General Warning

The purpose of this fact sheet is to give general introductory information about the complaints process. It does not contain legal advice.

WARNING: Alternative legal action should be considered before making a complaint. What is included in a complaint may be relevant to any current or future legal proceedings. If you are involved in legal action you should immediately see a lawyer and not proceed with a complaint.

If you (or the complainant, if you are complaining on their behalf) want financial compensation, support or money you should see a lawyer before making a complaint.

General complaint information

Complaints are rarely about just one thing. When you have a problem, it may be that a number of things have gone wrong. Below are some of the common areas where issues may arise that could lead to a complaint.

Discrimination	Disability and NDIS services	Policing, Custody and Detention
Seniors and Aged Care supports and services	Consumer and Business disputes	Phone and Internet services
Banking, Insurance and Superannuation	Energy and Water services	Housing and Real Estate
Health Care services	Employment issues	Education and Training providers
Government Agencies and Departments	Child Safety and Protection	State Fines and Debts
Corruption	Privacy and Access to Information	Media and Publications

There are different complaint bodies to handle different types of complaints. You should consider the different pathways available to decide the most appropriate pathway for your circumstances. One event could lead to multiple complaints. That means you may need to lodge more than one complaint to have all of your concerns addressed.

It is usually quickest and easiest to try to resolve a complaint directly with the person or body you are having a problem with. Many complaint handling bodies will not act on a complaint unless you to have tried to resolve your complaint directly. If you do not feel it is safe or appropriate to complain directly, you should contact the relevant complaint body to discuss your situation.

Complaints involving discrimination

There are state and federal complaints bodies that handle complaints that about discrimination. If your situation involves discrimination, you should consider making a

discrimination complaint in addition to any other complaints. Discrimination may occur when someone is treated less favourably on the basis of: race; sex; gender; disability; age; sexuality; relationship status; pregnancy; caring responsibilities; or having or being thought to have an infectious disease.

WARNING: The state and federal bodies that handle discrimination complaints have different rules, including time limits. You can make a complaint to both the state and federal complaint bodies, but they may decide not to address your concerns if you have already complained elsewhere. For example, if you have already lodged a discrimination complaint to anti-discrimination NSW, it is likely that Australian Human Rights Commission will decide not to act on your complaint. Please carefully review the discrimination factsheets for information about your options before making a discrimination complaint.

Therapeutic Goods Administration (TGA)

In this fact sheet, we introduce the Therapeutic Goods Administration (**TGA**). We outline how complaints can be made by people to the TGA.

The TGA is the Australian Government body that regulates medicines, medical devices, and other therapeutic goods to ensure they are safe, effective, and high quality. It is part of the Department of Health and Aged Care and oversees how these products are manufactured, supplied, advertised, imported and exported.

You can make a complaint to the TGA about side effects from medicines or problems with medical devices, as well as issues like faulty packaging, misleading advertising, counterfeit products, or illegal supply (including vapes).

Legislation and Key Terms

Relevant Legislation:

- *Therapeutic Goods Act 1989* (Cth)
- *Therapeutic Goods Regulations 1990* (Cth)
- *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth)

Other instruments which assist the TGA include:

- Therapeutic Goods advertising code
- Declared goods orders
- Excluded goods orders, determinations and specifications
- Instruments
- Manufacturing principles and guidelines
- Medical device notices and standards orders
- Therapeutic Goods determinations
- Therapeutic Goods Groups Orders
- Therapeutic Goods Orders

Key Terms: Below are key terms that appear throughout this factsheet and their meaning.

Authorised Prescriber Scheme means a program that allows certain doctors to regularly prescribe unapproved medicines or medical devices to patients with specific needs, without needing special permission each time.

Conformity Assessment Certificate means a document that shows a medical device has been checked and meets Australian safety and quality standards.

Good Manufacturing Practice (GMP) means a set of strict safety and hygiene rules that manufacturers must follow when making medicines and medical devices. It helps make sure the products are safe, clean, and high quality.

TGA means Therapeutic Goods Administration.

TG Act means the *Therapeutic Goods Act 1989* (Cth).

TGA Regulations means *Therapeutic Goods Regulations 1990* (Cth) and *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth). There are other regulations under the TG Act but these are the key ones regarding medicines and medical devices.

Special Access Scheme (SAS) is a way for doctors to access medicines or medical devices that are not officially approved in Australia, usually for patients with serious or rare conditions.

Step 1: What type of complaints can be made to this body?

The TGA regulates therapeutic goods including medicines, medical devices, and some health-related consumer products (like disinfectants, COVID-19 tests, or nicotine vapes). You can report a problem even if you're unsure whether the product caused harm or is breaking the law - your report helps protect others.	
Sub-category	**Example**
Side Effects or Reactions (Adverse Events)	**You should make a complaint if you or someone you know has an unexpected or harmful side effect or reaction from using a medicine, vaccine, vitamin, or medical device, even if you're not sure the product caused it.** This is called an adverse event, and it helps the TGA monitor safety. If the medicine or medical device was provided by a healthcare practitioner, like a GP, you should let them know and they may report to the TGA as well. You do not have to have sought medical treatment to report an adverse event to the TGA. *Examples:* • *Sarah buys vitamins from the supermarket. Shortly after taking them, she starts vomiting for several hours. She suspects it might be contaminated.* • *Graham takes a prescription medicine for a week and develops a rash. He tells his GP, who stops the medicine and reports the reaction.* • *A young Aboriginal woman experiences swelling and trouble breathing after a vaccine. Her local clinic helps her report it, even though they're not 100% sure it caused it.*
Faulty or Unsafe Medical Devices	**You should make a complaint if a medical device doesn't work properly, breaks easily, causes injury, or seems unsafe, even if no harm occurred.** This includes both adverse events and product defects. *Examples:* • *A diabetic patient's blood glucose monitor gives false low readings, leading to an insulin overdose and hospitalisation.* • *A person buys a walking aid that collapses because of a faulty locking mechanism, though they weren't hurt.* • *A nurse finds that a batch of pregnancy tests give false positives.*
Problems with Medicine or Vaccine Quality, Packaging or Labels	**You should make a complaint if you find an issue with the quality, labelling, or packaging of a medicine or vaccine, like damage, mislabelled dosage, contamination, or broken seals.** This includes both prescription and non-prescription products. *Examples:* • *Jenny buys an anti-inflammatory cream online and notices the box and tube are unsealed.*

	• *A patient finds the instructions on a medicine bottle are unreadable or show the wrong dosage.* • *John buys sterile bandages from a pharmacy. At home, he sees the plastic packaging is torn.*
Non-Compliant or Misleading Advertising of Therapeutic Goods	**You should make a complaint if you see an advertisement for a therapeutic good that seems misleading or unlawful.** This includes TV, radio, print, online, social media, and influencer content. Common breaches include ads that: • Make untrue or exaggerated claims • Say a product is "safe in all cases" • Promote prescription-only medicines to the public • Use fear or distress to sell products ("fear mongering") • Refer to serious diseases like cancer or heart disease (restricted representations) • Target children *Examples:* • *Mike sees an Instagram ad for Ozempic promoting weight loss. He knows Ozempic is prescription-only and not approved for weight loss ads.* • *Sarah buys a supplement advertised as "all natural", but the label shows synthetic additives.*
Counterfeit or Fake Medicines and Devices	**You should make a complaint if you suspect a therapeutic product is counterfeit (fake), even if you haven't used it.** Fakes might look like the real product but have different ingredients, misspellings, or poor packaging. *Examples:* • *Mandy buys blood pressure tablets from an overseas website. They're a different colour and logo than usual.* • *Ian buys condoms online. They arrive in strange packaging and break easily. The supplier later admits they're counterfeit.*
Illegal Supply or Import of Therapeutic Goods	**You should make a complaint if someone is importing, selling or supplying therapeutic goods that are not approved by the TGA.** This includes prescription-only medicines sold without a prescription, unregistered herbal remedies, and nicotine vapes supplied outside a pharmacy setting. *Examples:* • *A person sees an online ad for a "natural cancer cure" not listed on the TGA register.* • *Oliver finds out a tobacco shop sold nicotine vapes to his teenage sons.* • *Kate purchases hand sanitiser from an online store. After using the product, Kate suffers a severe reaction to her hands. Looking at*

	the ingredients and comparing them with other hand sanitisers she has used, Kate sees that the product contains a number of different ingredients. Kate tries to look up the brand on the Australian Register of Therapeutic Goods online but cannot find it. Kate suspects that the product may not be registered with the TGA.
Questionable or Unsafe Manufacturing of Therapeutic Goods	**You should make a complaint if you become aware that therapeutic goods are being made in unsafe or unhygienic conditions, or by someone without a proper license.** The TGA requires strict Good Manufacturing Practices (GMP). Breaches can pose serious health risks. *Examples:* • *A worker at a vitamin factory notices insect contamination and lack of hygiene in the packaging area.* • *A doctor hears that a beauty salon is making injectable skin treatments in a home garage.*
Unlawful Sale or Import of Nicotine Vaping Products	**You should make a complaint if you find nicotine vapes being sold or imported without a valid prescription or pharmacy process.** From 1 January 2024, it is illegal to import or sell disposable or non-therapeutic vapes, with or without nicotine, unless they are supplied through the TGA's authorised pharmacy prescription pathway. You should report any unlawful sale, advertising, or importation of vapes to the TGA *Examples:* • *Jane buys a vape containing nicotine from an overseas website. It arrives in plain packaging, with no TGA approval.* • *A minor told their parents that their friend bought a vape from a local servo.*
Exclusions	These complaint types fall outside the TGA's responsibility and should be directed to other agencies, organisations, or complaint bodies: • **Complaints about healthcare services or treatment decisions:** The TGA does not handle concerns about how a doctor, nurse, dentist, pharmacist, or clinic provided treatment, made a diagnosis, or communicated with you. • **Complaints about side effects or injuries from food, drinks, cosmetics, or household items:** If the product is not a therapeutic good (medicine, medical device, etc.), the TGA has no role, even if it caused harm. • **Complaints about medical fees, refunds, or business practices of health providers or pharmacies:** The TGA does not investigate billing disputes, refund issues, or poor customer service (e.g. delays, rudeness) from clinics or pharmacies. • **Complaints about product effectiveness in individual cases:** The TGA does not investigate claims like "this didn't work for me" unless it relates to a safety risk, defect, or breach of law. • **General product dissatisfaction without a safety or compliance concern:** The TGA is not responsible for investigating complaints based on taste, smell, texture, or

	aesthetic preferences if the product is safe, legal, and used correctly. • **Complaints about therapeutic goods that are clearly outside TGA regulation:** Some goods may seem health-related but are not considered therapeutic under Australian law (e.g. massage chairs, blue light glasses, general wellness apps). • **Workplace use or employer policies related to therapeutic goods:** The TGA does not investigate if your workplace forces or denies use of a medicine or vaccine, unless it involves unlawful supply or safety risks in the goods themselves. • **Breaches of privacy, discrimination, or human rights:** If your concern involves privacy breaches (e.g. health information shared without consent), discrimination in access to medicine, or rights-based issues, these are not handled by the TGA.
Additional Info	**You can report issues even if:** • The product was bought online, overseas, or from an informal source (e.g. markets, friends, social media). • You are not 100% sure the product caused the issue. • The product is not listed on the ARTG — reporting it can help the TGA investigate illegal imports or counterfeit items. • You are reporting on behalf of someone else, such as a patient, elder, friend, or child. **If you're unsure whether a product is a therapeutic good:** Check the Australian Register of Therapeutic Goods (ARTG) or contact the TGA's info line. Some items marketed as "natural" or "health products" may or may not be regulated by the TGA.

Step 2: What is the Jurisdiction of the complaints body?

Jurisdiction	Description
State	The TGA has the power to regulate therapeutic goods Australia-wide under the TG Act. Therapeutic goods include some consumer goods such as vitamin tablets and sunscreens, through to prescription medicines, vaccines, blood products and surgical implants.
Geographical Scope	The TGA has the power to handle reports and complaints about therapeutic goods throughout Australia.
Time limitations	There are no strict time limits for making complaints or reports to the TGA regarding therapeutic goods. However, it is best to report issues and lodge complaints with the TGA as soon as possible as there are time limitations on certain enforcement actions that the TGA may wish to take in relation to the company that is the subject of your report or complaint. For sponsors of therapeutic goods (e.g. pharmaceutical

Jurisdiction	Description
	companies and medical device suppliers), there are strict timeframes for reporting adverse events with therapeutic goods.

Exclusions	The TGA does not:
	• **Act for individuals:** The TGA does not reimburse patients or consumers for therapeutic goods or medical services. The TGA does not make any decisions regarding the Pharmaceutical Benefits Scheme or the Prescribed List of Medical Devices.
	• **Handle complaints about therapeutic goods used or supplied entirely outside Australia:** The TGA only regulates therapeutic goods that are imported into, supplied in, or manufactured for the Australian market. If the entire use and supply occurred overseas, the TGA has no authority to act.
	For example, if someone in Fiji uses a locally produced medicine that causes harm, the TGA cannot investigate. However, if a product was purchased overseas but imported by an Australian consumer for personal use, the TGA may still accept the report.
	• **Therapeutic goods sold via overseas websites that do not target Australian consumers:** If a product is purchased from a website based overseas and there is no clear targeting of the Australian market (e.g. no Australian pricing, shipping, or marketing), the TGA may not have jurisdiction over the supplier.
	For example, a US-based site selling unapproved supplements without shipping to Australia falls outside the TGA's remit.
	• **Complaints where the issue occurred before the TGA's regulatory responsibility began:** The TGA cannot investigate incidents that occurred before it had jurisdiction over a product or category.
	For example, older complaints about products that were not regulated as therapeutic goods at the time (such as disinfectants before COVID-19 reforms) may fall outside jurisdiction.
	• **Complaints made many years after the issue, where evidence can no longer be gathered or action is no longer viable:** The TGA does not publish a strict time limit, but it may decline to investigate where:
	  ○ The product is no longer on the market
	  ○ The sponsor/manufacturer no longer operates
	  ○ There is no way to inspect or verify the product, packaging, or effects
	• **Goods supplied in Australia under Special Access Scheme (SAS) or Authorised Prescriber Scheme, in some cases:**

Jurisdiction	Description
	While the TGA monitors these schemes, it may not investigate individual complaints unless there is a broader safety issue or breach of conditions. Complaints about whether access was fairly granted or not (e.g. being denied SAS access) are outside jurisdiction.
Exercise of discretion	The TGA exercises discretion in relation to the reports and complaints it receives and whether or not to take enforcement action. The TGA may work with a company to achieve compliance in the first instance. However, it may consider enforcement action if the company has repeatedly breached the TG Act, and / or the breach of the *TG Act* has impacted on patients or consumers' ability to use therapeutic goods safely or appropriately. The TGA has a number of enforcement tools available to it including warning letters, suspensions, cancellations, recalls, advertising directions, infringement notices, injunctions and court proceedings.

Step 3: Who can you make a complaint against?

The TGA can deal with reports and complaints regarding therapeutic goods (e.g. medicines and medical devices) which may include complaints against the sponsor (pharmaceutical company or medical device supplier), retailer (e.g. pharmacy) or healthcare professional.	
Respondent	**Description**
Sponsors	Sponsors are the companies legally responsible for a therapeutic good in Australia. Sponsors are listed on the Australian Register of Therapeutic Goods (see https://www.tga.gov.au/resources/artg). The sponsor's name is usually on the packaging, but if you only know the product name, the TGA can identify the sponsor during its investigation.
Manufacturers	The manufacturer is the company or facility that physically makes the therapeutic good. The TGA can take action if a product is made in breach of safety, quality, or Good Manufacturing Practice (GMP) standards. For example, the TGA can investigate a factory producing contaminated vitamins.
Importers	An importer brings therapeutic goods into Australia for sale or distribution. If the goods are unapproved, counterfeit, or illegally imported, the TGA can investigate the importer. This includes businesses or individuals importing goods in breach of TGA laws.
Distributors and Wholesalers	These are businesses that supply therapeutic goods in bulk to pharmacies, clinics, or other retailers. The TGA may investigate them if they knowingly distribute illegal, unapproved, or unsafe products.

Retailers (e.g. pharmacies, supermarkets, online sellers)	Retailers sell therapeutic goods directly to the public. The TGA can take action against them for unlawful advertising, supplying unapproved goods, or failing to comply with labelling and packaging standards. This includes physical stores, online platforms, and eBay/Amazon-style sellers.
Advertisers	Anyone promoting therapeutic goods, including companies, retailers, social media influencers, bloggers, or individuals, can be held responsible if they breach the Therapeutic Goods Advertising Code. The TGA often acts on complaints about misleading ads, especially online or on social media.
Private Individuals (in some cases)	If a private individual is selling or advertising therapeutic goods (e.g. online or through social media), the TGA may investigate them, especially if they are supplying unapproved goods or making false therapeutic claims. For example, an individual selling weight-loss injections on Facebook without approval.
Exclusions	The TGA is not responsible for, and will not investigate complaints regarding: • **Veterinary Medicine Suppliers or Vets:** The TGA does not regulate animal medicines or veterinary devices. These are regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA). • **Food or Drink Manufacturers:** The TGA does not handle issues with regular food or drink products — even if they make vague health claims. • **Cosmetic or Chemical Product Suppliers (unless therapeutic claims are made):** The TGA does not regulate general cosmetics, cleaning products, or chemicals — unless they are marketed with a therapeutic purpose (e.g. "kills viruses" or "treats acne"). • **Health Insurance Providers:** The TGA does not handle complaints about health insurance coverage, fees, or claim denials. • **Healthcare Practitioners (e.g. doctors, nurses, pharmacists):** The TGA does not deal with complaints about how a healthcare worker treated you, diagnosed a condition, or communicated. • **Hospitals, Clinics or Health Services (in terms of treatment decisions or conduct):** While the TGA may investigate if these entities unlawfully supply therapeutic goods, it does not handle complaints about how they run, provide care, or manage patients. • **App developers, device manufacturers, or wellness companies that do not make therapeutic claims:** If a product (e.g. fitness tracker, meditation app, blue-light glasses) does not

	make a therapeutic claim, the TGA has no power to investigate it.

Step 4: Are you eligible to make a complaint?

Eligibility	Description
Who can make a complaint?	Anyone can make a complaint to the TGA. Reports to the TGA generally come from consumers, family members, carers, healthcare professionals or a sponsor. Reports can be made anonymously, meaning the TGA will not record your name, but it can help the TGA's investigation if it can contact you later to ask for more information. The TGA may assign a pseudonym (a false name) for a notifier who wishes to be anonymous.
Pre-requisite Steps	No specific pre-requisite steps apply. However, you should provide as much detail as you can to the TGA regarding, for example, the relevant products, adverse event or problem, advertisement or activity and take and provide photos with your report where possible.
Have you tried to resolve your complaint directly?	You do not need to attempt to resolve your concerns directly prior to reporting it to the TGA, however if you have a concern about a side effect or problem with a medicine or medical device, you should contact a healthcare professional.
Is there a more appropriate organisation to resolve your complaint?	If your complaint involves a consumer good that is not a therapeutic good, it may be more appropriate to lodge a complaint with the ACCC or another regulator. When the TGA receives a complaint, it will first consider whether TGA can look into the issue being raised.
Can a complaint be made on behalf of someone?	Yes. You can raise a concern on behalf of another person or have someone act on your behalf during the process. For example, a carer, family member or healthcare professional (e.g. your GP) can make a report to the TGA on your behalf. For someone to act on your behalf, the TGA may require your written consent.
Exclusions	There are no eligibility exclusions for the TGA. Anyone, including members of the public, health workers, whistleblowers, or anonymous individuals, can make a complaint if the issue involves a therapeutic good and falls within the TGA's jurisdiction.
Additional information you need to know	Making a report to the TGA is free. You do not need a lawyer for the reporting process, but you can seek legal advice at any time.

Step 5: What remedies are available at this body?

The TGA regulates therapeutic goods to protect the health and safety of Australians. When someone makes a complaint, the TGA may use one or more of the following powers. **However: The TGA cannot provide any personal remedy to the complainant.** **The TGA does not provide refunds, replacements, compensation, or dispute resolution services for individuals.**	
Power	**Description**
No further action	The TGA may take no further action if the complaint: • Relates to a low-risk or one-off breach • Lacks sufficient evidence • Falls outside TGA jurisdiction • Is already being monitored or addressed The information may still be kept on record and used to identify patterns or support future action if similar complaints arise.
Referral	If, in reviewing a concern, the TGA determines that it is not the appropriate body to handle a matter, it may refer your concern to another agency. Other agencies can include Australian Pesticides and Veterinary Medicines Authority, Food Standards Australia New Zealand, Australian Prudential Regulation Authority, Australian Industrial Chemicals Introduction Scheme or Australian Health Practitioner Regulation Agency. The TGA can refer the entire report or specific and relevant aspects to that other agency.
Warning letters	If the TGA considers the issue is relatively low risk (e.g. does not present a significant risk to public safety), it may issue a warning letter to, for example, a sponsor (pharmaceutical company or medical device company) or to a retailer or advertiser (depending on the complaint). A warning letter typically includes: • the identified breach of the *TG Act* has been identified; • what corrective action must be undertaken and timeframes; • what other compliance action the TGA may undertake if the non-compliance is not remedied within the specified timeframe; and • education on how to remain compliant in the future.
Suspension of Therapeutic Goods or Licences	The TGA may suspend: • A product from the Australian Register of Therapeutic Goods (ARTG) • A manufacturing licence

	• A conformity assessment certificate During suspension, the good cannot be legally manufactured, imported, exported, or supplied. The TGA can extend or revoke the suspension depending on compliance.
Cancellation of Therapeutic Goods or Licences	The TGA may cancel: • A therapeutic good from the ARTG (making it illegal to supply unless exempt) • A manufacturing licence or related certificate Cancellation is used for: • Deliberate or repeated breaches • Serious compliance failures • Refusal or failure to take corrective action • Cancelled goods may also be seized or recalled.
Recall actions	A recall action removes or corrects therapeutic goods that pose a health or safety risk due to: • Contamination • Packaging or labelling errors • Unexpected side effects • Defects in performance or quality Recalls may be: • Voluntary (initiated by the sponsor) • Required (directed by the TGA) Recalls are assessed and coordinated based on the level of risk to public health.
Advertising directions and prevention notices	For advertising that breaches the Therapeutic Goods Advertising Code, the TGA can issue: Directions Notices, requiring the advertiser to: • Stop the advertisement • Remove unlawful claims • Issue a correction or retraction • Recover or destroy materials Prevention Notices - stop future publication of misleading or unlawful ads. Failure to comply can lead to further legal action.
Infringement notices (Fines)	Issued when the TGA believes the TG Act has been breached. • A financial penalty is applied (instead of starting court proceedings)

	• Penalty units can reach over $13,000 per breach (individuals) and over $66,000 (companies) • Multiple notices may be issued for multiple breaches If the fine isn't paid, the TGA may escalate to court.
Enforceable undertakings	An agreement between the TGA and a person or company to take corrective action without going to court. • Must be written and signed • Includes specific actions to ensure future compliance • If breached, the TGA can apply to the Federal Court to enforce it
Injunctions	The TGA may seek injunctions from the Federal Court to: • stop a company (or individual) from contravening the TG Act or regulations; or • force a company (or individual) to comply with the TG Act or regulations.
Civil penalties	In serious cases, the TGA may bring civil proceedings in the Federal Court and seek: • A declaration of breach • Civil penalties (large fines) • Injunctive or corrective orders Penalties can exceed $1 million per contravention for corporations.
Criminal prosecutions	For the most serious breaches, particularly those involving: • Knowingly supplying counterfeit or unapproved goods • Causing significant harm to the public • Repeat and wilful disregard of the law The TGA may: • Refer the case to the Commonwealth Director of Public Prosecutions • Prosecute in the Federal Court Maximum penalties include: • Up to 7 years imprisonment • Fines of over $1.3 million per offence

Step 6: Preparing your complaint. What should your complaint look like? What should it include?

Requirement	Description
Format	The TGA has specific online forms on its online portal (link from its website) for different types of reports as set out in Step 7. You should complete the relevant form for your complaint. The online forms differ depending on the complaint but generally, you will need to provide: • personal contact details; • information about the relevant product (product name, manufacturer, where and when you bought it); • details of your concern; and • any photos or electronic copies of the product or advertisement you can provide. Choose the correct form for your type of report: a perceived breach of the TG Act, an adverse event (which is separated into medicines, medical devices or vaccines), an issue with product quality, packaging or labelling, counterfeit products, or a concern with advertising. This will help your report get to the relevant team within the TGA. Further details about where to lodge your report is set out in **Step 7**.
Personal Details	You should provide: • your first and last name • email address • phone number Reports can be made anonymously or using a pseudonym, meaning TGA don't record your name as the notifier. Some of the TGA's online forms require you to provide your personal details. More information about how your personal information is treated by the TGA is available here: https://www.tga.gov.au/about-tga/what-we-do/who-we-are-and-what-we-do/treatment-information-provided-tga
Respondent's Details	You should provide the name of the manufacturer, sponsor, retailer, distributor or other company that your report relates to, with additional information such as contact details for the company if known. Information regarding the manufacturer and / or sponsor is typically on product packaging if you have this.
Relevant Facts	You should provide details regarding: • the product(s) (including product name, batch or serial numbers and expiry dates);

Requirement	Description
	• when the issue you are reporting occurred (e.g. when and where the advertisement took place, or when the adverse event occurred); and • details of the issue (e.g. what the advertisement was about and what the concern was, or what the adverse event was, whether you required treatment and, if so, what that treatment was). You should provide as much detail as possible to help the TGA understand your report. If you have any documents (for example, photos) to support your report they should be provided. If you lodge your report through one of the TGA's online report forms you can attach supporting documents.
What NOT to include	Do not make false or misleading statements in your report. This is an offence. If you are unsure of any of the information in your report (e.g. dates or times of events), say so in your report.

Step 7: Lodging your complaint and next steps.

Step	Description
Where to lodge your complaint	Ideally, all reports should be in writing via the TGA's online portal. You can lodge a report through the online portal using different forms for different concerns as follows: • For medicine or vaccine adverse events click here. • For issues related to medicine or vaccine product quality, packaging or labelling click here. • For medical device adverse events or problems click here. • For counterfeit products or other perceived breaches of the TG Act click here. For non-complaint advertising click here.
Receipt	If you submit through the online portal, you will receive a message delivery notification from the TGA's system confirming receipt of the report.
Initial assessment	After you report, the TGA will assess your report to determine if any action needs to be taken. If the TGA need more information and you provided details, it will contact you.
Close the matter	After assessing a concern, the TGA may close the matter, if the concern is not serious enough to warrant further consideration. If this occurs, the TGA may write to you and explain the outcome. Even if the TGA closes the matter, it will still have a record of your complaint and may investigate further at a future stage (for example, if other complaints are made in relation to the same product).

Step	Description
Investigations	The TGA may investigate your complaint further, particularly if it considers your report raises issues of public safety, it receives multiple reports regarding the product, and / or if parties involved have previously breached the TG Act. Reports may be shared with the product sponsor and / or manufacturer (without your name and contact information).
Outcomes	Following an investigation, the TGA can take a number of actions including to: • recall or cancel the product • limit who can buy it • require warnings or changes to the product's label • require the sponsor to do further research. When the TGA identify concerns or issues with products, it publishes safety alerts.

Step 8: Post-complaint – what if you are not happy with the outcome of your complaint?

Avenue	Description
Feedback to the TGA	If you are unhappy with the way your report to the TGA has been handled, or the outcome of a report made to the TGA, you can provide feedback as follows: **Post:** First Assistant Secretary Regulatory Practice and Support Division Therapeutic Goods Administration PO Box 100 WODEN ACT 2606 **Telephone:** 1800 020 653 **Email:** info@tga.gov.au Feedback or complaints will either be answered or acknowledged within 5 working days. Where feedback requires further investigation by the TGA, the acknowledgement will provide notification of this and associated timeframes for response.
Additional information you need to know	More information regarding the review process is available here.

Step 9: Overlapping or Related Jurisdiction to the complaints body?

Jurisdiction	Description
Office of Drug Control	The Office of Drug Control regulates and monitors the cultivation, import, export and manufacture of controlled substances to comply with Australia's obligations under International Drug Conventions. This includes the cultivation of cannabis for medicinal purposes. Website: https://www.odc.gov.au/ Access the tip off form here.
State/Territory medicines & poisons regulation units	Each State and Territory has its own laws that determine where consumers can buy a particular medicine or poison, and how it is to be packaged and labelled. **Australian Capital Territory** Pharmaceutical Services / Health Protection Service Telephone: 02 5124 9208 Email: hps@act.gov.au Website: ACT Health - Pharmaceutical Services **New South Wales** Pharmaceutical Services / NSW Ministry of Health Enquiry form: Pharmaceutical services - Pharmaceutical services enquiry form Email: MOH-PharmaceuticalServices@health.nsw.gov.au Website: NSW Ministry of Health - Pharmaceutical Services **Northern Territory** Medicines & Poisons Control / Department of Health, Northern Territory Telephone: 08 8922 7341 Email: poisonscontrol@nt.gov.au Website: Environmental health - Medicines and poisons control **Queensland** *Medicines* Healthcare Approvals and Regulation Unit Office of the Chief Medical Officer and Healthcare Regulation Branch Prevention Division, Department of Health Telephone: 07 3708 5264

Email: HARU@health.qld.gov.au

Website: Queensland Health – Medicines and Poisons

Poisons

Environmental Hazards Unit /. Prevention Division, Department of Health

Telephone: 07 3328 9310

Email: environmentalhazards@health.qld.gov.au

Website: Queensland Health - Poisons Management

South Australia

Medicines labelling and scheduling

Department for Health and Wellbeing / Office of the Chief Pharmacist

Telephone: 08 8204 1944

Email: Health.OfficeoftheChiefPharmacist@sa.gov.au

Website: SA Health Medicines and Technology Programs

Poisons labelling and scheduling

Controlled Substances Licensing / Public Health Services

Telephone: 08 8226 7100

Email: HealthControlledSubstances@sa.gov.au

Website: Controlled substances legislation

Tasmania

Department of Health and Human Services, Tasmania

Telephone: 03 6166 0400

Website: Tasmania Department of Health and Human Services - Pharmaceutical Services

Victoria

Department of Health / Medicines and Poisons Regulation

Enquiry form: Medicines and poisons regulation enquiry form- external site

Website: Victorian Government Health Information - Drugs and poisons regulation in Victoria

Western Australia

Department of Health, Western Australia

Telephone: 08 9222 6883

	Website: Western Australia Department of Health - Pharmaceutical Services Branch
Australian Competition and Consumer Commission (**ACCC**)	For products that are not therapeutic goods, the ACCC is the national agency for fair trading and competition matters, including: • price monitoring • franchising • product labelling • industry codes.
Australian Pesticides and Veterinary Medicines Authority (**APVMA**)	The APVMA is the Australian Government regulator of agricultural and veterinary chemical products. It regulates agricultural and veterinary chemicals to manage the risks of pests and diseases for the Australian community and to protect Australia's trade and the health and safety of people, animals, and the environment. Website: https://www.apvma.gov.au/ Phone: 61 2 6770 2300 Email: enquiries@apvma.gov.au
Food Standards Australia New Zealand (**FSANZ**)	Food Standards Australia New Zealand (FSANZ) is an independent statutory agency established to protect public health and safety by ensuring a safe food supply in partnership with food and health authorities in Australia and New Zealand. Website: https://www.foodstandards.gov.au/ Phone: +61 2 6228 8226
Australian Industrial Chemicals Introduction Scheme (**AICIS**)	The AICIS regulates chemicals (including polymers) that are manufactured or imported into Australia for an industrial use, such as in inks, paints, adhesives, solvents, cosmetics and personal care products, cleaning products, as well as in manufacturing, construction and mining applications. Website: https://www.industrialchemicals.gov.au/ Phone: +61 2 8577 8800 or 1800 638 528
Office of the Australian Information Commissioner (**OAIC**)	The Office of the Australian Information Commissioner can handle complaints about the way personal information has been handled by Australian Government agencies and some private organisations. The OAIC can also review freedom of information decisions that are made by Australian Government agencies and ministers. There are also State Government privacy and information complaint bodies who may also be able to assist.
Courts and Tribunals	Courts and tribunals can make binding and enforceable determinations. You may want to seek legal advice about the option of pursuing your complaint in court if it relates to seeking compensation.

Need help?

Organisations that can help you make your complaint, provide support or advocacy or give you more information

Organisation	Contact Details	How they can help
TGA	Website: https://www.tga.gov.au/ Phone: 1800 020 653 (Mon to Fri 9am – 5pm (AEST)	You can contact TGA directly if you have any further questions or need assistance with your complaint.
Translating and Interpreter Service	Website: www.tisnational.gov.au Telephone: 131 450	Provides interpreting and translation services for people if English is not their first language.
National Relay Service	Website: www.accesshub.gov.au	Provides a range of services to support people who are deaf or have a hearing or speech impairment to communicate.

Self-help tools and additional resources

Resource	How this helps
How to make a report	Guidance from TGA on how to make a complaint
Law Society: Know Your Rights	Guidance for individuals who are uncertain about where to start when seeking legal advice.
Call It Out	Online register for racism/discrimination experienced or witnessed towards First Nations Australians. Not an official complaints body.