



Fact sheet



Therapeutic Goods Act 1989

If your project involves the manufacture or supply of therapeutic goods in Australia, or export of therapeutic goods from Australia such as medicines, biologicals, vaccines or medical devices, you must obtain approvals in accordance with this Act.

1. What approvals do I need?

Approval is required to import into, export from or supply or manufacture therapeutic goods in Australia under the [Therapeutic Goods Act 1989](#) (the Act).

Therapeutic goods are broadly defined as products for use in humans in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury
- influencing, inhibiting or modifying a physiological process
- testing susceptibility to a disease or ailment
- influencing, controlling or preventing conception
- testing for pregnancy.

Therapeutic goods include things that are:

- used as an ingredient or component in the manufacture of therapeutic goods
- used to replace or modify parts of the anatomy.

The Therapeutic Goods Administration (TGA) website hosts online tools to help determine if your product is a therapeutic good. Tools are available for [medical devices](#), and [other therapeutic goods](#).

Generally, before a sponsor ('product owner') can supply a therapeutic good in Australia, the product must be authorised for that purpose by being listed, registered or included in the [Australian Register of Therapeutic Goods](#) (ARTG). Requirements for entry on the ARTG

depend on the type of therapeutic good and its risk level. Within the following categories, there are different classifications of therapeutic goods regulated according to their [level of risk](#):

- medicines
- medical devices (including in-vitro diagnostic medical devices)
- biologicals
- other therapeutic goods.

The [sponsor](#) of a product is responsible for applying to have their therapeutic good included in the ARTG. The sponsor is the person or organisation who exports, imports or manufactures, or arranges the exportation, importation or manufacture of therapeutic goods from or in Australia.

If the product you wish to supply is already entered on the ARTG under another sponsor but you wish to import the product directly from the overseas manufacturer yourself, you will need to apply to the TGA to have your therapeutic good included separately in the ARTG. Otherwise, you will need to contact the existing sponsor to make a retail arrangement to sell the product.

Once a product is entered in the ARTG, sponsors also have a range of post-market obligations including post-market monitoring and surveillance activities, mandatory adverse event reporting and undertaking product recalls when required. Guidance on these obligations in relation to [medical devices](#) and [biologicals](#) is available on the TGA website.

This fact sheet provides general information and does not constitute legal advice. You should seek independent legal advice tailored to your individual circumstances. The Major Projects Facilitation Agency (MPFA) assists major project proponents to navigate Australian Government approval processes. The MPFA does not grant approvals, nor administer the legislation listed in this fact sheet.

Exempt and excluded therapeutic goods do not need to be included in the ARTG. Exempt goods are listed within the [Therapeutic Goods Regulations 1990](#) and information on excluded goods is available on the TGA [website](#).

Under the Act, a [manufacturing licence](#) is needed to manufacture medicines and biologicals in Australia for supply in or export from Australia unless otherwise exempt. To obtain a licence, a manufacturer must demonstrate compliance with the applicable code of [good manufacturing practice](#) (GMP).

[GMP certification](#) or [GMP clearance](#) is required to manufacture therapeutic goods other than class 1 biologicals and medical devices at an overseas manufacturing site for supply to Australia.

A [conformity assessment certificate](#), issued by the TGA or a [comparable overseas regulator](#), is required to manufacture a medical device, including an instrument, apparatus, appliance, software, implant, reagent, material or other article intended for therapeutic use.

Manufacturers of therapeutic goods must also meet requirements for [labelling and packaging](#).

Advertising of goods, including through product names, must comply with the [Therapeutic Goods \(Therapeutic Goods Advertising Code\) Instrument 2021](#) (Advertising Code). [Guidance](#) on applying the Advertising Code rules is available from the TGA.

2. Who provides the approvals?

A delegate of the Secretary of the Department of Health and Aged Care authorises the inclusion of goods in the ARTG and makes decisions on whether to grant manufacturing licences and conformity assessment certificates.

The TGA, within the Department of Health and Aged Care, is responsible for processing applications for manufacturing licences and entries on the ARTG. The TGA undertakes desktop assessments and makes decisions on issuing conformity assessment certificates to medical device manufacturers and including medical devices in the ARTG.

The TGA also makes decisions on issuing GMP clearance to sponsors of therapeutic goods manufactured overseas.

3. How do I apply for the approvals?

Applications for manufacturing licences, GMP certification, GMP clearance and conformity assessment certificates are made online in the [TGA Business Services portal](#). This portal is also used to apply for product entry on the ARTG.

Please refer to the TGA website for step-by-step instructions on the individual application processes for:

- [manufacturing licences and overseas GMP certification](#)
- [GMP clearance](#)
- [conformity assessment certificates](#)
- [ARTG inclusion of a prescription medicine](#)
- [ARTG inclusion of a non-prescription medicine](#)
- [ARTG inclusion of a medical device](#)
- [ARTG inclusion of a class 1 biological](#)
- [ARTG inclusion of a class 2, 3 or 4 biological](#)

4. More information

Therapeutic Goods Administration

Further information on [manufacturing](#) and [supplying](#) therapeutic goods in Australia is available on the TGA website.

The TGA can be contacted by email at info@tga.gov.au.

Major Projects Facilitation Agency

If you would like assistance to identify potential Australian Government regulatory approvals required for your project, please refer to the [Major projects help tool](#) self-assessment.

The MPFA team can be contacted by email at MPFA@industry.gov.au.