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Life Sciences 2022

Australia: Law & Practice
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AUSTRALIA

Law and Practice

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1. LIFE SCIENCES REGULATORY FRAMEWORK

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Pharmaceuticals and medical devices are regulated as "therapeutic goods" in Australia. The principal legislation regulating therapeutic goods is the Therapeutic Goods Act 1989 (Cth) (TG Act). The TG Act provides a uniform, national system of regulation of the importation, exportation, supply, advertising and manufacture of therapeutic goods. All therapeutic goods must be included on the Australian Register of Therapeutic Goods (ARTG) prior to importation, manufacture and supply in Australia, unless specifically exempt.

In addition to the TG Act, regulations and legislative instruments govern specific types of therapeutic goods, and the conduct of manufacturers and sponsors, including the Therapeutic Goods Regulations 1990 (Cth) (TG Regulations), the Therapeutic Goods (Medical Devices) Regulations 2002 (Cth) (Medical Device Regulations), the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (Cth) and the Poisons Standard (Cth).

This regulatory framework is administered and enforced by the Therapeutic Goods Administration (TGA) in Australia. The TGA is part of the Australian Government Department of Health.

In addition, state and territory poisons and therapeutic goods legislation regulates matters such as the distribution, supply, storage, packaging and labelling of medicines based on scheduling classification in the Poisons Standard (Cth). These laws are applied and enforced by State and Territory Departments of Health. See **5.2 Different Classifications Applicable to Pharmaceuticals** for further information.

1.2 Challenging Decisions of Regulatory Bodies that Enforce Pharmaceuticals and Medical Devices Regulation

Certain decisions made by the TGA may be challenged via an internal review process under the TG Act. A person whose interests are affected by an "initial decision" made under the TG Act may request reconsideration of the decision by the Commonwealth Minister for Health (Minister). Examples of "initial decisions" include those regarding the registration and listing, or cancellation, of therapeutic goods on the ARTG.

An application for internal review to the Minister must be made in writing within 90 days of receiving notice of the TGA's initial decision.

As soon as practicable after receiving a request for internal review, the Minster must reconsider the initial decision and may either confirm or revoke the initial decision or make a substitute decision.

Other potential avenues for challenging TGA decisions include:

- merits review – if an affected person is dissatisfied with the outcome of internal review, an application may be made to the Administrative Appeals Tribunal (AAT) for merits' review of the Minister's decision; and
- judicial review – a person who is aggrieved by an administrative decision made pursuant to the TG Act may apply to the Federal Court of Australia seeking judicial review of the lawfulness of the decision.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Medicines

Medicines are regulated in accordance with a two-tiered system based on a risk assessment that takes into account active ingredients, thera-

peutic claims and benefits, and risks associated with use.

Higher-risk medicines must be "registered" on the ARTG. The TGA evaluates these medicines for quality, safety and efficacy. Medicines that are registered are all prescription medicines, most over-the-counter (OTC) medicines and some complementary medicines.

Lower-risk medicines must be "listed" on the ARTG. The TGA evaluates these medicines for quality and safety but not efficacy. Some OTC medicines, and most complementary medicines, are listed.

Medical Devices

Medical devices are categorised as either medical devices or IVDs (in vitro diagnostic devices).

Medical devices are classified into classes I, IIa, IIb and III (which includes Active Implantable Medical Devices (AIMD)). Classification is generally determined taking into account the intended purpose, degree of invasiveness in the human body, duration and location of use and whether the device relies on a source of energy other than the body or gravity.

The higher the classification level of a device, the more onerous the requirements for conformity assessment procedures that manufacturers must apply to their device to ensure compliance with mandatory essential principles.

IVDs are classified into four different classes. Higher classification is assigned to IVDs that would pose a greater risk to personal and public health if they generated an incorrect result.

2. CLINICAL TRIALS

2.1 Regulation of Clinical Trials

Regulatory requirements for the conduct of clinical trials in Australia are principally contained in the TG Act, TG Regulations and MD Regulations, but there are also additional state and territory legislative requirements. This legislative framework imposes various obligations and responsibilities on clinical trial sponsors, human research ethics committees (HRECs), approving authorities (institutions) and investigators.

Clinical trials must be conducted in accordance with international standards of good clinical practice:

- for medicines, the TGA has adopted the Guideline for Good Clinical Practice ICH E6 (R2) (annotated by the TGA);
- for medical devices, the TGA has adopted the standards for clinical evidence set out in ISO 14155:2020 (Clinical Investigation of Medical Devices for Human Subjects–Good Clinical Practice).

Clinical trials must also comply with the National Statement on Ethical Conduct in Human Research (National Statement) prescribed by the National Health and Medical Research Council (NHMRC). The National Statement outlines principles for ethical conduct in research and provides specific instructions for the formation and operation of HRECs.

Universities and other public-sector research institutions must comply with the Australian Code for the Responsible Conduct of Research 2018.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

All clinical trials require ethics approval by an HREC registered with the NHMRC before they can commence, and trials that involve the use of unapproved therapeutic goods are also subject to regulatory requirements in the TG Act, TG Regulations and MD Regulations.

The HREC reviews all scientific and ethical aspects of the clinical trial proposal, which may be supplemented by external expert advice.

Clinical trials of unapproved therapeutic goods may be conducted under one of two schemes.

- The Clinical Trial Notification (CTN) scheme: this involves a notification process. The TGA does not evaluate information relating to the trial at the time of notification. The sponsor and principal investigator submit trial information to an HREC, and the clinical trial must be notified to the TGA.
- The Clinical Trial Approval (CTA) scheme: this scheme requires the sponsor to submit information regarding the clinical trial, including scientific data for TGA evaluation and comment. TGA approval of the trial is subject to final HREC approval.

2.3 Public Availability of the Conduct of a Clinical Trial

The National Statement requires that researchers must register clinical trials on a publicly accessible register complying with international standards, (eg, the Australian and New Zealand Clinical Trials Registry). There is no mandatory register or repository of clinical trial results; however, the National Statement strongly encourages disseminating and communicating results to facilitate scrutiny and contribute to public knowledge and understanding.

The Australian Code for the Responsible Conduct of Research 2018, which applies to trials conducted at universities, public-sector research institutions and any clinical trials funded by the NHMRC, imposes a responsibility on researchers to disseminate research findings responsibly, accurately, and broadly. Trial registration is a prerequisite for publication of results in many medical journals.

2.4 Restriction for Using Online Tools to Support Clinical Trials

There are no restrictions on the use of online tools to support the conduct of clinical trials in Australia, noting that these mechanisms would form part of the clinical trial protocol and require HREC approval.

2.5 Use of Resulting Data from the Clinical Trials

Data resulting from clinical trials will include personal and sensitive information.

Personal information includes a broad range of information that could identify an individual. Sensitive information is personal information that includes health or genetic information about an individual.

Sponsors and others involved in the conduct of clinical trials in Australia must comply with privacy obligations under Commonwealth, state and territory legislation in respect of personal and sensitive information (including the Privacy Act 1988 (Cth) (Privacy Act) and Australian Privacy Principles). Obligations apply in respect of the collection, use, disclosure and transfer of clinical trial participants' personal and sensitive information.

Under the Privacy Act, health information may be used or disclosed to a third party or an affiliate in circumstances where:

- the clinical trial participant has provided consent; or
- it is for the same (primary) purpose for which the information was collected; or
- it is for a purpose which is directly related to the primary purpose of collection, and the individual would reasonably expect that the information would be used or disclosed for that purpose.

Otherwise, if disclosure is necessary for research relevant to public health and safety and it is impracticable to obtain the individual's consent, disclosure may be permitted if:

- it is conducted in accordance with guidelines under section 95A of the Privacy Act; and
- it is reasonably believed that the recipient will not disclose the information, or personal information derived from it.

2.6 Databases Containing Personal or Sensitive Data

The creation of a database containing personal or sensitive information will be subject to requirements under the Privacy Act, including the Australian Privacy Principles and/or relevant state and territory privacy legislation.

3. MARKETING AUTHORISATIONS FOR PHARMACEUTICAL OR MEDICAL DEVICES

3.1 Product Classification: Pharmaceutical or Medical Devices

The TG Act distinguishes between medicines and medical devices.

Pursuant to section 3 of the TG Act, medicines are defined as "therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human".

A medical device is defined in section 41BD. In summary, a medical device is:

- an instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application);
- specified in regulations or intended to be used for human beings for specified purposes, including the diagnosis, prevention, monitoring, treatment or alleviation of disease, or the investigation or modification of the anatomy or of a physiological process; and
- that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means.

The MD Regulations also distinguish between medical devices and IVDs.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biological medicinal products (including biosimilars) are evaluated by the TGA under the same pathways that apply to the evaluation of other prescription medicines.

For the purposes of the TG Act, biological medicinal products are not the same as "biologicals", which comprise, contain, or are derived from human cells or tissues, or comprise or contain live animal cells, tissues or organs, and are represented in any way to be, or are likely to be, for therapeutic use (section 32A). Biologicals are evaluated by the TGA under a separate pathway from biological medicinal products.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

Marketing authorisation for pharmaceuticals and medical devices continues indefinitely unless withdrawn by the sponsor, or suspended or cancelled by the TGA.

In order to maintain a pharmaceutical or medical device on the ARTG, annual charges apply.

The TGA may authorise the importation, manufacture and supply of medicines via a provisional approval pathway in certain circumstances, for a maximum of six years.

Suspension or Cancellation of Medicines and Medical Devices

The TG Act provides a number of grounds upon which medicines and medical devices may be suspended or cancelled from the ARTG, including:

- request of the sponsor;
- failure of a sponsor to comply with conditions of registration, listing or inclusion on the ARTG;
- suspension or revocation of a conformity assessment certificate;
- a potential risk of death, serious illness or serious injury if the therapeutic goods continue to be included in the Register;
- a significant breach of the Therapeutic Goods Advertising Code; or
- annual registration or listing charges are not paid within the prescribed timeframe.

Written notification of the TGA's intention to suspend or cancel the ARTG registration or listing must be provided to the sponsor and a reasonable opportunity afforded to make submissions. A decision to suspend or cancel the registration or listing of a medicine is an "initial decision" subject to internal review (see **1.2 Challenging Decisions of Regulatory Bodies that Enforce Pharmaceuticals and Medical Devices Regulation**).

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

Prescription Medicines

Marketing authorisation is obtained by submitting an application under section 23 of the TG Act, which comprises a dossier containing or referencing data to demonstrate the quality, safety and efficacy of the prescription medicine and must be presented in the common technical document (CTD) format.

"Category 1" applications are made in respect of new prescription medicines or variations to existing medicines that involve the evaluation of clinical, pre-clinical or bio-equivalence data (eg, new chemical entities, extensions of indication and new routes of administration). "Category 2" applications are made in respect of medicines accompanied by two independent evaluation reports from comparable overseas regulators in whose jurisdiction the product is approved for the same indication.

The approval process can be fast-tracked through a priority review pathway for certain new medicines or new indications for serious and life-threatening conditions.

The TGA also has a provisional approval pathway (based on preliminary clinical data) for provisional authorisation of prescription medicines providing a major therapeutic advance for treating serious conditions.

Medical Devices

The procedure for obtaining marketing authorisation will depends on the classification of the device.

In summary:

- Class I non-sterile, non-measuring medical devices, and Class I/Class 1 IVD (export only): the applicant must submit a copy of the manufacturer's Declaration of Conformity for the device with the application;
- Class 1 IVD medical devices that are not intended to be used for self-testing or point-of care can be "included" in the ARTG via a self-declaration process;
- for other classes of medical device or IVDs, the applicant must submit a copy of the "Manufacturer's Evidence" in order to obtain conformity assessment certification issued by the TGA, or submit certification from an overseas conformity assessment body. In certain cases, a declaration of conformity made by the manufacturer will be accepted (eg, for Class 1–sterile or measuring devices).

Applications to include a medical device in the ARTG can be made by a sponsor online via the TGA Business Services (TBS) portal. The TGA may approve the inclusion of a device in the ARTG or select an application for audit prior to approval.

Variation of ARTG Entry/Marketing Authorisation

Medicines

The procedure for varying a marketing authorisation depends on the nature of the variation and, specifically, whether the variation involves the evaluation of clinical, pre-clinical or bio-equivalence data.

ARTG entries for medicines and medical devices can be varied by seeking the TGA's approval to:

- correct an entry that contains incomplete or incorrect information; or
- make safety-related variations to an ARTG entry, for example, to reduce the class of persons for whom the goods are suitable; or
- make specified variations to an ARTG entry that do not affect the established quality, safety and efficacy of the medicine, which under certain conditions must then be approved by the TGA; or
- make other variations to an ARTG entry that do not have the effect of creating a separate and distinct good, provided that the change does not reduce the quality, safety or efficacy of the medicine

Applications for variation can be submitted online using the TGA Business TBS portal and completing a variation e-form.

If the variation requires the evaluation of clinical, pre-clinical or bio-equivalence data, it must be made pursuant to the prescription medicine registration process previously outlined. Further, if the variation creates a separate and distinct good, sponsors must apply to the TGA under section 23 of the TG Act for approval of a new registered medicine.

Medical devices

New devices that are devices of the same kind as devices already included on the ARTG (eg, they have the same sponsor, manufacturer or classification) may be supplied under an appropriate existing ARTG entry without further approval by the TGA.

Transfer of marketing authorisation

Marketing authorisations may be transferred from one sponsor to another. The TGA must be notified within three months of a change in sponsor name or entity.

3.5 Access to Pharmaceutical and Medical Devices without Marketing Authorisations

The following pathways allow patients to access unapproved therapeutic goods in Australia.

- Clinical trials – see **2. Clinical Trials** for further information.
- Authorised prescribers' scheme: medical practitioners may be granted authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified patients under their care.
- Special access scheme (SAS): health practitioners may access unapproved therapeutic goods for a single patient on a case-by-case basis. There are three categories of SAS pathways available:
  (a) Category A – a notification pathway to access therapeutic goods for patients who are 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;
  (b) Category B – an application pathway used to access therapeutic goods for patients that do not fit Category A and where the unapproved goods do not fall within Category C;
  (c) Category C – a notification pathway to access specific therapeutic goods (listed by the TGA) that are deemed to have an established history of use.
- Personal importation scheme: individuals can import a three-month supply of unapproved therapeutic goods for personal use (by that individual or a member of his or her immediate family).

Compassionate supply refers to situations when sponsors agree to provide a therapeutic good to a patient at a reduced or no cost. Compassionate supply may be provided for approved and unapproved products.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

Medicines

Sponsors are subject to a range of pharmacovigilance obligations in relation to medicines registered or listed on the ARTG. These obligations include:

- adverse event reporting;
- corrective action when necessary, eg, recalls;
- keeping specified manufacturing and distribution records;
- answering requests from the TGA for information within specified timeframes; and
- submitting Periodic Safety Update Reports in respect of certain medicines.

The TGA conducts inspections to assess whether sponsors are meeting their pharmacovigilance regulatory obligations. Failure to comply with ongoing obligations may result in the suspension or cancellation of the medicines from the ARTG and also constitute an offence attracting criminal and civil penalties.

Medical Devices

Ongoing obligations are imposed on sponsors of medical devices and IVDs included on the ARTG. These include:

- reporting to the TGA details of adverse events, investigations and performance issues;
- taking corrective action when necessary, eg, recalling devices;
- maintaining manufacturing and distribution records for prescribed periods; and
- providing annual reports for the first three years that a Class III, or Class IIb implantable device is available in Australia.

Failure to comply with ongoing obligations may constitute an offence attracting criminal and civil penalties.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

The TGA publishes a list of applications for new medicines, new combination medicines and new indications for already approved medicines that are under evaluation by the TGA. This list is updated on a monthly basis.

Applications for approval of new generic and biosimilar medicines are not currently published by the TGA. In 2020, the TGA proposed regulatory changes that would require applicants for first generic and biosimilar medicines to notify the patent-holder when their application is accepted for evaluation by the TGA. However, those changes have not yet been implemented.

Formal requests for information may be made by third parties to access documents held by the TGA, pursuant to the Freedom of Information Act 1982 (Cth). In these circumstances, any information considered confidential or commercially valuable and sensitive information (such as the dossier) will be exempt from disclosure.

Information and data submitted by a sponsor to the TGA for the purposes of obtaining marketing authorisation (eg, within a dossier) is considered confidential by the TGA and will not usually be disclosed in response to requests by third parties.

3.8 Rules against Illegal Medicines and/or Medical Devices

The importation, manufacture, supply and exportation of counterfeit medicines and medical devices is an offence under the TG Act attracting civil and criminal penalties (sections 42E and 42EA).

Therapeutic goods are considered counterfeit if:

- a false representation is made in respect of matters including the name, formulation, strength, sponsor or manufacturer of the goods; and
- this false representation is made on the goods, labelling, packaging, documentation or advertising materials.

The importation, sale, supply or offering for sale of counterfeit goods may also contravene Australian intellectual property laws.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

Border measures permit the Australian Border Force (Customs) to seize counterfeit medicines and medical devices. Pursuant to the TG Act, if the TGA notifies Customs that imported or exported therapeutic goods are counterfeit, the goods are deemed to be prohibited imports or prohibited exports and consequently will be forfeited.

Customs also has powers to seize counterfeit goods pursuant to intellectual property laws.

4. MANUFACTURING OF PHARMACEUTICAL AND MEDICAL DEVICES

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

Medicines

Australian sites that manufacture medicines are required to hold a manufacturing licence (also called GMP licences). There are limited exemp-

tions in the TG Regulations (regulation 17 and schedule 7).

Manufacturing licences are issued by the TGA. These licences are valid from the day of grant until revoked or suspended. Annual licence fees are payable to maintain a licence.

An applicant for a manufacturing licence must comply with the Manufacturing Principles set out in Therapeutic Goods (Manufacturing Principles) Determination 2020 (Cth). Unless exempt, medicines supplied in Australia must meet the PIC/S Guide to Good Manufacturing Practice (GMP) for Medicinal Products, (version PE009-14), excluding Annexes 4, 5 and 14, which are not adopted in Australia.

Manufacturing licences may be granted in respect of a full manufacturing process or certain steps, eg, processing, assembling, packaging, labelling, storing, sterilising, testing or releasing for supply of the medicines or of any component or ingredient of the medicines as part of that process.

It is an offence attracting criminal and civil penalties to manufacture medicines without a licence or in breach of conditions imposed on the licence.

Medical Devices

Australian manufacturers of medical devices (and IVDs) must have appropriate conformity assessment procedures in place for the device and relevant documentation demonstrating compliance of the device with the essential principles. For medical devices containing medicines or tissues of animal, biological or microbial origin, or Class 4 IVDs, manufacturers can provide conformity assessment evidence issued by the TGA, EU notified bodies or Australian conformity assessment bodies to support an application for inclusion in the ARTG.

Conformity Assessment Certificates issued by the TGA are typically valid for a period of five years.

5. DISTRIBUTION OF PHARMACEUTICAL AND MEDICAL DEVICES

5.1 Wholesale of Pharmaceutical and Medical Devices

Poisons and therapeutic goods legislation in each Australian State and Territory requires wholesalers of medicines to be licensed. Wholesale licences are required to store, distribute and supply poisons and therapeutic goods.

Applications for a wholesale licence must be submitted to the relevant State or Territory Department of Health. Application fees and ongoing annual licence fees apply. A wholesale licence remains in force unless suspended, cancelled or surrendered.

5.2 Different Classifications Applicable to Pharmaceuticals

Medicines are classified in Schedules in the Standard for the Uniform Scheduling of Medicines and Poisons, as follows:

- Schedule 2 – pharmacy medicines;
- Schedule 3 – pharmacist-only medicines;
- Schedule 4 – prescription-only medicines; and
- Schedule 8 – controlled drugs (drugs of addiction).

6. IMPORTATION AND EXPORTATION OF PHARMACEUTICALS AND MEDICAL DEVICES

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The importation and exportation of medicines and medical devices from Australia is principally regulated by the TG Act. In relation to controlled substances (eg, narcotic, psychotropic and precursor substances), additional regulations are contained in the Customs (Prohibited Imports) Regulations 1956 (Cth) and Customs (Prohibited Exports) Regulations 1958 (Cth) which are administered and enforced by the Office of Drug Control of the Department of Health.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Medicines and medical devices must be entered in the ARTG before they can lawfully be imported into or exported from Australia, unless they are exempt. Only the sponsor of the medicine or medical device, or a person acting on behalf of the sponsor indicated in the ARTG entry, is permitted to import or export goods.

A sponsor must be a resident of Australia or an incorporated body in Australia.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Pharmaceuticals and medical devices must be approved by the TGA and entered or listed on the ARTG prior to importation into Australia.

Unapproved medicines and medical devices can be imported into or exported from Australia in the following circumstances:

- for clinical trials (see **2. Clinical Trials** for further information);
- under the personal importation, authorised prescriber or special access schemes (see **3.5 Access to Pharmaceutical and Medical Devices without Marketing Authorisations** for further information);
- to enable medicines or medical devices to be stockpiled as quickly as possible where there is a threat to public health (emergency); and
- to supply substitute medicines or medical devices when approved goods are in short supply or unavailable.

The importation and exportation of controlled substances is prohibited without a licence and/or permit issued by the Office of Drug Control (Department of Health).

6.4 Non-tariff Regulations and Restrictions Imposed upon Importation

Non-tariff regulations and restrictions are imposed based on whether goods fall within the definitions of a “therapeutic good”, “medicine”, “medical device”, “in vitro diagnostic device” or “biological” in the TG Act.

Schedule 4 of the Customs (Prohibited Imports) Regulations 1956 and Schedule 8 of the Customs (Prohibited Exports) Regulations 1958 lists drugs that can only be imported or exported with the permission or licence of the Office of Drug Control (Department of Health).

6.5 Trade Blocs and Free Trade Agreements

Australia is a party to the following free trade agreements, which are currently in force:

- 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;
- Australia-Hong Kong;
- Peru-Australia;
- Indonesia- Australia Comprehensive Economic Partnership Agreement;
- Pacific Agreement on Closer Economic Relations (PACER) Plus; and
- Regional Comprehensive Economic Partnership Agreement (RCEP).

7. PHARMACEUTICAL AND MEDICAL DEVICE PRICING AND REIMBURSEMENT

7.1 Price Control for Pharmaceuticals and Medical Devices

Medicines

Medicines which are listed on the Schedule of the Pharmaceutical Benefits Scheme (PBS) (PBS-listed medicines) are subsidised by the Australian Government.

The price of these pharmaceuticals (ie, the amount of subsidy paid) is determined in accordance with the National Health Act 1953 (Cth) (NH Act), National Health Pharmaceutical Benefits Regulations 2017 (Cth) (NH Regulations) and the Community Pharmacy Agreement between the Government, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia.

The price the Australian Government pays for PBS-listed medicines comprises the ex-manufacturer price (determined by the Minister of Health) plus allowances (which are a wholesale mark-up, administration, handling and infrastructure fee, dispensing fee and, in some cases, a "dangerous-drug fee"). The amounts paid for allowances are contained in the Community Pharmacy Agreement.

A range of statutory price reductions under Part VII, Divisions 3A and 3B of the NH Act reduce, over time, the ex-manufacturer price paid by the Australian Government for pharmaceuticals listed on the PBS.

For pharmaceuticals that are not listed on the PBS, no subsidies are paid by the Government and patients must privately pay a full price set by sponsors, wholesalers and pharmacists.

Medical Devices

The PBS does not subsidise the cost of medical devices.

Under the Private Health Insurance Act 2007 (Cth), private health insurers are required to pay insurance benefits for certain medical devices that are included on the Prostheses List, provided:

- an insured person has appropriate insurance cover;
- the prostheses are provided as part of an episode of hospital treatment or hospital-substitute treatment; and
- a Medicare benefit is payable for the professional service associated with the provision of the prosthesis.

The Minister for Health is responsible for determining whether to list a prosthesis on the Prostheses List. Products currently listed on the Prostheses List include surgically implanted medical devices, devices designed and essential for implantation or for maintaining the implant, human tissue items and other specified devices.

7.2 Price Levels of Pharmaceutical or Medical Devices

Medicines

In determining the subsidy (ex-manufacturer price) of a PBS-listed medicine, the Department of Health will take into account the price of the medicine in reasonably comparable overseas countries. Other factors include:

- the Pharmaceutical Benefits Advisory Committee (PBAC) advice on clinical and cost-effectiveness;
- prices of alternative brands;
- comparative prices of items in the same therapeutic group;
- cost information provided by the responsible person; and
- prescription volumes, economies of scale, special storage requirements, product stability, special arrangements.

Medical Devices

For medical devices on the Prostheses List, the benefit paid is determined by the Minister for Health on the basis of advice from the Prostheses List Advisory Committee (PLAC). If a sponsor seeks a higher benefit in respect of its device, it will need to submit economic information to the PLAC for consideration.

7.3 Pharmaceuticals and Medical Devices: Reimbursement from Public Funds

Patients are required to make a co-payment for PBS-listed medicines (currently AUD42.50 or AUD6.80 for concession card-holders) and the Australian Government subsidises the remainder of the cost of PBS medicines from public funds.

Subsidised PBS-listed medicines are available to all Australians and concession card-holders who have a current Medicare card and visitors from overseas countries with which Australia has a Reciprocal Health Care Agreement.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Cost-benefit analyses are considered by the PBAC in determining whether to recommend a medicine for listing on the PBS and the subsidy (reimbursed price) of the medicine on the PBS.

Submissions made to the PBAC for listing of a new medicine or a new indication for a PBS-listed medicine are required to include an economic evaluation based on substituting the new medicine for the main comparator (a similar medicine already listed on the PBS). A full cost-effectiveness analysis is required if the medicine under consideration by the PBAC is claimed to be therapeutically non-inferior (or superior) to the main comparator medicine listed on the PBS but is likely to result in additional costs to the health system, or is claimed to be therapeutically inferior to the main comparator, but is likely to result in lower costs to the health system.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

The National Health (NH) Act and National Health (NH) Regulations impose requirements on the prescribing, dispensing and supply of PBS-listed medicines to ensure control over pharmaceutical spending by the Australian Government. These requirements include:

- requiring medical practitioners to obtain specific authority from the Department of Health before prescribing some PBS-listed medicines;
- ensuring patients that are prescribed certain PBS-listed medicines meet specified clinical criteria; and
- limiting the number of repeats that can be prescribed and dispensed.

State and territory poisons and therapeutic goods legislation also imposes controls on the prescribing, dispensing and supply of medicines.

8. DIGITAL HEALTHCARE

8.1 Rules for Medical Apps

A medical app may be regulated as a medical device if it falls within the definition of a medical device in section 41BD of the TG Act (see **3.1 Product Classification: Pharmaceutical or Medical Devices**). This definition includes software on its own or that is necessary for the application of a medical device, if it is intended to be used for certain purposes.

The MD Regulations provide classification rules for software-based medical devices that provide a diagnosis or screen for a disease or condition; monitor the state or progression of a disease or condition; specify or recommend a treatment or intervention; and provide therapy through the provision of information.

The essential principles also provide express requirements in relation to software-based medical devices.

Certain types of software-based medical devices (for example, consumer wellness products, telehealth-enabling technology, and apps for self-management of existing diseases that are not serious) are excluded from TGA regulatory requirements.

8.2 Rules for Telemedicine

There is no specific regulation for telemedicine beyond the requirements that generally apply to the provision of medical advice and health services by health practitioners.

Guidance notes on the use of telehealth services have been published by a number of regulatory and professional bodies, including the Australian Health Practitioner Regulation Agency, the Medical Board of Australia and the Royal Australian College of General Practitioners.

8.3 Promoting and/or Advertising on an Online Platform

All promotional and advertising activities in relation to medicines and medical devices–including via online platforms–must comply with the advertising regulations in the TG Act and Therapeutic Goods Advertising Code (noting that certain medicines, for example prescription medicines, must not be advertised to the public in Australia).

There are no special rules for online advertising or posting on social networks. The Therapeutic Goods Advertising Code confirms that social media influencers who have received, or will receive, valuable consideration for making a testimonial can be persons engaged in the marketing of therapeutic goods and the TGA has issued a specific social media advertising guide to aid compliance. Advertising via online platforms is also regulated by industry codes, including the Medicines Australia Code of Conduct and the Medical Technology Association of Australia Code of Practice.

8.4 Electronic Prescriptions

Electronic prescriptions are permitted in Australia. Prescribers must adhere to prescription requirements set out in the NH Act and state and territory regulations.

8.5 Online Sales of Medicines and Medical Devices

Medicines and medical devices may be sold online in Australia, subject to the same regulatory requirements as medicines and medical devices sold in physical pharmacies. For example, all medicines and devices must be entered or listed on the ARTG, subject to limited exemptions.

8.6 Electronic Health Records

Health information is protected as "sensitive information" under the Privacy Act and attracts

stricter forms of privacy protections and obligations than other "personal information".

Health information may be used:

- for the primary purpose for which it was created (eg, diagnosis of a condition);
- a directly related secondary purpose which is within the reasonable expectation of the individual to whom the information relates; or
- under certain strict circumstances (eg, under a court direction or for public health and safety).

Australia has a centralised electronic health record system, known as My Health Record. Health information stored in this database may include a patient's health summary, prescribed medication and dispensing history, pathology reports, diagnostic-imaging reports and discharge summaries. The system is an opt-out system regulated under the terms of the My Health Records Act 2012 (Cth).

New South Wales, Victoria and the ACT also have specific legislation regulating health records: Health Records and Information Privacy Act 2002 (NSW), Health Records Act 2001 (Vic) and Health Records (Privacy and Access) Act 1997 (ACT).

There are no special requirements with respect to storing health information on cloud platforms; however, privacy regulations can affect how cloud platforms are used. For example, the Australian Privacy Principles regulate the disclosure of personal information outside Australia and the responsibilities of organisations that "hold" personal information.

9. PATENTS RELATING TO PHARMACEUTICALS AND MEDICAL DEVICES

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

Statutory Framework

Patents are governed by the Patents Act 1990 (Cth) and Patents Regulations 1991 (Cth).

The patents legislation has undergone significant changes over time, most recently with the enactment of the "Raising the Bar" (RTB) Act. The RTB Act was introduced to raise the standards required to support the grant of a patent and to make them more consistent with those applying in other countries. Post-RTB Act patents (typically, post 15 April 2013) are therefore subject to stricter requirements than pre-RTB Act patents.

Patentability

Pharmaceutical and medical device patents must meet the same requirements for patentability as all other patents, including manner of manufacture, novelty, inventive step, and usefulness.

In the context of pharmaceuticals and medical devices, the following categories of subject-matter are not eligible for patent protection in Australia:

- human beings and biological processes for their generation;
- isolated naturally occurring DNA and RNA; and
- computer-implemented inventions characterised as mere schemes, abstract ideas or intellectual information that are implemented by generic computer technology.

Patent claims must also satisfy additional requirements such as sufficiency, support/fair

basis and clarity. Patents are required to disclose the best method known to the applicant of performing the invention at the time of filing the patent application, otherwise the patent may be subject to invalidation.

9.2 Second and Subsequent Medical Uses

Patentability

Second and subsequent medical uses, including in relation to new dosage regimes and new or selected patient populations, are patentable if they meet the standard requirements for patentability.

Claims to both methods of treatment and Swiss-type claims are allowable in Australia.

Infringement

Unauthorised "exploitation" of a claimed invention during the patent term constitutes direct infringement. "Exploit" is statutorily defined to include:

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

Swiss-Type Claims

Swiss-type claims are construed in Australia as method or process claims that are purpose-limited.

Whether there is infringement of a Swiss-type claim involves asking what the allegedly infringing manufacturer has done, not what it intended to do. In assessing this, the court has regard to all of the circumstances, including factors such as the product's formulation, dosage and packaging, and the product information submitted to the TGA.

A Swiss-type claim may be infringed by the importation of a pharmaceutical defined in the claim that is manufactured overseas.

Method of Treatment Claims

Method of treatment claims may be directly infringed by exploitation of the patented method. They may also be indirectly infringed by the supply in Australia of a product in certain circumstances where the use of that product by a person would infringe the method claim.

9.3 Patent Term Extension for Pharmaceuticals

A patentee may apply to the Australian Patent Office to extend the term of a standard patent if:

- one or more pharmaceutical substances (i) per se, or (ii) when produced by a process that involves the use of recombinant DNA technology, is in substance disclosed in the complete specification and falls within the scope of the claims; the "per se" requirement means that the pharmaceutical must itself be the subject of a claim (eg, it is not sufficient that the claimed substance is included in a method or process claim);
- goods containing, or consisting of, the substance are included in the ARTG;
- the time between the date of the patent (usually the filing date) and the first regulatory approval date (generally inclusion in the ARTG) for the substance is at least five years; and
- the term has not previously been extended.

The available period of the extension is a maximum of five years and is determined by the dif-

ference between the date of the patent and the first regulatory approval date, reduced by five years.

Process

An application must be made during the term of the patent and by the later of six months from patent grant or first inclusion of the relevant goods in the ARTG. If accepted by the Patent Office, the application is advertised and third parties then have three months to file a notice opposing the application.

9.4 Pharmaceutical or Medical Device Patent Infringement

A pharmaceutical or medical device patent will be infringed where a party "exploits" (as statutorily defined; see **9.2 Second and Subsequent Medical Uses**) a claimed invention without authorisation during the patent term. Australian law makes provision for direct and, in some circumstances, indirect infringement, as well as infringement by authorisation and as a joint tortfeasor.

Applying to list a product on the PBS before patent expiry for sale after expiry of the patent has been held not to be an "offer to sell" and therefore not to constitute patent infringement. However, where a patent applicant intends to obtain ARTG/PBS listing and to supply the product during the term of a valid patent, this may constitute threatened infringement and entitle a patentee to injunctive relief.

Injunctive relief can be sought for both actual and threatened infringement. In an application for an injunction for threatened infringement (on a quia timet basis), the court will have regard to whether the threat is imminent, the degree of probability and the seriousness of the apprehended injury and the requirements of justice between the parties.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Defences

The following exemptions to infringement relevantly apply in the context of pharmaceuticals and medical devices:

- exploiting a pharmaceutical or medical device patent solely for the purposes of obtaining regulatory approval; and
- exploiting a claimed invention for experimental purposes relating to the subject-matter of the invention.

In addition, during the extended patent term of a pharmaceutical substance, it is not an infringement for a person to use the claimed pharmaceutical substance per se for a non-therapeutic purpose or to exploit any form of the claimed invention other than the pharmaceutical substance per se.

Compulsory Licences

Compulsory and Crown Use (see **11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments**) licences are available in Australia. However, no compulsory licence has been granted to date and Crown Use licences are rarely used.

Any person may apply to the Federal Court for a non-exclusive, compulsory licence to work a patented invention on or after three years from the date of patent grant. The application must be made on the grounds that:

- demand for the invention is not being met in Australia on reasonable terms and it is in the public interest to grant the licence; or
- the patentee has engaged in restrictive trade practices in contravention of Australian competition law.

In addition, a person can apply to the court for a "patented pharmaceutical invention" (PPI) compulsory licence to the extent necessary to manufacture a pharmaceutical product in Australia for export to a developing country in need.

9.6 Proceedings for Patent Infringement

Standing

Infringement proceedings may be commenced by a patentee or the exclusive licensee. An exclusive licensee is a licensee who has been granted all exploitation rights related to a patent in Australia (including, significantly, manufacturing rights) to the exclusion of the patentee and all others.

Procedure

Where the patentee or exclusive licensee commences infringement proceedings in relation to a proposed generic or biosimilar entrant, they must certify to the TGA and to the proposed respondent that the proceedings are to be commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay.

An infringement action is commenced by filing an application and statement of claim with the Federal Court. The alleged infringer will have an opportunity to file a defence and may also file a cross-claim seeking revocation of relevant patent claims on the basis of invalidity. The patentee or exclusive licensee will file a defence to the cross-claim. Parties may then reply to any defences.

Once the pleadings are finalised, the parties will exchange written affidavit evidence, including expert evidence. Witnesses can be cross-examined on the content of the affidavits during the trial. The Federal Court commonly prefers experts to prepare a joint report and to give their evidence concurrently at the trial.

The parties may also engage in a range of pre-trial steps (eg, document production, experiments). The Court may require the parties to seek to narrow the dispute prior to the trial, such as by filing position statements on infringement, and product or process descriptions of the claimed invention.

In most cases, issues of liability for infringement and validity will be heard together by a judge at a trial. The question of pecuniary relief is often delayed until liability issues are determined.

Remedies

Remedies available for patent infringement include:

- injunctions;
- at the patentee's election, either damages or an account of profits;
- declarations of infringement; and
- orders for delivery-up or destruction of infringing products.

Additional damages may be available in certain circumstances for flagrant infringement.

9.7 Procedures Available to a Generic Entrant

A potential generic market entrant may seek to "clear the way" before launch by applying to revoke a patent with the aim of avoiding an infringement claim, including a possible interlocutory injunction application; however, it is not a requirement to so.

Alternatively, a generic may apply to the court for a declaration of non-infringement. Certain preconditions must be satisfied, including that the patentee has refused to admit that the relevant conduct is non-infringing.

If, in the process of applying for ARTG registration of a generic product, a generic relies upon

efficacy and safety data submitted to the TGA by an innovator, the generic is required to provide the TGA with a certificate to the effect that the generic:

- is not intending to market the product in a manner that would infringe a valid claim of a granted patent; or
- has notified the patentee of the application for registration.

In practice, it is rare for the second type of certificate to be provided.

The Government has proposed, but not yet implemented, changes to this certification regime, including requiring a certificate to be provided to both the patentee and the TGA earlier in the application process for the first generic entrant.

Other than the certification referred to above, the marketing authorisation procedure does not currently take account of patent protection and there is currently no patent linkage system.

10. IP OTHER THAN PATENTS

10.1 Counterfeit Pharmaceuticals and Medical Devices

Rights-holders may pursue civil proceedings in respect of counterfeit pharmaceuticals and medical devices, based on:

- infringement of registered trade marks, registered designs, patents or copyright;
- passing off at common law; or
- false or misleading or deceptive conduct under the Australian Consumer Law (ACL).

Criminal offences can apply in respect of counterfeits under the Trade Marks Act 1995 (Cth) and Copyright Act 1968 (Cth) and in respect of false or misleading representations under the ACL.

Rights-holders may lodge a Notice of Objection with the Australian Border Force (Customs) for the seizure of imported goods at the border that are suspected of infringing copyright or registered trade marks.

The manufacture and supply of counterfeit therapeutic goods is also subject to criminal and civil penalty provisions under the TG Act.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

There are no specific restrictions on trade marks for pharmaceuticals and medical devices. General trade mark requirements apply, pursuant to the Trade Marks Act 1995 (Cth), including:

- trade mark applications will be rejected if the use of the trade mark in relation to the specified goods would be likely to deceive or cause confusion; and
- trade mark applications will be rejected if the trade mark is not capable of distinguishing the applicant's goods in respect of which the trade mark is sought to be registered. This may be the case where the trade mark is identical or confusingly similar to an International Non-proprietary Name (INN), given that other pharmaceutical companies are likely to want to use the INN on their own products.

Naming of ingredients for pharmaceuticals, including chemical and biological substances, is regulated by the TGA.

Australian trade mark laws permit the importation of genuine goods manufactured outside Australia. Use of a registered trade mark in relation to genuine imported pharmaceutical or

medical devices will not constitute infringement of the trade mark if the trader can prove that:

- before the time of use, the trader had made reasonable enquiries in relation to the trade mark; and
- at the time of use, a reasonable person, having made those enquiries, would have concluded that the mark had been applied to, or in relation to, the goods by or with the consent of the owner of the registered mark (or others who can provide such consent, including an authorised user and an associated entity).

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Subject to satisfying the relevant requirements, the trade dress or design of pharmaceuticals and medical devices (and their packaging) may be protected by:

- registered designs, protecting shape or appearance of products;
- copyright, which may protect packaging (but not product information) as literary or artistic works;
- trade marks, including colour and shape marks;
- the tort of passing off, which protects goodwill; and
- prohibitions on misleading or deceptive conduct under the ACL, which can, for example, provide remedies for misleading representations arising from the trade dress as to the source, origin or fitness for purpose of the products.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Confidential information about an active component (ie, a substance not a device) given to the TGA in relation to an application to register a new therapeutic good has a five-year period of data exclusivity, commencing from the date of the first inclusion of the good in the ARTG. The exclusivity only applies if there have been no other therapeutic goods consisting of, or containing, the active component previously included in the ARTG. There is no exclusivity for new dosage forms, routes of administration or indications.

11. COVID-19 AND LIFE SCIENCES

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

In 2020, the TGA implemented a number of expedited pathways and exemption procedures for the regulation of medical devices during the COVID-19 pandemic, but these measures largely expired on 31 January 2021.

The TGA is currently prioritising applications for COVID-19 rapid antigen self-tests (RATs) and point-of-care tests and is conducting post-market review of all approved COVID-19 tests to verify their performance. An emergency determination under the Biosecurity Act 2015 was made in January 2022 to minimise price-gouging and exportation of COVID-19 RATs.

The TGA has implemented a provisional pathway and rolling review procedures to expedite registration of COVID-19 vaccines and treatments. To date, provisional determinations have been granted for five COVID-19 vaccines and eight medicinal treatments.

In March 2020, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia also imposed dispensing limits on certain prescription medicines, including medicines for which

demand was expected to increase due to COVID-19 symptom management.

11.2 Special Measures Relating to Clinical Trials

For clinical trials under the CTN scheme, the following variations to trial protocols in response to COVID-19 do not need to be notified to the TGA:

- deviations related to the supply of Investigational Medicinal Product (IMP) and resulting from restrictions that require patients to be managed remotely, eg, quarantine protocols and travel restrictions;
- other variations such as changes to the trial start/finish date, the principal investigator, number of participants, change in site address or the name of the trial-approving authority.

However, other variations to trials (including any changes to therapeutic goods, or sites) continue to require notification to the TGA.

Variations to clinical trials being conducted under the CTA scheme are being assessed by the TGA on a case-by-case basis.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

Applications for regulatory approval of pharmaceuticals and medical devices which relate to the prevention or treatment of COVID-19 are being expedited and prioritised for assessment by the TGA.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

In view of the COVID-19 pandemic, the TGA has adopted a risk-based approach to audits and inspections of domestic manufacturing sites to enable remote, hybrid or deferred Good Manufacturing Practice (GMP) inspections in place of on-site inspections when suitable.

The TGA also instituted a remote GMP inspections programme for overseas manufacturers.

To counter inspection disruptions caused by COVID-19, both domestically and overseas, the TGA has implemented a temporary change to documentation requirements for GMP clearance applications submitted through the Compliance Verification (CV) pathway, allowing sponsors to provide:

- a recently expired inspection report from a recognised regulator; and
- a GMP Clearance questionnaire and/or an inspection report issued following a successful remote inspection or distant assessment.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

In 2020, the Australian government prohibited the export of certain goods relating to COVID-19 (eg, disposable face masks, gloves and gowns, alcohol wipes and hand sanitiser). These prohibitions were repealed in December 2020. In January 2022, the Minister for Health made a determination under the Biosecurity Act 2015 restricting the export of rapid antigen tests.

With respect to imports, the Australian Federal Government has engaged in temporary emergency measures such as the International Freight Assistance Mechanism (IFAM) to fund international trade routes in and out of Australia that have been affected by COVID-19 response measures.

11.6 Drivers for Digital Health Innovation Due to COVID-19

During the COVID-19 pandemic, the Department of Health made available temporary Medicare rebates for telehealth services. From 1 January 2022, certain telehealth arrangements, including access to GP, specialists, nursing, midwifery and allied health services and telephone consulta-

tions for people residing in remote areas of Australia, have now been made a permanent, ongoing part of Medicare. These measures have been introduced to allow the Government to continue protecting patients in the pandemic and to assist in the transition to a "COVID normal" world.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

To date, the Australian Government has not announced any intention to institute any "Crown Use" measures, and there have been no applications by third parties for a compulsory licence in respect of COVID-19-related treatments or vaccines.

Australian Government authorities (and third parties authorised by those authorities) can seek access to patented technology, or technology for which a patent application is pending, without the authorisation of the rights-holder, under the "Crown use" provisions of the Patents Act. In summary, these provisions require that:

- the authority has tried for a reasonable period, without success, to obtain a licence to exploit the invention on reasonable terms;
- the Minister has approved the exploitation in writing;
- the invention is exploited for Crown purposes; and
- notice is given to the rights-holder 14 days before the exploitation starts.

However, no prior negotiation with, or prior notice to, the rights-holder in relation to Crown Use is required where the Minister considers that the exploitation of an invention is required for an emergency.

The authority is required to remunerate the rights-holder on terms that are agreed or otherwise determined by a court.

Compulsory licensing provides a similar mechanism to Crown Use for third-party entities, including private companies (see **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**).

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

The Australian Government has not introduced any statutory liability exemptions for COVID-19 vaccines or treatments. Any liability exemptions must be negotiated on a case-by-case basis as part of the Australian Government's commercial arrangements with suppliers.

In 2021, the Australian Government instituted a no-fault indemnity scheme for certain claims related to the administration of a TGA-approved COVID-19 vaccine delivered through a Commonwealth Government-approved programme, providing compensation covering the cost of injuries upwards of AUD1,000.

11.9 Requisition or Conversion of Manufacturing Sites

The Biosecurity Act 2015 empowers the Federal Minister for Health to issue requirements or directions as are necessary for the control or prevention of the spread of COVID-19 in Australia, subject to meeting certain statutory requirements. To date, the Government has not relied upon these powers to allow the requisition or conversion of manufacturing sites due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

The Australian Government Department of Finance issued a COVID-19 Procurement Policy Note (updated 11 January 2022) to assist entities who are considering undertaking procurements in the COVID-19 environment or are addressing contractual matters with affected suppliers.

The Policy Note emphasises mechanisms under the Commonwealth Procurement Rules which enable more streamlined processes to engage suppliers more urgently.

A number of Australian states have modified their public procurement processes in response to COVID-19. These modifications are dynamic and subject to further change, but currently include the following.

- NSW – under COVID-19 emergency procurement guidelines, the head of an agency can approve procurements up to a value sufficient to meet the immediate needs of the emergency, without the need to follow ordinary procurement requirements or procedures. The State Emergency Operations Controller (SEOCON) has centralised the procurement of critical goods and services to ensure supply for the NSW Government for the purpose of the COVID-19 pandemic.
- Queensland – the Government issues Procurement Advisory Notices to provide quick response guidance on key procurement considerations amid COVID-19.
- Tasmania – the procurement Treasurer released a PF-7 Procurement Framework–COVID-19 Emergency Procurement Measures applicable to procurement measures. The instruction allows relevant authorities to vary their procurement or contracting methods, for example using direct and limited tendering methods rather than going out to tender.
- Western Australia–the Government issued General Procurement Direction 2022/01 regarding the procurement of essential products (PPE and rapid antigen tests) in response to COVID-19.

Baker McKenzie comprises a strong and cohesive team of over 30 lawyers in its Australian healthcare and life sciences group who focus on the healthcare industry, closely aligned to the firm's regional and global counterparts, with a network of over 450 lawyers worldwide. The group includes members from across the firm's compliance, intellectual property, corporate and commercial, tax, competition, disputes, product liability, regulatory, employment and real estate practices. Reflecting all sub-sectors of the healthcare industry, Baker McKenzie's clients include pharmaceutical, diagnostics, medical device and biotech companies, as well as research institutions and contract research organisations (CROs). The firm has long-standing relationships with leading healthcare companies, and the team is valued for its service and in-depth understanding of clients' businesses. The lawyers also have strong relationships with the key Australian industry organisations and regularly present or participate as panellists at leading industry conferences.

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