medical devices will be sold.

In named-patient applications, a detailed informed consent from the patient in question must accompany the application,[30] which includes a declaration regarding the drug's lack of registration with the MCC and that the possible benefits and risks of the product have been fully explained.

The product may only be used for the treatment of the patient in the manner and for the period approved by the MCC.

v Pre-market clearance

According to Act 101 no one may sell any medicines without registration with the MCC.

An application for registration of a medicine must be submitted for review and approval by the MCC by a pharmaceutical company registered and operating in South Africa. The applicant must be registered with the South African Pharmacy Council[31] and have an operating licence from the MCC.

The application for registration of a medicine requires comprehensive data and supporting documents. All data submitted for evaluation should substantiate all claims and should meet technical requirements of quality, safety and efficacy of the product for

28 The MCC has issued guidelines on medicine donations to South Africa, which are available at www.mccza.com. All applications for donated medicines must be reviewed by the MCC (through the MCC fast-track procedure) before they can be released for distribution.

29 In a controversial move, in 2012 the MCC revoked its authorisation for the compassionate use of Bedaquiline (TMC207) for drug-resistant TB patients in South Africa, instead requiring access to the drug through clinical trials. The reasoning for the revocation of approval is that the current data available to the MCC remains Phase II in nature and, therefore, according to the MCC, insufficient to allow for approval for use outside a well-designed clinical trial. As a result of negotiation it was resolved that patients already receiving the drug under the previous authorisation may continue their treatment despite the revocation of authorisation for compassionate use distribution.

30 The Section 21 application form and guidelines for completion are available at www.mccza.com.

31 This is established in terms of the South African Pharmacy Act 1997.

the purposes for which it is intended. Copies of labels and patient information leaflets complying fully with all requirements, including prescribed warnings and notices, must be submitted with the application.

The MCC's Guidelines contain detailed information in this respect.

An abbreviated medicine review process is available for pharmaceutical products that are registered in countries with which the MCC aligns itself[32] if the evaluation report is readily available and the product has been approved by the authorities in the past three years.

Although Act 101 defines medical devices, it is silent on their regulation, and there is currently no comprehensive system of medical device regulation;[33] however, the draft device regulations will significantly change this position.

Regulations to Act 101 came into force in 2014[34] and these regulate the labelling and marketing of complementary medicines. The Regulations have amended the definition of complementary medicines, and all products making medicinal claims that do not fall within this definition are classified as medicines and accordingly cannot be marketed until they have been registered by the MCC, based on an assessment of clinical safety and efficacy. These products must carry a disclaimer regarding the health benefits claimed, but they may stay on the market until they are called up for assessment by the MCC.

vi Regulatory incentives

There is no linkage between the regulatory regime and patent or trademark protection in South Africa. Aside from the traditional patent protection that can be obtained for pharmaceuticals, the shape of a pharmaceutical tablet can conceivably be protected as a trademark[35] in South Africa. Existing case law has shown, however, that registration of the shape of a tablet as a trademark is difficult to attain or maintain once registered.

Patented pharmaceutical products enjoy no exclusivity apart from that granted by the patent itself. Extensions of the patent terms are not available. Patent registrations are currently easy to obtain because South Africa has a deposit-based patent filing system, with no examination system conducted for novelty, inventiveness and the like and no

32 The Council aligns itself with the following regulatory authorities: the United States (FDA), the United Kingdom (MHRA), Sweden (MPA), Australia (TGA), Canada (Health Canada), European Union (EMEA) and Japan (MWH).

33 Only electro-medical devices are regulated by the Directorate of Radiation Control under the Department of Health, which is responsible for regulatory control over the sale and use of electro-medical devices listed in the Hazardous Substances Act 1973.

34 General Regulations published in terms of Act 101: Government Notice R870 in Government Gazette 37032 dated 15 November 2013.

35 Provided that: it is capable of distinguishing; that the mark does not consist exclusively of a shape where the shape of the tablet is necessary to obtain a specific technical result or results from the nature of the goods themselves; or where the registration of such a shape as a trademark would be likely to limit the development of any art or industry.

provision made for opposition. All patent applications lodged with the patent office will be granted provided that certain formalities are complied with, such as providing a detailed patent specification and paying the requisite fee.

The regulatory regime is not originator-friendly and allows the registration of a generic in advance of patent expiration. The prevailing view is that the Patents Act also permits parallel importation,[36] and compulsory licensing in circumstances deemed an abuse of patent rights.

The intellectual property landscape is facing significant change because of the Draft National Policy on Intellectual Property (the IP Policy) published in September 2013. The IP Policy seeks to balance the rights of the owners of intellectual property and the interests of South Africa as a developing country. Some of the objectives of the IP Policy include ensuring that national intellectual property laws are appropriate to the level of development and innovation in South Africa and to improve access to IP-based essential goods and services, particularly education, health and food.[37]

vii Post-approval controls

Pursuant to Act 101, the MCC has published guidelines to assist in the reporting of adverse drug reactions associated with the use of registered medicines and in the management of safety data that arises during post-registration and post-marketing clinical trials.

Applicants for medicine registration are obliged to ensure that appropriate systems for pharmacovigilance are put in place and maintained by its pharmacovigilance officer who is responsible for the preparation, *inter alia*, of:

a adverse drug reaction reports;
b periodic safety update reports;
c company-sponsored post-registration study reports, when required; and
d ongoing pharmacovigilance evaluation.

Act 101 caters for the transfer of ownership of medicine registrations, and variations and revocation of registrations.

viii Manufacturing controls

Only medicines manufactured and packed at quality-controlled sites that are compliant with the current principles of good manufacturing practice (GMP) as prescribed by the MCC will be registered. Once a site has been found to comply with GMP, the MCC

36 Unless an express restriction is made on the importation and resale in South Africa and this restriction is communicated to the purchaser of the original patented article.

37 See Section VIII, *infra*, for some of the changes likely to come about as a result of the IP Policy.

may issue a manufacturing licence in terms of Section 22C(1)(b) of Act 101.[38] Should a change of ownership or a change of premises occur, a new manufacturing licence must be obtained.[39]

Manufacturing facilities must comply with the requirements set out in the MCC Guide to Good Manufacturing Practice for Medicines in South Africa.[40] This guide incorporates the Pharmaceutical Inspection Cooperation Scheme GMP Guide of July 2004.

GMP ensures that products are consistently produced and controlled to the standards of quality appropriate for their intended use and as required by the medicine registration or product specification.

ix Advertising and promotion

Act 101 permits advertising prescription medicines only to medical practitioners, dentists, veterinarians, pharmacists and others who are authorised to prescribe medicines, and only for informational purposes.

All advertising must be based on the claims that appear on the approved package insert. Advertising does not require prior approval by the MCC but the MCC Inspectorate does deal with any infringement as a contravention of the regulations.

Members in the industry also subscribe to the Code of Advertising Practice of the Advertising Standards Authority of South Africa, which promotes truthfulness and accuracy in advertising. In addition, a number of industry association codes, such as the Code of Marketing Practice by the Marketing Code Authority, the draft marketing code adopted by the Self-Medication Association of South Africa and the Pharmaceutical Industry Association of South Africa, are adhered to by their various constituent organisations and members.

The Consumer Protection Act 2008 (CPA), which governs supply, advertisement, marketing, contract terms, product warranties, product liability and product recall across all sectors, requires labelling and information to be in plain and comprehensible language. Warnings regarding hazardous or unsafe products must be drawn to the consumer's attention before they are purchased or used.

In the event of a conflict of laws, the legislation that provides the consumer with the most protection will prevail with the result that the advertising and marketing of medicines, medical devices, tribal medicines and complementary treatments must comply with the CPA in all respects.

A failure to provide adequate instructions for safe use is sufficient to trigger no-fault based product liability claims throughout the supply chain.

38 Act 101 of 1965.

39 Paragraph 7.7 of the MCC Good Wholesaling Practice for Wholesalers, Distributors and Bonded Warehouses (July 2012).

40 Version 5, November 2010.

x Distributors and wholesalers

Persons who, in the course of business, are engaged in the wholesale dealing of medicinal products for human and animal use, are required to hold a wholesale dealer's licence, unless exempt.[41]

'Wholesaler' refers to a dealer or trader who acquires medicine or medical devices from a manufacturer and sells or distributes them to the retail sector, and includes a wholesale pharmacy.[42] A wholesaler is prohibited from buying medicine from any source other than the original manufacturer or primary importer.[43] 'Distribution' means the procurement, purchase, holding, storage, sale, supply, import, export or movement of pharmaceutical products, with the exception of dispensing or providing pharmaceutical products directly to a patient or his or her agent.[44]

The definition of a wholesaler includes a distributor, and the licence issued to a wholesaler or distributor is the same.

To obtain a licence, the wholesaler is required to complete and submit to the MCC its standard application form. The applicant must specify the medicines, scheduled substances or medical devices to be distributed and sold as well as details of the layout and location of the business premises and the nature of the business conducted there. An inventory of equipment and a manual of procedures and practices to be implemented to ensure the safety, efficacy and quality of medicines to be distributed and sold must also accompany the application.

The MCC will issue a licence only once it is satisfied that the information contained in the application is accurate. A wholesaler is obliged to apply for the renewal of the licence every five years, and the MCC has the power to suspend or revoke the licence if the obligations imposed on the wholesale dealer are not complied with.[45]

xi Classification of products

Medicines are broadly grouped by Act 101 into four categories:

a Category A: medicines intended for human use that are ready to be administered;

b Category B: medicines that cannot normally be administered without further manipulation;

c Category C: medicines intended for veterinary use; and

d Category D: complementary medicines.

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41 Section 22C(1)(b) of the Medicines and Related Substances Act 101 of 1965. A comprehensive list of exemptions are contained in Appendix 2 to the MCC Guidelines for Licence to Act as a Wholesaler or Distributor (February 2004).

42 Section 22C of the Medicines and Related Substances Act 1965, together with Regulation 1.

43 Section 22H of the Medicines and Related Substances Act 1965.

44 MCC Good Wholesaling Practice for Wholesalers, Distributors and Bonded Warehouses (March 2012).

45 A comprehensive list of obligations is contained in the MCC Guidelines for Licence to Act as a Wholesaler or Distributor (February 2004).

The Act further classifies medicines into schedules that restrict their mode of dispensing and advertising. Schedule 0 medicines are available over the counter, while Schedule 1 and 2 medicines may only be dispensed by pharmacists. The remaining scheduled medicines require prescription by a medical practitioner.

xii Imports and exports

Act 101 prohibits the import or export of medicines or medical devices without a licence. The MCC may issue a licence subject to conditions as to the application of acceptable quality-assurance principles and distribution practices as the MCC may decide. A licence issued to a wholesaler or distributor is valid for a period of five years and may be renewed.

Prior to commencing business, an importer or exporter must appoint and designate a pharmacist to control the distribution of medicines or medical devices; and a natural person who resides in South Africa, who will be responsible to the MCC for compliance with the Act.[46]

Medicines and scheduled substances may only be imported through the Cape Town, Port Elizabeth or Durban airports and harbours as well as the Johannesburg international airport.

A person may only import or export a Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance if the Department of Health has issued a permit. If a permit is required to export the prescribed substances, the applicant must also submit a certified copy of the permit for importation issued by the country to which the prescribed substances will be exported.[47]

Only a pharmacist, pharmacist's intern or pharmacist's assistant acting under the personal supervision of a pharmacist, may export a Schedule 1, 2, 3, 4, 5 or 6 substance for analytical, educational or scientific purposes, or the manufacture of foods or cosmetics, unless a permit has been issued by the Department of Health for that purpose in accordance with the prescribed conditions.

If necessary, to protect the health of the public, the Minister of Health may prescribe conditions for the importation of more affordable medicines that are identical in composition, meet the same quality standards and are intended to have the same proprietary name as that of another medicine already registered in South Africa, but that are imported by a person other than 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 MCC.[48]

46 See Regulation 19 for a full list of requirements for an application.

47 See Regulation 15(2) read with Regulation 14(2) for a list of information that must be included in an application for a permit and Section 22A(11)(c) for when the issue of a permit may be refused.

48 See Regulation 7(1) for conditions relating to when such a medicine may be sold in South Africa.

xiii Controlled substances

Schedule 5 to 8 substances, including narcotic and psychotropic substances, are more strictly regulated by Act 101 than other scheduled substances. Only the Director General for Health may issue a licence for the import and export of these substances, unless the substance is exempt from control measures under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances of which South Africa is a signatory.

Only a person who has been authorised by the MCC may import and export unregistered controlled substances.

South African law regulates the possession and use of all narcotics because some are considered illegal drugs for which the possession or use constitutes a criminal offence. This is governed by the Drugs and Drug Trafficking Act 1992, whose provisions apply in conjunction with Act 101.

Defined dependence-producing substances may only be used where they have been prescribed by a medical practitioner.

xiv Enforcement

Each health act has a different enforcement procedure for violation of regulatory requirements for medicines and medical devices. The enforcement procedures are usually in the form of a prescribed fine or imprisonment, or both.

The Health Professions Act 1974 regulates the conduct of medical practitioners including general practitioners and specialist doctors. The Health Professionals Council of South Africa has the power to institute an inquiry into a complaint of unprofessional conduct against a medical practitioner. The NHA has a similar provision for nurses.

Both the Health Professionals Council of South Africa and the South Africa Nursing Council have the authority to make a guilty finding and to impose a fine, suspend a licence and, in serious cases, terminate a licence.

Act 101 also provides measures that the MCC (and in future the new regulating body SAHPRA) may implement to enforce the Act that includes fines and imprisonment as well as forfeiture of medicines confiscated.[49]

III PRICING AND REIMBURSEMENT

Regulations under Act 101 provide for transparency in the pricing of medicines and scheduled substances for South Africa.

The logistics fee is one of the three components that form the single exit price of medicines. The other two components are the price determined by the manufacturer and value added tax. The logistics fee is agreed through negotiations between the manufacturers or importers and the logistics service providers of the medicines.

49 Sections 29 and 30 of Act 101 deals with offences and penalties.

A manufacturer, importer, distributor or wholesaler may not charge any fee or amount other than the single exit price in respect of the sale of the medicine or scheduled substance to a person other than the state. Retailers must ensure that the single exit price is clearly and legibly reflected on the packaging in which the medicine is sold.

A pharmacist, wholesaler or distributor may not sell a medicine at a price higher than the price contemplated in terms of the Act, but a pharmacist or person licensed to dispense may charge a regulated dispensing fee.

A pharmacist must display a notice informing the public of the maximum fee structure used to determine the dispensing fee. The pharmacist must also provide an invoice in respect of each medicine, which clearly indicates the dispensing fee and the single exit price.

In terms of the Regulations, manufacturers and importers must submit a schedule reflecting the single exit price of a pack of each medicine or scheduled substance sold by them, including the pack size, dosage form and strength of the medicine or scheduled substance to the Director General. The manufacturers and importers must further supply the Director General with the following information:

a the total sales value of each medicine or scheduled substance sold in a particular year;

b the total value of discounts in respect of the sale of each medicine or scheduled substance in a particular year; and

c the total number of packs of each medicine or scheduled substance sold in a particular year.

Manufacturers and importers must submit a report and audit certificate compiled by independent auditors to the Director General.

The South African medical aid system allows members belonging to a medical aid scheme to be reimbursed by that medical scheme, according to the benefits accruing to the member under his or her particular medical aid scheme arrangement, for payment of treatment or medication provided by a health-care provider or pharmacist.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

The South African judicial system is made up of civil and criminal courts responsible for the administration of justice in South Africa.

Administrative decisions are governed by the Promotion of Administrative Justice Act 2000, which aims to ensure that all administrative procedures are fair, gives citizens the rights to ask for reasons for an administrative decision, and to have an unlawful or irrational administrative action reviewed by a court.

To give effect to the right to procedurally fair administrative action, an administrator is required to give a member of the public adequate notice of the proposed action, an opportunity to make representations, a clear description of the action, and notice of any review or appeal process available as well as a right to seek reasons for a decision.

Should a member of the public be dissatisfied with a decision and its reasons, they can make use of a departmental internal appeal procedure. If no such procedure exists, they may approach a court to review the decision within a stipulated period or, in some cases, lodge an appeal to a court.

Act 101 provides that any person aggrieved by a decision of the Director General of Health or the MCC may appeal against such a decision to an appeal committee. If still aggrieved, the party may appeal to the High Court in terms of the Act.

V FINANCIAL RELATIONSHIP WITH PRESCRIBERS AND PAYORS

Regulations under the Health Professions Act of 1974[50] prescribe ethical rules of conduct, which regulate, *inter alia*, the conduct of health practitioners and their relationship with medicine and medical device marketers and producers, and patients.

In general, no health practitioner may manufacture, sell, advertise or promote any medicine or medical device to the public or keep a pharmacy and, equally, may not advocate the preferential use or prescription of any medicine or medical device that would not be clinically appropriate or the most cost-effective option.

A health practitioner may not tout for business or accept a commission from anyone in return for the purchase sale or supply of any goods used in the practice; or pay or offer to pay any consideration in return for patients.

The regulations do not prevent a health practitioner from owning shares in a public pharmaceutical company, working for a pharmaceutical company, dispensing medicines and medical devices in terms of a licence, provided the practitioner informs a patient of these facts and obtains consent from the patient before prescribing a medicine or a medical device from the pharmaceutical company in respect of which the practitioner is involved. The Health Professions Council of South Africa (HPCSA) has published specific guidelines to assist practitioners.[51]

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Personal injury law falls within the common law system of delict (torts), applied in conjunction with relevant legislation such as the Consumer Protection Act 2008, which delineates and extensively provides for product liability.

The South African Law of Delict incorporates the doctrine of vicarious liability, whereby employers can be held liable for those acts or omissions of their employees that give rise to delictual liability. The State Liability Act 1957 provides for the State's vicarious liability for the delictual conduct of state employees.

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50 In addition to the specific constraints applied to health practitioners by the Health Professions Act, the Prevention and Combating of Corrupt Activities Act of 2004 provides measures to prevent and combat corruption and corrupt activities.

51 Guidelines on over servicing, perverse incentives and related matters (HPCSA Booklet 5); Guidelines for good practice in the health professions (HPCSA Booklet 2).

Delictual (tort) remedies are compensatory in nature, rather than punitive, and can be excluded by contract, to the extent allowed by the law.

According to regulation, compensation for research-related injury must be provided for in cases where approved health research involves more than minimal risk to human participants.[52] A special compensatory system for injury occurring from clinical trials is contained in the Department of Health Guidelines[53] and the SAMRC Guidelines on Ethics for Medical Research.[54]

Provision is made for compensation when, on a balance of probabilities, the participant's injury is attributable to the administration of a medicinal product under a clinical trial or any clinical intervention provided for in a research protocol that would not have occurred but for the inclusion of the participant in the trial. This would include compensation payable to children in utero through the participation of the subject's mother in the clinical trial.

Compensation is only payable for more serious injuries of an enduring and disabling character and not for temporary pain or discomfort or less serious or curable complaints. Compensation is also excluded for:

a the failure of a medicinal product to have its intended effect or to provide a benefit to the participant;

b the failure of a placebo to provide a therapeutic benefit; and

c injury arising through departures from the research protocol, wrongful acts by third parties and contributory negligence by the patient.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

There are no relevant cases on specific enforcement rules[55] relevant to pharmaceuticals and medical devices in South Africa. The pharmaceutical industry itself has not been an area of priority for the enforcement activity of the South African Competition Commission.

The Competition Commission commenced a far-reaching market inquiry into private health care in 2014. The inquiry is focused on understanding the cost drivers of private health care. The is assessing all current pricing regulation and pricing practices of private hospitals, medical schemes, health-care practitioners, and suppliers of pharmaceuticals, medical devices and other consumables. At the end of the inquiry, the Competition Commission may make recommendations on changes to any existing

52 Regulations relating to research with human participants' published in Government Gazette No. 38000 on 19 September 2014.

53 Section 4.11 of the Department of Health Guidelines.

54 Appendix IV: Clinical Trial Compensation Guidelines. These Guidelines are modelled on those of the Association of the British Pharmaceutical Industry.

55 Since South Africa has no specific precedents on contentious competition issues in the sector, it is expected that the debate will be shaped by reference to case law and developments in North America and the European Union.

legislation in the sector, initiate complaints against market participants and make recommendations to the Minister of Health on structural or legislative changes required to alleviate issues uncovered during the inquiry.

ii Transactional issues

In terms of Section 22H of Act 101, no wholesaler may purchase medicines from any source other than from the original manufacturer or the primary importer of the finished product and may only sell medicines into the retail sector.

The word 'sell' is broadly defined by Act 101 as to:

> *sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorise, direct or allow a sale or prepare or possess for purpose of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and 'sale' and 'sold' have corresponding meanings.*

VIII CURRENT DEVELOPMENTS

Once SAHPRA takes over from the MCC, there are likely to be significant changes to regulation and management of medicines and medical devices in South Africa.

The draft device regulations, propose to establish a comprehensive system of registration and classification of medical devices. The labelling and marketing of medical devices and procedures applicable to product recalls, importation and clinical trials will also be regulated. The implementation of these regulations will fundamentally alter the medical devices sector in South Africa. The date for publication of the final regulations is not yet known.

The regulations regarding the sale and marketing of complementary medicines have had a substantial impact on that sector and will continue to impact on the viability of the sale of complementary medicines in South Africa.

The outcome of the Competition Commission's market inquiry into private health care will impact on future regulation of the sector and may result in a number of market participants facing complaints for non-compliance with the Competition Act.

The CPA specifically allows class actions for damages claims by all or a class of consumers. There is increasing interest in South African litigation by foreign funders and recent cases are developing the rules applicable to class actions that will increase the risk.

The Protection of Personal Information Act 2013 is likely to come into force during 2016 (there is a one-year grace period for compliance). This will introduce extensive data protection obligations in respect of individual and company personal information.

The Copyright Amendment Bill was published for public comment in July 2015, and is intended to amend the Copyright Act 98 of 1978. It will establish an IP Tribunal to adjudicate IP disputes.

Finally, it is likely that a bill implementing changes set out in the IP Policy will be sent to Parliament shortly, which may result in substantial changes to South African patent law. These changes will be:

a making new patents harder to obtain by implementing a substantive patent examination procedure and providing for pre- and post-grant opposition of patents;

b expanding the more limited circumstances in which compulsory licences can be granted, which will adversely affect the patentee's rights and protection in terms of its patent;

c allowing products made under compulsory licence to be exported from South Africa; and

d limiting the remedies available to patent holders in South Africa.

These changes will understandably have significant ramifications for patent holders in the pharmaceutical industry.

Appendix 1

ABOUT THE AUTHORS

JILL DALEY

Norton Rose Fulbright

Jill Daley practises in all areas of intellectual property, regulatory and commercial law as a barrister and solicitor. In addition, Ms Daley is a licensed and practising pharmacist in Ontario with experience in community pharmacy, long-term care, addiction treatment and consulting. She has experience in a wide range of matters involving the innovative pharmaceutical, biotechnology, natural health product, medical device and cosmetic industries, including pre-clinical and clinical trial applications, packaging, labelling, advertising and marketing practices, submissions and responses to the Common Drug Review and the Patented Medicine Prices Review Board, provincial listing agreements, formulary listing, provincial interchangeability decisions as well as proceedings under the PM(NOC) Regulations. As part of her practice, Ms Daley advises on the practice of regulated health professionals. Ms Daley's counsel to clients includes developing industry-specific compliance programmes, document management and third-party responses to access requests. She advises clients on various privacy issues pursuant to the federal Personal Information Protection and Electronic Documents Act as well as provincial legislation pertaining to personal information and personal health information.

LIESEL KOK

Norton Rose Fulbright South Africa

Liesel Kok is a partner in the Johannesburg office of Norton Rose South Africa. She specialises in medical law and medical malpractice litigation in the firm's insurance litigation and dispute resolution division.

Ms Kok regularly represents a wide range of medical professionals and hospitals in civil litigation, disciplinary inquiries and judicial inquests. She has acted for large private hospital groups in high-profile, complex litigation relating to claims for damages following birth-related injuries such as cerebral palsy. Recent cases include the defence of claims for the administration of incorrect medication by nursing staff, complications during surgery, use of incorrect procedures and complications from surgery.

She also regularly advises medical and insurance clients on regulatory issues in health care, including changes in legislation and regulations governing medicines, licensing of hospitals and pharmacies, clinical trials and administrative law, which includes issues relating to the packaging, labelling, marketing, manufacturing and selling of products in the health-care industry.

As a partner in the insurance and dispute resolution division she has experience in product liability claims and was recently instructed by insurers to provide advice with regard to potential litigation in relation to defective breast implants. Ms Kok and her associate Justin Malherbe are leading in this instruction by the former chairman of Deneys Reitz, Michael Hart.

She has been a partner at Norton Rose Fulbright South Africa (and its predecessor firm, Deneys Reitz Inc) since 2004.

ROSALIND LAKE

Norton Rose Fulbright South Africa

Rosalind Lake is director in the competition team of Norton Rose Fulbright. She is a specialist in consumer protection and competition legislreskation and how it affects business in South Africa. She is the co-author of Juta's bestselling title *Understanding the Consumer Protection Act*, published in 2012.

Ms Lake advises clients from a multitude of sectors on bringing their practices into line with the requirements of consumer protection and competition laws. This includes all marketing practices, contractual and plain-language review and drafting, promotional competitions and promotional offers, all aspects of franchising; product warranties, product liability and product recall. She also has expertise in cartel investigations, leniency applications, merger notifications and competition law opinions, particularly in the manufacturing, airline, banking, commodities and mining sectors. She has extensive experience in developing and implementing compliance programmes. Rosalind also advises on sector specific regulatory issues, particularly in relation to foodstuffs and health care.

Ms Lake is a regular conference speaker, guest speaker and is often interviewed on television and radio as a specialist in consumer protection and competition-related topics She also frequently contributes articles to mainstream and specialist publications on these subjects. She attended Rhodes University where she obtained her BA and LLB. She also received her master of laws (with distinction) from Rhodes University.

ERNARD O'SHEA

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Bernard O'Shea has, for over 20 years, been focused on supporting the pharmaceutical and life sciences sectors, particularly in respect of regulatory and commercial issues. His knowledge of the regulatory landscape, combined with extensive industry knowledge, allows for efficient and insightful advice. He has advised on key industry issues, including transfer pricing, clinical trials, pricing and reimbursement and marketing practices. His clients include many multinational pharmaceutical and life sciences companies, emerging life science companies (both Australian and overseas), a range of research institutions, industry representative bodies, and overseas law firms that seek him out for expert advice. Bernard has a particular focus on the creation, protection and exploitation of intellectual property, and in this guise has been involved in many landmark licensing and joint venture arrangements, both local and international. Bernard is the national leader of the Norton Rose Fulbright life sciences and health-care 'headlight'.

ANDREW PARSONS

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Andrew Parsons is a corporate and commercial lawyer and a member of the South African life sciences and health-care practice. He specialises in, and has considerable experience in a wide variety of mergers and acquisitions, commercial, corporate, banking and finance law matters and JSE transactions.

He regularly advises South African and international clients on a range of commercial and corporate matters, Companies Act-related issues, merger and acquisition transactions, as well as banking and finance-related issues, structures and equity acquisitions, including in the field of Islamic finance. Mr Parsons holds a bachelor of arts degree, a bachelor of laws degree and has completed the coursework for a postgraduate diploma in tax. He is a member of the law societies of KwaZulu-Natal, the Northern Provinces and Cape Provinces. He is a director in the Durban office, joining the group in 1999 after having practised at another major Durban firm for 10 years.

KATE SHERBURN

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Kate Sherburn is an associate, working substantially in regulatory matters within the areas of pharmaceutical and life sciences, and providing advice around promotional activities and a range of commercial agreements. Kate has a particular focus on industry codes and compliance with industry codes. She has spent time working in-house with clients and understands the requirement to deliver business-usable advice. Her expertise crosses into related areas such as food, and agricultural and veterinary chemicals.

RANDY SUTTON

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Randy Sutton practises in the area of dispute resolution. He represents international and domestic clients in a variety of business sectors in court and administrative proceedings, mediations and arbitrations and has appeared in provincial and federal courts throughout Canada.

Mr Sutton has provided advice on commercial, contract, tort, product liability, product recall, insurance, defamation, intellectual property and franchise matters. He also provides ongoing risk management and insurance coverage advice. He has developed specific expertise in the area of class action litigation and has acted for a number of clients in class actions throughout Canada.

Mr Sutton is a member of the British Columbia, Saskatchewan and Ontario bars and practises throughout Canada. He is co-chair of Norton Rose Fulbright Canada's national class actions team, the partner responsible for professional liability matters in Ontario, a member of the firm's Canadian risk and audit committee and co-leads the firm's life sciences and health-care industry group in Canada.

KRISTIN WALL

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Kristin Wall practises in intellectual property law as a barrister and soliciter. Ms Wall has particular experience with litigation involving the innovative pharmaceutical industry, including proceedings under the Patented Medicines (Notice of Compliance) and Food and Drug Regulations as well as patent impeachment, infringement and damages actions. In

addition, Ms Wall advises on matters pertaining to data protection, patent listing, biologics, drug advertising, drug reimbursement/pricing and intellectual property implications of the Comprehensive Economic Trade Agreement, including patent term restoration.

Ms Wall's trademark practice focuses on providing opinions and advice on the registrability of trademarks, prosecuting trademark applications, brand strategy and general trademark litigation. Her copyright practice focuses on copyright authorship and ownership disputes and providing opinions on licensing and enforcement.

ALLISON WILLIAMS

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Allison Williams is an intellectual property and commercial lawyer based in Durban.

She has extensive experience in intellectual property law, including the registration and enforcement of trademarks globally, copyright, passing off and unlawful competition, franchising, domain name dispute resolution and transactional IP work, such as due diligences, licensing, assignments and IP structuring. Allison also specialises in general commercial law, black economic empowerment, consumer protection and data protection law.

Allison has practised in the field of intellectual property law for 17 years.

Allison has been a Fellow of the South African Institute of Intellectual Property Law (SAIIPL) since 2002 and has served on the SAIIPL's trademark and copyright law committees. She has also been a member of the International Trademark Association and Licensing Executives Society for many years.

Allison has written articles for the *China Business Law Journal* and authored the South African chapter for Getting the Deal Through *Trademarks* 2010.

Allison completed her BCom LLB degrees at the University of Natal, Durban in 1994. She started her articles in the Durban office of Deneys Reitz in 1995. Allison was admitted as an attorney in 1997, when she started specialising in intellectual property law. She qualified as a trademark practitioner through the SAIIPL in 2000, after passing specialist exams. Allison was appointed as a director of Deneys Reitz in 2001 and worked in the Johannesburg office until she resigned at the end of 2008. She pursued her career as a director and head of intellectual property in other Johannesburg law firms before joining Norton Rose Fulbright in January 2014.

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