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AUSTRALIA

Law and Practice

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1. Regulatory Framework

1.1 Legislation and Regulation

The primary legislation governing both pharmaceuticals and medical devices in Australia is the Therapeutic Goods Act 1989 (Cth) (the TG Act). The TG Act provides the overall regulatory framework for the regulation, approval and monitoring of therapeutic products and establishes the Australian Register of Therapeutic Goods (ARTG), on which all medicines and medical devices must be registered.

The Therapeutic Goods Administration (TGA) is the regulator in relation to all medicines and medical devices for human use. The TGA is responsible for enforcing the TG Act, administering the ARTG and assessing applications for marketing authorisation.

The TG Act is supplemented by the Therapeutic Goods Regulations 1990 and the Therapeutic Goods (Medical Devices) Regulation 2002 (MD Regulation) which regulate the assessment and approval of medical devices. The TG Act and Regulations are further supplemented by a range of legislative instruments, including the Therapeutic Goods Advertising Code (No 2) 2018.

Veterinary medicines are regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA) under the Agricultural and Veterinary Chemicals Act 1994 (Cth), the Agricultural and Veterinary Chemicals (Administration) Act 1994 (Cth), the Agricultural and Veterinary Chemicals Code Act 1994 (Cth), Agricultural and Veterinary Chemicals (Administration) Regulations 1995 (Cth) and the Agricultural and Veterinary Chemicals Code Regulations 1995.

Additional regulation regarding the supply, handling, storage and labelling of medicines is found in the Poisons Standard. The Poisons Standard is made under section 52D(2)(b) of the TG Act which provides for uniform categorisation of dangerous substances into Schedules. State and Territory poisons and controlled substances legislation then further regulate the supply, storage and use of certain substances based on the Schedule of the Poisons Standard into which they have been classified (eg, Schedule 4 poisons may only be supplied by a medical practitioner or pharmacist).

1.2 Challenging Decisions of Regulatory Bodies

Under section 60 of the TG Act a person who is affected by an initial decision of the Secretary of the Department of Health under the TG Act may request the Minister for Health to review the decision. The request for review must be made in writing within 90 days of receiving notice of the decision and may be accompanied by supporting information. If new information is provided in support of a review application, the Minister must either consider that information or remit the decision to a delegate to make a new decision. The Minister may decide to revoke the initial decision and make a substitute decision, or confirm the initial decision. On completion of the review, the person who requested the review may request reasons for the decision and may apply to the Administrative Appeals Tribunal within 28 days for further merits review.

The general requirements to challenge a decision made by the TGA are:

- the person must have been affected by the decision, or the sponsor; and
- the application for review must be made within 90 days of receiving notice of the decision.

Challenges to the legality of a decision made by the TGA, Secretary or Minister may be made to the Federal Court.

The process for reviewing decisions made by the TGA is specified in the TG Act and is specific to therapeutic goods regulation. Although it is not the same as the review process for decisions relating to other regulated products, the general procedure is similar to that for challenging any decision of a regulatory agency.

1.3 Different Categories

Medicines in Australia are regulated according to a two-tier system. Listed medicines are those made only with low-risk, pre-approved ingredients and which make limited therapeutic claims. These are assessed by the TGA for safety, but not efficacy, although sponsors must still have sufficient evidence to substantiate any claims. Some over-the-counter (OTC) and most complimentary medicines and vitamins are listed medicines.

Registered medicines are those considered higher risk and are subject to more rigorous evaluation by the TGA. Registered medicines are further divided into two categories: prescription-only (high risk) and non-prescription or OTC (lower risk). OTC in turn is divided into two categories: pharmacist-only (which must be displayed behind the counter and dispensed only in consultation with a pharmacist and general over-the-counter medications. Although both prescription and OTC medications must be approved by the TGA and registered on the ARTG, there are significant differences in how products in each category may be advertised and supplied to consumers.

Medical devices are classified either as a medical device or an in vitro diagnostic device (IVD). Each of these categories is divided into classes based on the intended purpose and risk level associated with the device. Medical devices are placed in classes I, IIa, IIb, III or Active Implantable Medical Device (AIMD) as

required by Schedule 2 of the MD Regulation. Class I devices present the lowest risk and are subject to the least scrutiny by the TGA, while class III and AIMD devices are considered the highest risk and are subject to the greatest scrutiny. Similarly, IVDs are placed in classes 1 to 4 according to the risk posed by an incorrect result, with class 1 being the lowest risk and class 4 the highest.

Biologicals are therapeutic products which include human cells or tissue, or contain live animal cells tissue or organs. These are regulated separately under Part 3-2A of the TG Act. Biologicals are further divided into classes 1 to 4. Some biologicals, such as fresh, viable human organs and reproductive tissue for IVF are excluded from TGA regulation. Excluded biologicals are listed in the Therapeutic Goods (Excluded Goods) Determination 2018.

2. Clinical Trials

2.1 Regulation of Clinical Trials

All clinical trials in Australia must conform with the Ethical Principles of the Declaration of Helsinki and to international Good Clinical Practice guidelines. Before a trial can go ahead it needs to be approved by independent ethics' committees that operate according to the guidelines issued by the National Health and Medical Research Council (NHMRC Guidelines).

2.2 Procedure for Securing Authorisation

All proposals to conduct clinical trials in Australia require ethical review and approval by a human research ethics committee (HREC). An HREC must conform to the National Statement on Ethical Conduct on Human Research 2007. An HREC must have notified its existence to the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC) and provided assurances that it is operating within NHMRC guidelines. HRECs in Australia (with the assistance of sub-committees) generally provide both an ethical and scientific review, which may be supplemented on an as-needed basis by external expert advice as the committee(s) concerned sees fit. Clinical trials conducted using therapeutic goods that have not been evaluated by the TGA for quality, safety and efficacy and entered into the ARTG for general marketing are required to make use of the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes in order for the products to be lawfully supplied for the purpose of a clinical trial. Under the CTN scheme, HREC approval must be obtained, with subsequent notification to the TGA. In the CTX scheme, the TGA has a direct role in the review of trial scientific data and must give an "approval" for the proposed trial programme to go ahead; however, HREC review is still required.

2.3 Public Availability of Databases

All clinical trials are registered on the Australian New Zealand Clinical Trials Registry (ANZCTR). The registry can be searched on the Australian Clinical Trials website administered by the Department of Health. The results are not made publicly available.

2.4 Restriction for Using Online Tools

There are no restrictions for using online tools to support clinical trials.

2.5 Use of Resulting Data

The data from clinical trials can be considered personal and sensitive data and any transfer of clinical trial results is subject to the Privacy Act and the Australian Privacy Principles (APPs) in the usual course. However, in certain circumstances, the Privacy Act permits the handling of health and personal information for health and medical research purposes, where it is impracticable for researchers to obtain individuals' consent. To facilitate this, the Privacy Commissioner has approved two legally binding guidelines issued by the National Health and Research Council:

- guidelines under section 95 of the Privacy Act – sets out the procedures for HRECs and researchers to follow when personal information is disclosed from a Commonwealth agency (ie, a Minister, Department, body established under a Commonwealth act, etc) for medical research purposes; and
- guidelines under section 95A of the Privacy Act – sets out a framework for HRECS to assess proposals to handle health information held by organisations for health research purposes (without consent).

2.6 Further Requirements for the Creation of a Database

The creation of a database containing personal or sensitive data will not be subject to further requirements.

3. Marketing Authorisations

3.1 Assessment Process and Criteria

Both medical devices and medicines are products which have a therapeutic use in relation to the human body. The key distinction between devices and medicines is whether the therapeutic purpose is achieved through pharmacological means.

A product will be classified as a medicine under section 3 of the TG Act if it is presented as having a therapeutic use and is represented to or is likely to achieve its principal intended therapeutic action through pharmacological, chemical, immunological or metabolic means and it is not a biological.

Under section 41BD of the TG Act, a product is a medical device if it is intended by its supplier to be used in the diagnosis, prevention, monitoring, treatment or alleviation of a disease or disability or the control of contraception, but does not achieve this purpose through pharmacological, chemical, immunological or metabolic means.

3.2 Granting a Marketing Authorisation

Biological medicines are evaluated in the same fashion as all other prescription medicines under the TG Act.

3.3 Period of Validity

There is no set period of validity for market authorisation; however, an annual renewal fee must be paid to maintain the ARTG listing or registration. The product will remain on the ARTG indefinitely unless the entry is voluntarily withdrawn by the sponsor, suspended or cancelled by the ARTG.

Provisional registration of medicines on the ARTG is valid for an initial period of two years or until a full registration is obtained. Up to two extensions of provisional registration for periods of no more than two years each may be applied for.

Suspension or cancellation of products from the ARTG is governed by sections 29D – 30B of the TG Act in relation to medicines and Part 4-6 of the TG Act in relation to medical devices. ARTG listing or registration may be cancelled under a range of circumstances, including if the product poses a risk of serious injury or illness to patients, the sponsor fails to comply with a condition of registration, makes false or misleading statements in relation to the product, significantly breaches the Therapeutic Goods Advertising Code or fails to pay the annual registration fee within 28 days.

If the TGA intends to cancel an ARTG registration or listing, the sponsor will be notified in writing and have the opportunity to request a review of the decision by the Minister or the AAT.

If the TGA is satisfied that there are circumstances which would justify cancelling a registration or listing which the sponsor is likely to be able to address, it may suspend the ARTG entry for up to six months. The period of suspension can be extended for additional six-month periods if considered necessary.

While an ARTG registration or listing is suspended or cancelled, the product must not be supplied or advertised for sale.

3.4 Procedure for Obtaining a Marketing Authorisation

To obtain market authorisation for a new medicine, a Category 1 (or Category 2 if the product is already registered in a comparable overseas market) application is made to the TGA under section 23 of the TG Act. A dossier in the Common Technical Document (CTD) format must be submitted as part of the application process. The TGA operates an eight-phase registration process with set milestones and legislated timeframes, starting with a pre-submission phase approximately three months prior to lodgement of the dossier.

The first step in obtaining marketing authorisation for a medical device in Australia is to classify the medical device according to the rules in Schedule 2 of the MD Regulations. For class I – IIb devices, an application is submitted by the sponsor through the TGA eBusiness portal. It must include evidence of the manufacturer's conformity assessment certificate, the classification of the device, GMDN code and description, device characteristics, intended purpose and device description. For Class III devices, a full design dossier must be submitted for assessment by the TGA.

A sponsor may apply to make a minor variation to an ARTG listing under section 9D of the TG Act provided it does not result in a separate distinct product (ie, one which has a different name, formulation, strength, dosage form, indication, directions for use or container). Minor variations which result in a separate distinct product require a Category 3 application under section 23. Major variations (eg, those which require an evaluation of a full data set) require a new Category 1 application.

An ARTG listing may be transferred to a new sponsor by submitting a Notification: Transfer of Sponsorship to the TGA.

3.5 Access to Unauthorised Products

Approval may be given under section 19 of the TG Act to supply or use therapeutic goods which are not enter on the ARTG for an approved clinical trial, through the Authorised Prescribers Scheme or the Special Assess Scheme.

Clinical trial sponsors must either submit a Clinical Trial Notification or apply for a Clinical Trial Exemption in order to use an unapproved therapeutic good.

Medical practitioners may be authorised to prescribe a particular unapproved therapeutic good in relation to a specific condition or class of patients without seeking individual approvals from the TGA. The unapproved product must only be supplied directly to the specified class of patients in the practitioner's immediate care and the total number of treatments must be reported to the TGA every six months.

The Special Access Scheme (SAS) allows medical practitioners to request authorisation to supply an unapproved therapeutic good to a particular patient on a case-by-case basis. There are three SAS pathways: Categories A, B and C.

Under Category A, medical practitioners may prescribe unapproved medicines or biologicals, without prior TGA approval when a patient has:

- 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; or unapproved medical devices when a patient has:
- a condition that is reasonably likely to lead to the person's death within less than a year or, without early treatment, to the person's premature death.

Category B applies to less urgent cases and requires pre-approval. A Category B application must specify the diagnosis, details of previous treatment and a clinical justification and justification as to why no product on the ARTG is suitable. Sufficient safety and efficacy data and details of intended patient monitoring must also be provided.

Category C allows the use of certain therapeutic products with an established history of use in relation to particular indications. Products which can be prescribed under this scheme and their indications are listed in the:

- Therapeutic Goods (Authorised Supply of Medicines) Rules 2019;
- Therapeutic Goods (Authorised Supply of Specified Medical Devices) Rules March 2018; and
- Therapeutic Goods (Authorised Supply of Specified Biologicals) Rules April 2018.

Unapproved medicines and medical devices may also be imported under sections 18(1) and 41HA(1) of the TG Act by patients for personal use or use by an immediate family member.

The Minister may exempt medicines under section 18A, or medical devices under Part 4-6A of the TG Act from registration requirements in the event of an emergency or to allow stockpiling for a possible future emergency.

3.6 Ongoing Obligations

Medicines

Sponsors of all medicines registered or listed on the ARTG must provide the TGA with the name and contact details of a nominated pharmacovigilance contact person located in Australia within 15 days of the medicine being approved, and update these details as necessary. The sponsor must report to the TGA any serious adverse reactions associated with the use of the medicine in Australia and any clinically and medically relevant follow-up information with 15 days.

The sponsor must also report any significant safety issue which requires the urgent attention of the TGA as soon as possible, but no later than 72 hours after the sponsor receives the information.

Failure to notify the TGA in writing, as soon as the sponsor becomes aware, of inaccuracies in the information provided about the medicine, or that its use may be harmful, is subject to civil and criminal penalties under sections 29A, 29AA of the TG Act:

Medical Devices

There is a range of ongoing conditions imposed on the sponsor of any medical device registered on the ARTG by section 41 FN of the TG Act. Additional conditions, including specific post-market monitoring obligations may be imposed by the TGA, either at or after registration of a medical device (see sections 41FO, 41FP of the TG Act).

Section 41MP of the TG Act and MD Regulation 5.7 make it a criminal offence for the sponsor of a medical device not to report an adverse event which has caused or might cause the death or serious injury of a patient to the TGA within:

- 48 hours for an event which represents a serious threat to public health;
- ten days for an event resulting in death or serious injury;
- 30 days for an event which might lead to death or serious injury.

Regulation 5.11 of MD Regulation requires sponsors of medical devices of class AIMD, III, IIb or class 4 IVD to provide the TGA with a report in each of the first three years of registration detailing any adverse events related to the device, however minor.

3.7 Third-Party Access to Pending Applications

All information submitted in support of an application for registration or listing on the ARTG will be considered confidential by the TGA. There is no mechanism by which third parties can request the content of an application. An information request could be made for access to information under the Freedom of Information Act 1982 (Cth); however, these will be rejected in relation to any commercially confidential information.

Only details of successful registrations or listings are published on the publicly searchable version of the ARTG.

3.8 Rules Against Illegal Medicines and/or Medical Devices

The manufacture, import, export or supply of therapeutic goods which are not entered on the ARTG is subject to civil and criminal penalties under the TG Act sections 19B, 19D (medicines)

and 41MI, 41MIB (medical devices). It is also an offence to act as a wholesaler of therapeutic goods which are not entered on the ARTG. Counterfeit goods will not be registered on the ARTG (even if they are purported to be), so manufacturing or supplying them will be an offence under the TG Act.

Part 5-2 of the TG Act specifically addresses counterfeit therapeutic goods. The intentional manufacture, import, export or supply of goods about which false representations are made relating to their identity, composition, strength, source or sponsor are subject to civil and criminal penalties. Complaints regarding suspected counterfeit goods can be made to the TGA, which will then investigate and take enforcement action as necessary.

State and Territory poison and therapeutic goods' legislation also restricts the purchasing, sale and storage of medicines listed in certain schedules of the Poisons Code. Each State or Territory Act includes penalties for the unauthorised supply of certain classes of medicine, eg, those in Schedules 3, 4, 8 and 9.

3.9 Border Measures

Imports or exports of therapeutic goods may be seized by Customs officials under section 229 of the Customs Act 1901 (Cth) and section 42F of the TG Act upon notification by the TGA that the goods are counterfeit.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Manufacturing Plants

Manufacturing of medicines is regulated by Part 3-3 of the TG Act. A manufacturer must hold a valid licence in relation to the production of a particular medicine at a particular manufacturing site. A manufacturer may apply to the TGA for a licence for a manufacturing site, or in some circumstances several sites, under section 37 of the TG Act. Licences are valid until revoked or suspended.

The application must specify the site, the type of good to be produced, the steps in the manufacture which will be carried out and details and qualifications of the people who will have control of the manufacturing process. The TGA must be satisfied that the manufacturer is able to meet the requirements of the Therapeutic Goods (Manufacturing Principles) Determination 2018 in order to grant a licence. In practice, these requirements adopt the majority of the PIC/S Guide to Good Manufacturing Practice (GMP) - 1 January 2017, PE009-13.

Manufacturing sites for veterinary medicines must be licensed under Part 8 of the Agricultural and Veterinary Chemicals Code (AgVet Code). Applications for a manufacturing licence under the AgVet code are made to the APVMA.

Through a Memorandum of Understanding between the TGA and APVMA in June 2009, TGA inspections in relation to TGA manufacturing licences may also be used to meet APVMA licensing requirements for the product of veterinary medicines.

Additional manufacturing licences are required by legislation at State and Territory level. Licensing requirements differ in each State and Territory, but licences are generally obtained by application to the relevant Department of Health.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Wholesale and retail sale of pharmaceutical products is regulated by the following legislation at State and Territory level:

- Poisons and Therapeutic Goods Act 1966 (NSW);
- Drugs, Poisons and Controlled Substances Act 1981 (Vic);
- Health Act 1937 (Qld);
- Controlled Substances Act 1984 (SA);
- Medicines and Poisons Act 2014 (WA);
- Poisons Act 1971 (Tas);
- Medicines, Poisons and Therapeutic Goods Act 2008 (ACT);
- Medicines, Poisons & Therapeutic Goods Act 2012 (NT).

Wholesale suppliers must obtain a licence from the relevant State or Territory Department of Health. The details of the application process, the scope of the licence, duration and fees vary in each State and Territory. Holders of wholesale licences may only supply medicines to people who are authorised to possess and use those medicines (ie, pharmacists and medical practitioners) and are generally required to comply with the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8 and the Medicines Australia Code of Conduct.

5.2 Different Classifications

Medicines are broadly classified into prescription and non-prescription (OTC) and complimentary medicines.

The Poisons Standard further classifies medicines and poisons into ten schedules, with Schedule 1 being the least regulated and Schedule 10 the most. Medicines are listed in Schedules 2, 3, 4 and 8.

- Schedule 2 – pharmacy only;
- Schedule 3 – pharmacist only;

- Schedule 4 – prescription only;
- Schedule 8 – controlled drugs (ie, drugs of addiction).

Restriction on the sale and supply of scheduled medicines is governed by poisons and therapeutic goods legislation in each State and Territory. Schedule 2 and 3 are OTC medicines, but may only be supplied in a pharmacy (with Schedule 3 being required to be supplied in consultation with a pharmacist). Schedule 4 medicines may only be provided on prescription and Schedule 8 medicines may only be prescribed by an authorised medical practitioner.

6. Import and Export of Pharmaceuticals and Medical Devices

6.1 Governing Law and Enforcement Bodies

The import and export of therapeutic goods are regulated by TGA under the TG Act. Additional restrictions on the import and export of certain controlled substances (eg, narcotics) are imposed by the Customs (Prohibited Imports) Regulations 1956 and the Customs (Prohibited Exports) Regulations 1958, and administered by the Office of Drug Control as part of the Federal Department of Health.

Customs checks at the border are conducted by the Australian Border Force.

6.2 Importer of Record

Only the sponsor of a medicine or medical device which is listed or registered on the ARTG may act as the importer of record.

6.3 Prior Authorisations

Therapeutic goods must not be imported unless they have been approved by the TGA and entered on the ARTG.

If the medicine is an import-controlled substance under the Customs (Prohibited Imports) Regulations 1956 and the Customs (Prohibited Exports) Regulations 1958, the importer must obtain an annual licence from the Office of Drug Control and an import permit for each consignment.

Importation of medicines and medical devices for personal use or use by a family member for up to three months is exempt from the requirements of ARTG registration. However, this does not remove the licensing requirements for import controlled substances. Travellers may also bring prescription medications for personal use in their personal baggage, provided a valid prescription can be provided to the Australian Border Force on arrival.

6.4 Non-tariff Regulations and Restrictions

Non-tariff regulation of therapeutic goods is imposed by technical description (ie, composition, active ingredient). The types of products which are regulated are defined by the definitions of therapeutic good, medicine, biologicals and medical devices in the TG Act, along with the information listed in the ARTG. Import and export-controlled substances are listed in Customs (Prohibited Imports) – in particular Schedule 4 and Regulations 1956 and the Customs (Prohibited Exports) Regulations 1958 – in particular Schedule 8.

6.5 Provisions on Trade/Regulatory Facilitation

Australia is currently party to 11 free trade agreements:

- Australia-New Zealand;
- Singapore-Australia;
- Australia-United States;
- Thailand-Australia;
- Australia-Chile;
- ASEAN-Australia-New Zealand;
- Malaysia-Australia;
- Korea-Australia;
- Japan-Australia;
- China-Australia;
- Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP);
- Australia-Hong Kong; and
- Peru-Australia.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control

Medicines

Under the Pharmaceutical Benefits Scheme (PBS), governed by the National Health Act 1953 and the National Health (Pharmaceutical Benefits) Regulations 2017, Australian residents who hold a current Medicare Card, or those visitors from countries with which Australia has a Reciprocal Health Care Agreement, can purchase certain pharmaceuticals by paying a capped "co-payment", with the remainder of the price for the pharmaceutical paid by the Australian government to the dispensing pharmacist. The National Health Act 1953 provides that an "approved ex-manufacturer price" is set by the Pricing Section of the Department of Health in consultation with the manufacturer, which determines the co-payment provided to the pharmacist.

In order to have a pharmaceutical listed in the Pharmaceutical Benefits Scheme, following the registration of the pharmaceutical with the TGA, the applicant must submit an application

with associated submissions in accordance with a prescribed timetable, to the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC will consider whether the pharmaceuticals should be included in the PBS and make its recommendation. The Pricing Section of the Department of Health will then negotiate with the applicant to set the price for the PBS pharmaceutical. While the pharmaceutical is on the PBS, it may be subject to statutory price reductions or reductions due to price disclosures.

Those pharmaceuticals not covered by the PBS are priced at the discretion of the supplier.

Medical Devices
Medical Devices are not covered by the PBS and therefore pricing is at the discretion of the supplier. Private health funds provide rebates on the prices of medical devices for consumers who have an appropriate policy, and public hospital budgets can pay for medical devices associated with the care of patients in public hospitals. Pricing of medical devices supplied through hospitals to patients with private health insurance is based on agreed prices which are entered on the Prosthesis List.

7.2 Price Comparison
One of the factors which influence the price of pharmaceuticals under the PBS is the price of items in reasonably comparable overseas countries. However, there are a number of different other factors, including prices of alternate brands and drugs, ministerial directions, PBAC advice, cost information provided by the manufacturer and economies of scale, which are taken into account.

Given that other pharmaceuticals and medical device prices are set by the retailer, it is unclear the extent to which the price of the products in other countries affects price levels in Australia.

7.3 Reimbursement from Public Funds
Pharmaceuticals which are under the PBS are subsidised by the Australian government.

To the extent pharmaceuticals and medical devices are used during public hospital care, they are funded by public hospitals, which are managed at a state or territory level, with funding contributions from the Commonwealth government.

7.4 Cost Benefit Analysis
In determining whether a pharmaceutical is accepted on to the PBS and therefore provided at a subsidised price to Australian consumers, the PBAC considers a submission from the applicant which addresses an economic evaluation of the benefits of the pharmaceuticals inclusion on the PBS. The PBAC will also consider submissions regarding the reasons for the listing of the pharmaceutical on the PBS, the clinical evaluation of the benefits of the pharmaceutical, the use of the pharmaceutical in practice, as well as any other relevant information.

When addressing the economic evaluation in an application to the PBAC, applicants may address whether the pharmaceutical proposed to be included in the PBS is superior, non-inferior or inferior to a comparator, and whether the pharmaceutical therefore has cost-minimisation, or cost-effective benefits.

Medical devices are not covered by the PBS and therefore pricing is at the discretion of the supplier or as negotiated for inclusion in the Prosthesis List for supply in hospitals to patients covered by private health insurance.

7.5 Prescriptions and Dispensing
The National Health Act 1953 and regulations including the National Health (Pharmaceutical Benefits) Regulations 2017 regulate the dispensing of pharmaceuticals which are the subject of the PBS, including regulating the issuing of prescriptions for medical practitioners, as well as regulating the maximum quantities and limits on repeat prescriptions. For example, section 51 of the National Health (Pharmaceutical Benefits) Regulations 2017 prohibits the supply of pharmaceutical benefits greater than the number specified in the prescription.

In addition, state and territory legislation governs the dispensing of pharmaceuticals on a state-by-state basis, including by setting penalties for breaches for pharmacists and medical practitioners that breach their obligations. For example, in NSW it is the Poisons and Therapeutic Goods Act 1966 and the Poisons and Therapeutic Goods Regulation 2008.

8. Digital Healthcare

8.1 Rules for Medical Apps
Medical apps will only be regulated if they fall within the definition of a medical device in section 41BD of the TG Act. This will depend on whether the manufacturer intends the app to have a therapeutic purpose – ie, the diagnosis, prevention, monitoring, treatment or alleviation of a disease or disability of the control of contraception. If the app is only intended generally to promote or facilitate a healthy lifestyle (eg, wellness apps) it will not be regulated.

Apps which form an integral part of a hardware medical device (eg, apps which control or are integrated into hardware) will be regulated as part of that device.

In December 2019, the MD Regulation was amended to introduce specific requirements for standalone software medical devices. These changes include specific classification rules for

software devices and additional essential principles which apply to their design and will enter into force on 25 August 2020.

8.2 Rules for Telemedicine

Medical practitioners are regulated by the Australian Health Practitioner Regulation Agency (AHPRA) under the Health Practitioner Regulation National Law. This does not impose any separate rules relating to telemedicine; however, the AHPRA has published Guidelines for Technology-Based Patient Consultations to clarify the expectations on health practitioners providing telemedicine.

The availability of subsidised telehealth services under Medicare is limited to geographical areas outside of major cities.

8.3 Promoting and/or Advertising on an Online Platform

Until 1 July 2020, advertising through traditional media channels (eg, broadcast and print media) must be pre-approved by the TGA; however, advertising through non-traditional channels, including internet and social media, does not require pre-approval from the TGA or delegate body (see sections 42B, 42BA, 42C of the TG Act and regulation 5BA).

Online advertising must still comply with the general rules imposed by the TG Act, Therapeutic Goods Advertising Code (No 2) 2018 and Medicines Australia Code of Conduct, in particular the prohibition on advertising prescription-only medicine directly to consumers in section 42DL of the TG Act.

8.4 Electronic Prescriptions

Electronic prescribing (e-Prescribing) was introduced in 2019 as an alternative to conventional paper-based prescriptions. It is being actively encouraged by the Federal Government as part of the National Digital Health Strategy.

National Health (Pharmaceutical Benefits) Amendment (Active Ingredient Prescribing) Regulations 2019 was introduced in October 2019 and requires that any electronic prescription for a medicine under the Pharmaceutical Benefits Scheme must be made by reference to the active pharmaceutical ingredient, rather than the brand name of the medicine.

8.5 Online Sales

Online sales of medicines and medical devices are generally permitted in Australia, subject to the same restrictions as sales from physical premises. The operation of pharmacies is regulated by separate legislation in each State and Territory, with some variation in requirements.

8.6 Electronic Health Records

The Australian Government introduced a single electronic health record system called My Health Record in 2012. The system includes electronic health records created in relation to treatments under Medicare and the PBS. Under the My Health Record system, medical practitioners store participating patients' health records in a government-run and administered online platform. Access to this system is strictly regulated by the My Health Records Act 2012 (Cth), My Health Records Regulation 2012, the Healthcare Identifiers Act 2010 (Cth), the Healthcare Identifiers Regulations 2010 and the My Health Records Rule 2016.

Outside of the My Health Record system, health information is regulated as Sensitive Information under the Privacy Act 1988 (Cth) and the Australian Privacy Principles (APPs). In addition, New South Wales, Victoria and the ACT have specific legislation regulating health records: Health Records and Information Privacy Act 2002 (NSW), Health Records Act 2001 (Vic), Health Records (Privacy and Access) Act 1997 (ACT).

There are no special requirements in relation to cloud platforms; however, sending health data to a cloud-provider overseas (or outside of NSW, Victoria or the ACT) is restricted. The State and Territory legislation prohibits transfer of information outside the State, unless the recipient guarantees that the State legislation will be complied with. Similarly, under the Privacy Act, information can only be transferred overseas subject to guarantees of compliance with the APPs.

9. Licensing

9.1 Customary Deal Structures

Deals in Australia take a variety of frameworks: there is no fixed customary structure for licensing.

9.2 Dispute Resolution Provisions

Unless this is a term of the licence, parties cannot be required to mediate or arbitrate before commencing proceedings. It is a common term in licensing agreements that the parties have an obligation to participate in a dispute resolution protocol before proceedings are issued. This may include an obligation to mediate formally. Alternatively, the parties may include an arbitration clause in lieu of a mediation clause but this is less common in agreements drafted in Australia in this field.

It is important that any clauses which mandate that mediation or arbitration occur are tightly drafted, so that there can be no dispute as to the mechanism and facilitation of the dispute resolution process (otherwise they may be ineffective).

9.3 Diligence Obligations Provisions

Due diligence obligations are either defined by "reasonable efforts" or "best efforts". "Best efforts" or "best endeavours" clauses are enforceable in licences and should be avoided: Transfield Pty.Ltd. v Arlo International Ltd. [1980] HCA 15; (1980) 144 CLR 83. It is preferable for parties to negotiate and agree milestones, and failure to meet milestones may be a termination event.

9.4 Change of Control

It is a common provision that licensors (less common for licensees) will have a right of termination of a licence (without consent) when a change in control occurs.

9.5 Termination

The consequences of termination will depend on whether the termination is at fault or at will: if the termination is at fault then the entitlement of the at-fault party to continue use of data produced under the agreement, etc, may be more limited.

10. Patents

10.1 Applicable Laws

The relevant legislation is the Patent Act 1990 (Cth) (Patents Act).

The requirements for patentability are the same as for other kinds of inventions. An invention is patentable if the invention:

- satisfies the manner of manufacture test; and
- is novel; and
- involves an inventive step; and
- is useful.

However, certain things in the medical field are not patentable inventions under the Patents Act, such as human beings and the biological processes for their generation. Isolated gene sequences are also not a manner of manufacture, and therefore are not patentable inventions: D'arcy v Myriad Genetics Inc [2015] HCA 35.

Methods of use are permissible subject-matter in Australia (although Swiss claims are also valid patent claims).

10.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known product are patentable inventions, as long as they meet the patentability requirements, namely that they:

- satisfy the manner of manufacture test; and
- are novel; and
- involve an inventive step; and
- are useful.

Whether or not the new dosage regime or new selected patient population is a patentable invention will likely turn on whether or not the new dosage regime, or new or selected patient population, involves an inventive step. Patents for dosage regimes have been treated with caution in terms of achieving the requirements of inventive step (for example, the dosage patent for Rosuvastatin which was held invalid in AstraZeneca AB v Apotex Pty Ltd; AstraZeneca AB v Watson Pharma Pty Ltd; AstraZeneca AB v Ascent Pharma Pty Ltd [2015] HCA 30 (2 September 2015))

In this regard, the relevant question is:

"whether the notional person(s) skilled in the relevant art(s), in all the circumstances, which include a knowledge of all the relevant prior art and common general knowledge in the field, would directly be led as a matter of course to try what is now claimed as an invention, in the expectation that it might well produce a solution to the problem at hand".

A patent gives a person an exclusive right, during the term of the patent, to exploit the invention, and to authorise another person to exploit the invention: section 13 of the Patents Act.

A person will infringe a second or subsequent pharmaceutical product patent if they exploit the invention.

"Exploit" includes:

- where the invention is a product, make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
- where the invention is a method or process, use the method or process or do any act mentioned in in the first point in respect of a product resulting from such use.

A person can infringe a patent by supply of product for use in a method – supply of a drug which will be used in a method of treatment (section 117 of the Patents Act).

10.3 Patent Term Extension

There is provision for an extension to the term of a patent relating to pharmaceutical substances per se if regulatory approval was not obtained until at least five years after the date of the patent. Extensions of time cannot be obtained in relation to methods or processes involving pharmaceutical substances.

An application for an extension of term must be made within the term of the patent, and within six months after the latest of the following dates:

- the date the patent was granted;
- the commencement of the first inclusion in the Australian Register of Therapeutic Goods;
- the date of commencement of the extension-of-term provisions.

The extension period that can be obtained is the difference of the time period from the filing date of the patent to the first regulatory approval date reduced by five years.

The acceptance of an application for an extension of term will be advertised, and third parties have three months from the date of publication of the notice of acceptance in the Official Journal to oppose the extension of term on the basis that the requirements for the extension of term are not met.

10.4 Patent Infringement

A patent gives a person an exclusive right, during the term of the patent, to exploit the invention, and to authorise another person to exploit the invention: section 13 of the Patents Act.

A person will infringe a pharmaceutical or medical device patent if they exploit the invention.

"Exploit" includes:

- where the invention is a product, make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
- where the invention is a method or process, use the method or process or do any act mentioned in the first point in respect of a product resulting from such use.

Applying for marketing authorisation does not infringe a patent; it is specifically exempted - seeking registration of certain goods on the ARTG is not an infringement: section 119A of the Patents Act. Making an application to list a pharmaceutical product on the PBS is not an exploitation of an invention which is the subject of a patent: Apotex Pty Ltd v Warner-Lambert Company LLC (No 3) [2017] FCA 94.

A threat of infringement is actionable, and seeking registration on the ARTG and/or the PBS may set up a basis to bring proceedings on a quia timet basis. The threat need not be imminent.

10.5 Defences to Patent Infringement

There are specific exemptions in the Patents Act to infringement, including:

- exploitation solely for the purposes connected with obtaining the inclusion in the ARTG of goods that are intended for therapeutic use and are not medical devices, or therapeutic devices: section 119A;
- for non-pharmaceuticals, exploitation solely for obtaining an approval required by a law of the Commonwealth or of a State or Territory to exploit a product, method or process: section 119B;
- an act was done for experimental purposes relating to the subject matter of the invention: section 119C.

The alleged infringer can assert in proceedings alleging patent infringement that it has not infringed the patent because the patent is invalid and should be revoked.

A person may apply to the Federal Court for an order requiring the patentee to grant the applicant a licence to work the patented invention: section 133. The Court may order a compulsory licence to be granted if the reasonable requirements of the public are not being met with respect to a patented invention – ie, where Australian industry is unreasonably affected by the actions of the patentee in relation to the manufacture or licensing of the invention.

10.6 Bringing Proceedings

The patentee and the exclusive licensee can bring proceedings for infringement.

The Patents Act defines an exclusive licensee as the licensee that has the right to exploit the patented invention throughout the patent area to the exclusion of the patentee and all other persons.

Relief that a court may grant includes:

- declarations for infringement;
- an injunction (subject to the terms the court thinks fit);
- delivery-up of infringing products;
- damages or an account of profits.

The first step in an infringement proceeding is the pleading of each party's case. The applicant will file documents with the Federal Court initiating the proceedings – an originating application, statement of claim, and genuine steps statement. The alleged infringer will then file its defence and any cross-claim. The initiating party will then file any defence to cross-claim and any reply to the defence.

After the close of pleadings, evidence will be led by both parties, including expert evidence in relation to the infringement, and the conducting of experiments to establish infringement if necessary.

There will be case-management conferences throughout the proceeding before the judge, at which a timetable is set for the preparation and filing of the parties' evidence, and then for matters relating to the hearing, including a timetable for the filing of submissions, preparation of joint report by experts, if evidence is to be taken concurrently at the hearing, and court book preparation.

10.7 Available Procedures

A potential generic entrant may seek to revoke a patent (either in a court proceeding or through a request for re-examination).

A person can ask the patentee in writing for a written admission that the doing of a particular act has not or would not infringe a patent, having provided the patentee with full written particulars of the act done, or proposed to be done, together with an undertaking to pay the patentee's reasonable expenses of obtaining advice about infringement.

If the patentee refuses or fails to make the admission, the person can seek a declaration of non-infringement from the Federal Court of Australia. The patentee must be joined as a respondent in this proceeding.

Clearing the way is not a requirement for generic market entry.

The authorisation procedure for pharmaceuticals and medical devices does not take account of patent protection (patent linkage).

11. IP Other Than Patents

11.1 Counterfeit Pharmaceuticals and Medical Devices

The owner of a trade mark, registered design or copyright related to a medicine or medical device (including packaging, trade dress and promotional material) can initiate civil action in the Federal Court of Australia for infringement of their IP rights. It is also a criminal offence to apply a registered trade mark falsely or knowingly to distribute products which infringe copyright or contain a falsified trade mark.

The owner of trade marks or copyright can lodge a Notice of Objection under the Trade Marks Act 1995 (Cth) or the Copyright Act 1968 (Cth) with the Australian Border Force. The Notice lists the relevant trade marks or copyright works and allows the Australian Border Force to seize infringing products at the border and hold them for ten days to allow the IP owner to start infringement proceedings.

11.2 Restrictions on Trade Marks

There are no special trade-mark provisions relating to pharmaceuticals and medical devices.

However, section 41 of the Trade Marks Act 1995 (the Act) prevents the registration of trade marks in relation to pharmaceuticals or veterinary substances which are identical or confusingly similar to a notified International Non-Proprietary Name (INN) or a notified INN stem.

An application may also be rejected under section 43, where a trade mark, or part of a trade mark, to be used in relation to pharmaceuticals or veterinary substances is the same as, or may connote, a notified INN and use of the trade mark in respect of the goods covered by the specification is not restricted to the particular substance indicated by the INN. Use of such a trade mark would be likely to give rise to deception or confusion.

There are no specific restrictions under Australian trade-mark law on importation and distribution of genuine pharmaceuticals or medical devices.

However, there are certain restrictions on parallel importation of genuine goods in Australia. A parallel import is a non-counterfeit product imported from another country without the permission of the intellectual property-owner. Pursuant to section 120 of the Act, an Australian trade mark-owner could, in certain circumstances, exercise its exclusive rights to restrict the parallel importation of genuine trade-marked goods, but would be unsuccessful in doing so as the importer is likely to be able to argue that the trade mark was applied with the authorisation of the owner or under section 122A be able to demonstrate that they made "reasonable inquiries" to ensure the trade mark has been applied to the imported goods with the consent of the trade mark-owner.

11.3 IP Protection for Trade Dress or Design

Under section 17 of the Act, "a trade mark is a sign used or intended to be used to distinguish goods or services provided in the course of trade by a person from goods or services so dealt with or provided by any other person". "Sign" is defined to include "shape" and "colour". Because goods such as pharmaceuticals essentially have shape and colour, it is harder to establish that these features can in fact function as a trade mark and satisfy the general registrability requirements for trade marks.

In order to establish the existence of registrable trade-mark rights in these aspects, it is necessary to establish that these

aspects are distinctive, ie, no other traders without improper motive are likely to want to use the shape or colour for their similar goods. Extensive evidence of use is usually required to establish distinctiveness, except where it can be shown that the shape is entirely concocted or that the colour does not give a utilitarian, ornamental and economic function and the market on the goods for which the colour mark is sought to be registered does not have a proven competitive need for the use of colour. Colour schemes, rather than unitary colours, are more likely to satisfy the criteria for trade-mark registration. However, colour combinations which function as a colour code for treatments are considered to convey a direct reference to the character and quality of the goods and thus are not registrable as trade marks.

Pharmaceutical shapes and colours may also be protectable under an action for misleading or deceptive conduct under the Australian Consumer Law, or the tort of passing off, where the trade mark-owner has a reputation such that a third party's use of the shape or colour (or a similar shape or colour) would be likely to mislead or deceive consumers.

11.4 Data Exclusivity

Under section 25A of the TG Act there is a data exclusivity period of five years from the date of registration for information provided to the TGA in relation to the registration of a medicine containing a novel active ingredient (ie, not previously registered on the ARTG).

For veterinary medicines, section 14B of the AgVet Code imposes a ten-year data exclusivity period for information provided to the APVMA for the registration of a novel active ingredient.

During these periods, a competitor seeking to register a generic product cannot refer to information submitted by the originator to show the safety or efficacy of the medicine.

Bird & Bird has a multi-disciplinary team of over 250 specialist lawyers globally who advise on every aspect of the business cycle of a life science product or service. The team provides guidance on incorporation, development, financing and partnering, mergers and acquisitions, protection and exploitation of intellectual property, and the regulatory framework. The firm has extensive experience in technology transfers, IP licensing and corporate transactions, data protection, regulatory and privacy issues, competition law, R&D collaborations, clinical trials, marketing arrangements, trade-mark and patent disputes, public procurement and product liability. Bird & Bird has 30 offices in key business centres across the globe, ideally placed to advise clients on multi-jurisdictional mandates.

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Jane Owen is a partner and head of the firm's intellectual property group in Sydney. Jane has deep-level experience of complex IP strategy and disputes, on which she advises clients from a range of IP-rich industries. This advice traverses complex patent litigation through to research and commercialisation structures. Her specific focus is in the life sciences and higher education fields, in which she has over two decades of experience in all aspects of IP, including portfolio establishment, IP strategy, commercialisation and enforcement. Jane's IP disputes experience covers the fields of complex patent infringement and revocation, trade mark and passing off, design infringement, disputes on ownership of IP, trade mark and patent oppositions, re-examination requests and appeals from decisions of the Commissioner of Patents and the Registrar of Trade Marks.

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