

TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

1. What are the principal statutes, regulations, and competent authorities that govern the import, wholesale distribution, retail sale, and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?

The Therapeutic Goods Act 1989 (Cth) (the Act) is the primary legislation regulating therapeutic goods (including medicines, medical devices, and biologics) in Australia. The Act sets out requirements for the import, export, manufacture, supply, and advertising of therapeutic goods. The Act is administered by the Therapeutic Goods Administration (TGA), part of the Australian Government Department of Health, Disability and Ageing. The TGA regulates access and the quality of therapeutic goods in Australia.

The supporting legislation to the Act includes:

- Therapeutic Goods Regulations 1990;
- Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021; and
- Therapeutic Goods (Medical Devices) Regulations 2002.

Australian states and territories have their own statutes and regulations which govern manufacture, possession, supply, storage, recording and use of scheduled medicines and poisons. These include but are not limited to the territories listed below.

- New South Wales:
 - Medicines, Poisons and Therapeutic Goods Act 2022
 - Poisons and Therapeutic Goods Act 1966;
 - Poisons and Therapeutic Goods Regulation 2008; and
 - Poisons and Therapeutic Goods (Poisons List) Proclamation 2016.
- Queensland:
 - Medicines and Poisons Act 2019;
 - Therapeutic Goods Act 2019; and
 - Therapeutic Goods Regulation 2021.
- Victoria:
 - Drugs, Poisons and Controlled Substances Act 1981; and
 - Therapeutic Goods (Victoria) Act 2010.
- South Australia:
 - Controlled Substances Act 1984;
 - Controlled Substances (Poisons) Regulations 2011;

- Controlled Substances (Controlled Drugs, Precursors and Plants) Regulations 2014; and
- Controlled Substances (Poppy Cultivation) Regulations 2016.
- Western Australia:
 - Therapeutic Goods Law Application Act 2024.
- Australian Capital Territory:
 - Medicines, Poisons and Therapeutic Goods Act 2008
- Northern Territory:
 - Medicines, Poisons and Therapeutic Goods Act 2012; and
 - Medicines, Poisons and Therapeutic Goods Regulations 2014.
- Tasmania:
 - Poisons Act 1971;
 - Therapeutic Goods Act 2001; and
 - Therapeutic Goods Regulations 2022.

Division of powers

The Act establishes a national system and will take precedence over any inconsistent states and territory laws or regulations.

Other legislation

In Australia, the import, wholesale distribution, retail sale, and export of therapeutic goods for commercial supply requires businesses to comply with other application state and territory legislation, including but not limited to:

- Customs Act 1901
- Narcotic Drugs Act 1967
- Gene Technology Act 2000; and
- Competition and Consumer Act 2010 and the Australian Consumer Law

For example, under Australian Consumer Law, it is unlawful for a business to make statements in trade or commerce that: are misleading or deceptive; or are likely to mislead or deceive.¹ It is illegal to include unfair contract terms in standard form consumer contracts with consumers and small business.

The Australian Consumer Law also includes consumer guarantees:²

- A product sold to a consumer must be of acceptable quality.
- Acceptable quality means the product:
 - is safe, durable and free from defects
 - has an acceptable appearance and finish
 - does everything that similar products are commonly used for.
- The product must be fit for purpose.
- The product must match the description.
- Services must be provided with an acceptable level of care and skill.

¹ ACCA, 'False or misleading claims', www.accc.gov.au/consumers/advertising-and-promotions/false-or-misleading-claims accessed 17 May 2026.

² ACCA, 'Consumer rights and guarantees', www.accc.gov.au/consumers/buying-products-and-services/consumer-rights-and-guarantees accessed 17 May 2026.

- Services must be fit for purposes.
- Services must be supplied within a reasonable time, if there's no agreed time frame.

2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use, risk classes for devices, etc.) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?

Products can be classified as a therapeutic good either by: (1) the nature of the product – for example, drugs will be therapeutic goods due to the constitution, action or active ingredient; and (2) by the 'claims' that are made in relation to the product.

Therapeutic goods must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be imported into, manufactured, supplied in or exported from Australia, unless an exemption applies.

Therapeutic Goods are classified by the TGA into four main categories:

1. medicines
2. medical devices,
3. biologicals, and
4. other therapeutic goods (OTGs).

Medical devices are classified based on risk, with higher classes requiring stricter regulatory oversight: reg 3.1 Therapeutic Goods (Medical Devices) Regulations 2002 (Cth).

Medical device classifications

Item	Column 1 Medical device	Column 2 Class	Column 3 Class	Column 4 Class	Column 5 Class
1	Medical devices other than IVD medical devices	I	IIa	IIb	III
2	IVD medical devices and in - house IVD medical devices	1	2	3	4

Scheduling is a national classification system for pharmaceuticals/medicines. Medicines and chemicals are classified into Schedules according to the level of regulatory control over the availability of the medicine or chemical required to protect public health and safety. The Schedules are published in the Standard for the Uniform Scheduling of Medicines and Poisons.³

The schedules are:

- Schedule 1 – not currently in use
- Schedule 2 – Pharmacy Medicine
- Schedule 3 – Pharmacist Only Medicine

³ Australian Government, Department of Health, Disability and Ageing, 'The Poisons Standard (the SUSMP)', 2 February 2026, www.tga.gov.au/products/regulations-all-products/legislation-and-legislative-instruments/poisons-standard-susmp accessed 17 May 2026.

- Schedule 4 – Prescription Only Medicine OR Prescription Animal Remedy
- Schedule 5 – Caution
- Schedule 6 – Poison
- Schedule 7 – Dangerous Poison
- Schedule 8 – Controlled drugs
- Schedule 9 – Prohibited Substance
- Schedule 10 – Substances of such danger to health as to warrant prohibition of sale, supply and use

The scheduling determines who can supply therapeutic goods, how it can be distributed and advertised with penalties associated for non-compliance.

Premarket review and approval is required by the TGA of goods which are required to be registered or listed on the Australian Register of Therapeutic Goods (ARTG) and not exempt. All therapeutic goods must be included in the ARTG unless an exemption applies.

LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?

All therapeutic goods which are required to be registered or listed on the ARTG must be entered on the ARTG before they can be imported into, manufactured, supplied in or exported from Australia, unless an exemption applies.

The entity responsible for the ARTG entry is known as the ‘sponsor’ and is responsible for compliance with TGA requirements and all ongoing obligations related to the therapeutic goods. Wholesalers must comply with the Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8 (GWP). The GWP is enforced through state and territory licensing and covers:⁴

1. Buildings and grounds
2. Storage facilities
3. Personnel
4. Stock handling and stock control
5. Transport
6. Management of complaints, return of unused and/or damaged goods and product recalls
7. Management of records, documentation and standard operating procedures
8. Cold chain medicines
9. Security arrangements and procedures
10. Additional measures for management of controlled drugs (cd) and other goods with high illicit value (GHIV)

⁴ Australian Government, Department of Health, Disability and Ageing, ‘Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8’, 13 October 2010, www.tga.gov.au/resources/publication/corporate-reports/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8 accessed 17 May 2026.

Australian based manufacturers of medicines and biologicals are required to hold a licence to manufacture. To obtain a licence, a manufacturer must demonstrate compliance with the relevant code of Good Manufacturing Practice (GMP). This is usually, but not always, done through an on-site inspection. Overseas manufacturers of medicines supplied to Australia are also required to meet an acceptable standard of GMP. If acceptable documentary GMP evidence cannot be provided, the TGA will undertake on-site inspections in the same manner as those conducted for the Australian manufacturers. In Australia it is an offence to manufacture therapeutic goods for human use without a licence or certification unless the manufacturer is exempt from this requirement under the Act.

If a business intends to import and/or export-controlled substances such as narcotics and medicinal cannabis, there are additionally licences and permit requirements issued by the Office of Drug Control, part of the Australian Government Department of Health, Disability and Ageing (ODC). The primary legislation for these licences and permits is under the Narcotics Drugs Act 1967 (Cth) and its associated regulations.⁵

The manufacture of therapeutic goods in Australia must also comply with relevant Australian Standards under the Australian Consumer Law.⁶

4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies, or other retailers), and what key conditions attach to them?

In Australia, certain pharmaceuticals are prescription only and can only be supplied through a licenced pharmacy under Therapeutic Goods Legislation and Poisons legislation.

Retail pharmacies must be owned by a registered pharmacist. This is to prevent overservicing of the Australian public. Pharmacist must be registered with the Pharmacy Board of Australia (the Board) and meet the Board's registration standards in order to practise in Australia. The Board is supported by the Australian Health Practitioner Regulation Agency (AHPRA).

Each state and territory has separate legislation, guidelines and requirements including the regulation of premises and inspections.

If a pharmacist is compounding medicines, in addition to complying with legislation relevant to the practice of pharmacy, pharmacists must meet the requirements for the pharmacy premises that apply in the jurisdiction where the premises are located.

The state or territory pharmacy premises regulatory authority or responsible body may conduct inspections of approved or registered premises and their associated facilities.

These state or territory-based authorities cooperate closely with the Pharmacy Board of Australia to ensure the safety of the Australian community and assist in resolving matters such as non-compliance with the Pharmacy Board of Australia's Guidelines on compounding of medicines and other guidelines set by the Pharmacy Board of Australia and the authorities.

⁵ Australian Government, Department of Health, Disability and Ageing, 'Medicinal cannabis', www.odc.gov.au/medicinal-cannabis accessed 17 May 2026.

⁶ ACCC, 'Product safety responsibilities', www.accc.gov.au/business/selling-products-and-services/product-safety-responsibilities accessed 17 May 2026.

Australian has a Pharmaceutical Benefits Scheme (PBS) which makes essential prescription medicines more affordable for Australians by subsidising costs. A pharmacy must obtain approval from the Australian Government Department of Health, Disability and Ageing to dispense medications under the PBS.⁷

Community pharmacies

Community pharmacies must be licensed or registered with the relevant state or territory pharmacy authority. For example, in New South Wales, all pharmacies must be registered with the Pharmacy Council of NSW. The Council manages the registration of the premises and business ownership. To become registered, the pharmacy must submit floor plans, lease agreements and other documentation outlining its business structure and arrangements which can include on-site inspections.

Internet pharmacies

Pharmacies cannot operate as online-only. However, a pharmacy can operate as hybrid online and must be associated with a physical premises.

Other retailers

In Australia, certain drugs such as Schedule 4 and Schedule 8 drugs must be sold through a pharmacy. Medicines such as vitamins and herbal remedies may be classified as unclassified and can be sold in supermarkets.

E-prescribing is regulated in Australia and can be used instead of paper prescribing. However, a patient is entitled to a paper prescription if they request.

To use e-prescribing, section 2.2 of the Declaration of Conformance requires a declaration that the software:

- (a) complies with the *National Health Act 1953* (Cth) including subordinate legislation and instruments which define requirements for electronic prescriptions, electronic medication charts, and electronic medication chart prescriptions (Commonwealth (Pharmaceutical Benefits) legislative framework; and
- (b) complies with the statutory requirements of each State and Territory.

5. What rules govern the sale of therapeutic products to consumers over the internet (including social-media and marketplace platforms)?

In Australia, pharmacies cannot operate as online-only for the sale of therapeutic goods to consumers through social media and marketplace platforms. Pharmacies can operate as hybrid online but must be associated with a physical premises.

The online sale of therapeutic goods is permitted but must comply with all the laws, licences and guidelines required of all pharmacies in Australia including the requirements of the states and territories and the TGA.

⁷ Australian Government, Department of Health, Disability and Ageing, 'Pharmaceutical Benefits Scheme (PBS)', www.pbs.gov.au/pbs/home accessed 17 May 2026.

For goods to be imported or sold in Australia, even though online means, they must comply with the Therapeutic Goods legislation.

Advertising therapeutic goods to consumers in Australia is regulated under the Act, the Therapeutic Goods Regulations 1990 and Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021.

Consumer-based advertising for therapeutic goods must comply with the Therapeutic Goods Advertising Code (the Code). It contains both general and specific advertising requirements depending on the type of therapeutic good. The principles for advertising under the Code state that therapeutic goods must not, among other key sections: mislead, or be likely to mislead, directly or by implication; contain any restricted representations claims (even if the product is registered or listed) which refers to a serious form of disease, without obtaining approval by the TGA.

The advertising of Schedule 4 and Schedule 8 drugs to consumers is prohibited. Under the Act and the Code:

- prescription medicines are banned from being advertised to the public which are listed under Schedule 4 or Schedule 8;
- Schedule 3 medicines, excluding those listed in Appendix H of the Poisons Standard, must not be advertised to the public; and
- unregistered medicines must not be advertised to the public, including those supplied under the Special Access Scheme and the Authorised Prescriber Scheme.

The Special Access Scheme (SAS) and the Authorised Prescriber (AP) scheme allow certain registered health practitioners to access ‘unapproved’ therapeutic goods for patients under their care.⁸

There are civil and criminal penalties for breaching the bans on advertising.

IMPORT

6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?

All therapeutic goods which are required to be registered or listed must be entered on the ARTG before they can be imported into Australia, unless an exemption applies.

In addition to the excluded products, the only other exceptions to the requirement to be registered or listed on the ARTG are those products supplied through one of the following mechanisms:

- clinical trials – special and experimental uses;
- authorised prescribers;
- Special Access Scheme;
- personal importation; and

⁸ Australian Government, Department of Health, Disability and Ageing, ‘Special Access Scheme & Authorised Prescriber Scheme Online System’, <https://compliance.health.gov.au/sas> accessed 17 May 2026.

- exemptions in the national interest, to deal with emergencies.

These schemes cannot be used to facilitate commercial supply.

If a business intends to import controlled substances such as narcotics and medicinal cannabis, there are additionally licences and permit requirements issued by the ODC.

Customs

Customs legislation, including the Customs Act 1901 (Cth) regulates the importation of goods into Australia.

Border inspections

The Australian Border Force (ABF) has jurisdiction to conduct both routine and risk-based inspections of imported therapeutic goods. Therapeutic goods can be detained by ABF for TGA assessments. Unauthorised imported therapeutic goods may be seized, forfeited and destroyed by the ABF. If therapeutic goods contain any biological, animal or plant-based materials, they may be subject to quarantine by the ABF and require clearance by the Australian Department of Agriculture, Fisheries and Forestry.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties, or other restrictions apply?

In addition to the excluded products, the only other exceptions to the requirement to be registered or listed on the ARTG are those products supplied through one of the following mechanisms:

- clinical trials – special and experimental uses;
- authorised prescribers;
- Special Access Scheme;
- personal importation; and
- exemptions in the national interest, to deal with emergencies.

Under the Personal Importation Scheme (PIS), some therapeutic goods not entered in the Australian Register of Therapeutic Goods (ARTG) can be imported for personal use or for an immediate family member. This includes many medicines that are not approved in Australia.

However, individuals must follow certain conditions:

- The products must be for personal use or for the use of an immediate family member – they cannot be sold, supplied or given away to others. Immediate family is limited to the individual's parents, grandparents, spouse, de facto spouse, child or ward of that person.
- If the medicine is prescription-only in Australia, there must be a valid Australian prescription or written authority.
- The PIS does not allow the importation of controlled substances. Some prescription medicines are also controlled substances, and not eligible for personal importation.

- The import cannot be more than a three-month supply at the maximum prescribed dose (prescription-only medicines) or dose recommended by the manufacturer (non-prescription medicine). The total quantity imported within any 12-month period must not exceed a 15-month supply.
- Individuals must keep imported medicines in their packaging with any labels intact when importing.⁹
- The import must not include any vaping products.
- The import must not be prohibited under Australian customs or quarantine rules, such as animal products.¹⁰

8. May foreign suppliers ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification, or labelling obligations – if any – must they satisfy?

No, foreign suppliers cannot lawfully ship therapeutic goods directly to consumers unless under the PIS and this is strictly not for commercial purposes.

9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?

Parallel imports, or ‘grey imports’, are genuine brand-name goods imported and sold by unauthorised distributors, typically bypassing official supply chains to offer lower prices.

All therapeutic goods that are required to be registered or listed on the ARTG must be entered on the ARTG before they can be imported into Australia, unless an exemption applies.

Australia has a system of registration of patents and trademarks. Parallel imports may infringe those intellectual property rights.

Further, therapeutic goods which are listed or registered on the ARTG may have specific product packaging and labelling requirements which parallel imports may not comply.

EXPORT

10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public-health emergencies), and how are such measures administered and enforced?

Therapeutic goods made for export from Australia must generally comply with the Australian therapeutic goods legislation unless an exception applies. The Therapeutic Goods Administration

⁹ Australian Government, Department of Health, Disability and Ageing, ‘Personal Importation Scheme’, 19 January 2026, www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/personal-importation-scheme accessed 17 May 2026.

¹⁰ Australian Government, Department of Health, Disability and Ageing, ‘Can I import a medicine for personal use?’, 12 April 2019, www.tga.gov.au/news/blog/can-i-import-medicine-personal-use#:~:text=You%20can't%20sell%20the,appropriate%20access%20to%20a%20medicine accessed 17 May 2026.

(TGA) regulates the export of medicines, medical devices, and human substances to ensure they meet safety and quality standards.

If a business intends to export controlled substances such as narcotics and medicinal cannabis, there are additionally licences and permit requirements issued by the ODC.

In Australia, generally there are no quantitative quotas that restrict the export of therapeutic goods providing that the business complies with all of the requirements of the TGA and the ODC. The Australian government may introduce temporary export restrictions during public health emergencies such as Covid-19. The TGA, ODC and AFP would enforce those export restrictions.

11. Is there any form of ‘export-only’ or ‘dual-labelling’ authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing, and if so, what standards, labelling, or record-keeping obligations apply?

All therapeutic goods must be entered on the ARTG before they can be manufactured and exported from Australia, unless an exemption applies.

Australian based manufacturers of medicines and biologicals are required to hold a licence to manufacture and must comply with the GMP.

Export only¹¹

Therapeutic goods can be listed in the ARTG as ‘Export Only’, this means they cannot be supplied in Australia.

Export Only medicines must be: listed in the ARTG before export; safe for their intended purpose(s) of use; manufactured according to manufacturing principles for medicinal products; and of acceptable presentation. They must also comply with required quality and safety standards; and are subject to the advertising provisions in sections 42DKB, 42DLA and 42DLC of the Act.¹²

Businesses exporting therapeutic goods listed with ARTG as export only must comply with same standards and record keeping as required for domestic commercial supply. Labelling would need to comply with the requirements of the importing country.

To facilitate export, the TGA issues export certification for medicines that are registered or listed in the ARTG under section 58 of the Act. If certification is required by the importing country, the TGA can issue a Certificate of Pharmaceutical Product (CPP) or a Certificate of Listed Product (CLP).

Dual labelling

Dual labelled ingredient names were required to show both the old and new ingredient name on medicine labels until the end of 30 April 2023. After this date, for most names, labels can show

¹¹ Australian Government, Department of Health, Disability and Ageing, ‘Export of medicines’, 19 October 2022, www.tga.gov.au/products/medicines/application-and-market-authorisation/export-medicines accessed 17 May 2026.

¹² Australian Government, Department of Health, Disability and Ageing, ‘Exporting medicines from Australia’, 1 June 2021, www.tga.gov.au/resources/guidance/exporting-medicines-australia accessed 17 May 2026.

the new ingredient name only or continue with both names while work is done to change the label.¹³

Medicine sponsors have three years to update labels to show only the new name. For example, labels of medicines containing ‘lidocaine (lignocaine)’ will need to be updated to show ‘lidocaine’.

The transition period for most dual labelled ingredients started on 1 May 2023 and ends 30 April 2026. Medicines released for supply from 1 May 2026 must show the sole name.

Ingredient names that are changing to show new names only are found in the list of affected ingredient names marked as ‘Dual labelling – until 30 April 2023’.

Medicine sponsors should also update Product Information (PI) and Consumer Medicine Information (CMI) documents to reflect sole names as labels are updated during the transition period.

A small set of ingredient names will continue with dual labelling.

LABELLING, TRACEABILITY, AND PRODUCT INFORMATION

12. What local language labelling, patient information, unique device identification, serialisation, anti-counterfeiting, or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?

The Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines made under section 10 of the Act sets out what kinds of information are required to be included on the label of prescription and other related medicines of the kind described in section 3 of the Order, and in what circumstance.¹⁴

PRICING, REIMBURSEMENT, AND MARKET ACCESS

13. Are there any price-control, reimbursement, public procurement, or stock/supply-obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

In Australia, the PBS is the primary price control and subsidy regime for prescription medicines. Under the PBS, the Australian government set the approved ex-manufacturer price (AEMP) for the pricing quantity for each PBS listed brand of pharmaceutical item and if applicable the

¹³ Australian Government, Department of Health, Disability and Ageing, ‘Dual labelled medicine ingredient names transition to sole names’, 28 April 2025, www.tga.gov.au/products/medicines/labelling-and-advertising/medicines-and-biologicals/labelling-requirements-information-sponsors/dual-labelled-medicine-ingredient-names-transition-sole-names#:~:text=Dual%20labelling%20ended%20for%20most,will%20continue%20with%20dual%20labelling accessed 17 May 2026.

¹⁴ Australian Government, Federal Register of Legislation, ‘Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines’, www.legislation.gov.au/F2016L01285/latest/text accessed 17 May 2026.

proportional ex-manufacturer price (PEMP) and claimed price for pack quantities. Prices are agreed or determined at the ex-manufacturer level rather than the price to pharmacist's level.¹⁵

Under the National Health Act 1953, the Minister for Health and Aged Care (or the Minister's delegate) can exercise discretion to reduce pricing.

Therapeutic goods not listed with the PBS are at full cost to the consumer.

Medical devices do not have a national reimbursement scheme equivalent to the PBS. The Australian government sets the minimum benefit that a private health insurer must pay for medical devices listed on the Prescribed List of Medical Devices and Human Tissue Products.¹⁶

Public procurement

Therapeutic goods for public hospitals are procured through a tender process. This is similarly done with private hospitals.

Stock/supply

Australia maintains a National Medical Stockpile.¹⁷ It is a strategic reserve of drugs, vaccines, antidotes and personal protective equipment for use in national health emergencies, so Australia is more self-sufficient during an emergency and able to meet high levels of demand.

ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions, and remedial measures (administrative, civil, or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

TGA

The TGA has a number of investigative powers and can impose penalties and recalls for defective products.¹⁸

With non-compliance, the TGA will consider:

- the risk of harm or injury related to a product itself, including the way in which a product is used or being promoted for use;

¹⁵ Australian Government, Department of Health, Disability and Ageing, PBS 'Ex-manufacturer price', 1 May 2026, www.pbs.gov.au/info/industry/pricing/ex-manufacturer-price#:~:text=The%20spreadsheets%20set%20out%20the,core%20price%20in%20the%20Act) accessed 17 May 2026.

¹⁶ Australian Government, Department of Health, Disability and Ageing, 'Prescribed List', www.health.gov.au/our-work/prescribed-list#:~:text=Private%20health%20insurers%20are%20required,List%20or%20change%20current%20listingsg accessed 17 May 2026.

¹⁷ Australian Government, Department of Health, Disability and Ageing, 'National Medical Stockpile', www.health.gov.au/our-work/national-medical-stockpile accessed 17 May 2026.

¹⁸ Australian Government, Department of Health, Disability and Ageing, 'Imposing requirements to undertake a recall or public notification', 24 February 2026, www.tga.gov.au/resources/guidance/use-legislative-powers-related-recalls-and-other-market-actions#:~:text=might%20use%20them,-Imposing%20requirements%20to%20undertake%20a%20recall%20or%20public%20notification,depending%20on%20the%20therapeutic%20good: accessed 17 May 2026.

- the compliance history and behaviour of the responsible person or business; and
- the size, reach and compliance history of the industry sector.

The TGA can:

- issue warning letters;
- suspend a therapeutic good from the ARTG, preventing the entity from import, export, manufacture, or supply;
- cancel a therapeutic good from the ARTG;
- commence a market action which is a set of steps undertaken via the Procedure for Recalls, Product Alerts and Product Corrections (PRAC) – these are undertaken to resolve a problem with a therapeutic good already supplied in the Australian market;
- issue directions or prevention notices to address advertising non-compliance;
- use powers under the *Telecommunications Act 1997* that require internet service providers to block access to certain websites if they are in breach of the Act;
- seek injunctions or interim injunctions from the Federal Court or the Federal Circuit Court to restrain an entity from contravening the Act or the regulations, or compel compliance with the Act, or regulations if an entity refuses or fails to comply.¹⁹

If the Secretary of the Department of Health, Disability and Ageing believes, on reasonable grounds, that a person is not complying with the Act or an instrument made under the Act in relation to particular goods and it is in the interests of public health or safety, the Secretary may issue a notice of enforceable directions to that person to take steps to address non-compliance. These steps may include (but are not limited to) re-labelling the goods or destroying the goods

The Act includes certain civil penalties. Where appropriate, the TGA may apply to the Federal Court for an order against an entity to pay a penalty for breaching the Act. If the Court finds that an entity has breached the Act it may order the entity pay the penalty. For example, some maximum civil penalties in the Act are 5,000 penalty units for an individual, or 50,000 penalty units for a corporate body. One commonwealth penalty unit as of 1 April 2026 is AUD330.

Serious non-compliance may warrant criminal proceedings. There are a range of criminal offences contained in the Act where this may apply. In such instances, the TGA will prepare a brief of evidence which is referred to the Commonwealth Director of Public Prosecutions (CDPP).

Maximum criminal penalties for entities are up to five years imprisonment and fines of up to 4,000 penalty units for therapeutic goods, or seven years imprisonment and fines of up to 5,000 penalty units for vaping goods.

The Narcotic Drugs Act 1967 sets out offences that can lead to criminal penalties, including those where intent does or does not need to be proved. Serious breaches may result in criminal proceedings. The Narcotic Drugs Act also contains civil penalty provisions and allows the ODC to seek court-ordered penalties for breaches of these provisions.

¹⁹ Australian Government, Department of Health, Disability and Ageing, 'Compliance actions and outcomes', 31 October 2025, www.tga.gov.au/safety/compliance-and-enforcement/compliance-actions-and-outcomes accessed 17 May 2026.

15. Is there recent case law, legislative or policy developments, noteworthy enforcement trends, or anticipated reforms that may significantly alter the regulation of trade, distribution, or cross-border movement of therapeutic products in the future?

Please refer to our article relating to the *Lorrna Jane* and *Peptide Clinics* cases.²⁰

The Therapeutic Goods Administration has been focused on medicinal cannabis, vaping, cosmetic surgery and AI software as a medical device.

In 2025, the TGA announced the implementation of a Unique Device Identification system for medical devices.²¹

The TGA is currently asking for feedback on proposed changes to Australian medicine labelling rules, namely: the Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines (TGO 91); and Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines (TGO 92).²²

These orders will revoke automatically in October 2026 and will need to be replaced.

²⁰ Hall & Wilcox, 'Health & Community Law Alert: the dangers of making therapeutic claims in retail products: Lorna Jane and Peptide Clinics cases', 20 October 2021, www.lexology.com/library/detail.aspx?g=2816c406-f478-4884-b4e6-8338c3523704 accessed 17 May 2026.

²¹ Australian Government, Department of Health, Disability and Ageing, 'Unique Device Identification (UDI) hub', www.tga.gov.au/products/medical-devices/labelling-and-advertising/unique-device-identification-udi-hub accessed 17 May 2026.

²² Australian Government, Department of Health, Disability and Ageing, 'Consultation: Proposed changes to labelling of medicines supplied in Australia', 17 March 2026, www.tga.gov.au/resources/consultation/consultation-proposed-changes-labelling-medicines-supplied-australia accessed 17 May 2026.