International Comparative Legal Guides

Drug & Medical Device Litigation 2026

A practical cross-border resource to inform legal minds

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1 Regulatory Framework

1.1 Please list and describe the principal legislative and regulatory bodies that apply to and/or regulate pharmaceuticals, medical devices, supplements, over-the-counter products, and cosmetics.

The Therapeutic Goods Administration (**TGA**) is the regulatory agency responsible for therapeutic goods in Australia. Therapeutic goods are broadly defined under the *Therapeutic Goods Act 1989* (Cth) (**TG Act**) as products for use in humans in connection with: preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; influencing, inhibiting or modifying a physiological process; testing susceptibility to disease; influencing, controlling or preventing conception; testing for pregnancy; or replacing or modifying an anatomical part. Therapeutic goods include medicines (including prescription, over-the-counter and complementary medicines), biologicals, supplements, vaccines and medical devices. The TG Act requires most therapeutic goods to be registered on the Australian Register of Therapeutic Goods (**ARTG**) before they can be promoted or supplied in Australia. The TG Act is supported by the *Therapeutic Goods Regulations 1990* (Cth) (**TG Regulations**), the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) (**TG MD Regulations**), and various other regulations, orders and determinations.

Cosmetics are only regulated by the TGA if therapeutic claims are made. Otherwise, the chemical ingredients in cosmetics are regulated as industrial chemicals under the *Industrial Chemicals Act 2019* (Cth), which is administered by the Australian Industrial Chemicals Introduction Scheme.

1.2 How do regulations/legislation impact liability for injuries suffered as a result of product use, or other liability arising out of the marketing and sale of the product? Does approval of a product by the regulators provide any protection from liability?

Australia has a largely statutory product liability regime, found within the Australian Consumer Law (**ACL**). In *Peterson v Merck Sharp & Dohme (Australia) Pty Ltd* (2010) 184 FCR 1 (***Vioxx***), the Federal Court of Australia considered whether the TGA's approval of the anti-arthritic prescription medicine Vioxx provided the companies with any protection from liability. In that decision, the Court found that compliance with the TGA requirements was not sufficient to discharge a company's duty of care, and found no basis in the TG Act to support such an argument. The Court was also hesitant to accept compliance with the TGA approval system as a relevant factor in determining whether a company had discharged its duty of care, since to do so would mean that a manufacturer could never be held to have fallen short in the discharge of its duty of care. Approval was also not a sufficient defence to statutory claims under the former *Trade Practices Act* (the precursor to the ACL), which relates to misleading and deceptive conduct and the requirement that consumer goods be fit for purpose and of merchantable quality. In short, Australia does not recognise a U.S.-style defence of pre-emption.

1.3 What other general impact does the regulation of life sciences products have on litigation involving such products?

While statutory approval is not a complete defence to litigation, it is relevant to the standard of care and to an assessment of a safety defect or whether a product is of acceptable quality. Under the Australian statutory product liability regime, a product cannot be defective purely because of its compliance with a mandatory standard. Therefore, to the extent that the regulations impose specific requirements, compliance with these requirements cannot found an allegation of defect. However, regulatory action in relation to a life sciences product (for example, a recall, product alert or product correction) may be a trigger for plaintiff lawyers to investigate and potentially commence litigation. Further, in the past, Parliamentary reviews of the TG Regulations have played an important part in product liability litigation; for example, in the transvaginal mesh litigation and the ASR prosthetic hip litigation.

1.4 Are there any self-regulatory bodies that govern drugs, medical devices, supplements, OTC products, or cosmetics in the jurisdiction? How do their codes of conduct or other guidelines affect litigation and liability?

Self-regulation of promotional activities is a critical part of the Australian regulatory regime. Several industry bodies have developed codes and guidelines that regulate the manner in which their members may promote their products and interact with healthcare practitioners and the general public. Industry peak bodies that have such codes include:

- Medicines Australia: the Medicines Australia Code of Conduct (**MACC**) in respect of prescription medicines (edition 20 came into effect on 30 March 2025);
- the Medical Technology Association of Australia: the Medical Technology Industry Code of Practice (**MTIC**)

in respect of medical devices (edition 13 was released in January 2023);
- the Generic and Biosimilar Medicines Association (**GBMA**): the GBMA Code of Practice in respect of generic medicines (edition 5 was released in June 2021); and
- Pathology Technology Australia: the Pathology Technology Industry Code of Practice in respect of *in vitro* diagnostic medical devices (**IVDs**) (edition 4 was released in December 2021).

1.5 Are life sciences companies required to provide warnings of the risks of their products directly to the consumer, or to the prescribing physician (i.e., learned intermediary), and how do such requirements affect litigation concerning the product?

Yes. At common law, life sciences companies are required to take reasonable steps to ensure that consumers are warned of foreseeable risks associated with the use of their products. Failure to do so may lead to a claim of negligence against the company. A failure to warn consumers that a product has a defect, is of unacceptable quality or is otherwise unfit for purpose may result in a claim against the company pursuant to the ACL. There is no express authority for the learned intermediary principle, and it has not been widely considered. The defence was raised before the Court at first instance in *Vioxx* (see question 1.2), which was unwilling to apply it as it considered the defence too categorical an articulation of the duty of a therapeutic good manufacturer. The Court opined that the defence assumed that a physician is best equipped to receive a warning from the drug supplier and does not contemplate other situations in which a manufacturer's duty to take reasonable care may not be sufficiently discharged. In considering the appeal in the vaginal mesh litigation (*Ethicon Sàrl v Gill* [2021] FCAFC 29), the Full Federal Court of Australia held that in assessing whether a product was defective for the purposes of the ACL and for claims in negligence, the relevant question was whether a manufacturer of the device will furnish doctors with sufficient information, advice and warnings to permit a balanced, cautious and informed judgment to be made by the doctor and an informed choice by the patient. This finding was recently cited in the Supreme Court of Victoria's decision in the *Bayer Essure* class action (*Turner v Bayer Australia Ltd* [2024] VSC 760), which held that, in that case, product information and warnings supplied through "learned intermediaries" were sufficient to inform consumers of potential risks.

2 Manufacturing

2.1 What are the local licensing requirements for life sciences manufacturers?

Australian manufacturers of therapeutic goods other than medical devices must hold a manufacturing licence issued by the TGA, and, in certain cases, a wholesaler's licence issued by the Department of Health of the state or territory where their manufacturing premises are located.

Before therapeutic goods manufactured overseas can be sold in Australia, their manufacturers must obtain either a Good Manufacturing Practice (**GMP**) clearance or a GMP certification from the TGA. A GMP clearance typically applies where there are mutual recognition arrangements with the manufacturer's local regulator.

Australian and overseas manufacturers of medical devices must hold evidence that a device has undergone an appropriate conformity assessment procedure before it can be included in the ARTG. For devices that contain medicines or materials of animal, microbial, recombinant or human origin, and Class 4 IVDs, the TGA will accept conformity assessment evidence issued by the TGA, Australian Conformity Assessment Bodies and comparable overseas regulators and assessment bodies, including EU notified bodies, United States FDA, Health Canada, Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency and Singapore's Health Sciences Authority.

The TGA is currently conducting a review of the Australian medical device regulations. Among other things, this review is considering how to improve the process by which new devices are brought to market.

2.2 What agreements do local regulators have with foreign regulators (e.g., with the U.S. Food and Drug Administration or the European Medicines Agency) that relate to the inspection and approval of manufacturing facilities?

The TGA has various international agreements and arrangements with foreign regulatory authorities. Some of these allow member countries to rely on each other's GMP inspection programmes, including many of the medicines regulatory authorities of the EU Member States and the U.S. FDA under the Pharmaceutical Inspection Cooperation Scheme. There are also information-sharing agreements in place with other major international regulators.

2.3 What is the impact of manufacturing requirements or violations thereof on liability and litigation?

In an action under the ACL relating to a safety defect, a manufacturer can claim in its defence that the defect only existed because the manufacturer had complied with a mandatory standard pursuant to section 142(b) of the ACL. If this defence is made out, the Commonwealth may have to compensate the claimant.

If a manufacturer fails to comply with manufacturing requirements, it could give rise to liability under the ACL and common law.

3 Transactions

3.1 Please identify and describe any approvals required from local regulators for life sciences mergers/acquisitions.

Life sciences companies are subject to the same laws regulating mergers and acquisitions as other industries in Australia. There are no additional approval requirements for life sciences products.

A new merger regime came into effect on 1 January 2026, and imposes statutory obligations on certain mergers and acquisitions in Australia. The new regime established the Australian Competition and Consumer Commission (**ACCC**) as the primary decision maker on all transactions above a prescribed threshold. Notification is now mandatory for acquisitions of shares or assets that are *connected with* Australia and that meet prescribed financial notification thresholds (based on revenue and transaction value). When assessing mergers, the ACCC will consider industry-specific competitive dynamics, such as

losses of dynamic competition in life sciences markets where significant and long-term investments in research and development are required to reach scale.

3.2 What, if any, restrictions does the jurisdiction place on foreign ownership of life sciences companies or manufacturing facilities? How do such restrictions affect liability for injuries caused by use of a life sciences product?

Australia has a foreign investment approval regime that regulates foreign investment in Australia. The regime (commonly known as the FIRB regime) applies to "foreign persons", including corporations looking to invest in Australian land or entities, including life sciences companies and manufacturing facilities. The Australian Treasurer is advised by the Foreign Investment Review Board (**FIRB**), a non-statutory body, and may decide to prohibit a foreign investment in a life sciences company if it would be contrary to the national interest. The Treasurer may also apply conditions to safeguard national interests. The FIRB regime also imposes civil and criminal penalties for proceeding with a transaction that is a "significant action" or a "notifiable action", unless and until the FIRB provides a statement of no objection. Foreign persons proposing to invest in a manufacturer of essential medicines or medical devices are encouraged by the FIRB to voluntarily seek foreign investment approval. Essential medicines include those that are listed in the Pharmaceutical Benefits Scheme (**PBS**), and essential medical devices include the manufacture of personal protective equipment and diagnostic equipment, pacemakers and prosthetics.

4 Advertising, Promotion and Sales

4.1 Please identify and describe the principal legislation and regulations, and any regulatory bodies, that govern the advertising, promotion and sale of drugs and medical devices, and other life sciences products.

The advertising, promotion and sale of life sciences products in Australia is governed by the TG Act and the TG Regulations. The TGA is the primary regulator. The TGA also administers and enforces the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (Cth) (**TGAC**), which generally applies to the advertisement of therapeutic goods to consumers, but not to healthcare professionals or as part of a public health campaign. Under the TGAC, "advertise" means any statement, pictorial representation or design that is intended, directly or indirectly, to promote the goods, including on the label, packaging or other material accompanying the goods. In practice, this definition is applied broadly. The advertising of these products is also governed by the *Competition and Consumer Act 2010* (Cth) including the ACL and subordinate legislation, which regulates the advertisement of consumer goods generally. The ACCC administers these instruments. Further, as described above, there are a number of industry bodies that self-regulate promotional activities for specific industry sectors, and some of these industry codes have mandatory effect as a condition of registration on the ARTG.

Prescription medicines can only be advertised to healthcare professionals. Such advertisement is regulated by the MACC and supporting guidelines. It is an offence to advertise prescription medicines to consumers. Compliance with the MACC is often a condition of a prescription medicine's listing. The advertisement of medical devices is governed by the TGAC and MTIC (see question 1.4).

4.2 What restrictions are there on the promotion of drugs and medical devices for indications or uses that have not been approved by the governing regulatory authority ("off-label promotion")?

Off-label promotion is generally prohibited. The TG Act imposes a general prohibition against the advertisement of therapeutic goods that have not been included in the ARTG (for that intended purpose). This prohibition does not apply to advertisements directed exclusively at healthcare professionals, wholesalers of therapeutic goods and purchasing officers at hospitals and certain other healthcare organisations, although this exemption does not override the specific statutory prohibitions on advertising (see below). Any communications that are exclusive to such groups also must comply with the various industry codes that regulate interactions between medical device companies and healthcare professionals.

There is also a separate provision in the TG Act that makes it an offence to advertise a medicine (but not a medical device) for an indication that is not an approved indication on the ARTG.

The MACC allows medical company personnel to provide information on unapproved medicines or indications to healthcare professionals only in response to an unsolicited request. Companies that invite healthcare professionals to speak at a sponsored event must ensure that the professional is familiar with the product's approved indications and with the obligation not to advertise unapproved products or indications. Companies must be able to provide documentary evidence of this briefing. In digital medical information applications, the MACC allows information regarding unapproved medicines and uses to be provided to healthcare professionals only if they execute a search using specific search terms related to the medicine, and through secure, password-protected platforms.

Similarly, there is nothing in the MTIC that prohibits the advertising of unapproved medical devices or uses to healthcare professionals or otherwise delivering information to healthcare professionals about pre-approval medical devices. However, any such communications to healthcare professionals must comply with the principles and requirements set out in the MTIC.

4.3 What is the impact of the regulation of the advertising, promotion and sale of drugs and medical devices on litigation concerning life sciences products?

The existence of self-regulation and complaints mechanisms under the industry codes means that company disputes rarely end in litigation. The ACL protects consumers from advertising that is misleading and deceptive (see question 1.2) and allows for contracts entered into as a result of the misleading advertising to be set aside, or for damages to be awarded. Liability for advertising that breaches a statutory guarantee is strict.

The TGA continues to remain active in pursuing action against companies and persons who breach the TG Act and TGAC, and there have been multiple actions in recent years that have led to significant penalties being ordered against companies and individuals for breaches of the mandatory rules for advertising and sale of medicines, including the ban on advertising prescription-only medicines to the public and prohibitions of misleading claims. Notably, in 2024 the Federal Court

of Australia imposed the largest penalty for contravention of the TG Act, ordering Medtronic Australasia Pty Ltd to pay a civil penalty of AU$22 million for supplying a medical device while it was not included on the ARTG. In 2026, an individual was sentenced to a seven-month prison term (released on conditions including good behaviour), community corrections order and fines for unlawfully advertising and supplying black salve and bloodroot capsules and other unapproved therapeutic goods.

5 Data Privacy

5.1 How do life sciences companies that distribute their products globally comply with data privacy standards such as GDPR and other similar standards?

The GDPR does not have any direct application in Australia. Rather, data privacy in Australia is primarily regulated by the *Privacy Act 1988* (Cth) (including the Australian Privacy Principles and the Notifiable Data Breaches Scheme contained in the Act), as well as certain state legislation, including legislation that deals specifically with health information.

Most medium and large businesses, and many small businesses, that carry on business in Australia are required to comply with the *Privacy Act*. There are significant penalties for serious or repeated breaches of the *Privacy Act*. The Australian Information and Privacy Commissioner has powers to request and share information, including with foreign privacy authorities. The *Privacy Act* underwent significant changes introduced in 2024 by the *Privacy and Other Legislation Amendment Act 2024* (Cth), including the introduction of anti-doxxing measures, a new statutory tort for serious invasions of privacy, and expanded investigative and monitoring powers of the Information Commissioner. From 10 December 2026, businesses are required to update their privacy policies to disclose when personal information is used in wholly or substantially automated processes that could significantly affect an individual's rights or interests. A further stage of privacy reforms is expected in the next 12 months.

With regard to Australian companies operating abroad, while we are not experts in European law, we do understand that Australian life sciences companies that distribute or advertise their products in the EU are required to appoint a representative in an EU Member State, subject to a number of exceptions.

5.2 What rules govern the confidentiality of documents produced in litigation? What, if any, restrictions are there on a company's ability to maintain the confidentiality of documents and information produced in litigation?

When ordered to produce documents concerning a particular issue in the litigation (via discovery or subpoena), a company must produce all responsive documents in its possession, custody or control, save for documents subject to privilege. This includes production of confidential documents. Parties often enter into an agreement limiting access to confidential documents to certain persons (for example, lawyers and experts). However, if the documents so produced are later tendered into evidence in the litigation, it can be very difficult to maintain confidentiality over them and a Court order is required.

Parties to litigation compelled to produce documents also have the protection of the *Harman* obligation, a common law doctrine that prevents the parties, without leave of the Court, from using documents produced on compulsion for any other purpose than that for which the documents were produced, unless and until the documents are received into evidence.

5.3 What are the key regulatory considerations and developments in Digital Health and their impact, if any, on litigation?

The TGA regulates digital health products under its existing regulatory framework, with the TG Act defining "medical devices" to include some digital health devices, such as diagnostic software. The regulation of medical devices, including software as a medical device (**SaMD**), is based on the risk the device poses to patients or healthcare professionals. Similar to other medical devices, unless excluded, SaMDs must be included on the ARTG before they can be supplied in Australia. However, the TG MD Regulations and associated legislative instruments and TGA guidance exclude certain types of software from the medical device regime, such as consumer products aimed at maintaining general health and well-being, and clarify the classification rules for software. These rules may indirectly affect litigation, particularly where they exclude certain products from the therapeutic goods framework, potentially classifying them as "consumer products" instead. Regulatory bodies, including the ACCC and TGA, continue to assess the impact of digital health technologies, such as artificial intelligence (**AI**), on competition, consumer protection, and potential misuse. Under Australia's therapeutic goods regime, AI-based software is generally regulated as a medical device where it is intended to be used for:

- diagnosis, prevention, monitoring, prediction, prognosis, or treatment of a disease, injury, or disability;
- alleviation of, or compensation for, an injury or disability;
- investigation of anatomy or physiological processes; or
- control or support of conception.

Under the *My Health Records Act 2012* (Cth), healthcare provider organisations and the Australian Digital Health Agency have mandatory notification obligations in relation to data breaches involving My Health Record information where the breach has caused, or is likely to cause, serious harm. Certain clinical decision support system (**CDSS**) software is exempt from specific regulatory requirements. Non-compliance with the *My Health Records Act* or *Privacy Act* can result in civil penalties for serious breaches, while minor breaches may avoid penalties if corrective actions are taken and cooperation is demonstrated.

6 Clinical Trials and Compassionate Use Programmes

6.1 Please identify and describe the regulatory standards, guidelines, or rules that govern how clinical testing is conducted in the jurisdiction, and their impact on litigation involving injuries associated with the use of the product.

Therapeutic goods must not be supplied in Australia unless they are registered on the ARTG or are subject to an exemption. Clinical trials involving unapproved therapeutic goods (including unapproved indications) are subject to the Clinical Trial Notification (**CTN**) or the Clinical Trial Approval (**CTA**) schemes, both of which enable sponsors to obtain from the TGA an exemption from the general registration requirement.

The CTN Scheme is a notification process generally used for therapeutic goods for which there is adequate preclinical

information available. The sponsor must notify the TGA of the proposed testing. The testing protocol is then reviewed by a Human Research Ethics Committee (**HREC**). Absent further action from the TGA, notification of the TGA and approval by an HREC is sufficient for an exemption to apply.

The CTA Scheme is an evaluation process and involves a review of limited, scientific data prior to the start of a trial. The process is generally used for novel treatments where there is limited preclinical information available, or where the treatment itself is high risk. The CTA Scheme involves an application to the TGA that must receive TGA approval. If approved, the proposed trial is then reviewed by a HREC. For both the CTN or CTA Schemes, the institution or organisation at which the trial will be conducted gives the final authorisation for the conduct of the trial at the site, following approval by the reviewing HREC.

The conduct of clinical trials is also subject to certain guidelines; in particular, the *Guidance on Good Clinical Practice*, the *National Statement on Ethical Conduct in Human Research* and the *Australian Code for the Responsible Conduct of Research*. The *National Statement on Ethical Conduct in Human Research* is the national ethical standard against which all tests involving humans, including clinical tests, must be reviewed, and builds upon the *Helsinki Declaration*. The *Guidance on Good Clinical Practice* is an international ethical and scientific standard for the conduct of clinical trials, which has been adopted by the TGA with some modification.

Almost universally, HREC approval for a clinical trial will not be given unless the trial sponsor has agreed to indemnify participants in the trial, and the investigations and institution are in accordance with a standard form of indemnity.

Product liability litigation in Australia will typically involve careful scrutiny of the results of clinical trials to determine whether they included a signal that ought to have resulted in the sponsor acting differently. However, because Australia does not have a doctrine of pre-emption, less attention is paid to the regulatory consequences of clinical trial data than in some other jurisdictions.

6.2 Does the jurisdiction recognise liability for failure to test in certain patient populations (e.g., can a company be found negligent for failure to test in a particular patient population)?

There is very little specific law on this topic in Australia. Certainly, representing that a product is suitable for use in certain populations if the data does not support that conclusion could give rise to liability under Australian law. However, the outcome in *Vioxx* (see question 1.2) suggests that a company cannot be found negligent for failure to test for "undiscoverable" flaws in prescription medicines.

6.3 Does the jurisdiction permit the compassionate use of unapproved drugs or medical devices, and what requirements or regulations govern compassionate use programmes?

Yes. Australia's Special Access Scheme (**SAS**) provides for the importation or supply of unapproved therapeutic goods to an individual patient in some circumstances. The SAS is intended for exceptional clinical circumstances, considered on a case-by-case basis. Healthcare practitioners are expected to have exhausted all available treatment options on the ARTG before making an SAS application.

A healthcare practitioner may access unapproved therapeutic goods through three pathways:

- Category A is a notification pathway for seriously ill patients with life-threatening diseases. A health practitioner's decision that the use of the product is appropriate triggers an exemption. Prior approval from the TGA is not required to access the Category A pathway.
- Category B is for patients who do not fall into Category A or C. Category B applications must be reviewed and approved by the TGA.
- Category C is a notification pathway for healthcare practitioners to access certain goods that are not on the ARTG but have an established history of use for a particular indication. These therapeutic goods are then included on published legislative instruments for specific indications and types of health practitioners. Prior approval from the TGA is not required to access the Category C pathway. However, the pathway cannot be used if the product, indication and/or type of health practitioner do not match those listed in the legislative instrument.

In certain circumstances, a medical practitioner may become an authorised prescriber of a specified unapproved therapeutic good, or a class thereof, for a particular condition or class of patients in their immediate care.

6.4 Are waivers of liability typically utilised with physicians and/or patients and enforced?

Waivers are sometimes used in the context of supplying unapproved goods, but are of limited utility because it is not possible to waive liability for causes of action arising under the ACL. It is more effective to provide patients with a detailed informed consent form detailing the known risks of the product as well as the risks inherent in an unapproved use, and ask patients to acknowledge that they are aware of and have accepted these risks.

6.5 Is there any regulatory or other guidance companies can follow to insulate or protect themselves from liability when proceeding with such programmes?

The TGA has published guidance for health practitioners and sponsors involved in providing patients with access to unapproved therapeutic goods through the SAS (see question 6.3). The guidance published by the TGA is regularly updated but only provides health practitioners and sponsors with an overview of the scheme.

7 Product Recalls

7.1 Please identify and describe the regulatory framework for product recalls, the standards for recall, and the involvement of any regulatory body.

Therapeutic good recalls are primarily coordinated via the specialist regulator; the TGA (see question 7.2). More generally, for consumer goods such as cosmetics, product recalls are regulated by the ACCC under the ACL. The ACL imposes duties on suppliers to notify consumers and the regulator of voluntary recalls, and gives the government the power to order compulsory product recalls in the rare case that the regulator is of the opinion that the supplier has not taken satisfactory steps in its voluntary recall action. In the absence of statutory criteria, a supplier's decision to undertake a voluntary

recall is based on common law duties. A supplier's duty of care may extend to recalling products with an identifiable safety-related defect.

The ACCC issues product safety recall guidelines to assist suppliers conducting a recall in accordance with the ACL.

Statutory obligations are triggered only once a supplier initiates a recall. Suppliers must notify consumers of a recall where the product may cause injury, where it is unlikely to meet a mandatory safety standard, or where it is subject to a ban. The ACL requires that the government (in practice, the ACCC) be notified of any recall action within two business days of it being commenced. For certain types of products, other regulators may need to be notified of any recall, and each regulator may impose specific recall obligations on suppliers. This information is provided by Product Safety Australia. The TGA must be notified of product recalls relating to drugs or medical devices.

7.2 What, if any, differences are there between drugs and medical devices or other life sciences products in the regulatory scheme for product recalls?

The recall of therapeutic goods is coordinated by the TGA. From 5 March 2025, the Uniform Recall Procedure for Therapeutic Goods (**URPTG**) was replaced by the Procedure for Recalls, Product Alerts and Product Corrections (**PRAC**), with the aim of reducing regulatory complexity and improving efficiency in corrective actions for medicines, biologicals, and medical devices in Australia. Key changes introduced by the PRAC include updating recall terminology (e.g., replacing the categories of "recall" and "non-recall" actions with a single category of "market actions") and reducing the recall process steps from 10 to five.

While this document is not law, in practice it is the framework for any recall action relating to therapeutic goods. It provides for early engagement with the TGA about any proposed recall action and consultation before the recall is initiated. Under the PRAC, there are four types of market actions that sponsors of these products may take: recalls; product corrections (including relabelling); product alerts; and quarantines.

7.3 How do product recalls affect litigation and government action concerning the product?

While a recall will increase the risk of litigation and regulatory investigation, the vast majority of recalls do not result in any follow-on action of this sort. In litigation, the publication of a product recall notice is not in itself an admission of liability, provided it does not contain words to that effect.

7.4 To what extent do recalls in the United States or Europe have an impact on recall decisions and/or litigation in the jurisdiction?

Recalls of internationally distributed products in other jurisdictions may trigger a recall of those products in Australia. Australian regulators are often proactive in seeking information from local sponsors. The TGA regularly receives information about recalls of therapeutic goods overseas by agencies such as the FDA and the EMA. If a product that is the subject of an overseas recall is entered on the ARTG or has otherwise been imported and distributed in Australia, the TGA will assess whether the importer will be required to recall the products in Australia.

If recall action is taken in relation to products that are also "consumer goods", there is also a requirement to notify the ACCC of the recall action within 48 hours (see question 7.6 below).

7.5 What protections does the jurisdiction have for internal investigations or risk assessments?

There are few protections for internal investigations or risk assessments, except for a legitimate claim of legal professional privilege (**LLP**) over the relevant material. Natural persons (but not corporations), if compelled to give evidence, may also claim privilege against self-incrimination, but this privilege does not protect that individual from a notice issued to a third party.

7.6 Are there steps companies should take when conducting a product recall to protect themselves from litigation and liability?

Manufacturers owe a continuing duty to consumers to take reasonable care to prevent a defective product from causing harm. Failure to recall defective products may amount to negligence if the company is aware of the defect (or ought reasonably to be aware) and a person is harmed as a result of using the product. The ACCC provides guidance on the content of recall communications for consumer goods. The recall notice should include a product description, a picture of the product, a description of the defect or why the product is being recalled, a statement of the hazard and how it could lead to injuries, and a list of immediate actions the consumer should take, and should provide the contact details for assistance with accessing a refund or having the product repaired or replaced. Any recall notice for consumer goods should be submitted to the ACCC for comment prior to publishing. A supplier must also notify the Minister within 48 hours of initiating a recall. Failure to do so is unlawful. A supplier who fails to comply with a compulsory recall notice may be found guilty of a criminal offence. More generally, recall communications should be carefully reviewed to ensure that accurate information is provided but that admissions are not made improperly.

8 Litigation and Dispute Resolution

8.1 Please describe any forms of aggregate litigation that are permitted (i.e., mass tort, class actions) and the standards for such aggregate litigation.

Class actions are available under Part IVA of the *Federal Court of Australia Act 1976* (Cth) and similar class action regimes have since been enacted in New South Wales, Victoria, Queensland, Western Australia and Tasmania. The procedure is substantially the same in each jurisdiction and permits a class action to be commenced if:

a) there are seven or more persons who have claims against the same defendant or defendants;
b) the claims arise out of similar or related circumstances; and
c) the claims give rise to a substantial common issue of fact or law.

There is no requirement that every class member must have a claim against every defendant. Nor is there any certification requirement.

These regimes operate alongside various provisions that permit multi-party claims and, in certain circumstances,

claims brought by regulators seeking declaratory relief or redress for individuals.

8.2 Are personal injury/product liability claims brought as individual plaintiff lawsuits, as class actions or otherwise?

Personal injury or product liability claims can be brought as individual lawsuits and in class actions through the mechanisms outlined in question 8.1.

8.3 What are the standards for claims seeking to recover for injuries as a result of use of a life sciences product? (a) Does the jurisdiction permit product liability claims? (b) Are strict liability claims recognised?

Generally, product liability claims resulting in injury will be based on negligence and breaches of the ACL. In claims based on negligence, a claimant must prove, on the balance of probabilities, that the manufacturer owed them a duty of care, that that duty of care was breached, and that the breach caused the claimant's injury. The ACL contains a number of statutory consumer guarantees relating to defective products that operate as "strict liability" provisions, and a regime for liability for "safety defects" closely modelled on the 1985 European Product Liability Directive. Claimants need only prove that, on the balance of probabilities, the product has a safety defect, that the product was not fit for purpose or was not of acceptable quality and that this caused their loss.

8.4 Are there any restrictions on lawyer solicitation of plaintiffs for litigation?

There are few restrictions on lawyer solicitation of plaintiffs. In NSW, the Solicitors' Conduct Rules require solicitors to ensure that any advertising of their services is not false, misleading or deceptive, offensive or otherwise prohibited by law. Solicitors must also not seek instructions in a manner likely to oppress or harass a person.

In class actions, notice must be given to class members, enabling them to opt out of proceedings. Opt-out notices are generally given by way of newspaper advertisements and, more recently, through publication online and on social media platforms. Direct notification is also used where possible. The form of an opt-out notice must be approved by the Court, and the Court will exercise a supervisory jurisdiction over communications with group members who are not clients of the law firms in question.

In the pacemaker class action proceedings of *Courtney v Medtel Pty Ltd* (2002) 122 FCR 168, the Federal Court of Australia accepted that there was nothing in the law preventing respondents from communicating with group members, provided that such communication "does not infringe any other law or ethical constraint (such as a professional conduct rule)". The same principle would presumably apply to communications to group members by plaintiffs' lawyers. A number of Courts have practice notes, which seek to control communications to group members by defendants' lawyers. Those restrictions do not apply to the plaintiffs' lawyers.

8.5 What forms of litigation funding are permitted/utilised? What, if any, regulation of litigation funding exists?

Australia has an active commercial litigation funding industry. Commercial litigation funders can enter into funding agreements pursuant to which the funder agrees to pay the cost of the litigation in exchange for a percentage of any amount received by the claimants. The use of litigation funding has steadily increased since 2006 when the High Court held it was not an abuse of process, but the law in this area – especially in class actions – is fast developing.

In late 2022, the requirement (which was only introduced in 2020) for litigation funders to hold an Australian Financial Services licence was removed. In 2020, legislative amendments were made in one Australian jurisdiction (Victoria) to permit the Court to approve contingency fees arrangements for lawyers in class actions, which has seen the Victorian Supreme Court emerge as the class action forum of choice. In 2023, the Full Federal Court confirmed that the Federal Court has the power to make a common fund order (**CFO**) when approving settlement, which requires all group members to contribute to a litigation funders' commission, regardless of whether they signed up to a funding agreement. This decision has brought greater certainty to parties and litigation funders alike.

In 2024, the Full Federal Court endorsed a contingency fee arrangement for lawyers, similar to the regime in Victoria, but styled as a "solicitor CFO". This arrangement requires all group members to pay a percentage of the settlement or judgment sum to the plaintiffs' law firm (rather than a litigation funder) as payment for the firm's costs and disbursements in relation to the class action. In 2025, the High Court confirmed that the Federal Court does have the power to make a CFO or funding equalisation order (**FEO**) for the benefit of third-party funders at a late stage of a class action, but does not have the power to make a CFO for the benefit of solicitors in the absence of express legislative authority.

An FEO requires unfunded group members to contribute to the total commission payable by the funded group members, so all group members contribute equally to that commission amount.

The decision affirms the existing Australian litigation funding landscape; while Federal and relevant State Courts can make CFOs for the benefit of third-party funders at the time of settlement or judgment, Victoria remains the only jurisdiction where contingency fees are available for plaintiff firms thanks to specific state-based legislation. As a result, the Victorian Supreme Court remains an appealing jurisdiction for class action plaintiffs due to its unique allowance of contingency fee arrangements.

8.6 What is the preclusive effect on subsequent cases of a finding of liability in one case? If a company is found liable in one case, is that finding considered *res judicata* in subsequent cases?

There are three related concepts in Australian law. *Res judicata* means that once a claim by one party against another is determined, the claim merges in the judgment and cannot be litigated again. *Issue estoppel* is broader and prohibits relitigating an issue of fact or law that has been finally determined as between the parties in question. *Anshun estoppel* is broader still, and prohibits a party from raising issues in litigation that they could and should have raised in earlier litigation.

Each of these doctrines only operates in litigation involving the same parties or persons claiming through them. They do not prevent a defendant from raising a defence to a claim by B that had been unsuccessfully raised in a claim by A.

8.7 What are the evidentiary requirements for admissibility of steps a company takes to improve their product or correct product deficiency (subsequent remedial measures)? How is evidence of such measures utilised in litigation?

For such evidence to be admissible, it must be relevant to a fact in issue in the proceedings, and must not be excluded by an exclusionary rule of evidence, including the opinion rule and the hearsay rule. However, the business records rule creates an exception to the hearsay rule in respect of business records that are kept by a company in the course of, or for the purpose of, its business, insofar as they contain representations made by a person with personal knowledge of the asserted facts. As a result, documents obtained on discovery that record a company's processes will usually be admitted into evidence if relevant. Plaintiffs' lawyers often rely on documents created in the context of remedial action as admissions of prior negligence or breach of relevant legal standards.

8.8 What are the evidentiary requirements for admissibility of adverse events allegedly experienced by product users other than the plaintiff? Are such events discoverable in civil litigation?

Life sciences companies usually keep an adverse events database, portions of which are likely to be discoverable in litigation. Further, the business records rule (discussed above) would likely enable any such database to be admitted into evidence. Whether such evidence will be given weight depends upon the issue in the litigation to which the evidence is said to be relevant.

8.9 Depositions: What are the rules for conducting depositions of company witnesses located in the jurisdiction for use in litigation pending outside the jurisdiction? For example, are there "blocking" statutes that would prevent the deposition from being conducted in or out of the jurisdiction? Can the company produce witnesses for deposition voluntarily, and what are the strategic considerations for asking an employee to appear for deposition? Are parties required to go through the Hague Convention to obtain testimony?

Depositions are not part of Australian litigation practice. However, there are no blocking statutes that prevent the taking of evidence in Australia for the purpose of foreign proceedings. The *Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters* is the usual mechanism to obtain such evidence. A party to foreign proceedings may ask their Court to issue a letter of request to an Australian Court. The letter of request must comply with the domestic rules of the relevant Court for taking evidence. State and Territory Supreme Courts may make an order giving effect to such letters of request. This power is discretionary, but the Australian Court will generally make an order if it is satisfied that the domestic procedural requirements were followed and the request is made for a legitimate purpose. The Court then issues a subpoena requiring the individual to attend and give evidence. Witness examination is conducted in the manner prescribed for taking evidence outside of trial in the relevant Australian jurisdiction.

8.10 How does the jurisdiction recognise and apply the attorney-client privilege in the context of litigation, and with respect to in-house counsel?

Australia recognises and applies LPP in litigation and regulatory investigations. Several cases have considered the application of LPP to in-house counsel. For a communication to attract LPP, it must have been made in the in-house lawyer's capacity as a lawyer, and not some other capacity, have been made for the dominant purpose of giving or receiving legal advice or for use in actual or anticipated litigation, and must otherwise comply with the requirements to establish LPP.

8.11 Are there steps companies can take to best protect the confidentiality of communications with counsel in the jurisdiction and communications with counsel outside the jurisdiction for purposes of litigation?

In order for a communication to attract privilege under Australian law, it must be a:

a) confidential communication between the client and the person or between a lawyer acting for the client and the other person; or
b) confidential document that was prepared for the dominant purpose of the client being provided with legal services in relation to the litigation.

The best way to protect such communications is to ensure that they remain confidential by limiting distribution on a need-to-know basis and to make the privileged purpose of the communication clear on the face of the document.

It is also possible for privilege in a document to be waived if the document is disclosed in a way that is incompatible with the retention of confidentiality over that material. Since privilege over confidential material may be waived inadvertently, companies should be judicious about the distribution of material.

8.12 What limitations does the jurisdiction recognise on suits against foreign defendants?

The suit must satisfy the requirements of the rules of the relevant Court for invoking the jurisdiction of the Court, in respect of an issue outside its jurisdiction. However, since one ground to invoking such jurisdiction is that there is a tortious claim in respect of which damage has been suffered in Australia, there is seldom a question about this. The jurisdiction of the Court is not invoked until the originating process is properly served on the foreign defendant. Each jurisdiction has its own requirements for the service on foreign defendants.

8.13 What is the impact of U.S. litigation on "follow-on" litigation in your jurisdiction?

"Copy cat" or "follow on" class actions are increasingly common in Australia, with plaintiff class action firms and litigation funders closely following U.S. litigation and assessing whether to bring a similar claim in Australia.

There is some concern for the use of documents obtained in U.S. regulatory proceedings to be used as the fruits for "follow-on" claims in Australia. Both U.S. and Australian laws

permit the adverse findings in public enforcement proceedings to be used to establish the same facts in follow-on litigation. *Bray v F Hoffmann-La Roche Ltd* [2003] FCAFC 153 involved a class action that "followed on" from pecuniary penalty proceedings in Australia and the U.S. against the respondent group of companies.

8.14 What is the likelihood of litigation evolving in your jurisdiction as a result of U.S. litigation?

As noted above, there have been many instances of "copycat" litigation, in which class actions were brought that mirror proceedings commenced in the U.S. given the relatively developed plaintiffs' bar, availability of litigation funding and low barriers to commencement of a class action in Australia.

8.15 For EU jurisdictions, please describe the status and anticipated impact of the Collective Redress Directive and Product Liability Directive on drug and medical device litigation in your jurisdiction.

This is not applicable for Australia.

Greg Williams is internationally recognised as an experienced litigation lawyer, with particular expertise providing regulatory and litigation advice to pharmaceutical and medical device companies. Greg's expertise encompasses the whole product life cycle, including registration, reimbursement, advertising disputes, and product safety and recalls. He is particularly skilled in providing strategic advice on pricing and reimbursement issues, successfully guiding clients through challenging Australian reimbursement applications. Greg also defends product liability claims and class actions, having represented several high-profile cases. Greg is also recognised by numerous directories, including *Chambers Asia-Pacific* as Band 1 for Life Sciences and by *Who's Who Legal* as a Thought Leader in Life Sciences Product Liability.

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