

# Medicinal product regulation and product liability in Australia: overview

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A Q&A guide to medicinal product regulation and product liability law in Australia.

The Q&A gives a high level overview of key issues including pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability.

For information on patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, visit *Pharmaceutical IP and Competition Law in Australia: overview*.

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## Regulatory overview

### Pharmaceuticals

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

### Legislation

The key federal legislation governing pharmaceuticals in Australia is the Therapeutic Goods Act 1989 (Cth) (TG Act), which:

- Provides a national framework for the regulation of medicinal products.
- Provides a national system to control the quality, safety, efficacy and timely availability of "therapeutic goods" (including pharmaceuticals, medical devices and biologicals) distributed in, or exported from, Australia.
- Regulates the advertising, labelling and supply of therapeutic goods in Australia, among other things.

The TG Act is underpinned by a number of other legislative instruments, most notably the:

- Therapeutic Goods Regulations 1990.
- Therapeutic Goods (Medical Devices) Regulations 2002.

Additionally, state and territory legislation regulates the sale and distribution of therapeutic goods at the wholesale level.

Under the TG Act and delegated legislation, "therapeutic goods" (goods with a "therapeutic use", that is, preventing, diagnosing, curing, or alleviating disease, ailment, defect or injury) are divided into two categories:

- Medicines, defined as therapeutic goods (aside from 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 (examples include prescription drugs and vitamins).
- Medical devices, defined as instruments, apparatus, appliance, software, implant, reagent, material or other articles intended to be used for humans for the purpose of (among other things) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease (examples include in vitro diagnostics, heart valves or syringes, and contraceptive devices) (*see Question 3*).

With some limited exceptions, therapeutic goods cannot be imported into, exported from, manufactured in, or supplied for use in Australia unless they are included in the Australian Register of Therapeutic Goods (ARTG).

A large proportion of registered prescription medicines are supplied under the Pharmaceutical Benefits Scheme (PBS) established by the National Health Act 1953 (Cth) (NH Act). This scheme means that certain necessary drugs selected by an expert panel are supplied to consumers at a reduced cost due to a subsidy by the Commonwealth Government. The prices of pharmaceuticals listed on the PBS are regulated by the NH Act. Beyond the PBS, Schedule 4 of the Therapeutic Goods Advertising Code (No. 2) 2018 also sets out conditions under which information about the price of prescription medicines and some pharmacy-only medicines can be provided to the public.

- In relation to supranational (international) laws, the TGA takes the approach that local regulation of therapeutic goods should align with comparable international regulatory counterparts "wherever possible" ([www.tga.gov.au/ws-sg-index](http://www.tga.gov.au/ws-sg-index)). By way of example only, technical guidelines for applications to register medicines in Australia align closely with requirements set out in or by the following:
  - EU guidelines.
  - Guidelines issued by the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use.
  - The Food and Drug Administration (US).

## Regulatory authorities

In Australia, pharmaceuticals are primarily regulated at the federal level. The TG Act is administered by a Commonwealth (federal) agency called the Therapeutic Goods Administration (TGA), part of the Australian Government's Department of Health ([www.tga.gov.au](http://www.tga.gov.au)). The TGA:

- Regulates medicines and medical devices.

- Administers the TG Act.
- Carries out assessment and monitoring activities to ensure that all therapeutic goods meet acceptable standards of quality, safety and efficacy.

The TGA is an active regulator that continues to monitor the market for compliance and take appropriate enforcement action as needed. At a high level, the regulator takes a risk-based approach to compliance, and prioritises those matters which involve public safety, alleged serious breaches of the TG Act or otherwise involve repeated or wilful non-compliance. Lower compliance risk activities may be subject to education and guidance from the TGA. The scaled approach then moves up through issuing warning letters, suspension from the ARTG, court-enforceable undertakings, injunctions, infringement notices (fines), and civil and criminal penalties.

The TGA publishes information on its compliance and enforcement strategy and announcements about specific enforcement activities on its website ([www.tga.gov.au/hubs/compliance-and-enforcement/compliance-management](http://www.tga.gov.au/hubs/compliance-and-enforcement/compliance-management)).

Other national regulators such as the Australian Competition and Consumer Commission (ACCC) can be involved in certain enforcement activity where conduct breaches the Australian Consumer Law (ACL). This is contained in the Competition and Consumer Act 2010 (Cth) (CCA) and is the primary source of consumer protection law in Australia.

## Biologicals

2. Briefly outline any additional or alternative regulation of large molecule (biological) medicines, and discuss how combination products and gene therapies are classified and regulated in your jurisdiction.

A biological is defined in the TG Act as a thing that comprises, or is derived from human cells or human tissues, and that is used to:

- Treat or prevent disease, ailment, defect or injury affecting persons.
- Diagnose a condition of a person.
- Influence, inhibit or modify the physiological processes of a person.
- Test the susceptibility of a person to disease or ailment.
- Replace or modify the anatomy of persons.

Under the Therapeutic Goods (Things that are Biologicals) Specification 2017 (No. 1), things that comprise or contain live animal cells, tissues or organs are biologicals.

Biologicals can be regulated in three ways:

- As excluded goods (not regulated as therapeutic goods).
- Under the Biologicals Regulatory Framework (BRF) introduced in May 2011.
- As therapeutic goods, but not as biologicals.

Relevantly, the term "biological" does not have the same meaning under the TG Act as, and should not be used interchangeably with, the term "biological medicine". Biological medicines (such as recombinant products) are not considered to be biologicals under the TG Act and are treated under the general category of therapeutic goods (see Therapeutic Goods (Things that are not Biologicals) Determination No. 1 of 2011). The BRF and the Australian Regulatory Guidelines for Biologicals provide further information on the regulation of these products.

Combination products are regulated as medicines under the TG Act (*see Question 1*).

With respect to gene therapy the TGA has advised that:

- "In vivo" gene therapies, where the gene is transferred to cells inside the patient's body, fall under the existing prescription medicine pathway for supply in Australia. They should look to the Australian Regulatory Guidelines for Prescription Medicines for guidance on relevant obligations.
- "Ex vivo" gene therapies, where the gene is delivered to cells outside the body that are then transferred back to the body, are considered class 4 biologicals. They should look to the Australian Guidelines for Biologicals for guidance on relevant obligations.

See [www.tga.gov.au/sites/default/files/presentation-regulation-ethics-and-reimbursement-novel-biological-therapies-australia-update.pdf](http://www.tga.gov.au/sites/default/files/presentation-regulation-ethics-and-reimbursement-novel-biological-therapies-australia-update.pdf).

## Medical devices and health care IT

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of medical software, health care IT, e-health (such as mobile health apps), or laboratory diagnostic testing kits?

Medical devices and in vitro diagnostic devices (IVDs) are classified as therapeutic goods and are also regulated under the TG Act (*see Question 1*). Like pharmaceutical products, medical devices must be registered on the ARTG before they can be imported, exported from, or supplied in Australia. IVDs are regulated as a subset of medical devices.

The Therapeutic Goods (Medical Devices) Regulations 2002 (Cth) (TG (MD) Regulations) set out requirements for the safety and performance of medical devices, known as essential principles. These regulations define an IVD as a medical device that is all of the following:

- A reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for in vitro use.
- Intended by the manufacturer to be used in vitro for the examination of a specimen derived from the human body, solely or principally for:
  - giving information about a physiological or pathological state or a congenital abnormality;
  - determining safety and compatibility with a potential recipient; or
  - monitoring therapeutic measures.
- Not a product that is:
  - intended for general laboratory use; and
  - not manufactured, sold or presented for use as an IVD medical device.

While regulated under the same legislation as ordinary medical devices, IVDs are classified separately and are subject to additional, IVD-specific regulations.

Under the TG Act a medical device is defined as:

- Any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following purposes:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
  - investigation, replacement or modification of the anatomy or of a physiological process; or
  - control of conception.
- That does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.
- An accessory to the said instrument, apparatus, appliance or material or other article.

Like medicines, medical devices must comply with certain labelling obligations. The TG (MD) Regulations sets out these requirements at Essential Principle 13 of Schedule 1, including specific information that must be provided with a medical device, such as:

- The manufacturer's name.
- The intended purpose and user of the device.
- Sufficient information for the user to be able to identify the device.

- Handling and storage requirements.
- Any warnings, restrictions or precautions.
- Any special opening instructions.
- If applicable, indications of single use only.
- Where it is custom-made, a note to this effect and that the device is only intended for that individual or health professional.
- The batch code lot number or serial number.
- If, applicable, the date up to which the device can be used.

Because of the broad nature of the definition of medical devices, software, mobile phone apps and diagnostic or processing software can be classified as medical devices if they are deemed to meet the above criteria. If so classified, these types of products are not regulated separately from other medical devices. The level of scrutiny given to all medical devices by the regulator depends on the product's level of risk.

The TG (MD) Regulations are scheduled to be amended by the Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019 (Cth), passed in December 2019. This responds to the changing medical device (and IVD) market, particularly programmable medical devices and software as a medical device.

The amendments also reclassify certain devices and implement reforms in relation to personalised medical devices and growth in that market. Due to the 2019 novel coronavirus disease (COVID-19) pandemic, the TGA and the government have delayed some of these amendments, notably:

- From 25 February 2021, new classification rules for medical device software will come into effect, as well as changes to the definition of "custom-made medical devices" to limit the personalised medical devices benefiting from the exemption from registration on the ARTG.
- From 25 November 2021, six other medical device categories will be reclassified to align with the European Medical Device Regulations.

Adjacent to medical devices that are or which incorporate software is the increase in telehealth services. The TGA does not directly regulate telehealth, as this tends to fall within the remit of bodies that regulate health professionals. However, the TGA may cover those aspects of the provision of telehealth services which can be caught under current (and impending) medical device definitions.

## **Pricing, government funding and reimbursement**

### **National health care system**



4. What is the structure of the national health care system, and how is it funded? Explain briefly how medicines are introduced into that system.

Australia has a universal healthcare scheme providing free or subsidised health care services, called Medicare. It is financed largely from general tax revenue, which includes a Medicare levy that is charged based on an individual's taxable income.

Commonwealth national funding is mainly provided through:

- Subsidies for pharmaceuticals listed on the Pharmaceutical Benefits Scheme (PBS).
- Free or subsidised treatment by medical practitioners (classified as "bulk billing").
- Substantial grants to state and territory governments, contributing to the cost of providing free access to public hospitals.
- Specific purpose grants to state and territory governments and other bodies.

State and territory governments supplement Medicare funding with their own revenues, mainly by funding public hospitals.

A large number of medicinal products prescribed by doctors and dispensed in pharmacies are directly subsidised by the PBS and supplied to consumers at a reduced cost. To be included on the PBS, a drug must first be included on the ARTG and then selected by an expert panel for inclusion.

Drugs used in public hospitals are primarily funded through agreements between the states/territories and the Commonwealth Government. The states and territories are responsible for allocating these funds.

Under special funding arrangements, the Commonwealth Government also pays for some expensive drugs that can only be supplied from hospitals to outpatients.

Australians are also encouraged, through tax incentives, to have private health insurance. Depending on the level of cover, this may assist in funding drugs not listed on the PBS.

## Price regulation

5. How are the prices of medicinal products regulated?

The price of drugs supplied on the PBS is regulated by the NH Act.

For 2020, the maximum cost of a subsidised pharmaceutical product (a product listed on the PBS) is AUD41 for general patients. For concessional patients, that is, patients with health care cards or pensioners, the maximum cost of a PBS listed pharmaceutical product is AUD6.60. This amount is called a co-payment, as part of the product paid for by the patient. The remainder is paid for by the Commonwealth Government. The amount of the co-payment is adjusted on 1 January each year in line with the Consumer Price Index (CPI).

The price of over-the-counter (OTC) medicines (products for which a patient does not require a prescription, and which are not listed on the PBS) is not regulated.

## Reimbursement

6. When is the cost of a medicinal product funded by the government or reimbursed? How is a pharmacist compensated for dispensing services?

The Commonwealth Government subsidises the cost of medicines listed on the PBS that are obtained on prescription. Australians holding concessional cards receive a larger subsidy (see [Question 5](#)).

If a pharmaceutical supplier wants to have a new drug listed on the PBS, it must apply to a specific body within the Department of Health. The Minister for Health can list drugs on the Schedule of Pharmaceutical Benefits, on a favourable recommendation by an expert panel, the Pharmaceutical Benefits Advisory Committee (PBAC), under the PBS listing process and the NH Act.

If the PBAC decides to make a positive recommendation, the application is considered by the Department of Health, which may obtain advice within the department on the price it should pay to the pharmaceutical supplier.

The Department of Health undertakes price negotiations with the supplier based on PBAC recommendations. If agreement is reached, this is sent to the Minister for approval and legislative implementation. Currently, if a drug is expected to cost more than AUD20 million a year, it is considered by Cabinet.

If agreement cannot be reached, a price determination can be made by the Minister. In such circumstances, patients may need to pay a special patient contribution to make up the difference between the price determined by the Minister and the price claimed as appropriate by the supplier.

Once a drug has been approved for listing under the PBS, it is included in the Schedule of Pharmaceutical Benefits.

Reimbursement under the PBS is paid by the government to the dispensing pharmacist (as the pharmacist will have purchased the drug at an unsubsidised price from the manufacturer or wholesaler).

## Clinical trials

7. Outline the regulation of clinical trials.

## Legislation and regulatory authorities

The supply of therapeutic goods for use in clinical trials is regulated by the TGA under the TG Act and associated regulations. Unapproved therapeutic goods can be imported into and supplied in Australia for use in a clinical trial, under either the:

- Clinical Trial Approval Scheme (CTA Scheme).
- Clinical Trial Notification Scheme (CTN Scheme).

These schemes are used for clinical trials involving therapeutic goods not on the ARTG, or use of a registered or listed therapeutic good in a clinical trial beyond the conditions of its marketing approval.

The conduct of a clinical trial in Australia (under either scheme) must comply, as relevant, with:

- The TG Act.
- Therapeutic Goods Regulations 1990 (Cth) (TG Regulations).
- National Statement on Ethical Conduct in Human Research (2007) - Updated 2018, issued by the National Health and Medical Research Council (NHMRC).
- Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2), with annotations by the TGA (for investigational medical products and investigational biologicals).
- Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155) (for investigational medical devices).
- The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for Medicinal Products, PEO09-14, 01 July 2018, as adopted by the TGA (that is, excluding Annexes 4, 5 and 14).
- The procedural protocol as approved by the Human Research Ethics Committee (HREC) responsible for monitoring the conduct of the trial.
- Other relevant requirements of Commonwealth and/or state and territory legislation, such as privacy legislation.
- Other site specific requirements.

Other relevant guidelines include the:

- International accepted standard, Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95), as adopted and annotated by the TGA.
- NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods.

For further information on clinical trials in Australia, see the Australian Clinical Trial Handbook (Version 2.3, November 2020): [www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf](http://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf).

## Authorisations

**CTA Scheme.** The sponsor submits an application to conduct clinical trials involving unapproved therapeutic goods to the TGA for evaluation and comment. A CTA trial must not be commenced until the approval process is favourably completed.

**CTN Scheme.** The sponsor notifies the TGA of its intention to conduct a clinical trial involving an unapproved therapeutic good. All materials relating to the proposed trial protocol are submitted directly to a Human Research Ethics Committee (HREC) by the researcher at the sponsor's request. The HREC is responsible for:

- Assessing the scientific validity of the trial design.
- Assessing the risk versus harm of the therapeutic good.
- Assessing the ethical acceptability of the trial process.
- Approving the trial protocol.

The institution or organisation at which the trial is conducted gives final approval to conduct the trial at the site, having due regard to advice from the HREC.

In practice, the CTN Scheme is more common.

The CTA Scheme is more expensive, reflecting the need for the TGA to evaluate the submitted data. The CTA Scheme is generally for high risk or novel treatments where there is no or limited knowledge of safety (for example, high risk biologicals), and/or in circumstances where a HREC would not have the relevant expertise to assess the safety of the product.

An unapproved therapeutic good can only be imported into and supplied in Australia for the conduct of a clinical trial under the CTN or CTA scheme.

The sponsor under the CTN or CTA scheme can be an individual, company, institution or organisation that takes overall responsibility for the conduct of the trial. The sponsor must be a legal Australian entity (an overseas company cannot be the sponsor of a trial in Australia).

If the sponsor needs to be changed or transferred, a new CTN or CTA application must be submitted to the TGA by the new sponsor. Generally, the TGA will not object to the change or transfer if all necessary approvals (for example, from the HREC) are obtained and the original sponsor can continue with its obligations until the new sponsor assumes responsibility.

## Consent

Clinical trial participants or subjects must give informed consent to participate in a clinical trial. Guidance on what amounts to informed consent can be found in the:

- National Statement on Ethical Conduct in Human Research (2007) - Updated 2018, issued by NHMRC.
- Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2), with annotations by the TGA.

Multi-centre clinical trials should also abide by the principles set out in the NHRMC's National Approach to Single Ethical Review of Multi-Centre Research.

## **Trial pre-conditions**

All CTN and CTA trials must have an Australian sponsor, which will be responsible for the conduct of the trial. Additionally, before commencing a clinical trial, there must be legal and financial agreements in place between all relevant parties. This should include, in particular, indemnities as well as procedures for the compensation and treatment of trial participants. Relevant insurances must be obtained and all documents required by the Guideline for Good Clinical Practice must be filed.

## **Procedural requirements**

The Guideline for Good Clinical Practice also sets out the various procedural requirements for running a clinical trial. These include, for example, the maintenance of quality assurance and quality control systems with standard operating procedures for the conduct of the trial.

Additionally, a trial must also be monitored and any adverse events reported. A number of documents must be filed both during and after the clinical trial.

The NHMRC National Statement on Ethical Conduct in Human Research (2007) (updated 2018) sets out the circumstances when a clinical trial should be suspended or discontinued. Where the risk to trial participants can no longer be justified by the potential benefits of the research, the research must be suspended and consideration given to whether the trial ought to be discontinued (or at least modified). Further, if HREC withdraws approval for a trial (for example, due to a breach of the trial protocol or a condition of the HREC's approval), that trial must be suspended, and may need to be subsequently discontinued.

Any use and/or disclosure of personal information of trial participants must comply with the Privacy Act 1988 (Cth) and any other relevant legislation, code or guideline that applies in the state or territory where the clinical trial is being conducted.

## **Transparency and reporting requirements**

Sponsors must report to the TGA according to the requirements in the NHMRC guidance document titled Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods. Under this guidance, matters sponsors must report to the TGA include:

- Suspected unexpected serious adverse reactions for medicines and biologicals from Australian sites.
- Significant safety issues and overseas regulatory actions.

The NHMRC has also published information regarding the reporting of serious breaches in a guidance document entitled Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (2018).

## Manufacturing and distribution

8. What is the authorisation process for manufacturing and distributing medicinal products?

### Application

A manufacturer or sponsor must submit an application to the Manufacturing Quality Branch of the TGA for a licence to manufacture medicinal products, with the relevant application fee.

In relation to medicinal products, manufacture is broadly defined in the TG Act to mean production of the products, or any part of the process of producing the products or bringing them to their final state, including processing, assembling, packaging, labelling, storage, sterilising, testing, or release for supply of the products or of any product component or ingredient.

To distribute medicinal products in Australia, the product must be included on the ARTG (*see Question 9*).

### Conditions

In manufacturing products for supply and sale in Australia, manufacturers must comply with the TG Act and show compliance with manufacturing principles, including the relevant codes of good manufacturing practice (GMP).

The Therapeutic Goods (Manufacturing Principles) Determination 2020 outlines the manufacturing principles that apply to various types of therapeutic goods.

Therapeutic goods must be manufactured in compliance with the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products (PE 009-14, 1 July 2018), with some specified exceptions (for example, certain veterinary products and products derived from human blood or plasma). Guidance relating to the manufacture of active pharmaceutical ingredients is provided at Part II of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products.

The TGA may also undertake inspections (including unannounced inspections) of Australian manufacturers to ensure compliance with the applicable manufacturing principles.

Additionally, standards have now been developed requiring holders of manufacturing licences to be "fit and proper" persons.

### Restrictions on foreign applicants

Only Australian manufacturers can apply to the TGA for a manufacturing licence for Australian manufacturing.

Overseas manufacturers wanting to supply their products in Australia must provide evidence that their medicinal products are manufactured to the standard required of Australian manufacturers for the same products, at each manufacturing site. If no acceptable GMP evidence is produced, the TGA will inspect manufacturing sites in the country where the product is manufactured before considering it for listing on the ARTG.

## Key stages and timing

A licence is issued specifically to each manufacturer, and relates to specific goods and a specific site.

The applicant is provided with a GMP certificate containing GMP codes for the authorised steps in the manufacture. The GMP codes certify that the manufacturing site has met acceptable criteria (quality management, documentation and standard operating procedures) for those steps.

Compliance with GMP codes is checked through regular on-site inspections by the TGA. On average, an inspection takes between one and five working days.

A licence can apply to more than one site provided that all sites comply with the relevant guidelines.

A licence can also be transferred to a third party. If the licence is transferred the TGA may regard the transfer as if it were a new application for a manufacturing licence.

## Fee

A summary of TGA fees is available at [www.tga.gov.au/schedule-fees-and-charges](http://www.tga.gov.au/schedule-fees-and-charges).

## Authorisations, variations, and renewals

A licence remains in force until revoked or suspended (*section 39, TG Act*).

An application to vary a licence can be made to:

- Include additional manufacturing sites or remove existing sites.
- Change the person in charge of product and quality control.
- Vary the manufacturing site authorisation (for example, in relation to dosage forms and manufacturing steps).
- Update the manufacturer's name and/or address.

Such an application is completed online through the TGA Business Services.

If a manufacturer intends to stop manufacturing therapeutic goods, it must request the TGA to suspend or revoke its manufacturing licence.

Separately, the TGA can suspend or revoke a licence for a reason listed in section 41 of the TG Act, including a breach of a licence condition, or if the licence holder is convicted of an offence against the TG Act or an Australian law

involving fraud or dishonesty. However, the TGA must, unless the TGA considers that failure to revoke or suspend the licence immediately would create an imminent risk of death, serious illness or serious injury, give the licence holder:

- Notice in writing of the proposed action.
- Reasons for the proposed action.
- An opportunity to make, within such reasonable time as specified in the notice, a submission to the TGA about the proposed action (except if the proposed action relates to a failure to pay the annual licensing charge or an applicable inspection fee).

## Monitoring compliance and imposing penalties

The Manufacturing Quality Branch of the TGA can conduct inspections to assess compliance with GMP codes. The frequency of inspections depends on a range of factors, including:

- The degree of risk to patients and consumers.
- The extent to which a manufacturer has complied with GMP codes in the past.
- The type of products manufactured and how they are manufactured.
- Whether there have been significant changes within a manufacturing company.

New licence applicants are scheduled for an inspection as soon as possible after receipt of the licence application.

Additionally, to ensure compliance with the TG Act, the TGA has broad powers to:

- Enter and search premises.
- Inspect, examine and remove samples of the goods for testing.
- Inspect any book, record or document on the premises and take extracts from or make copies of them.

If the TGA has reasonable grounds to believe that there is an imminent risk of death, serious illness or injury, it can also seize items found on the premises for evidentiary purposes only. The TGA's powers for entry, searches, seizures and warrants are in Part 6-2 of the TG Act.

The TGA can also revoke or suspend a granted manufacturing licence for a period of time (*section 41, TG Act*).

In addition, under the TG Act, it is a criminal offence to breach a condition of a licence (with a maximum penalty of five years of imprisonment or 4,000 penalty units (AUD888,000), or both, if there is, or likely to be, harm or injury to a person). Separately, a civil penalty may also apply, in which case the maximum fine for a body corporate is 50,000 penalty units (AUD11.1 million).

The ability to seek review of a decision of the TGA is set out in section 60 of the TG Act.

## Marketing

### Authorisation procedure

9. What is the authorisation process for marketing medicinal products?

### Application

Marketing applications for medicinal products (referred to as therapeutic goods in Australia) must be made to and approved by the TGA, subject to some exceptions. A therapeutic good cannot be imported, marketed and supplied in Australia before it is included in the ARTG.

The information in an application depends on the type of therapeutic good (for example, prescription, complementary, or OTC medicine, or a medical device or biological). For example, an application to register a prescription medicine on the ARTG requires a sponsor to provide data supporting the quality, safety and efficacy of the medicine for its intended use (*see below, [Key stages and timing](#)*).

### Exceptions

The following therapeutic goods can be imported, marketed and supplied in Australia without first being included in the ARTG:

- Exempt therapeutic goods, as set out in Schedules 5 and 5A of the Therapeutic Goods Regulations 1990 (Cth).
- Excluded therapeutic goods, as set out in the Therapeutic Goods (Excluded Goods - Hand Sanitisers) Determination 2020, Therapeutic Goods (Excluded Goods) Determination 2018, and Therapeutic Goods (Medical Devices - Excluded Purposes) Specification 2020.
- Unapproved therapeutic goods imported into and supplied in Australia to be used in a clinical trial.

### Authorisation conditions

Before approving a medicine and including it in the ARTG, the TGA must be satisfied that it complies with all relevant legislative requirements in Australia. Statutory standards under sections 3 and 10 of the TG Act include the:

- Therapeutic Goods Orders (TGOs).
- British Pharmacopoeia (BP).

- European Pharmacopoeia (Ph Eur).
- US Pharmacopoeia-National Formulary (USP).

Each of the BP, Ph Eur and USP are defined under the TG Act as default standards.

An exemption may be sought from the requirements of the TG Act with the consent of the Secretary of the Department of Health.

Criminal offence provisions and civil penalties are likely to apply if therapeutic goods are imported into, exported from, or supplied in Australia, which do not comply with the relevant standards (*sections 14 and 14A, TG Act*).

An ARTG entry is specific to the therapeutic good entered on the ARTG and the sponsor who made the application.

## Key stages and timing

Medicinal products included in the ARTG are entered as registered or listed medicines, depending on their ingredients and intended purpose. Registered medicines are considered by the TGA to pose a higher risk than listed medicines.

All prescription medicines are registered medicines.

Most OTC medicines (such as painkillers, antihistamines, and anti-fungal treatments) are registered medicines. Some OTC medicines are listed medicines (such as vitamins and herbal supplements).

The registration process involves a detailed review by the TGA of the quality, safety and efficacy of the medicinal product.

Registration requires a sponsor to apply to the TGA, providing data supporting the quality, safety and efficacy of the product for its intended use. The Australian Regulatory Guidelines for Prescription Medicines (ARGPM) aim to assist sponsors to prepare applications to register new prescription or other high-risk medicines for human use in Australia.

The TGA has implemented general dossier requirements which are mandatory for applications to register a prescription medicine in the ARTG (see [www.tga.gov.au/publication/general-dossier-requirements](http://www.tga.gov.au/publication/general-dossier-requirements): last updated in July 2018).

The timeline for processing a registration application is imposed by the TG Regulations. The TGA must:

- Accept or reject an application for evaluation within 40 working days.
- If the application is accepted, evaluate it within a further 255 working days.

There are also a priority review pathway and a provisional approval pathway, which can fast track prescription medicines onto the market.

Under the priority review pathway, which is only available for medicines for serious or life-threatening conditions, the TGA takes a flexible approach. It seeks to complete its review of a medicine up to three months earlier than the standard pathway.

Under the provisional approval pathway, the TGA can provisionally approve certain medicines that provide promising treatment for serious or life-threatening conditions, while clinical trials are still ongoing. It is a condition of provisional approval that the clinical trials will be completed, and additional evidence is submitted for TGA's review and assessment as to whether ongoing approval will be granted.

## Fee

A summary of fees can be found at [www.tga.gov.au/schedule-fees-and-charges](http://www.tga.gov.au/schedule-fees-and-charges).

## Effect of authorisation and related protections

Once a therapeutic good is entered onto the ARTG, it can be imported into, manufactured, supplied and offered for supply in Australia.

In Australia, there is a five year data exclusivity period for information relating to a new active component (a substance that is, or together with other substances are, primarily responsible for the biological or other effect of the therapeutic good containing it), provided that no other therapeutic goods containing the active component have previously been included in the ARTG. However, data exclusivity does not extend to new dosages forms, new routes of administration or new indications of registered medicines.

## Authorisations, variations, and renewals

Medicines remain listed or registered in the ARTG until their listing or registration is cancelled. Annual fees apply (see [www.tga.gov.au/schedule-fees-and-charges](http://www.tga.gov.au/schedule-fees-and-charges)).

An ARTG entry can be transferred from one sponsor to another if there is a change in the sponsor. This may occur if, for example, the original sponsor sells its therapeutic goods business. In such a case, the TGA must be notified and an update of the ARTG entry with the new sponsor name should be requested.

The TGA can suspend or cancel ARTG entries if there is deliberate and ongoing non-compliance with the regulatory requirements under the TG Act.

## Monitoring compliance and penalties

The TGA monitors the ongoing compliance of manufacturers with the required standards following authorisation. Post-marketing activities to ensure compliance include:

- Investigating reports of problems.
- Laboratory testing of products on the market.
- General surveillance activities.
- Manufacturer inspections.

Under the TG Act, the TGA has considerable powers to require further information on a product. These powers are exercisable both before and after a product achieves registration or listing.

The TGA's enforcement powers under the TG Act include criminal prosecutions and fines. It is an offence for a person to:

- Import, export, manufacture or supply medicinal products for use in humans if the goods are not registered or listed.
- Make a statement in connection with an application for registration for a medicinal product that is false or misleading in a material particular. These offences are punishable by imprisonment for five years and/or a maximum fine of 4,000 penalty units (AUD888,000). The penalties may be higher in some circumstances.

In addition, other penalties can apply for a failure to comply with the TG Act. These include suspension or cancellation of ARTG registrations and recall of medicinal products.

## **Protection of confidential information**

Information provided to the TGA, including documents and information disclosed in a marketing authorisation application and other regulatory submissions, are treated as official information by the TGA. This includes any commercially confidential information provided to the TGA, being information "not in the public domain or publicly available, and where disclosure may undermine the economic interest or competitive position of the owner of the information".

Official information (including commercially confidential information) is not disclosed to the public except in certain circumstances including:

- To the extent required by law.
- If required in connection with legal proceedings.
- For the purposes of public accountability, including disclosure on request to other government agencies, or a request for information by parliament.
- It is in the public interest to release the information and it is lawful to do so.

## **Release requirements**

Once a therapeutic good is entered onto the ARTG, it can be imported into, manufactured, supplied and offered for supply in Australia. Any advertising of therapeutic goods (other than prescription medicines which cannot be advertised to the public) must comply with the Therapeutic Goods Advertising Code (No. 2) 2018 (Cth).

## **Pharmacovigilance**

10. What pharmacovigilance obligations and other commitments apply after a company has obtained marketing authorisation? Are there further conditions on how the medicinal product is distributed and made accessible to patients?

## Post-marketing commitments and pharmacovigilance obligations

The TG Act imposes strict requirements on post-marketing pharmacovigilance. They are set out in the TG Act and the Pharmacovigilance Responsibilities of Medicine Sponsors: Australian recommendations and requirements (June 2018) (Requirements and Recommendations).

The TGA's Therapeutic Product Vigilance document (September 2017) provides further guidance on pharmacovigilance responsibilities and procedures (see [www.tga.gov.au/sites/default/files/therapeutic-product-vigilance.pdf](http://www.tga.gov.au/sites/default/files/therapeutic-product-vigilance.pdf)).

Under the TG Act and Requirements and Recommendations, sponsors must report suspected adverse drug reactions received from all sources. In addition, sponsors must provide the TGA with:

- Any information that contradicts information already provided to the TGA.
- Information that suggests that the medicine may not be as effective as information already provided to the TGA suggests.
- Information that indicates that the quality, safety or efficacy of the medicine is unacceptable.
- Information that indicates that use of the medicine in accordance with its recommendations for use may have an unintended harmful effect.

Failure to do so is a criminal offence and also renders the person responsible liable to a civil penalty.

In most cases, the information must be provided to the TGA within 15 days of the sponsor becoming aware of it. However, in more serious cases, the required timing may be the next business day, and no later than 72 hours after becoming aware.

Sponsors must also notify the TGA within 72 hours of any action taken by a foreign regulatory agency to suspend or recall a product, or any addition or modification to the Product Information.

It is a criminal offence to fail to report adverse drug events to the TGA. Failure to report may result in a term of imprisonment of 12 months. Civil penalties of up to AUD6.66 million (30,000 penalty units) may also apply.

## Other conditions

The TG Act sets out requirements that sponsors must comply with to maintain a listing or registration on the ARTG. These include ensuring that:

- The medicine does not create an imminent risk of death, serious illness or serious injury.

- The medicine continues to comply with the applicable standards and any conditions imposed on the registration or listing by the TGA.
- Any advertising complies with the relevant advertising codes.
- Any request for information by the TGA is met within timelines set out in the TGA Act.
- An annual fee is paid.

A registration or listing on the ARTG may also be suspended if a medicine poses a potential risk of death, serious illness or injury if it continues to be included on the ARTG and the risk could be eliminated during the suspension period.

Failure to comply with the relevant standards or legislation may also result in a product recall.

Further, since 1 January 2019, sponsors of prescription medicines and some OTC medicines must report medicine shortages to the TGA. A shortage of medicine is considered to have occurred if demand for the medicine cannot be met at any time for the next six months.

A medicine shortage must be reported to the TGA within ten working days. In case of a shortage with a critical patient impact, an initial report must be submitted to the TGA within two working days. Any remaining information must then be submitted to the TGA in the next three working days.

## Abridged procedure

11. Is there an abridged procedure for marketing authorisation? Which medicinal products can benefit from it and what conditions and procedure apply? What information can the applicant access and rely on?

To support the registration of a new generic medicine, an applicant must submit data from a bioequivalence study, ideally using a reference product obtained in Australia. Provided that the generic product has a sufficiently similar plasma concentration/time profile to the reference product, the two products can be considered bioequivalent. Where an overseas reference product is used, the applicant must show that the overseas and Australian reference products are identical.

To register a biosimilar biological medicine on the ARTG, clinical data must be submitted to show comparability with the reference biological medicine, relating to physicochemical, biological and immunological characteristics, as well as efficacy and safety.

There is a five-year data exclusivity period for information about a new active component, provided that no other therapeutic goods containing the active component have previously been included in the ARTG. Data exclusivity does not extend to new dosages forms, new routes of administration or new indications of registered medicines. An

application for a generic or biosimilar medicine is prevented from relying on and referencing any data that is subject to this exclusivity period.

Abbreviated applications are also accepted for applications to register an additional brand of a product that is already registered.

In the case of cross-licensing, a sponsor can authorise the TGA to use information on its already registered brand for the benefit of another sponsor. However, the new brand must be identical to the first brand or at least very similar.

12. Are foreign marketing authorisations recognised in your jurisdiction?

The evaluation of certain applications for registration of a medicinal product is shortened if the sponsor can provide two independent evaluation reports from specified countries with regulatory standards similar to Australia (the US, Canada, Sweden, The Netherlands and the UK), in which an identical product has obtained authorisation.

## Parallel imports and cross-border trade in medicines

13. Are parallel imports of medicinal products into your jurisdiction allowed? What are the general requirements for imports of medicinal products into your jurisdiction? Are particular foreign markets or products favoured?

Australia has a legislative framework that encourages the parallel importation of many products, including, at least in theory, pharmaceutical products. However, each parallel imported pharmaceutical product must comply in all respects with all applicable Australian regulatory and labelling requirements for pharmaceuticals and the parallel importer must obtain:

- Marketing approval from the TGA to sell the pharmaceutical product in Australia (inclusion of the product on the ARTG).
- A PBS listing, if it wants the product to qualify for government reimbursement.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, see *Pharmaceutical IP and Competition Law in Australia: overview*.

## Restrictions on dealings with health care professionals

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for health care establishments or individual medical practitioners?

Despite the TGA's broad powers in relation to advertising, in practice much of the regulation of the advertising of prescription products is through a self-regulatory scheme operated by Medicines Australia (the peak industry body representing innovator pharmaceutical companies). For medical devices and technologies, the relevant industry body is the Medical Technology Association of Australia (MTAA).

The TGA, in its marketing approval, requires the promotion of all prescription products to comply with the Medicines Australia Code of Conduct (Code). The current edition of the Code (Edition 19) sets out standards of conduct relating to marketing prescription products. In particular, it contains detailed provisions on:

- The form and content of advertising directed at health care professionals (HCPs) for prescription pharmaceuticals.
- Promotional activities carried out by pharmaceutical companies.

No item or offer can be given or made to HCPs except:

- Educational items that do not bear the name of any medicine or product, which otherwise comply with the Code.
- Sponsorship for educational events, which are strictly prescribed by the Code.
- Hospitality offered by companies to HCPs, provided it is simple, modest, secondary to the educational content and provided in an environment that enhances education and learning.

If the Code has been breached, the Code Committee can impose a range of sanctions, depending on the nature of the breach. The Committee can also recommend to the Medicines Australia Board that a member company be suspended or expelled.

Similar requirements exist under the MTAA Code of Practice relating to medical devices.

Updates on the Code and Edition 19 can be found at <https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>.

The increased emphasis on anti-bribery and corruption in recent years has led to significant pressure on pharmaceutical, medical device and technology companies in Australia. Under the Criminal Code Act 1995 (Cth), it is an offence to influence a foreign public official in the exercise of the official's duties by offering, providing, promising (directly or indirectly through an intermediary) a benefit to another person that is not legitimately due to that person.

The UK Bribery Act 2010 and the US Foreign Corrupt Practices Act 1977 also have a significant impact on companies operating in Australia. Those with head offices, bank accounts or other business operations in the UK and the US are subject to the extraterritorial operation of those acts.

## Selling restrictions

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order?

The most notable limitations on the sale of medicinal products are in the Poisons Standard (SUSMP). This legislative instrument consists of decisions on classifying medicines and poisons into schedules, for inclusion in state and territory legislation.

Medicines and poisons are classified into schedules, according to the level of regulatory control required to protect public health and safety. Different conditions apply to the packaging, labelling and sale of poisons, depending on how they are classified in the SUSMP. The SUSMP classifies substances based on risk:

- Schedule 2: medicines that can only be sold by pharmacies and persons licensed under the regulation to sell them (pharmacy medicines).
- Schedule 3: medicines that can only be sold by pharmacists personally (other shops are not licensed to sell them) (pharmacist only medicines).
- Schedule 4: medicines that can only be supplied on prescription from a medical professional (prescription only medicines).

Labelling requirements for substances listed on the SUSMP include mandatory warnings and safety directions depending on the particular schedule, along with recordkeeping requirements that, for example, keep track of when medicines have been supplied.

Online sales of the three categories of medicines listed above have been quite limited. For example, advertising prescription products to the general public is prohibited. Therefore, pharmaceutical products cannot be advertised on Australian-based internet sites accessible to the public. Although the internet can be used to provide accurate and scientifically reliable information on prescription products, this information must be non-promotional.

Since the 2019 novel coronavirus disease (COVID-19) pandemic, the Commonwealth Government has made legislative changes to facilitate e-prescribing. In certain circumstances, medicines can be dispensed without attendance at a pharmacy. This does not apply to Schedule 8 (controlled drugs) and Schedule 4 (prescription only medicines) substances listed in Appendix D, which remain subject to normal prescribing and dispensing rules. These substances are subject to additional controls due to their potential for abuse. In some instances, pharmacies will accommodate home delivery of dispensed medicines under the scheme, removing the need for physical attendance at a pharmacy.

Non-prescription pharmaceutical products (OTC medicines) are not subject to the same restrictions. OTC medicines can be sold at pharmacies, as well as in supermarkets, health food stores and other retailers. OTC medicines registered on the ARTG can be advertised and sold to the public, including on internet sites. All adverts remain strictly regulated by law and industry standards, such as the Therapeutic Goods Advertising Code (see [Question 16](#)).

In limited circumstances individuals can purchase up to a three months' supply of medicines from overseas, such as from an online store, and have them imported into Australia under the Personal Importation Scheme, provided the medicines are not being sold or supplied to another person. In this instance, the medicine does not need to be approved for supply in Australia. Reliance on the Personal Importation Scheme can carry legal and safety risks for individuals. The onus is on the importing party to ensure that they comply with all relevant laws and take their own safety precautions.

## Advertising and promotion

16. What restrictions apply to the advertising and promotion of medicinal products and the provision of samples, and how are adverts and promotional activity regulated?

## Legislation and regulatory authority

The primary regulation of the advertisement, promotion and provision of samples of therapeutic goods is the Therapeutic Goods Advertising Code (No.2) (2018) (the Code), along with other restrictions and requirements (including in relation to labelling) in the TG Act and delegated legislation.

The TGA regulates and enforces restrictions on advertising medicinal products. The Therapeutic Goods Advertising Code Council regulates the Code.

Under the TG Act, the concept of advertising is broad. The TG Act definition of "advertise" includes any statement, pictorial representation or design intended, whether directly or indirectly, to promote the use or supply of therapeutic goods, and captures labels, packaging, and any material included with the package in which the goods are contained.

In addition to the TG regime, the ACCC enforces breaches of the Competition and Consumer Act 2010 (Cth) (CCA). This deals with offences relating more broadly to advertising, product safety and consumer protection. It also has a broad application, which includes traditional advertising as well as online activities and conduct generally occurring in the course of trade or commerce.

Key industry bodies such as Medicines Australia also have self-regulation which includes advertising and promotion, in particular if directed at health care professionals (see [Question 14](#)). The Medicines Australia Code of Conduct is available on its website, at [Introducing Code Edition 19 – Medicine Australia \(medicinesaustralia.com.au\)](#).

## Restrictions

An advertisement of a medicinal product can only refer to the indications that have been included in the ARTG for that specific product.

Advertising prescription products directly to consumers is prohibited.

Advertising certain medicinal products that can only be supplied by a pharmacist is also prohibited. However, there are some exceptions to this.

OTC products available without prescription from pharmacies, health food stores, supermarkets and by direct marketing can be advertised to the general public, subject to:

- The TG Act.
- The TG Regulations.
- Relevant state and territory legislation.
- The Code, which sets out specific requirements on the content of adverts for medicinal and other products.

Under section 20 of the Code, adverts for therapeutic goods cannot contain an offer of a sample, other than the following goods listed in Schedule 3 of the Code:

- Condoms.
- Goods that are or contain sunscreen.
- Stoma devices for self-management.
- Continence catheter devices for self-management.

In addition, advertising of OTC medicines must not infringe Schedule 2 of the CCA (the ACL). Specifically, any representations made in adverts must be documented, genuine and not misleading or deceptive to the public. Businesses should take particular care to avoid making false claims about matters including (but not limited to) the:

- Benefits, performance characteristics or composition of a product (including where an inaccurate comparison is drawn between different products).
- Sponsorship of a product.
- Need for the product.

## **Internet advertising**

The internet can be used to promote prescription pharmaceutical products to HCPs, provided that the advert complies with the regulatory regime and the internet site can only be accessed through a secure system designed to prevent access by members of the general public.

The internet can also be used to promote OTC products, such as through the supplier's website.

All forms of advertising (including online advertising) are covered by the ACL. The same laws apply to social media channels. Accordingly, businesses should take care to avoid making false or misleading claims in online advertising (as they would for other advertising channels) and social media channels to mitigate the risk of misleading the general public (or HCPs, in the case of prescription pharmaceutical products).

## Data privacy

17. Do privacy and data protection laws impact on pharmaceutical regulation in your jurisdiction?

### The Privacy Act

The Privacy Act 1988 (Cth) (Privacy Act) and the Australian Privacy Principles (APPs) regulate the way private sector organisations and government agencies collect, hold, use and disclose personal information.

Personal information is information or an opinion about an identified individual or an individual who is reasonably identifiable, whether true or not, whether recorded in a material form or not.

The Privacy Act and the APPs are enforced by the Office of the Australian Information Commissioner (OAIC).

The Privacy Act imposes stricter obligations for sensitive information (such as health information). Some of the key obligations under the Privacy Act and APPs relate to:

- Open and transparent management of personal information (including requiring entities to have a privacy policy that is APP 1 compliant).
- Providing individuals with the right not to identify themselves or to use a pseudonym.
- Mandatory notification to individuals of certain matters (such as the types of organisations to which the individuals' personal information is likely to be disclosed, and the countries in which the recipients are located).
- Consent for collection of sensitive information and for certain uses and disclosures of personal information.
- Limitations on how personal information can be used and disclosed, including in relation to use of personal information for direct marketing.
- Overseas disclosure of personal information.
- Quality and security of personal information.
- Access to and correction of personal information.

Where cross-border data transfers will involve data containing personal information, that transfer must not occur without the transferring entity either:

- Taking steps as are reasonable in the circumstances to ensure that the recipient of the data will not breach the APPs (such as by putting contractual protections in place).
- Being satisfied that the recipient is subject to a law or binding scheme that has the overall effect of protecting the personal information in a manner substantially similar to the Australian Privacy Act and APPs.

Where neither of these options can be achieved, the transferor must obtain the individual's consent.

Following the Privacy Amendment (Notifiable Data Breaches) Bill 2016, the Privacy Act was amended to establish a regime for mandatory notification of eligible data breaches. Certain organisations must now comply with particular notification requirements if they become aware that there are reasonable grounds to believe that there has been an eligible data breach, or if the Information Commissioner directs them to do so.

## **Clinical trials and other research**

Generally, health information (a type of sensitive information), like other forms of personal information, cannot be used or disclosed for a purpose other than for which it was collected, unless the individual consents to that other purpose. However, the Privacy Act permits handling health information for health and medical research purposes, in certain circumstances where it is impracticable to obtain an individual's consent.

The NHMRC guidelines on this issue are legally binding. Researchers must follow them when handling health information without the individual's consent. They are:

- Guidelines under Section 95 of the Privacy Act 1988, 2014.
- Guidelines under Section 95A of the Privacy Act 1988.

Use and disclosure of genetic information (also a kind of sensitive information) is not prohibited, but a health service provider must have the individual's informed consent. Section 16B(4) of the Privacy Act contains an exemption to the consent requirement if certain conditions are met.

## **The TG Act**

When the TGA collects personal information, for example when an adverse event is reported, the information provided is assessed and entered into the TGA's Adverse Drugs Reactions System (ADRS), and will only be disclosed:

- Under subsection 61(3) of the TG Act to state and territory health departments (for information in relation to vaccines).
- If disclosure is required or authorised by law. One example is under subsection 61(7) of the TG Act, where it is necessary to ensure safe use of the medicine, including by providing the information to the company supplying the drug in Australia.

The personal information of a person reporting an adverse event is also recorded in the ADRS, and will only be disclosed in the circumstances set out above.

Some information on adverse events may be released to the public by the Secretary of the Department of Health under subsection 61(5C) of the TG Act. However, this only includes details such as the name of the medicine or

vaccine involved in the adverse event, or statistics on other reported adverse events. It will not include any personal information as defined under the Privacy Act.

## Other privacy schemes

Other schemes exist in Australia to protect information. For example:

- Information relating to Medicare and PBS are regulated under the NH Act, which contains legally binding privacy guidelines.
- Australia's e-health record system (My Health Records Act 2012 (Cth), My Health Records Rule 2016 and My Health Records Regulation 2012, together with the Healthcare Identifiers Act 2010 (Cth), provide the legislative framework for this). The My Health Records Act has its own mandatory data breach notification obligations, different to those under the Privacy Act.
- A number of Australian states and territories have privacy laws on the handling of personal information and health information, as well as call recording and other surveillance activities.

## Packaging, labelling and tracking

18. Outline the regulation of the packaging and labelling of medicinal products.

## Legislation and regulatory authority

Requirements for the packaging and labelling of pharmaceutical products vary according to whether the product is a medicinal product (prescription or non-prescription), device or poison.

The TGA enforces the legislation.

Packaging must comply with the following (depending on the product):

- The TG Act, the TG Regulations and the TG (MD) Regulations.
- Relevant state and territory medicinal products legislation.
- TGO 69 (and following amendments) on General Requirements for Labels for Medicines (Old Scheme).
- TGO 91 on Standard for Labels of Prescription and Related Medicines (New Scheme).
- TGO 92 on Standard for Labels of Non-Prescription Medicines (New Scheme).
- TGO 87 on General Requirements for Biologicals Labelling.

- TGO 80 on General Requirements for Child Resistant Packaging.
- TGO 95 on Child Resistant Packaging Requirements for Medicines.
- The SUSMP and its amendments, incorporated in the Poisons Standard. This contains all mandatory warning statements on the packaging or labelling of therapeutic drugs (prescription and non-prescription) and poisons.
- The Therapeutic Goods Advertising Code (for non-prescription medicines).
- Code of Practice for Tamper Evident Packaging.
- Required Advisory Statements for Medicine Labels (RASML).

New labelling requirements for prescription and non-prescription medicines (TGO 91 and 92) came into effect on 31 August 2016. There was a transition period until 31 August 2020 during which the Old Scheme under TGO 69 remained in force.

The requirements for the packaging and labelling of medical devices are contained in the TG (MD) Regulations, Sch 1.

## Information requirements

Prescription only or pharmacist only medicines must have a Product Information (PI) document and a Consumer Medicine Information (CMI) document. The PI contains technical information intended for HCPs. The CMI contains general information about the medicine for the patient and must be in plain English.

The Minister for Health can, by legislative instrument, require specified advisory statements to be put on the labelling of particular medicines or classes of medicines.

The following main items of information must be included on the labels of all therapeutic goods:

- The product name.
- The name(s) of all the active ingredients in the goods.
- The quantity or proportion of all active ingredients in the goods.
- Warning statements, where applicable.
- Storage conditions.
- Expiry date of the goods preceded by the expiry date prefix.
- Directions for use of the goods.
- If the goods are included on the ARTG, the registration or listing number.
- The name or address of the manufacturer or sponsor of the goods.

If the therapeutic good is a therapeutic device and that device is within a package that contains two or more identical or different therapeutic devices, additional requirements must be met.

If the therapeutic good contains blood, cells or tissues collected from a donor the labelling must contain additional specified information.

## Serialisation

In July 2020, the TGA drafted Therapeutic Goods Order (TGO) 106 on Medicines - Standard for Serialisation and Data Matrix Codes. This sets out requirements for serialisation and data matrix codes on the labels of certain medicines in the Australian supply chain. The TGA then sought feedback from the industry on the draft. The TGA is reviewing the submissions and plans to amend the draft order with the feedback in mind.

## Other conditions

All particulars contained on labelling for therapeutic goods must be written:

- In English.
- In durable and legible characters and:
  - all registration and listing numbers must be at least one millimetre in height;
  - under the New Scheme, active ingredients must generally be at least three millimetres in height; and
  - in all other cases at least 1.5 millimetres.
- In metric measurements for all active ingredients in therapeutic goods.

Any medicines that present significant risk of toxicity to children if accidentally ingested must be contained in child resistant packaging. The packaging must retain these child-resistant properties for the necessary number of openings and closing to fully use the contents.

## Product safety, quality and liability

19. Outline the key regulators and their powers in relation to medicinal product safety.

### TGA

The TGA is responsible for regulating medicines and medical devices in Australia. It is also the key regulator in relation to managing product safety issues, including product recalls.

While product recall actions are typically initiated by the sponsor of the relevant medicine or medical device, the TGA co-ordinates the recall and monitors the conduct of it. The sponsor is responsible for recovering the product from the market and taking any other necessary corrective action.

The TG Act enables the Secretary of the Department of Health to mandate recall actions in certain circumstances, for example (in the case of medicines), if:

- The registration or listing of the therapeutic goods is suspended or cancelled.
- The manufacturing principles have not been observed in the manufacture of the goods, or one or more of the manufacturing steps was carried out by a manufacturer that did not hold a valid licence.
- It appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable, or that the presentation of the goods is unacceptable.
- The goods are manufactured or supplied unlawfully in Australia.
- The goods fail to comply with applicable standards.

In these circumstances, the Secretary can require the sponsor or supplier (as relevant) to, among other things:

- Take specified steps, in the specified manner and timeframe, to recover goods that have already been distributed.
- Inform the public or a particular group of persons, in the specified manner and timeframe, of the steps that have been taken.
- Publish, in the specified manner and timeframe, specified information relating to the manufacture or distribution of the goods.

Detailed guidance about recall procedures is set out in the latest version of the TGA's Uniform Recall Procedure for Therapeutic Goods (URPTG), which came into effect on 12 December 2019.

Failure to comply with the recall requirements imposed by the Secretary is an offence punishable by imprisonment, a fine, or both. Penalties are more severe if the failure to comply has resulted in, will result, or is likely to result in, harm or injury to any person. Failure to comply also renders the responsible individual or body corporate liable to a civil penalty (a fine).

The TGA can also cancel the registration or listing for therapeutic goods in certain circumstances, including where it believes that failure to cancel would create an imminent risk of death, serious illness or serious injury.

## **ACCC**

The ACCC is Australia's key consumer watchdog. In certain circumstances, it can commence legal action on behalf of groups of individuals where a breach of the ACL has resulted in harm to consumers. The authors have not yet seen the ACCC play a significant role in the pharmaceutical or medical device product liability sector in Australia.

20. Are there any mandatory requirements relating to medicinal product safety?

## Reporting adverse reactions and events

Australian sponsors are legally responsible for the receipt, handling and reporting of adverse event reports relating to their medicines and medical devices.

**Medicines (including vaccines).** For medicines, sponsors must report to the TGA:

- All serious unexpected and serious expected adverse reactions occurring in Australia that become known to the sponsor and are associated with use of the medicine and/or the active ingredient in the medicine.
- All serious unexpected and serious expected adverse reactions reported in worldwide literature that become known to the sponsor, that occur in Australia and are associated with use of the medicine and/or the active ingredient in the medicine. This must be accompanied by a copy of the relevant published article.
- All clinical and medically relevant information in relation to serious adverse reactions occurring in Australia that becomes available to the sponsor due to follow-up activities.
- Any suspected increase in the frequency of serious adverse reactions to the medicine.

Sponsors are not typically required to report non-serious adverse reactions occurring in Australia, though these must be included as line listings in Periodic Safety Update Reports (PSUR) if PSURs are required, or if otherwise requested by the TGA.

Sponsors must also report to the TGA any significant safety issues identified by the sponsor due to its ongoing review and analysis of information relating to its medicine. Such information may include, for example:

- Adverse reactions reported in other countries.
- Actions taken by overseas regulatory agencies in respect of the medicine.
- Results of post-registration clinical trials.
- Safety issues published in scientific or medical literature.
- Signals of possible teratogenic effects or other significant hazards to the public.
- Any observed changes in the nature, severity or frequency of adverse reactions.

All serious adverse reactions must be reported to the TGA as soon as possible and no later than 15 calendar days from receipt by the sponsor. Significant safety issues identified by the sponsor must be reported to the TGA within 72 hours of the sponsor becoming aware of the issue.

Compliance with these reporting obligations is a condition of the registration or listing of medicines on the ARTG.

Additional general reporting obligations apply (*see Question 10, [Post-marketing commitments and pharmacovigilance obligations](#)*).

**Medical devices.** For medical devices, sponsors must report all adverse events to the TGA that occur in Australia and meet the following criteria:

- An adverse event has occurred.
- The medical device is associated with the adverse event.
- The event led to or might lead to death or serious injury, or might lead to death or serious injury if it were to occur again.

An adverse event is an event that led to death, serious injury or serious deterioration to a patient, user or other person, including:

- A life-threatening illness or injury.
- Permanent impairment of a body function.
- Permanent damage to a body structure.
- A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

An adverse event associated with a medical device occurring in Australia must be notified to the TGA within:

- 48 hours (after the sponsor becomes aware of the event) if the information relates to an event that represents a serious threat to public health.
- Ten days if the event led to death, serious injury or serious deterioration.
- 30 days if the information relates to an event that would be considered a near adverse event.

These reporting requirements are specified by the TGA as conditions to include medical devices in the ARTG.

## Product recalls

See [Question 19](#). Most product recalls are initiated voluntarily but can be ordered in certain circumstances. The conduct of the recall is the sponsor's responsibility and is co-ordinated and monitored by the TGA.

The recall strategy varies depending on the product and the nature of the risk. The content of recall letters, adverts and media releases must be approved by the TGA before being despatched.

Detailed requirements on the procedure for product recalls are set out in the URPTG. This also contains guidance on conducting "non-recall actions", such as issuing safety alerts and product notifications

21. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

## Legal provisions

Australia's product liability laws are a mixture of common law and various federal, state and territory statutes.

Most product liability claims are based on the common law tort of negligence, which is fault-based, and breach of the ACL.

## Substantive test

**Negligence.** The common law test of negligence is fault-based. A manufacturer has a duty of care to take reasonable steps to prevent foreseeable harm to consumers.

This duty of care appears in obligations relating to product design, testing, manufacture, distribution and, in some cases, recall from the market.

It also imposes a duty to give adequate warnings of risks associated with uses of a product, to enable users to adjust their use of the product to avoid or minimise danger, or to make an informed decision about whether to use it.

To establish liability, a claimant must prove all of the following:

- Loss or damage has been suffered.
- The manufacturer's conduct is in breach of the common law duty of care.
- The loss or damage was caused by the manufacturer's breach of duty.

**Contract.** Contractual liability for harm caused by faulty goods arises if there is a breach of an express contractual warranty or a warranty implied under statute. Breaches usually relate to:

- Merchantable quality.
- Fitness for purpose.

**ACL.** The ACL imposes a form of strict liability. Under Part 3-5, manufacturers are directly liable to consumers for injury or property damage suffered due to a defective product. Goods are considered defective if their safety is not such as persons generally are entitled to expect.

The ACL also imposes a statutory guarantees regime under Part 3-2. Manufacturers are directly liable to consumers for:

- Goods that do not correspond with their description.
- Goods of unacceptable quality.
- Goods that do not conform to a sample.
- Goods unfit for a stated purpose.
- Non-compliance with express warranties.

A manufacturer is liable if it engages in misleading or deceptive conduct, or conduct likely to mislead or deceive (*section 18, ACL*). This conduct can be express or implied, and silence can be a breach in some circumstances. However, misleading conduct is not available as a cause of action in personal injury claims.

22. Who is potentially liable for defective medicinal products?

The elements of each cause of action differ.

### **Negligence**

Generally, the manufacturer of goods owes a duty of care to the buyer and user to safeguard them against the foreseeable risks of injury when using the product as intended. A duty of care may exist in relation to anyone involved in supplying pharmaceuticals, including wholesalers, retailers, doctors or pharmacists.

A non-manufacturing distributor of goods, who is ignorant of a dangerous defect in those goods, does not owe the same duty of care as that of a manufacturer. There must be something more, that is, knowledge of or reasonable grounds to suspect the risk. Retailers, importers and distributors are not expected to test or inspect products that the manufacturer delivers in sealed containers not normally opened until they reach the ultimate consumer.

If any party in the supply chain adds to or modifies a product, including packaging or labelling, that party also owes a duty to the buyer and user in relation to those changes.

Doctors may be liable in negligence for inappropriately prescribing medicines (for example, prescribing a drug despite it being contraindicated in the patient) or for "failing to warn" patients of known risks. "Off label" prescriptions typically carry greater risks for physicians.

### **Contract**

Contractual remedies are only available to parties to the contract. Since, in most circumstances, the retailer has a contractual relationship with the buyer, the retailer bears liability for any defect or fault according to the express and implied terms of the contract of sale.

### **ACL**

Manufacturers of goods can be liable under different parts of the ACL, including Part 3-3 (product safety) and Part 3-2 (consumer guarantees). The legislation broadly defines manufacturer. Apart from the actual manufacturer, it includes any company that:

- Holds itself out to be the manufacturer.
- Applies its name or brand to the goods.
- Permits someone to promote the goods as those manufactured by the company.

- Imports the goods in circumstances where the actual manufacturer has no presence in Australia.

Suppliers (for example, pharmacists) can also be liable under Part 3-2 of the ACL for failing to comply with the consumer guarantees. They may have recourse against manufacturers in some circumstances.

In Australia, the risk of product liability claims is managed through implementing measures including:

- The inclusion of indemnification clauses and exclusion clauses in contract.
- Insurance.

Any indemnification or exclusion clause must be sufficiently clear and specific to mitigate the risk of unenforceability. In addition, it is important to note that a supplier cannot contract out of the consumer guarantees under the ACL. Accordingly, where a term is negotiated into a contract to manage risk, it is important to ensure that the term is not precluded by the relevant legislation, including the ACL.

23. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

The available defences depend on the cause of action.

## **Negligence**

The following defences may be available:

- Causation defences, including specific causation: how could ingestion of this pharmaceutical have reasonably foreseeably caused this condition in this individual?
- Voluntary assumption of risk.
- Contributory negligence.

A number of statutory defences also exist, although these differ between jurisdictions.

## **ACL**

There are a number of specific defences to an action brought under different parts of the ACL. Under Part 3-2 it is a defence if:

- Goods are not reasonably fit for purpose or are not of acceptable quality because of an act or default of a third party, or a cause independent of human control occurring after the goods have left the control of the corporation.

- In the case of goods not reasonably fit for purpose, the consumer did not rely on or it was unreasonable for the consumer to rely on the manufacturer.
- In the case of goods not of acceptable quality, defects were drawn to the consumer's attention, or if the consumer examines the goods in relation to defects that the examination ought to reveal.

Under Part 3-5 there are four defences:

- The defect did not exist when the goods were supplied by the manufacturer.
- The goods were only defective because of compliance with a mandatory standard.
- The state of scientific or technical knowledge at the time the goods were supplied did not enable the defect to be discovered.
- In the case of a manufacturer of a component used in the product, the defect is attributable to the design of the finished product or to any markings, instructions or warnings given by the manufacturer of the finished product, rather than a defect in the component.

24. How can a product liability claim be brought?

A product liability claim can be brought by commencing proceedings in either of the relevant courts of each jurisdiction. Under the ACL, claims are most commonly brought in the Federal Court of Australia.

### **Limitation periods**

This is a difficult question given the diversity of causes of action and jurisdictions that can be involved in product liability claims. However:

- For most causes of action and most jurisdictions, the limitation period is three years.
- For most causes of action and most jurisdictions, the three years start running when some appreciable (that is, more than negligible) damage occurs.
- Some jurisdictions have a discoverability test to determine when time starts running.
- Most jurisdictions have provisions to obtain a time extension, often based on a discoverability test.

There are some statutes of repose under the ACL.

### **Class actions**

Class actions for product liability claims are expressly permitted where seven or more persons have claims against the same person, and all the claims both:

- Are in respect of, or arise out of, the same, similar or related circumstances.
- Give rise to a substantial common issue of law or fact.

(*Federal Court of Australia Act 1976* (Cth).)

If these requirements are met, any one of those persons can begin a representative action in the Federal Court of Australia. A similar statutory procedure for class actions exists in the Victorian, New South Wales and Queensland Supreme Courts.

Other group action procedures exist in the other states and territories under their rules of court.

25. What remedies are available to the claimant? Are punitive or exemplary damages allowed for product liability claims?

Australia has undergone significant civil liability reform resulting in caps, thresholds and other limitations on the amount of pecuniary damages that can be recovered. These limitations apply to any claim for personal injury, regardless of whether the claim is brought at common law, under contract or under the ACL. The limitations are not uniform.

At common law (tort and contract), remedies include:

- General damages, including for pain and suffering, loss of amenities and loss of expectation of life.
- Special damages, including for loss of wages and earning capacity (both past and future), and medical and hospital expenses.

Under the ACL, the main remedy for breach is compensation.

Exemplary, punitive or aggravated damages can be awarded by the courts in very limited circumstances, although not for claims brought under the ACL. They have also been abolished for personal injury in some jurisdictions.

## **Local establishment, representation and residency requirements**

26. What local requirements apply to businesses and individuals (such as the person responsible for releasing a product onto the market) acting within or in relation to the jurisdiction?

For an individual to be a sponsor of therapeutic goods in Australia (marketing authorisation holders), that person must be an Australian resident. For a corporation to be a sponsor of therapeutic goods, it must be incorporated in Australia.

The TGA provides guidance in relation to sponsor obligations on its website ([www.tga.gov.au/sponsors-ongoing-responsibilities](http://www.tga.gov.au/sponsors-ongoing-responsibilities)).

For obligations in relation to manufacture and distribution and marketing authorisation, see [Question 8](#), [Question 9](#) and [Question 10](#).

## Reform

27. Are there proposals for reform and when are they likely to come into force?

In December 2016, the Australian Productivity Commission released its inquiry report into Australia's IP arrangements. It made recommendations to amend Australia's IP laws, including in relation to patents and specifically, pharmaceutical patents. In August 2017, the Australian Government released its response, supporting a number of the recommendations such as the:

- Prospective abolition of the innovation patent system.
- Raising of Australia's inventive step requirement for patents.
- Possible introduction of a system for transparent reporting and monitoring of settlements between originator and generic pharmaceutical companies, to detect pay for delay payments.

In February 2020, the Australian Government passed the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and the Other Measures) Act 2020, which phases out the innovation patent system. The last day that a new innovation patent can be filed is 25 August 2021. Existing innovation patents and innovation patents filed before 25 August 2021 will remain in force until their expiry.

The Australian Government has recently approved the following two enhanced transparency measures for prescription medicines evaluated by the TGA:

- Measure 1: early publication of major innovator medicine applications once accepted for evaluation under section 25 of the TG Act. The TGA will make such publications on its website from January 2021.
- Measure 2: earlier notification of generic medicine applications to the innovator. Applicants for the first generic and biosimilar of an originator product will have to notify the patentee when their application is accepted for evaluation by the TGA. This intends to provide the opportunity for early negotiation and resolution of disputes due to potential patent infringement and invalidity before a generic or biosimilar

medicine is included in the PBS, and to reduce litigation. Legislative changes to introduce this earlier patent notification scheme are planned to be introduced to Parliament in late 2020.

In February 2019, the TGA released a consultation paper seeking feedback on how software, including Software as a Medical Device (SaMD), is regulated in Australia. The key changes proposed are:

- SaMD products would be appropriately classified in the classification rules for medical devices, according to the potential harm they could cause patients.
- SaMD products would be excluded from the personal importation provisions in the TG (MD) Regulations. As such, SaMD products would need to be included in the ARTG and have an Australian sponsor.
- The essential principles for medical devices would include clear and transparent requirements to show the safety and performance of regulated software.

Due to COVID-19, a number of medical device reforms have been delayed, including the Therapeutic Goods Amendment (2019 Measures No.1) Regulations 2019. These were introduced to effect reforms arising from the Expert Review of Medicines and Medical Devices Regulation. They address, among other things, the risk classifications of software as a medical device (*see Question 3*).

Throughout 2020, the TGA and the Australian Government also facilitated a number of short-term regulatory changes in response to COVID-19. In particular, these included exemptions for certain medical devices such as ventilators, personal protective equipment and in vitro diagnostic medical devices, and to facilitate faster, broader access to necessary equipment.

In May 2020, the TGA announced a proposal to reclassify low dose cannabidiol (CBD) preparations under the Poisons Standard from Prescription Only to Pharmacy Only Medicine. This would ultimately permit the sale of CBD medicines by a pharmacist. An interim decision to proceed with the down-scheduling was made in September 2020, with a proposed implementation date of 1 June 2021. The interim decision will be subject to further consultation before a final decision is made.

The Australian Government has also proposed reforms in relation to country of origin labelling for Australian made complementary medicines.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, see *Pharmaceutical IP and Competition Law in Australia: overview*.

### **Contributor profiles**

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**Areas of practice.** Head of DLA Piper's Life Sciences practice across the Asia-Pacific and in Australia; leads DLA Piper's Life Sciences Intellectual Property and Regulatory practices in Australia; pharmaceutical, bioscience and medical technology patent litigation and advice; IP; pharmaceutical, bioscience and medical technology regulation; biotechnology and life sciences.

### Recent transactions

- Offers a level of experience unique to the Australian market, being both a US attorney and an Australian solicitor, having advised and acted for many of the world's leading life sciences companies in those jurisdictions.
- Acting in Hatch-Waxman patent disputes in the US and in the Australian component of equivalent complex multi-jurisdictional patent disputes, including in patent disputes before trial courts, intermediate appeal courts (the US Court of Appeals for the Federal Circuit and the Full Federal Court of Australia) and final appeal courts (the US Supreme Court and the High Court of Australia).
- Has acted in some of the largest and most innovative life sciences disputes in Australia, for many of the world's largest innovator life sciences companies, including the first three cases to address claims on undertakings as to damages in pharmaceutical patent litigation by generic pharmaceutical companies, their suppliers and the Commonwealth of Australia, and the first biologic/biosimilar patent litigation in Australia, as well as in opposition proceedings for innovator life sciences companies before IP Australia.
- Has managed and co-ordinated multi-jurisdictional patent litigation for multinational innovator life sciences companies.
- Advising numerous life sciences companies in relation to patent issues, including international patent protection strategies and patent portfolio management.
- Advising life sciences companies on a broad range of regulatory issues including registration of pharmaceuticals and medical devices and technologies, promotion of products, compliance with industry codes, and clinical trials.
- Advising multinational life sciences companies on, and managing, the IP and life sciences regulatory aspects of, multinational corporate transactions.
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**Professional qualifications.** Australian Capital Territory, 2004; New South Wales, 2006; High Court of Australia, 2008

**Areas of practice.** IP and litigation; pharmaceutical and medical device regulation; life sciences.

**Recent transactions.**

- Advising a medical devices company on establishing its operations in Australia, including in relation to the regulation, advertising and promotion of its medical devices and the regulation of health care professionals in Australia.
- Acting in pharmaceutical patent infringement and revocation proceedings before the Federal Court of Australia and in patent opposition proceedings before the Australian Patent Office, and the first litigation involving biosimilars in Australia.
- Advising on and overseeing the IP and life sciences regulatory aspects of international corporate transactions, including major acquisitions of multinational medical devices businesses.

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**Areas of practice.** Competition law advisory and litigation; class actions; cartel investigations and merger clearance.

**Recent transactions.**

- Advising on labelling and promotional activities to eliminate the risk of breaching the Australian Consumer Law.
- Advising on pharmaceutical distribution strategies and internal competition law investigations.

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**Areas of practice.** Product liability; class actions and mass torts; insurance litigation; civil/commercial litigation.

**Recent transactions.**

- Currently acting for a global pharmaceutical company in a Federal Court class action relating to pelvic mesh devices.
- Currently acting for various global pharmaceutical companies and medical device companies in litigation, claims and advisory work.
- Currently acting for a global food company in a Federal Court class action.
- Regularly acting for Australian, US and international companies on product related issues: product recalls, other regulatory issues or product liability claims.

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**Professional qualifications.** New South Wales and High Court of Australia, 2002; Victoria and Federal Court, 2004; England and Wales, 2003; Registered Patent Attorney, 2008

**Areas of practice.** Patent and trade mark litigation and disputes; infringement and freedom to operate advice; patent licensing and strategy.

**Recent transactions.**

- Advising on infringement and validity of patents and conducting infringement risk analysis.
- Acting for innovator and generic companies in patent infringement and revocation proceedings involving pharmaceutical compositions and methods of medical treatment.
- Acting in Federal Court trade mark infringement proceedings, oppositions to trade mark registration before the Australian trade marks office and appeals of office proceedings.

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### Recent transactions.

- Federal Court patent infringement and revocation proceedings.
- Australian Patent Office opposition proceedings.
- Advising pharmaceutical, medical device and biotechnology companies on Australian regulatory and compliance issues.

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**Areas of practice.** IP and litigation; pharmaceutical and medical device regulation; life sciences; copyright; trade mark and domain name disputes.

### Recent transactions

- Acting in Federal Court patent infringement and revocation proceedings, and patent opposition proceedings before the Australian Patent Office.
- Advising multinational life science companies in relation to infringement and validity of Australian patents.

- Advising pharmaceutical, bioscience and medical device companies on Australian regulatory and compliance issues.

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**Areas of practice.** Patent, trade mark and copyright litigation and disputes; infringement and freedom to operate advice.

### Recent transactions.

- Federal Court patent and trade mark infringement and revocation proceedings.
- Australian Patent Office opposition proceedings.
- Australian Trade Mark Office opposition proceedings.
- Advising on patent and trade mark infringement risks and assessments of patent validity.

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**Areas of practice.** IP and technology; pharmaceutical and medical device regulation; life sciences; consumer goods; brand protection; data protection and privacy.

### Recent transactions.

- Advising a global medical device company (subsidiary of a Fortune 500 company) specialising in infection prevention on regulatory matters relating to doing business in a number of markets across the Asia Pacific, in particular in relation to the sale and distribution of medical devices.
- Advising a global beverages and food business on regulatory compliance and labelling considerations for production of hand sanitizer product developed in response to COVID-19.
- Advising a US dental and orthodontic services disruptor on their entry into the Australian market, including regulatory advice on custom-made medical devices and compliance with Australian health and medical regulations.

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- Advising on labelling and promotional activities to eliminate the risk of breaching the Australian Consumer Law.
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- Currently acting for an international food company in a Federal Court class action.
- Currently advising multiple global pharmaceutical and medical device companies in litigation, claims and clinical trial work.
- Regularly acting for Australian, US and international companies on product related issues: product recalls, product liability claims and other regulatory work.

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