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Medicinal product regulation and product liability in Australia: overview

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REGULATORY OVERVIEW

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

Legislation

The Therapeutic Goods Act 1989 (Cth) (TG Act):

- 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.

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

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). This scheme means that certain necessary drugs which are selected by an expert panel are supplied at a reduced cost. The prices of pharmaceuticals listed on the PBS are regulated by the National Health Act 1953 (Cth) (NH Act).

Therapeutic goods are divided into two categories:

- Medicines (such as prescription drugs and vitamins, each of which is regulated separately).
- Medical devices (such as in vitro diagnostics, heart valves or syringes).

Regulatory authorities

The TG Act is administered by a Commonwealth Federal agency called the Therapeutic Goods Administration (TGA), which is part of the Australian Government's Department of Health and Ageing (*see 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 medical products are of acceptable standard.

2. Briefly outline how biologicals and combination products are regulated in your jurisdiction.

Biologicals are 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.

Importantly, biologicals can be regulated in three ways:

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

The BRF and the Australian Regulatory Guideline for Biologicals provide further information on the regulation of these products.

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

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of health IT issues and mobile medical applications?

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 also 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.

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The Therapeutic Goods Medical Devices Regulations 2002 (Cth) (TG (MD) Regulations) define an IVD medical device 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.

All IVDs must be included on the ARTG before importation, supply, or export from Australia. While regulated under the same legislation as ordinary medical devices, IVDs are classified separately and additional essential principles setting out requirements for safety and performance exist.

Software, or mobile medical applications, can also be classified as medical devices. Under the TG Act, a medical device is defined as both:

- 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:
  - 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;
  - control of conception;
- That does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.

Because of the broad nature of this definition, software, mobile phone applications and diagnostic or processing software can be classified as medical devices. These types of products are not regulated separately from other medical devices. The level of scrutiny given to all medical devices by the regulator will depend on the product's level of risk.

PRICING, STATE FUNDING AND REIMBURSEMENT

4. What is the structure of the national healthcare system, and how is it funded?

A major part of Australia's healthcare system is called Medicare. Medicare 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 PBS.
- Free or subsidised treatment by medical practitioners (classified as "bulk billing").
- Substantial grants to state and territory governments to contribute to the costs 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 funding public hospitals.

A large number of medicinal products, where prescribed by doctors and dispensed in pharmacies are directly subsidised by the PBS. The price of drugs supplied on the PBS is regulated by the NH Act.

Drugs used in public hospitals are primarily funded through agreements between the states and territories, as well as the Commonwealth Government. The states and territories are responsible for the allocation of these funds. Under special funding arrangements, the Commonwealth Government also pays for some expensive drugs which can only be supplied from hospitals to outpatients. Australians are also encouraged, through tax incentives, to have private health insurance which, depending on the level of cover, may assist in funding drugs which are not listed on the PBS.

5. How are the prices of medicinal products regulated?

For 2015, the maximum cost of a subsidised pharmaceutical product (that is, a product listed on the PBS) is A$37.70 for general patients. For concessional patients, that is, patients who hold healthcare cards or are pensioners, the maximum cost of a PBS listed pharmaceutical product is A$6.10. This amount is called a co-payment, as part of the product is paid for by the patient and 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 (that is, products for which a patient does not require a prescription and are not listed on the PBS) is not regulated.

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

The PBS subsidises the cost of medicines listed on the PBS that are obtained on prescription. Australians holding concessional cards receive a larger subsidy.

If a pharmaceutical supplier wants to have a new drug listed on the PBS, it must make an application to specific bodies in the Department of Health. The Minister for Health is empowered to list drugs on the Schedule of Pharmaceutical Benefits, on favourable recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC) in accordance with the PBS listing process and the NH Act.

Where the PBAC decides to make a positive recommendation, it will be considered by the government which may refer the matter to the Pharmaceutical Benefits Pricing Authority (PBPA) so that it may calculate the price the Commonwealth Government will pay the manufacturer for producing the drug.

The Department of Health undertakes price negotiations with the supplier based on PBAC recommendations and, if an agreement is reached, this is sent to the Minister for approval. Currently, if a drug is expected to cost more than A$5 million a year, it is considered by the Commonwealth Department of Finance and Administration. If a drug is expected to cost more than A$20 million a year, it is considered by Cabinet.

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

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

The reimbursement is paid by the government to the pharmacist (as the pharmacist will have purchased the drug at its full price from the manufacturer or wholesaler).

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials in Australia are conducted under either the:

- Clinical Trial Exemption Scheme (CTX Scheme).
- Clinical Trial Notification Scheme (CTN Scheme).

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

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

- The TG Act.
- Therapeutic Goods Regulations 1990 (Cth) (TG Regulations).
- National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Research involving Humans 2007.
- Note for Guidance on Good Clinical Practice (*CPMP/ICH/135/95*), as adopted by the TGA.
- Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95), as adopted by the TGA.

Authorisations

CTX Scheme. This is an approval process by which the sponsor of the clinical trial submits an application to conduct clinical trials to the TGA for evaluation and comment. A CTX trial may not be commenced until the approval process is favourably completed.

CTN Scheme. This is a notification scheme by which all materials relating to the proposed trial protocol are submitted directly to the Human Research Ethics Committee (HREC) by the researcher at the request of the sponsor. The HREC is responsible for:

- Assessing the scientific validity of the trial design.
- Assessing the safety and efficacy of the medicine or device.
- Assessing the ethical acceptability of the trial process.
- Approving the trial protocol.

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

In practice, the CTN Scheme is more common. The CTX Scheme is more expensive, reflecting the increased work by the TGA to evaluate the data provided. The CTX Scheme is the preferred scheme where a HREC does not have the relevant expertise to assess the safety of the product for which the trial is being suggested.

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:

- National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Research involving Humans 2007.
- Note for Guidance on Good Clinical Practice (*CPMP/ICH/135/95*), as adopted by the TGA.

Multi-centre clinical trials should also abide by the principles set out within the NHRMC's National Approach to Single Ethical Review (the National Approach).

Trial pre-conditions

All CTN and CTX trials must have an Australian sponsor, 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 the procedure 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 are significant and include, for example, the maintenance of quality assurance and quality control systems with standard operating procedures for the conduct of the trial. Additionally, the trial must also be monitored and any adverse events reported. As is required before a trial is commenced, a number of documents must be filed both during and after the clinical trial.

MANUFACTURING

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

Application

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

Conditions

In manufacturing products for supply and sale in Australia, manufacturers must comply with the TG Act and be able to demonstrate, during a factory audit, compliance with manufacturing principles, including the relevant codes of good manufacturing practice (GMP). As such, 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, with some specified exceptions (for example, certain veterinary products and products derived from human blood or plasma) (The Therapeutic Goods (Manufacturing Principles) Determination No 1 of 2013).

The PIC/S Guide also incorporates the ICH Harmonised Tripartite Guideline to Good Manufacturing Practice for Active Pharmaceutical Ingredients. Currently, the Guide to Good Manufacturing Practice for Medicinal Products - Part II provides

guidance relating to the manufacture of active pharmaceutical ingredients.

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

Restrictions on foreign applicants

Overseas manufacturers who wish to supply their products in Australia must provide evidence that their medicinal products are manufactured to the standard that is expected 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

When a licence is issued, it is specific 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 audits by the TGA. These can take from less than one day to up to several days. For a full-step manufacturer audit, a minimum of two whole days is generally allocated.

A licence can apply to more than one site provided it complies 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 can be found at *https://www.tga.gov.au/sites/default/files/fees-140701-8.pdf*.

Period of authorisation and renewals

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

Monitoring compliance and imposing penalties

The Manufacturers Assessment Branch of the TGA, under the Office of Manufacturing Quality, has the power to audit manufacturers' compliance with GMP codes. The frequency of audits depends on:

- The degree of risk to patients and consumers.
- The extent to which a manufacturer complied with GMP codes in the past.
- The type of products manufactured and how they are manufactured.

New licence applicants are scheduled for an audit as soon as possible after receipt of that 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 these.

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 found in Part 6-2 of the TG Act.

The TGA can revoke or suspend the granted manufacturing licence for a period of time (*section 41, TG Act*). However, the TGA must 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 is specified in the notice, a submission to the TGA in relation to the proposed action (except if the proposed action relates to a failure to pay the annual licensing charge or an applicable inspection fee).

An exception from these requirements can be made if the TGA considers that failure to revoke or suspend the licence immediately would create an imminent risk of death, serious illness or serious injury.

MARKETING

Authorisation and abridged procedure

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

Application

Marketing applications for medicinal products must be made to and approved by the TGA, subject to some exceptions. A product cannot be marketed in Australia before it is listed on the ARTG.

Authorisation conditions

Before approving a medicine, the TGA must be satisfied that it complies with all legislative requirements in force in Australia. Statutory standards under the TG Act ss 3 and 10 include the Therapeutic Goods Orders (TGOs), the British Pharmacopoeia (BP), the European Pharmacopoeia (Ph Eur) and US Pharmacopoeia-National Formulary (USP). Since 1 July 2009, each of the BP, Ph Eur and USP are defined under the TG Act as default standards. Therefore, if no relevant standard is specified in a TGO, any of the Pharmacopoeia applies. An exemption may be sought from the requirements of the TG Act with the consent of the Secretary of the Department of Health and Ageing. Offences and civil penalties 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*).

Key stages and timing

Medicinal products that are included in the ARTG are entered as registered or listed goods, depending on their ingredients and intended purpose.

The registration process involves a detailed review by the TGA of the quality, safety and efficacy of the medicinal products in question. Prescription products are subject to registration requirements. While many OTC medicines are listed, other OTC products are registered.

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 (2013) (ARGPM) aim to assist sponsors to prepare applications to register new prescription or other high risk medicines for human use in Australia.

The timeline for processing an application for registration is set down 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.

Fee

A summary of fees can be found at *https://www.tga.gov.au/sites/default/files/fees-140701-8.pdf*.

Period of authorisation and renewals

Medicines remain listed or registered in the ARTG until their listing or registration is cancelled. Annual fees apply (*see https://www.tga.gov.au/sites/default/files/fees-140701-8.pdf*.).

Monitoring compliance and imposing penalties

The TGA monitors the continued 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.

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

The TGA's powers of enforcement 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 (A$680,000). The penalties may be higher in some circumstances.

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

10. What commitments and pharmacovigilance obligations apply after a company has obtained marketing authorisation? Are there further conditions concerning how the drug is distributed and accessible to patients?

Post-marketing commitments and pharmacovigilance obligations

The TG Act imposes strict requirements on post-marketing pharmacovigilance. These requirements are set out in the TG Act and the Australian Requirements and Recommendations for Pharmacovigilance Responsibilities of Sponsors of Medicines (June 2014) (Requirements and Recommendations).

Under the TG Act and Requirements and Recommendations, sponsors are required to 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 also provided to the TGA suggests.
- Information that indicates that the quality, safety or efficacy of the medicine is unacceptable.
- Information that indicates that the 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 the information. However, in more serious cases, the required timing may be the next business day, and no later than 72 hours after becoming aware.

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

It is a criminal offence to fail to report adverse drug effects to the TGA. Failure to report may result in a term of imprisonment of 12 months. Civil penalties of up to A$5.1 million (30,000 penalty units) may also apply.

Other conditions

The TG Act sets out a number of requirements which sponsors must comply with in order 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 where a medicine poses a potential risk of death, serious illness or injury if it continues to be included on the register and the risk could be eliminated during the period of suspension.

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

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

Medicines that fall within the definition of essential similarity (such as generics) are exempt from the requirement to provide data from non-clinical studies and clinical trials. However, instead of safety and efficacy data, data from appropriate bioavailability studies must normally be submitted. Provided that the essentially similar product has a sufficiently similar plasma concentration/time profile to a leading brand in Australia, the two products can be considered bioequivalent.

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?

Foreign marketing authorisations (MAs) are recognised to the extent that the evaluation time of certain applications for

registration of a medicinal product will be shortened if the sponsor can provide two independent evaluation reports from specified countries with regulatory standards similar to Australia, and in which an identical product has obtained authorisation.

Parallel imports

13. Are parallel imports of medicinal products into your jurisdiction allowed?

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

- Marketing approval from the TGA to sell the products in Australia.
- A PBS listing, if it wants its products to qualify for government reimbursement.

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

Restrictions on dealing with healthcare professionals

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare 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 (which is 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 18) sets out standards of conduct relating to the marketing of prescription products. In particular, it contains detailed provisions relating to:

- The form and content of adverts directed at doctors for prescription pharmaceuticals.
- Promotional activities carried out by pharmaceutical companies.

No item or offer can be given or made to healthcare professionals (HCPs) except (*Code*):

- Educational items which 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 which relate to medical devices.

Updates on the Code and Edition 18 can be found at *https://medicinesaustralia.com.au/code-of-conduct/*. Edition 18 contains new transparency reporting obligations that are expected to commence on 1 October 2015.

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 as 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.

SALES AND MARKETING

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 Poisons List is the list of substances to which the Poisons and Therapeutic Goods Act and its Regulation apply. It is divided into eight schedules according to a pattern that is uniform in most respects throughout Australia.

Different conditions apply to the packaging, labelling and sale of poisons depending on the way they are classified in the Poisons List. For example:

- Some medicines (Schedule 2) can be sold only by pharmacies and persons licensed under the Regulation to sell them.
- Other medicines (Schedule 3) can be sold only by pharmacists personally (other shops are not licensed to sell them).
- Other medicines (Schedule 4) can only be supplied on prescription.

The advertising of prescription products to the general public is prohibited. Therefore, pharmaceutical products cannot be advertised on Australian-based internet sites that are accessible by the public. While the internet can be used as a means of providing accurate and scientifically reliable information on prescription products, this information must be non-promotional. The Code and TG Act both define promotion and advertising very broadly. It is therefore unadvisable to use this medium without legal review.

Non-prescription pharmaceutical products can be advertised to the public where they are listed on the ARTG. Therefore, over-the-counter (OTC) products can be advertised on Australian-based internet sites that are accessible by the public. These advertisements are strictly regulated by law and industry standards such as the Therapeutic Goods Advertising Code.

ADVERTISING

16. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

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

The Australian Consumer and Competition Commission enforces breaches of the Competition and Consumer Act 2010 (Cth) (CC

Act), which deals with offences relating more broadly to advertising.

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 of 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 legislations.
- The Therapeutic Goods Advertising Code, which sets out specific requirements on the content of advertisements for medicinal and other products.

In addition, advertising must not infringe the CC Act. Any representations made in advertisements must be documented, genuine and not misleading.

Internet advertising

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

DATA PROTECTION

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

The Privacy Act 1988 (Cth) (Privacy Act) regulates the way private sector organisations and government agencies collect, hold, use and disclose personal information. The Privacy Act imposes stricter obligations in respect of sensitive information (such as health information).

Some of the key obligations under the Privacy Act relate to:

- Open and transparent management of personal information (including requiring entities to have a privacy policy that complies with the Privacy Act).
- 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.

Significant changes to the Privacy Act commenced on 12 March 2014. The changes include a new set of harmonised Australian Privacy Principles (or APPs) that replace the two sets of principles that applied to government agencies and to organisations. The reforms also include new enforcement powers and remedies in relation to investigations, including heavy fines for serious or repeated interferences with the privacy of individuals.

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).
- Where the disclosure is required or authorised under a law. One example where this might occur is under subsection 61(7) of the TG Act, where it is necessary to do so to ensure the safe use of the medicine, including by providing the information to the company which supplies 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 in relation to adverse events may be released to the public by the Secretary of the Department of Health and Ageing 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 related to other reported adverse events. It will not include any personal information as that term is defined under the Privacy Act.

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

- Information relating to Medicare and PBS are regulated pursuant to the NH Act, which contains legally binding privacy guidelines.
- The Personally Controlled Electronic Health Records Act 2012 (Cth) provides the legislative framework for Australia's e-health record system.
- A number of Australian states and territories have privacy laws dealing with the handling of personal information and health information.

PACKAGING AND LABELLING

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.
- The TG (MD) Regulations.
- Relevant state and territory medicinal products legislation.
- TGO 69 (and following amendments) on General Requirements for Labels for Medicines.
- TGO 37 on General Requirements for Labels for Therapeutic Devices.

- TGO 87 on General Requirements for Biologicals Labelling.
- TGO 80 on General Requirements for Child Resistant Packaging.
- The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and its amendments, incorporated in the Poisons Standard 2013. This contains all mandatory warning statements to be included 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.

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 and Ageing can, by legislative instrument require specified advisory statements to be incorporated 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.
- Expiry date of the goods preceded by the expiry date prefix.
- Directions for use of the goods.
- If the goods are included on the Australian Register of Therapeutic Goods, 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.

Other conditions

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

- In the English language.
- In durable and legible character and:
  - for all registration and listing numbers must not be less than one millimetre in height; and
  - in all other cases not less than 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 necessary to fully use the contents.

PRODUCT LIABILITY

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

The 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 is responsible for co-ordinating the recall and for monitoring the conduct of the recall as it is carried out. The sponsor of the affected product is responsible for recovering the product from the market and for 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 in question 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 while the manufacturer 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 actions that can be required by the Secretary include a requirement on the sponsor or the person supplying the goods (as relevant):

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

Detailed guidance about recall procedures are set out in the TGA's Uniform Recall Procedure for Therapeutic Goods (URPTG).

Failure to comply with the recall requirements imposed by the Secretary constitutes an offence punishable by imprisonment, a fine, or both. Penalties are more severe if the failure to comply has resulted in, will result or, 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 the imposition of a civil penalty (fine).

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

The Australian Competition and Consumer Commission

The Australian Competition and Consumer Commission (ACCC) is Australia's key consumer watchdog. In certain circumstances, the ACCC has the power to commence legal action on behalf of groups of individuals where a breach of the Australian Consumer Law

(ACL) has resulted in harm to consumers. We have not yet seen the ACCC play a significant role in the pharmaceutical or medical device product liability space in Australia.

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

Reporting of adverse reactions and adverse events

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

Medicines. 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 that are associated with the use of the medicine and/or the active ingredient in the medicine.
- All serious unexpected and serious expected adverse reactions reported in the worldwide literature that become known to the sponsor, that occur in Australia and that are associated with the 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 as a result of 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 that occur in Australia, although 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 as a result of 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 are required to report all adverse events to the TGA which occur in Australia and which meet the following three 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".

The reporting requirements described above are specified by the TGA as conditions on the inclusion of medical devices in the ARTG.

Product recalls

Product recalls are discussed in *Question 19*.

Most product recalls are initiated voluntarily, but can be mandated in certain circumstances. The conduct of the recall is the responsibility of the sponsor and is co-ordinated and monitored by the TGA.

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

Detailed requirements regarding the procedure for product recalls are set out in the URPTG. That document also contains guidance about 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.

The majority of product liability claims are based on a number of causes of action:

- The common law tort of negligence, which is fault-based.
- Breach of the Australian Consumer Law (ACL) provisions.

Substantive test

The substantive tests include negligence and contract.

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 manifests itself 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 the 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 or not to use the product.

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

- That loss or damage has been suffered.
- That the manufacturer's conduct is in breach of the common law duty of care.
- That 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 of a warranty implied under statute. Breaches usually relate to:

- Merchantable quality.
- Fitness for purpose.

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

The ACL also introduces a regime of statutory guarantees 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 that are unfit for a stated purpose.
- Non-compliance with express warranties.

A manufacturer is liable if it engages in misleading or deceptive conduct, or conduct that is likely to mislead or deceive (*section 18, ACL*). This conduct can be express or implied, and silence can also be a breach in some circumstances. However, misleading conduct is no longer 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, which would not normally be 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 purchaser and user in respect of those changes.

Doctors may be liable in negligence for inappropriately prescribing medicines (for example, prescribing a drug despite it being contraindicated in the patient in question) 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 the liability for any defect or fault according to the express and implied terms of the contract of sale.

ACL

Manufacturers of goods can be held 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, but may have recourse against manufacturers in some circumstances.

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 relied on.

Negligence

The following defences may be available:

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 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 as regards 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 defective only because there was 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 provision to obtain an extension of time, 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 both (*Federal Court of Australia Act 1976* (Cth)):

- The claims of all those persons are in respect of, or arise out of, the same, similar or related circumstances.
- The claims of all those persons give rise to a substantial common issue of law or fact.

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 state of Victoria. Other group action procedures exist in the other states and territories under their respective Rules of Court.

Foreign claimants

Provided a claimant fits within the jurisdiction of a "consumer" under the ACL, he or she is entitled to bring an action in Australia.

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

Australia has undergone a process of significant civil liability reform that has resulted in caps, thresholds and other limitations being placed 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 in relation to claims brought under the ACL. They have also been abolished for personal injury in some jurisdictions (as a result of reform).

REFORM

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

The most significant single set of reforms to Australia's intellectual property (IP) laws in years has now been passed into law.

The Intellectual Property Laws Amendment (Raising the Bar) Act 2012 (Raising the Bar Act) amended each piece of IP legislation in Australia, although the effects of the Act will be most keenly felt in the areas of patent law and trade mark law.

In February 2015 the Australian Parliament passed the Intellectual Property Laws Amendment Bill 2014 to amend the Patents Act 1990, Trade Marks Act 1995, Designs Act 2003, and the Plant Breeder's Rights Act 1994. The amendments will enable Australian medicine producers to apply to the Federal Court from 25 August 2015 to obtain a compulsory licence to manufacture and export patented pharmaceuticals to countries experiencing health crises.

For information on pharmaceutical 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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ONLINE RESOURCES

Australian legislation: ComLaw

W www.comlaw.gov.au

Description. Australian Government website containing up to date, Commonwealth (Federal) and Territory Legislation.

Practical Law **Contributor profiles**

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Areas of practice. Patents, copyright, trade marks and designs; pharmaceutical and medical device and technology regulation; biotechnology and life sciences.

Recent transactions

- Acting for a number of life sciences companies in connection with patent infringement and revocation proceedings involving pharmaceutical molecules, formulations, biologics and medical devices and technologies.
- Advising a number of life sciences companies on intellectual property management strategies including post patent strategies.
- Advising life sciences clients on a broad range of regulatory issues including registration of pharmaceuticals and medical devices and technologies, Pharmaceutical Benefits Scheme reimbursement, promotion of products, compliance with industry codes and product recalls.

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Areas of practice. Pharmaceutical, bioscience and medical technology patent litigation and advice; intellectual property; life sciences.

Recent transactions

- Acting or has acted in a number of Australia's and the United States' leading patent cases, including cases in the Federal Court of Australia, the United States Court of Appeals for the Federal Circuit and the Supreme Court of the United States.
- Advising and acting for, or has advised and acted for, many of the world's leading innovator life sciences companies in patent infringement and revocation litigation, often as a member of a global team working together to resolve complex, multi-jurisdictional patent issues and disputes.
- Advising or has advised numerous Australian and international pharmaceutical, bioscience and medical technology clients in relation to patent issues, including international patent protection strategies and patent portfolio management.

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Qualified. 1992, Victoria; Federal Court and High Court of Australia, 2000

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

Recent transactions

- Advising on structuring distribution arrangements to eliminate risk of breach of cartel provisions, third line forcing and misuse of market power.
- Advising on levels of discounts to customers at which the risk of allegations of predatory pricing, misuse of market power and anti-competitive agreements are triggered.
- Advising on competition issues arising on cross licence arrangements in between competitors in respect of intellectual property rights.

Qualified. 1994, Victoria; Federal Court and High Court of Australia, 2005

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.
- Currently acting for a supplier of a product that has been involved in a widespread product recall arising from fears of a Hepatitis A outbreak.
- Currently acting in Supreme Court of Victoria litigation arising from an AFL club's supplements programme.
- Currently acting in a Supreme Court of Victoria class action arising from the 2014 Mickleham bushfire.
- Recently acted in a Supreme Court of Victoria group proceeding involving more than 200 claims of equitable contribution arising from the manufacture of asbestos products (judgment pending).
- Regularly acting for Australian, US and international companies on product related issues, be they product recalls, other regulatory issues or product liability claims.

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Areas of practice. Pharmaceutical patent litigation; product liability litigation; class actions; pharmaceutical and medical device regulation and compliance; commercial agreements for life sciences companies; contractual disputes.

Recent transactions

- Advising top ten innovator clients in relation to pharmaceutical patent revocation and infringement proceedings in the Federal Court of Australia.
- Advising medical device companies in relation to product registration and regulation, as well as litigation.
- Representing pharmaceutical and medical device clients defending product liability actions.
- Preparing commercial supply and distribution agreements for companies in the life sciences sector.

Qualified. 1994, New South Wales; 1994, the Federal Court and High Court of Australia; 2004, High Court of Hong Kong SAR

Areas of practice. Brands and trade mark clearance, protection, and enforcement

Recent transactions

- Acting for pharmaceutical clients in trade mark clearance matters and brand protection advice.
- Acting for pharmaceutical clients in the prosecution of trade mark applications.
- Contentious trade mark matters including domain name disputes, oppositions, removal actions and infringement matters.

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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 appeal of office proceedings.

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Recent transactions

- Acting in Federal Court and High Court patent infringement and revocation proceedings.
- Acting in Federal Court trade mark infringement proceedings, and oppositions to trade mark registration before the Australian trade marks office.
- Advising on infringement and validity of patents and conducting infringement risk analysis.