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Medical Devices & Consumer Health Products 2022

Australia: Law & Practice
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Australia: Trends & Developments
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AUSTRALIA

Law and Practice

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1. APPLICABLE PRODUCT SAFETY REGULATORY REGIMES

1.1 Medical Devices

All products that are considered therapeutic goods in Australia are regulated under the Therapeutic Goods Act 1989 Cth (TG Act) as well as the Therapeutic Goods Regulations (TG Regulations) and the Therapeutic Goods (Medical Devices) Regulations (Device Regulations). All therapeutic goods must be registered on the Australian Register of Therapeutic Goods (ARTG). This legislation and the administration of the ARTG are enforced by the Therapeutic Goods Administration (TGA).

Medical Devices

Medical devices are considered therapeutic goods and are governed by Chapter 4 of the TG Act. Product safety for medical devices is covered in the TG Act's "essential principles", set out in Part 4-2. Any medical devices that are also consumer goods will also be subject to the broader product safety requirements in the Australian Consumer Law (ACL), contained at Schedule 2 of the Competition and Consumer Act 2002 (Cth) (CC Act). These laws are administered by the Australian Competition and Consumer Commission (ACCC).

Pharmaceuticals and Blood Products

Pharmaceuticals and blood products are also considered therapeutic goods under the TG Act and are regulated accordingly.

Personal Protective Equipment

Items of personal protective equipment such as aprons, face masks, gloves, goggles, gowns and visors that are intended to be used for the prevention of the transmission of disease, including in surgical, clinical and consumer settings, will be considered medical devices under the TG Act and are regulated as therapeutic goods in Australia.

Medical Instruments

Medical instruments are classified as medical devices under Chapter 4 of the TG Act and will therefore be regulated as therapeutic goods.

1.2 Healthcare Products

Cosmetics, biocides and nutritional supplements are regulated across various regimes.

Cosmetics

Cosmetic ingredients in Australia are regulated under the Industrial Chemicals Act 2019 (Cth) which regulates the chemicals used in cosmetics. Since 1 July 2020, this scheme has been administered by the Australian Industrial Chemicals Introduction Scheme (AICIS) (previously NICNAS). Further restrictions and conditions regarding ingredients are also mandated under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). This is a federal standard, but manufacturers should note that state and territory legislation applies in respect of the medicines and poisons caught by the SUSMP, and that legislation is not consistent throughout Australia (for example, the storage requirements for scheduled medicines and poisons change across state and territories).

Manufacturers of cosmetics must also be aware that "cosmetics" which make therapeutic claims are governed by the TGA. A cosmetic may be categorised as a therapeutic good due to claims made in its marketing, labelling or packaging or because of its intended purpose. This follows from the broad purposive definition of "therapeutic goods" under the TG Act. Such products are considered therapeutic goods (and regulated as such), rather than merely cosmetics.

Biocides

Although dependent on a product's intended purpose, labelling and promotion, generally a disinfectant making biocidal claims (for example, that a product is virucidal, sporicidal, tuberculocidal or fungicidal) is required to be listed on the ARTG under Item 16, Schedule 4, of the TG Regulations.

Food and Nutrition Supplements

A large range of products fall into this classification, not all of which are regulated in Australia. Supplements include vitamins and sports supplements (such as protein powders).

In Australia, all vitamins are regulated by the TGA for safety and quality as a low-risk complementary medicine or a prescription medicine, depending on the vitamin and the dosage. The TGA only permits products to represent that they contain vitamins if they meet certain requirements.

Sports supplements in Australia are regulated as either foods or medicines. It is not always easy to determine which regime is applicable. Sports supplements which contain a substance scheduled under the SUSMP, or which make therapeutic claims, are likely to be regulated as medicines by the TGA. Otherwise, sports supplements are likely to be regulated under the Australia New Zealand Food Standards Code.

1.3 New Products/Technologies and Digital Health

The regulatory landscape must constantly adapt to new technologies and products.

Medical Apps and Wearables

Both wearable devices and medical apps fall, with regard to regulation, under the umbrella description of "software as a medical device", which has been the subject of recent and ongoing reform in Australia. That reform has been aimed at clarifying whether such devices should be classified as "medical devices" and governed by the TGA, or as consumer goods whose sale is regulated by the ACCC.

There are five categories of regulation for software with a healthcare dimension.

- SaMD (software as a medical device), being software which on a standalone basis is capable of meeting the definition of a medical device and is independently regulated by the TGA as a medical device.
- SiMD (software in a medical device), being software that is integral to a medical device's functioning, and which is regulated as part of the original hardware medical device.
- Software accessory, being software which can control or adjust a medical device, and which is specifically intended to be used with the medical device; this is independently regulated by the TGA.
- Exempt software, which includes certain clinical decision support systems.
- Excluded products, which are not medical devices and are therefore not subject to TGA regulatory requirements, such as consumer health products, healthcare enabling technology, population-based analytics and laboratory information management systems.

In addition, the reforms have addressed the appropriate risk-based classification for such devices. The previous regulatory framework confined "harm" to the risk arising from physical interaction with a medical device. The reformed classification system takes account of the risk of patient harm where information is the source of harm. For example, the risk that software may incorrectly diagnose a disease or specify a therapy to be delivered.

Telemedicine

The provision of health services via telemedicine is increasingly common in Australia, especially in light of the COVID-19 pandemic. The manner in which that service is provided, and compliance with a practitioner's prescribing and Code of Conduct duties, are largely matters for medical professionals, with the support of the Australian government and Australia's Medicare benefits regime.

The use of telemedicine relies heavily on the use of electronic prescribing software, and enabling software that allows the provision of telehealth services. Software in this category will generally be exempt from the TG Act, under the Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021.

CBD

The TGA is responsible for governing regulatory standards for medicinal cannabis products in Australia. Medical cannabis, including cannabidiol (CBD), is an unapproved therapeutic good in Australia. However, there are mechanisms available under the TG Act to access unapproved therapeutic goods of this nature, in circumstances where the TGA is satisfied that existing ARTG-listed medicines are not sufficient or appropriate. These mechanisms include the Special Access Scheme (SAS) and the Authorised Prescriber (AP) pathway.

CBD is also scheduled in the SUSMP, which controls the manner in which listed medicines or poisons are made available to the public. Depending on its dose preparation, CBD is scheduled as either a Prescription Only Medicine (Schedule 4) or a Pharmacist Only Medicine (Schedule 3).

1.4 Borderline Products

The classification of borderline products is discussed above. Australia does not have any intermediate categories of therapeutic products. This means that products will either be "therapeutic goods" for the purposes of the TG Act, in which case they will be regulated under that Act (noting that there are very limited categories of products which are therapeutic goods but are exempted from the regulatory regime) or they are not therapeutic goods, in which case they will not be subject to specific regulation (although they will be subject to general regulatory requirements as appropriate, for example, the ACL or the AICIS regime for industrial chemicals).

2. COMMERCIALISATION AND PRODUCT LIFE CYCLE

2.1 Design and Manufacture

Entities involved in the manufacture of therapeutic goods are broadly defined under the TG Act, and include entities involved in the assembling, packaging, processing, refurbishing and labelling of therapeutic goods. There are strict requirements for such entities, which are triggered by an application to list a product on the ARTG (rather than marketing a product).

Manufacturers of medicines and biologicals in Australia are required to hold a licence under the TG Act. That licence is generally specific to a manufacturing location. To obtain such a licence, a manufacturer must demonstrate compliance with the principles of Good Manufacturing Practice (GMP), which is a legislative instrument prescribing the standards, procedures and practices to be employed in the manufacturing of therapeutic goods for use in humans.

The listing of medicines and biologicals on the ARTG when manufactured by an overseas manufacturer is also dependent on obtaining "GMP Clearance" from the TGA for listed manufacturing steps.

A different regime applies in respect of medical devices (which may include software, see **1.3 New Products/Technologies and Digital Health**). In order to be listed on the ARTG all medical devices must comply with the "Essential Principles", which set out the requirements for the safety and performance characteristics of medical devices in Australia. Medical devices are also required to demonstrate compliance with the conformity assessment procedures, which set out the requirements relating to the application of quality management systems for medical devices, and other requirements imposed on manufacturers. Manufacturers are required to provide details of a medical device's design and manufacturing processes. However, the level of detail required varies dependent upon the risk classification of a medical device (as identified by the class of medical device). The medical device classification rules are found in the Device Regulations.

It is a requirement that all therapeutic goods supplied in Australia have a listed "sponsor", being a resident in Australia or an Australian incorporated entity. The sponsor of therapeutic goods maintains ongoing responsibilities in relation to ensuring that the goods continue to conform to terms of their approval, advertising compliance, any corrective actions, adverse event reporting, compliance with reporting requirements and ongoing maintenance of records in relation to the therapeutic goods.

2.2 Corporate Social Responsibility, the Environment and Sustainability

There are a range of voluntary codes available to corporations operating within Australia regarding compliance with corporate social responsibility, environment and sustainability outcomes.

However, there are relatively few strict legal obligations imposed upon corporations in this area. Notably, large businesses and other entities in the Australian market with annual consolidated revenue of at least AUD100 million are required to prepare annual Modern Slavery Statements in compliance with the Modern Slavery Act 2018 (Cth).

2.3 Advertising and Product Claims

The advertising of therapeutic goods is required to comply with the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (TGAC), made under the TG Act. The TGAC applies to advertising other than advertising directed at healthcare professionals or wholesalers. Advertising of therapeutic goods will also be subject to general consumer laws under the CC Act and the ACL. The advertising of certain therapeutic goods will also be subject to more specific codes of practice, such as:

- the Medicines Australia Code of Conduct for the promotion of prescription-only medicines;
- the Generic and Biosimilar Medicines Association Code of Practice;
- the Medical Technology Industry Code of Practice for medical device and technology companies; and
- the Pathology Technology Industry Code of Practice, Australia's industry code of conduct for in vitro diagnostic products.

Each of these codes is predominantly concerned with advertising directed to healthcare professionals.

Under the TG Act, therapeutic goods are defined to include goods which are represented in any way to be for therapeutic use. Therefore, the making of any claims that could be considered therapeutic in nature is strictly prohibited for goods that are not listed on the ARTG. For products that are listed on the ARTG, therapeutic claims (other than indications) may only be made where the sponsor of the goods had, at the time the claim was made, information or evi-

dence that supported the claim and complied with the relevant requirements.

2.4 Marketing and Sales

As above, where products are therapeutic goods, their promotion to the general public will be subject to both the TGAC and the ACL. Both the TGAC and the ACL prohibit the making of claims which are false, misleading or deceptive in relation to products.

The TGAC also contains a number of specific prohibitions in relation to the promotion of therapeutic goods, including a number directed at avoiding encouraging excessive use of therapeutic goods or causing people to delay necessary medical attention or the use of prescribed treatments.

The TGAC also contains specific requirements for advertisements and labelling of some types of medicines and medical devices. Section 24 of the current TGAC, which became mandatory from 1 July 2022, also prohibits endorsements of products by health practitioners, health professionals, medical researchers and health consumer organisations and imposes certain restrictions on the use of testimonials.

Furthermore, there are certain types of representations which are either prohibited or restricted in relation to therapeutic goods. Restricted representations, which are representations which mention a serious form of a disease, condition, ailment or defect, may not be used without TGA approval.

Generally, statements in advertising regarding COVID-19 are prohibited representations, subject to a limited number of carve-outs which permit representations contributing to the Australian Government's public health messaging.

2.5 Internationalisation

The TGA has various mutual recognition arrangements with other countries, and their counterpart regulatory authorities, to support international regulatory collaboration. These agreements recognise the strength and comprehensive nature of the Australian therapeutic goods regime. The mutual recognition arrangements, where applicable, permit Australian manufacturers of therapeutic goods to submit evidence of compliance with GMP or conformity assessment to foreign regulators as evidence for approval.

In particular, the Australian regulatory regime for medical devices is closely aligned (although not identical) to the European system, meaning that conformity assessment certificates issued by a European notified body are generally accepted by the TGA.

2.6 Post-marketing Obligations, Including Corrective Actions and Recalls

The Australian regulatory regime places various post-market obligations on the sponsors of therapeutic goods.

Post-market Surveillance Obligations

Sponsors have post-market surveillance obligations to ensure devices continue to meet the regulatory, safety and performance requirements as at the time of their entry onto the ARTG. As mentioned at **2.1 Design and Manufacture**, the sponsor of a therapeutic good maintains ongoing responsibilities in relation to manufacturing, advertising compliance, any corrective actions, adverse event reporting, compliance with reporting requirements and ongoing maintenance of records in relation to the therapeutic good. In the case of certain high-risk devices, sponsors are also required to provide consecutive Annual Reports to the TGA following ARTG listing, to identify any performance or safety issues at an early stage in the product's life.

In addition, any product listed on the ARTG may be selected by the TGA for specific post-market review. A review of this kind may target any aspect of the product, throughout its life cycle on the ARTG.

Record-Keeping Requirements

A sponsor of a therapeutic good is required to keep distribution records for either five or ten years, depending upon the type and classification of the therapeutic good. There may be additional retention requirements in respect of patient health information gathered in relation to a therapeutic good under state and territory privacy laws.

Corrective Actions and Regulators

There are a range of mechanisms available under the TG Act when a sponsor identifies that corrective action is required, due to a safety or efficacy defect, in a therapeutic good. These vary depending upon the type of therapeutic good and the nature of the corrective action required. There are four recall actions available to sponsors: recall, product defect correction, hazard alert and product defect alert.

The appropriate recall action is determined in consultation with the TGA, which co-ordinates and monitors the recall action. While sponsors voluntarily notify most recalls to the TGA, the TGA has the power to mandate a recall action under the TG Act if necessary. Guidance regarding recall action is provided by the "Uniform Recall Procedure for Therapeutic Goods" (URPTG), which is intended to assist the sponsors of therapeutic goods to conduct recalls and non-recall actions using a standardised systematic procedure.

Further, for consumer products (which some products described in **1. Applicable Product Safety Regulatory Regimes** are), the ACL imposes strict notification obligations upon manufacturers in two scenarios. Firstly, where a supplier takes voluntary recall action because of a safety risk, it must give written notice that such action has been taken within two days of initiating the recall. Secondly, any supplier of consumer goods that becomes aware of the death or serious injury or illness of any person which the supplier considers was caused or may have been caused by the use or foreseeable misuse of those goods must notify the ACCC of that fact within two days of becoming aware of it. "Serious injury or illness" means an acute physical injury or illness that requires medical or surgical treatment by, or under the supervision of, a medical practitioner or a nurse. The condition will not be considered a "serious injury or illness" within the meaning of the ACL if it is an ailment, disorder, defect or morbid condition (or an aggravation of one).

3. REGULATOR ENGAGEMENT AND ENFORCEMENT

3.1 Regulatory Authorities

The TGA is responsible for enforcing the TG Act, the TG Regulations and the Device Regulations and for administering the ARTG. The TGA deals with issues surrounding the supply, import, export, manufacturing and advertising of therapeutic goods.

The ACCC is responsible for administering and enforcing the CC Act and the ACL. The ACCC covers a range of areas, including product safety issues, consumer guarantees, and misleading and deceptive conduct (including in relation to products).

3.2 Regulatory Enforcement Mechanisms

The ACCC has regulatory, investigatory and prosecutorial power for all matters under the CC

Act and ACL. The investigative powers extend to functions such as seizing goods or documents and interviewing witnesses, typically pursuant to a warrant. The ACCC can also issue substantiation notices and product safety notices, restrict the nature of representations made to consumers, and commence compulsory recall actions. Lastly, the ACCC enforces the CC Act and ACL by issuing penalty notices and can commence court proceedings seeking declaratory relief, injunctive relief or civil penalties. Certain breaches may also be referred to the Commonwealth Director of Public Prosecution to consider criminal prosecution.

The TGA also has various regulatory, investigative and enforcement powers. Firstly, in administering the ARTG, the TGA can issue product defect alerts and product notifications in relation to therapeutic goods listed on the ARTG. Where it finds that products are not compliant, the TGA can cancel ARTG listings. The TGA is also empowered to conduct investigative actions such as searches and seizures in relation to compliance with the TG Act and on more general public health grounds in certain circumstances. Finally, the TGA can take a range of enforcement measures, including issuing infringement notices, ordering recall action, commencing court proceedings and referring matters for potential criminal prosecution.

4. LIABILITY

4.1 Product Safety Offences

A range of product safety offences exist under the TG Act. For example, offences exist in relation to the importing, exporting, manufacturing or supplying of a therapeutic good that is not registered on the ARTG or does not comply with the applicable standards. There are also offences in relation to goods which are registered on the ARTG, such as advertising the goods for indications which are not accepted or making a false statement in relation to an ARTG listing. Penalties include imprisonment for up to five years.

The ACL also provides a range of product safety offences. For example, it is an offence to supply consumer goods that do not comply with the relevant safety standards or information standards. Similarly, it is an offence to not comply with a recall notice, or to supply goods that have been banned. The ACL also contains offences for engaging in misleading and deceptive conduct, which could include making misleading representations in relation to a product's safety. The maximum penalty for a corporation for the most severe of the ACL's offences is the greater of AUD10 million, three times the value of the benefit gained by the contravention, or 10% of the company's turnover in the preceding year. The maximum penalty for an individual is AUD500,000.

4.2 Product Liability

In addition to the traditional mechanisms of the common law tort of negligence, breach of contract or breach of statutory duty, product liability claims may be brought under a number of statutory causes of action found in the ACL.

Part 3-5 of the ACL governs manufacturers' liability for safety defects in products and is based on the European Product Liability Directive. Goods are considered defective if they are not as safe as consumers are generally entitled to expect. The regime is one of strict liability, meaning no fault is required on the part of the manufacturer for liability to arise. Any person who suffers loss or damage because of conduct that contravenes Chapter 2 or 3 of the ACL will be entitled to recover that loss in a claim for damages. A number of defences are available, including a development risks defence (also known as the "state of the art" defence).

The ACL also provides that when goods are supplied to consumers, the manufacturers, importers and suppliers of those goods are responsible for any failure by the goods to comply with certain guarantees. One of these statutory guarantees is that the goods are of acceptable quality, which includes being safe and free from defects. The guarantees cannot be excluded by contract.

Under Part 5-4 of the ACL, a range of remedies are available for breaches of consumer guarantees. Claims brought against manufacturers will be limited to an award of damages, but claims brought against suppliers may give rise to a wider range of remedies depending on whether or not a "major failure" has taken place.

4.3 Judicial Requirements

Australia has a federal court system as well as a hierarchy of courts in each state and territory. The High Court of Australia hears constitutional matters, as well as appeals from the Full Court of the Federal Court and the Courts of Appeal in each state or territory. Claims relating to medical devices and product safety may fall under the jurisdiction of either federal or state courts. Claims regarding defendants located in Australia and conduct that occurred in Australia can be commenced in any court of competent jurisdiction, but cross-vesting legislation allows the movement of proceedings to another court if they are in a clearly inappropriate forum.

In order for foreign entities to come under the jurisdiction of Australian courts, they are required to be validly served with an originating process. This requires the entity to have a sufficient nexus to Australia to justify the claim being brought in the jurisdiction. There are circumstances in which such entities may be served outside of Australia, which differ depending on the rules of the various courts. However, if it is alleged that conduct has resulted in damage occurring in Australia, that will generally be sufficient to trigger the jurisdiction of an Australian court.

Furthermore, corporations will be subject to statutory claims under the ACL in respect of conduct occurring outside of Australia if the corporation in question is "carrying on business in Australia". The test of whether a corporation is carrying on business in Australia is multifactorial and may extend to the operations of an Australian subsidiary or local supplier, depending on the degree of control exercised over that subsidiary.

Australia is also party to the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters, 1965. Therefore, where authorised, service may also be effected through means prescribed in the Hague Convention.

4.4 Costs

In Australian proceedings, costs typically "follow the event", meaning the unsuccessful party will be required to pay the costs of the successful party. Costs will include court filing fees and other expenses, as well as the fees of the lawyers involved.

Costs are calculated in various ways across jurisdictions. In some, the reasonableness of costs is assessed and an order is made on that basis. In others, the courts have a scale which is used to limit the costs recoverable for legal fees and disbursements. In either case, costs ordered will typically not amount to the total of the costs incurred in the proceeding.

Some jurisdictions have limits on costs recoverable specifically for small personal injury claims. However, these limits are subject to exceptions including where valid costs agreements evidence consent to bearing additional costs.

In class actions or representative proceedings, there are statutory provisions that only permit costs orders to be made against the applicant who commenced the proceedings, and not all members of the class.

Finally, rules reflecting Calderbank offers (ie, those made without prejudice save as to costs) also apply in most jurisdictions, whereby offers of settlement that are not accepted may trigger costs penalties for the party that rejected the offer, where they end up no better off than that offer at trial. Many courts have rules which provide for "Offers of Compromise", with similar costs consequences to a Calderbank offer, but which make those consequences more difficult to disturb.

4.5 Product-Related Contentious Matters

Australia provides various judicial review options for decisions made by public authorities, in respect of which a company is impacted. Australian law also commonly provides for merits review by an administrative appeal tribunal of decisions made by public authorities.

Those mechanisms (and the pathways to judicial review) vary, dependent upon the nature of the administrative law decision. There are, for example, rights to review certain decisions made under the TG Act regarding therapeutic goods, certain decisions made in relation to the listing of medicines on the pharmaceutical benefits scheme and certain decisions made in respect of Freedom of Information requests.

Australian law also provides broad powers to commissions of inquiry, which are regularly tasked by federal or state governments to undertake reviews. Such reviews, when conducted under the auspices of the Royal Commission Act 1902 (Cth), have broad coercive powers to summon witnesses and obtain relevant evidence. There is a strong link in Australia between the conduct of a Royal Commission, and a rise in related class actions and regulatory activity. For example, following delivery of the Final Report of the Royal Commission into Misconduct in the Banking, Superannuation and Financial Services Industry in 2019, there was a rise in financial services class actions and regulatory action by the Australian Securities and Investments Commission.

4.6 Class Actions, Representative Actions or Co-ordinated Proceedings

Class actions or representative proceedings are available in the Federal Court of Australia and the Supreme Courts of New South Wales, Queensland, Tasmania and Victoria. The class action mechanism is often used for product liability claims concerning medical devices.

The rules governing class actions are mostly identical across the different jurisdictions. In order to bring representative proceedings, seven or more persons must have claims against the same legal person, arising out of the same, similar or related circumstances and giving rise to a substantial common issue of law or fact. The proceedings are led by a lead applicant, and it is not necessary for any other members of the class to be individually identified. Unlike other jurisdictions, it is also not a requirement that the common issues predominate over those which are not common.

Australian representative proceedings operate on an "opt out" basis. This means that all persons who fall within the group definition will be bound by the outcome of the proceedings unless they actively opt out. There is also no certification requirement for Australian class actions, meaning that once a class action that meets the basic requirements is commenced, it is on foot unless the defendants can convince

the court that representative proceedings are an inappropriate vehicle to resolve the dispute.

The Pelvic Mesh Case

A prominent current example of a medical device class action is the pelvic mesh case commenced in 2012. The proceeding was brought on behalf of Australian women who allege they sustained injuries as a result of pelvic mesh implants. The first-instance trial was held in the Federal Court in 2017, with judgment being delivered in favour of three lead applicants in late 2019. An appeal was heard by the Full Court of the Federal Court in February 2021, with judgment delivered in March 2021 again in favour of the three applicants. The appellants sought special leave to appeal to the High Court of Australia, and this application was refused in November 2021. The Court is now in the process of determining the entitlements of the group members, other than the three lead applicants.

4.7 ADR Mechanisms

Several avenues exist in Australia to resolve disputes outside of formal litigation. There are statutory requirements for claimants to take genuine steps to resolve claims before commencing litigation. In practice, these rules are often ignored in product liability class actions. Courts also have procedures for both voluntary and court-ordered mediation, which typically takes place confidentially and without prejudice.

For class actions specifically, court approval is required for any proposed settlement order. The court must be satisfied that the settlement is fair and reasonable in the circumstances and in the interests of the group members.

There are a number of other alternative dispute resolution processes available in most circumstances. Arbitration is commonly used in commercial contexts, either voluntarily or court-ordered. Parties select an arbitrator or arbitrators and will be bound by their decision, either contractually or under statute. Mediation is also common, whereby a neutral third party will assist parties to come to an agreement which best accommodates each of their interests.

In highly technical matters, parties may agree to have their disputes referred for expert determination. Here, parties will be bound by the decision of an appointed independent expert in the field. This is becoming increasingly common, particularly in the Federal Court.

4.8 Interrelation Between Liability Mechanisms

Where a product is defective (in safety or efficacy) it is possible that there will be simultaneous investigations by the relevant regulator as well as civil proceedings brought by affected consumers. While a civil litigant could report (or threaten to report) a product defect issue, such an action would be unlikely to be utilised to apply pressure to a corporation. This is for two reasons. First, the relevant Australian regulators (the TGA and the ACCC) are vigilant in monitoring product safety risks, and are likely to be aware of claims made by civil litigants and investigate them utilising their own powers (including in other jurisdictions). Second, sponsors of therapeutic goods and manufacturers of consumer products also have ongoing obligations to notify the regulator of adverse events or events where death, serious injury or illness may have eventuated. Sponsors have additional reporting responsibilities which provide regulators with transparency over adverse event reporting trends.

Furthermore, Australian legal practitioners are prohibited by their professional conduct rules from threatening an opponent with a criminal consequence for failing to behave in a particular way in respect of a civil claim.

For the reasons set out above, such threats are rare.

5. POLICY AND LEGISLATIVE REFORM

5.1 Policy Development

The TGA is currently undertaking a programme of reform in relation to the safety of medical devices, as a result of a number of inquiries conducted since 2015 in relation to patient safety. In particular, the TGA has responded to the 2017 Final Report of the Senate Community Affairs References Committee report on the number of women in Australia who have had transvaginal mesh implants and related matters. In 2019, the TGA also announced its Action Plan for Medical Devices, which outlined three main strategies for reform:

- to improve how new devices get on the market;
- to strengthen monitoring and follow-up devices already in use; and
- to provide more information to patients about the devices they use.

These regulatory reforms are ongoing, but have, so far, included the reforms in relation to software in medical devices outlined at **1.3 New Products/Technologies and Digital Health**, as well as:

- aligning the definition of "medical device" in the TG Act more closely with the equivalent definitions in the European Union, to further support the harmonisation of the regulatory scheme for medical devices in Australia with international jurisdictions like the EU;
- reclassifying a number of kinds of devices to better align with their classification in the EU or to respond to perceived areas of risk, including certain high-risk medical devices such as spinal implantable medical devices, as well as surgical mesh;
- addressing the advances in materials science and computing technology that have led to a rise in complex, patient-specific, custom-made medical devices, and ensuring that those devices are appropriately classified and their manufacturers captured under the TG Act; and
- aligning Australia with the regulatory reform undertaken in the USA and the EU in relation to IVD companion diagnostics (pathology tests designed to identify the presence or absence of specific biomarkers and assist in the safe use of precision medicines, such as cell-based therapies, immunotherapies and targeted therapies).

5.2 Legislative Reform

See **5.1 Policy Development**.

5.3 Impact of COVID-19

The pandemic has seen several interesting developments take place with respect to product liability. Firstly, both the TGA and the ACCC have taken a strict stance on any advertising that references COVID-19, subject to limited exceptions more recently to permit public health messaging. The TGA has issued a large number of infringement notices to companies, most commonly for making therapeutic claims in relation to products which are not listed on the ARTG (which is prohibited, as outlined in **2.3 Advertising and Product Claims**). The ACCC has been similarly active in the area, regulating any advertising which could be misleading or deceptive to consumers, such as making representations about a product's abilities to protect consumers from the virus. In a high-profile example, a popular manufacturer of "active wear" clothing was the subject of enforcement action by both the TGA and the ACCC in respect of the same conduct. The manufacturer released a line of clothing which it claimed had been treated with

a product that would protect its wearers from COVID-19 and stop the spread to others. Both regulators deployed their respective powers to take action. The manufacturer later admitted that it had falsely represented that it had a reasonable scientific or technological basis to make such claims, and the Court held that the manufacturer had made false and misleading representations to consumers, and engaged in conduct liable to mislead the public.

To manage potential shortages created by the additional demand and global supply chain interruptions, the TGA took a range of measures in relation to ARTG listings aimed at bolstering the national stockpile. Examples of the arrangements include:

- an emergency exemption for domestically manufactured ventilators that were not ARTG-listed but demonstrated compliance with minimum technical requirements;
- an emergency exemption allowing the government to purchase personal protective equipment such as face masks that were not previously ARTG-listed; and
- excluding hand sanitisers that met certain formulation and advertising requirements from the application of certain therapeutic goods regulations.

These exceptions were permitted on the basis that sponsors certified they held evidence supporting a device's safety and performance and confirming either that the device met the Essential Principles or that such information could be obtained from the manufacturer.

However, these measures did not signal a permanent relaxing of product safety requirements. Rather, commencing in late 2020, the TGA began to undertake an ongoing post-market review of all face masks on the Australian market to ensure that all masks, including those introduced under the relaxed requirements under an emergency exemption, were compliant. The TGA has a discretionary power to cancel the ARTG listings of masks that do not meet the necessary regulatory requirements or are not performing as intended. As of June 2022, over 1,200 ARTG listings of face masks have been cancelled, either by the TGA or voluntarily by their manufacturers in anticipation of the review.

Clayton Utz is an independent Australian firm established in 1833, with more than 180 partners and 1,300 employees across six offices, and one of the largest commercial litigation practices in Australia, including a specialist five-partner product safety and product liability team. The firm handles the most complex, significant and high-profile matters, for clients including many of Australia's top financial institutions, multinational corporations operating in a range of sectors, and state and Australian government departments and agencies. Clayton Utz is also a global leader in pro bono, with one of the largest pro bono practices of any law firm outside of the USA.

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Trends and Developments

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Regulation of Consumer Health Products in Australia

Medical devices are regulated by the Therapeutic Goods Association (TGA) to ensure that therapeutic goods are in line with their intended purpose and risk-based classification and that they comply with the Essential Principles. This process involves pre-market assessment of the medical devices (conformity assessment), market authorisation (inclusion on the Australian Register of Therapeutic Goods (ARTG)) and ongoing post-market monitoring to ensure compliance with the requirements and standards (tga.gov.au/sme-assist/medical-devices-regulation-introduction).

However, the line between medical devices and "consumer health products" has become increasingly blurry with the influx of technology development, particularly focused on "lifestyle" products. The TGA released a series of regulatory reforms in February 2021 (the reforms) which sought to, among other things, clarify the definition of "medical device". In addition to providing clarity, the reforms were designed to align Australia with international regulatory frameworks and remove unnecessary regulatory burden (TGA, "Regulatory changes for software based medical devices" (February 2021), p5). As a result, products classified as "consumer health products" are no longer considered to be medical devices and are therefore not subject to TGA regulatory requirements. The basis of this exclusion was that consumer health products are low risk and do not pose significant risk to safety, and that the existing consumer law framework and product oversight by the Australian Competition and Consumer Commission (ACCC) was a suitable means of regulating these products.

The jurisdictional crossover that has arisen from the reforms between the TGA and ACCC has been most apparent recently in the regulation of software-based medical devices and vaping devices, and is also apparent in the regulation of medicinal cannabis.

Vaping

Concerns have grown recently in Australia regarding the significant increase in the use of vaping products by young people in Australia and the propensity of these products to act as a "gateway" to smoking. Australia has some of the strictest global rules regarding advertising and access to tobacco products, which are not permitted to be sold to persons under the age of 18.

The majority of vaping products sold in Australia contain nicotine, which is an addictive drug. Following two rounds of public consultation, a decision was made by the TGA to amend Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) to include an entry for nicotine (See "Notice of final decision to amend the current Poisons Standard – nicotine", tga.gov.au/scheduling-decision-final/notice-final-decision-amend-current-poisons-standard-nicotine). This change was effective from 1 October 2021. As a consequence of this amendment, nicotine vaping products are now categorised as prescription-only products in Australia. Consumers also require valid prescriptions from an Australian doctor to import them from overseas websites.

In addition to prohibitions on the supply of nicotine products, it is an offence under the Therapeutic Goods Act to advertise therapeutic goods that refer to substances, or goods containing substances, which are included in Schedule 3, 4 or 8 of the current SUSMP (Therapeutic Goods Act 1989 (Cth), Section 42DL(10)). The applicable penalty is not one of strict liability, but requires a nexus between reliance on the advertisement and the possibility of harm to the consumer.

The TGA has been swift to utilise penalty provisions in respect of the updated nicotine listing. In a recent example, the TGA issued two infringement notices totalling AUD26,640 to a pharmaceutical company for the alleged unlawful advertising of nicotine vaping products on its website (tga.gov.au/media-release/precision-pharmaceuticals-pty-ltd-fined-and-directed-cease-alleged-unlawful-advertising-nicotine-vaping-products). Unusually, and as an indication of the seriousness with which the TGA regards advertising of this kind, an executive officer of the company was also issued with an infringement notice in the amount of AUD2,664, and the TGA directed the company to cease promoting the use and supply of nicotine vaping products.

While vaping products containing nicotine are regulated by the TGA, vaping products which do not contain nicotine continue to be regulated by the ACCC and must remain compliant with Australian Consumer Law (Nicotine vaping products and vaping devices, Guidance for the Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 and related matters, at p7 (tga.gov.au/sites/default/files/nicotine-vaping-products-and-vaping-devices_0.pdf)).

Medicinal Cannabis

Most medicinal cannabis products are unapproved therapeutic goods which have not been assessed for safe use in Australia by the TGA. Medicinal cannabis products generally contain cannabidiol (CBD) or tetrahydrocannabinol (THC), or both substances. Both CBD and THC are listed under the SUSMP schedules. However, their classification depends on the concentration of CBD and THC:

- Schedule 3: low dose CBD (where the product contains at least 98% CBD concentration and 1% or less THC);
- Schedule 4: higher-dose CBD (where the product contains 2% or less THC and other non-CBD cannabinoids) (at least 98% CBD concentration and 1% or less THC);
- Schedule 8: high dose therapeutic CBD and THC dominant (up to 98% of either CBD or THC); and
- Schedule 9: all other cannabis products.

Irrespective of their SUSMP classification, medicinal cannabis products must be registered on the ARTG to be supplied in Australia. As of June 2022, there are no Schedule 3 medicinal cannabis products registered on the ARTG. However, there are two exemptions where non-therapeutic use of cannabis products is permitted under the SUSMP:

- where cannabis sativa seed product (with CBD concentration of up to 75mg/kg) is sold as an ingredient for food; and
- where hemp seed oil (containing 50mg/kg or less of cannabinoids and 20mg/kg or less of THC) is used for purposes other than internal use.

In these circumstances, supply of the exempt cannabis products will be regulated by the ACCC and subject to the Australian Consumer Law.

As scientific evidence for the use of CBD and THC to treat medical conditions continues to

evolve, it is expected that the TGA will reconsider the SUSMP classifications of CBD and THC and, where appropriate, approve products for entry on the ARTG.

Software as a Medical Device

In recent years the TGA has become increasingly focused on the regulation of medical devices which involve software or are themselves software. This interest arises from three forces at work in the Australian market. First, software increasingly plays an integral role in many traditional medical devices. Second, with advances in artificial intelligence and computing technology, the role of software in clinical decision-making has assumed increased importance. Third, as consumer software products expand and evolve rapidly, the border between medical devices and health and lifestyle software has become increasingly blurred.

Highly sophisticated software now plays a role in every aspect of Australian life, including monitoring, regulating and informing consumer health and the provision of healthcare services. In recent years, the TGA has grappled with two key questions in regulating software:

- When is software (either by itself or in tandem with a physical product) a medical device?
- What is the appropriate classification for medical devices of this kind bearing in mind the level of associated risk?

Recent Changes to the Legality of Testimonials and Endorsements in Advertising

One aspect of the increased interaction between consumer goods and therapeutic goods is the role of new players in a traditionally tightly regulated area. There are strict rules in Australia regarding the advertising of therapeutic goods, particularly directly to consumers. However, those rules were historically designed to apply to already heavily regulated industries/professions: manufacturers of therapeutics goods (generally large device companies) and medical professionals. Their application to "influencers" operating on social media platforms which are not the subject of regulatory scrutiny has been largely untested.

Significant steps were taken in this regard by Part 6 of the new Therapeutic Goods Advertising Code 2021 (the Code) (which became mandatory on 1 July 2022), which sought to clarify the rules regarding the use of testimonials and endorsements in advertising.

The Code has prohibited the inclusion of the following in advertisements:

- paid or incentivised testimonials of any nature, irrespective of whether the financial relationship is disclosed; and
- testimonials made by a person who is engaged in the production, marketing or supply of the goods ("relevant person"), which has been defined to include "influencers, direct sellers and other persons who have, or will receive, valuable consideration for making the testimonial".

The terms "engaged in" and "other persons" have not been defined by the Code and have not been clarified by the TGA's Guidance on applying the Advertising Code rules (the Guidance) or the TGA's specific guidance on the use of testimonials and endorsements in advertising (the Specific Guidance).

The Guidance and Specific Guidance have, however, provided a much-welcomed clarification concerning the distinction between testimonials and endorsements, and have sought to provide guidance for sponsors who seek to engage influencers to assist in the marketing of their therapeutic goods. Notably, the Specific

Guidance states that testimonials made by influencers, bloggers or brand ambassadors are not permitted under the Code. There is, however, no equivalent ban on endorsements.

Given that influencer and brand ambassador marketing has become a major strategy for sponsors seeking to promote their therapeutic goods, it has been observed that the Code has the potential to significantly disrupt the marketing approaches of sponsors who engage in the advertisement of medicines and medical devices directly to consumers. The aftermath of the Code's introduction has also been met with confusion and frustration by many influencers, who have argued that there is a "grey area" between endorsement and testimonials and who have expressed concerns that the Code will inhibit their ability to connect with their audiences.

It remains to be seen how the TGA will respond to the need for clear and up-to-date guidance in this evolving and expanding area of therapeutic goods regulation.

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Clayton Utz is an independent Australian firm established in 1833, with more than 180 partners and 1,300 employees across six offices, and one of the largest commercial litigation practices in Australia, including a specialist five-partner product safety and product liability team. The firm handles the most complex, significant and high-profile matters, for clients including many of Australia's top financial institutions, multinational corporations operating in a range of sectors, and state and Australian government departments and agencies. Clayton Utz is also a global leader in pro bono, with one of the largest pro bono practices of any law firm outside of the USA.

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