

Therapeutic goods: a quick guide

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Introduction

[Therapeutic goods](#) are health-related products. They are used in humans for various reasons including managing illnesses or injuries, altering bodily processes, preventing or testing for pregnancy or replacing or modifying part of the body. [Therapeutic goods include](#) medicines (complementary, over-the-counter and prescription), medical devices (such as bandages and pacemakers) and other goods such as blood products and disinfectants. [Foods](#) and [cosmetics](#) are generally not therapeutic goods. In Australia, therapeutic goods are [regulated by the Therapeutic Goods Administration \(TGA\)](#).

This quick guide provides an overview of how therapeutic goods are approved, how their supply is regulated, and how they are monitored for safety in Australia. It focuses on areas likely to be of interest to the Australian Parliament and is not intended as a comprehensive account of the TGA's functions.

Therapeutic Goods Administration (TGA)

The TGA regulates therapeutic goods to ensure they are of high quality, safe to use and work as intended. The TGA administers the [Therapeutic Goods Act 1989](#) (the Act) which sets out requirements and obligations for the [supply](#), [import](#), [export](#), [manufacture](#) and [advertising](#) of therapeutic goods.

The TGA is part of the Australian Government Department of Health. It is largely self-funded and operates on a [cost recovery](#) basis. The [TGA charges fees](#) for services (such as evaluating a new product) and imposes annual charges on industry. All monies received by the TGA are credited to the Therapeutic Goods Administration Account, which is a [special account](#) established under section 45 of the Act. These monies are used to fund regulatory activities in Australia and to allow the TGA to participate in [international regulatory activities](#) for therapeutic goods.

Approval process for therapeutic goods

A person or organisation wishing to supply a therapeutic good in Australia must apply for [market authorisation](#) from the TGA. The TGA assesses the application, and if market authorisation is granted, the therapeutic good is entered on the [Australian Register of Therapeutic Goods \(ARTG\)](#).

In [most cases](#), therapeutic goods must be entered on the ARTG before they can be [lawfully imported into, supplied in, or exported](#) from Australia. For cases where patients can access products that have not been approved for use in Australia, see the section below on 'Access to unapproved goods'.

The [ARTG can be searched online](#). Each entry has a [Public Summary](#) document detailing the date the product was included on the ARTG, its intended use and the name of the product's sponsor (usually a pharmaceutical company or device manufacturer). Many medicines have further information in the form of a [Consumer Medicines Information \(CMI\)](#) leaflet (for patients) and a [Product Information \(PI\)](#) document (for health professionals).

Medicines may be prescribed to treat a different disease or group of people than is specified in the ARTG entry. This is known as ['off-label' prescribing](#), and it is a common practice.

The TGA takes a [risk-based approach to assessing applications](#) for market authorisation. Lower risk products receive a lesser degree of checking based on certification, whereas higher risk products undergo a more detailed process involving active evaluation of information provided by sponsors.

The application pathways for medicines and medical devices are briefly outlined below.

Application pathways for medicines

Applications to include a medicine on the ARTG follow [different pathways](#), depending on the level of risk involved:

- **Listed medicines** (such as vitamins and complementary medicines) contain only [certain low-risk ingredients](#) and only make low-level health claims from a list of [permitted indications](#) (reasons for use). The [application pathway](#) is based on self-certification by sponsors, with an emphasis on the safety and quality of the product, rather than its efficacy (effectiveness).
- **Assessed listed medicines** also contain only [certain low-risk ingredients](#), but make intermediate level health claims. The [application pathway](#) involves self-certification of quality and safety by sponsors, but evaluation of efficacy evidence by the TGA.
- **Registered medicines** (including all prescription medicines) contain higher-risk ingredients and may make high level health claims. The [application pathway](#) involves an assessment by the TGA of the safety, quality and efficacy of the medicine. The TGA generally has [255 working days to complete](#) an [evaluation of a new prescription medicine](#). Scientific and clinical experts evaluate the detailed dossier of data and evidence (from clinical trials and other sources) submitted by the sponsor. The TGA can also seek advice from the expert [Advisory Committee on Medicines](#). A senior TGA regulator considers all this information and decides whether the benefits of the medicine outweigh the risks, and therefore, whether it should be registered for supply in Australia.
 - Sponsors of new vital and lifesaving prescription medicines can seek permission to follow a [priority review pathway](#), which allows for faster assessment of applications (around 150 working days).
 - Sponsors of promising new prescription medicines (with only preliminary clinical data available) can seek time-limited registration through the [provisional approval pathway](#). Sponsors can apply for full registration when sufficient clinical data to confirm safety and efficacy become available.

All pathways require evidence that medicines are made according to [Good Manufacturing Practice \(GMP\)](#). GMP describes principles and procedures to ensure therapeutic goods are of high quality.

The TGA [inspects Australian \(and some overseas\) manufacturers](#) to ensure compliance with GMP standards.

Information on approval decisions

The TGA publishes its reasons for approving or not approving prescription medicine applications in [Australian Public Assessment Reports for prescription medicines \(AusPARs\)](#). [AusPARs can be searched](#) by brand name, active ingredient or sponsor on the TGA website.

The TGA does not assess medicines for cost effectiveness, and the inclusion of a medicine on the ARTG does not mean that its cost will be subsidised by the Australian Government. A medicine sponsor seeking a subsidy must follow a separate application process to have the medicine listed on the [Pharmaceutical Benefits Scheme \(PBS\)](#). This process is outlined in the Library's [quick guide to the PBS](#).

Scheduling

[Medicines are classified into Schedules](#) which determine how freely they will be available to the public. [For example](#):

- Unscheduled products (such as aspirin and paracetamol) are available for general sale from stores such as supermarkets
- Schedule 2 (S2) medicines (such as diarrhoea medicines and antihistamines) are available on the shelf at pharmacies
- Schedule 3 (S3) medicines (such as some asthma inhalers) are kept behind the counter at pharmacies, and can be purchased following consultation with a pharmacist. They do not require a prescription
- Schedule 4 (S4) medicines (such as antibiotics and cholesterol medicines) must be prescribed by an authorised healthcare professional and
- Schedule 8 (S8) medicines are controlled drugs (such as very strong pain relievers) with strict requirements for prescribing and supply.

The Schedules are published in the [Poisons Standard](#) and are given legal effect through [state and territory legislation](#).

The Secretary of the Department of Health (or their delegate) makes [decisions on the scheduling of medicines \(and chemicals\)](#), and other changes to the Poisons Standard. The [Secretary may make a medicine scheduling decision](#) on their own initiative, as part of the registration process for a new medicine (described above) or following an [application from a sponsor or other interested party](#) to reschedule a medicine (to make it easier or harder to access).

When deciding on a schedule for a medicine, the Secretary or delegate may seek advice from the [Advisory Committee on Medicines Scheduling](#). [Interim](#) and [final scheduling decisions](#), and the reasons for these decisions, are [published on the TGA website](#).

Application pathways for medical devices

[Medical devices](#) are used in humans to treat illness, or modify or monitor functions of the body. They generally achieve this through physical, mechanical or chemical means. They are classified according to risk, ranging from lowest risk (Class I) for items such as bandages, to highest risk (Class III and Active Implantable Medical Devices) for items such as heart valves and pacemakers.

In order to have a medical device included in the ARTG, the manufacturer must:

- demonstrate that the device meets the [Essential Principles](#) set out in Schedule 1 of the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#). The Essential Principles detail the design and manufacturing requirements for medical devices to ensure they are safe and perform as intended and
- undertake [conformity assessment](#), which is the systematic and ongoing examination of evidence and procedures to ensure that a device conforms to the Essential Principles. Some low risk devices only require manufacturer self-assessment of conformity, while higher risk devices will require a conformity assessment certification issued by the TGA or a [European notified body](#) (an organisation designated by a European Union country to assess the conformity of certain products before they are placed on the market).

The [degree of scrutiny](#) the TGA applies to applications depends on the level of risk associated with the device. Some low risk devices can be ‘auto-included’ in the ARTG upon application (with supporting evidence held by the sponsor), some devices can be included in the ARTG based on the information provided in the application (outlined above), and some higher risk applications will be audited by the TGA.

Manufacturers or sponsors seeking to speed up the process for either TGA conformity assessment or inclusion of the device on the ARTG can apply for [Priority Review](#). To be eligible, they must demonstrate that the device offers a major improvement over existing treatments for a serious medical condition.

Access to unapproved goods

Therapeutic goods generally need to be entered on the ARTG before they can be sold in Australia. However, there are a number of ways that patients can gain [access to products that have not been approved](#) for use in Australia.

- The [Special Access Scheme \(SAS\)](#) allows a health practitioner to access an unapproved therapeutic good for an individual patient on a case-by-case basis.
 - SAS category A is for patients who are terminally ill or facing premature death without treatment. The prescribing doctor notifies the TGA that they are prescribing an unapproved therapeutic good to the patient.
 - SAS category B is the general pathway followed when neither category A nor category C applies. The health practitioner must apply to the TGA for approval before the unapproved product can be accessed and supplied to the patient.
 - SAS category C applies to designated [medicines](#), [medical devices](#) and [biologicals](#) (human cell or tissue-based products, or live animal products) with an established history of use for a particular condition. Health practitioners must notify the TGA that they are prescribing an unapproved therapeutic good from one of these lists.
- Doctors can apply to the TGA to become an ‘[Authorised Prescriber](#)’ of a specific unapproved good to specific patients with a particular medical condition. Such doctors also need to have their application approved by a human research ethics committee or endorsed by a specialist college.
- Depending on the level of risk involved, a sponsor of a [clinical trial](#) can make either a [notification or application to the TGA](#) to use an unapproved good in the trial.
- Under the [Personal Importation Scheme](#), individuals can legally import a three month supply of some unapproved therapeutic goods for personal use, without TGA approval. A doctor’s prescription is required for S4 and S8 medicines.

- If a [medicine included in the ARTG is in short supply](#), the Secretary (or delegate) can [approve the import and supply of a substitute medicine](#) that is not on the ARTG.

Monitoring of goods on the market

The TGA also monitors therapeutic goods once they have been approved and are on the market. This is known as [post-market monitoring](#). Depending on the type of good and the degree of risk involved, post-market monitoring activities may include risk management plans, collecting reports of adverse events and reactions, reviewing worldwide complaints data for medical devices, auditing manufacturers and scanning medical literature and media reports to identify safety issues.

[Adverse events](#) are unintended and sometimes harmful events (including side effects) associated with the use of a therapeutic good. The TGA records reports of adverse events in two [searchable Databases of Adverse Event Notifications](#) (DAEN): one for [medicines and vaccines](#) and one for [medical devices](#). An adverse event report does not necessarily mean that the therapeutic good caused the event, nor that it is unsafe. Rather, the TGA uses reports to identify when a safety issue may be present. Reporting of adverse events by consumers and health professionals is voluntary, but sponsors and manufacturers must report serious adverse events to the TGA.

The TGA has a number of ways of letting the health professionals and the public know of safety concerns for medicines on the market. These include:

- [monitoring communications](#) to highlight potential concerns about a therapeutic good
- [alerts](#) where a safety concern has been investigated and advice needs to be given
- [recalls](#) when a therapeutic good needs to be modified or removed from the market and
- the [Medicines Safety Update](#) publication for health professionals.

The TGA can also [restrict access to a product, or remove it from the ARTG](#) altogether.

Therapeutic goods reforms

In October 2014 the Australian Government announced an independent review to investigate how therapeutic goods regulation could be streamlined and enhanced, without undermining quality or safety. The [Expert Panel Review of Medicines and Medical Devices Regulation](#) provided two reports to the Government in 2015, [recommending extensive legislative and administrative changes](#) to the system. The Government [accepted 49 of the 58 recommendations](#) (in full or in principle) and made [provision for the reforms](#) in the 2016–17 Budget.

The two tranches of reform legislation were introduced into the Australian Parliament in [December 2016](#) and [September 2017](#), and subsequently passed. Many of the reforms have now been implemented (including the priority review and provisional approval pathways for medicines and changes to the SAS scheme), but others are still [in progress](#).

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