Australian Government
Department of Health
Therapeutic Goods Administration

Export of medicines from Australia

Version 1.0, December 2019

TGA Health Safety Regulation

Copyright
© Commonwealth of Australia 2019
This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

About this guidance

This guidance is to assist:

- Australian sponsors planning to export medicines (including prescription, over-the-counter and complementary medicines) for commercial purposes
- authorised agents acting on behalf of the Australian sponsor of the medicine who are exporting for commercial purposes
- people planning to export a medicine for non-commercial use (e.g. for a family member or friend)

To export medicines you must meet certain regulatory requirements set out in Australia's therapeutic goods legislation, in addition to other relevant Commonwealth and state or territory legislation. Criminal and civil penalties may apply if you do not meet these legal requirements.

The TGA only regulates the export of therapeutic goods for human use. If you wish to export veterinary medicines, you should contact Australian Pesticides and Veterinary Medicines Authority (APVMA).

If your product is not making therapeutic claims, it may not be considered a therapeutic good under Australia's therapeutic goods legislation. You may find the tool Is my product a therapeutic good? of assistance to determine if the product is considered to be a therapeutic good.

Export regulation

The major legislation that controls the approval and regulation of therapeutic goods in Australia is the *Therapeutic Goods Act 1989* (the Act). The TGA is responsible for administering the Act which provides a uniform national framework for the import, manufacture and supply, and export of therapeutic goods. The Act is supported by the *Therapeutic Goods Regulations 1990* and various Therapeutic Goods Orders (TGOs) and determinations.

Regulatory role of the TGA

The export of medicines from Australia is regulated by the TGA.

The TGA is committed to:

- ensuring that medicines exported from Australia comply with the same quality and safety standards as those supplied in Australia
- the protection of public health and safety through the export of safe medicines of an appropriate quality
- continued participation in international arrangements, including export certification, that promotes the safety and quality of medicines exported from Australia

Exports are important to the future of the Australian medicines manufacturing sector.

Export regulation of medicines:

- ensures that medicines leaving Australia meet appropriate safety and quality standards to support public health
- encourages the development and manufacture of Australian export products

Risk-based regulation

The TGA's risk-based approach to regulating medicine is designed to protect and advance public health.

The level of regulatory control of medicines in Australia is commensurate with the assessed risk posed by the product to public health and safety.

For Export only medicines, an assessment is conducted to ensure they meet standards for quality equivalent to those for the Australian domestic market.

ARTG inclusion is required before export

The *Therapeutic Goods Act 1989* requires therapeutic goods to be included in the Australian Register of Therapeutic Goods (ARTG), before they can be imported into, supplied in, or exported from Australia unless the goods are the subject of an exemption, exclusion, approval or authority.

If you intend to export a medicine for commercial purposes, you need to ensure the medicine is either:

- registered or listed in the ARTG and authorised for supply in Australia
- listed in the ARTG as an Export only medicine

Exemptions

Some therapeutic goods are exempt from the requirement to be entered in the ARTG. In some cases, the exemption may be subject to compliance with certain conditions. For information about exempt therapeutic goods refer to Schedule 5 of the *Therapeutic Goods Regulations 1990*.

Medicines that are extemporaneously compounded by a pharmacist for the medical treatment of a **particular person** are exempt from the requirement to be included in the ARTG under Item 6 of Schedule 5 of the *Therapeutic Goods Regulations 1990*.

Only sponsors and agents can export commercially

Every ARTG entry is in the name of a sponsor who is responsible for applying for and maintaining the ARTG entry.

In order to export a medicine on a commercial scale, you must be either:

- the Australian sponsor named in the ARTG entry for the medicine
- an authorised agent of the Australian sponsor

Other legislation and requirements applicable to export

When preparing to export medicines commercially, you need to ensure that you are complying with other applicable Australian or State and Territory legislation, such as:

- *Customs Act 1901* and the *Customs (Prohibited Exports) Regulations 1958*
- *Industrial Chemicals (Notification and Assessment) Act 1989* and the National Industrial Chemicals Notification and Assessment Scheme
- *Environment Protection and Biodiversity Conservation Act 1999*
- *Food Standards Australia New Zealand Act 1991*
- *Gene Technology Act 2000* and the Gene Technology Regulations 2001
- *Competition and Consumer Act 2010* and the Australian Consumer Law
- *National Measurement Act 1960*
- *Agricultural and Veterinary Chemicals Code Act 1994*

Contact the relevant Embassy, High Commission or Consulate of the importing country to ensure you meet their importation requirements.

Importing therapeutic goods for export purposes

Therapeutic goods that are imported into Australia for export purposes only, are exempt from being included in the ARTG if the goods remain subject to customs control under the Customs Act 1901 (Item 4, Schedule 5 of the *Therapeutic Goods Regulations 1990*).

If the sponsor holds the medicine in a storage facility in Australia (outside of customs control), the medicine must be included in the ARTG prior to export.

Exporting medicines authorised for supply

Medicines authorised for supply in the Australian market will already be registered or listed in the ARTG **for supply in Australia** and are permitted for export, provided:

- you are the Australian sponsor of the medicine or an authorised agent of the sponsor
- the product is identical to the one approved for supply in Australia

Export names

If you want to export a medicine under a trade name not already included in the ARTG, you must submit a grouping application to add the proposed export name(s).

Grouping applications for listed medicines are submitted through TGA Business Services.

Grouping applications for registered medicines are submitted using a Grouping application form to add an export name to a registered product (hyperlink to be inserted).

Exporting a different version of a medicine

Each product in the ARTG is a separate and distinct good, and has a separate entry.

To export a different 'version' of a product that is available for supply in the Australian market (including differences in formulation, container type, shelf life, indications, directions for use, label warning statements etc.) then either:

- submit a new, grouping or variation application to the TGA
- submit an Export only listing application to the TGA

Controlled substances

The Office of Drug Control, as part of the Australian Government Department of Health, regulates and provides advice on the export of controlled substances from Australia.

Controlled substances (such as narcotic, psychotropic and precursor substances) are prohibited for export without a licence and permit under the *Customs (Prohibited Exports) Regulations 1958*.

To export a therapeutic good that contains a controlled substance you need a licence and permit from the Office of Drug Control.

If you are unsure if the good you are exporting contains a controlled substance you should:

- check the list of controlled substances that require a licence and permit to export
- contact the Office of Drug Control

If you are travelling overseas as part of a sporting team, military exercise, medical emergency team or medical aid mission, or are travelling with a medical kit, you should contact the Office of Drug Control for further information.

We also suggest you contact the country to which you will be travelling to ensure you meet their importation requirements.

Export only medicines

Export only medicines are required to be listed under Section 26 of the *Therapeutic Goods Act 1989*. The purpose of an export only listing is to ensure that all products exported from Australia comply with standards that are similar to the standards applied to products supplied in Australia.

Export only medicines:

- **must** be listed in the ARTG before export is commenced
- **must** be:
  - safe for their intended purpose(s)
  - manufactured according to manufacturing principles for medicinal products
  - of acceptable presentation and not make false or misleading representations

- **must** comply with required quality and safety standards
- **must** not be supplied within Australia, including Australian duty free outlets
- **must** not be advertised in any misleading way

Advertising restrictions for export only medicines

Part 5-1 of the *Therapeutic Goods Act 1989* (the Act) regulates advertising that is accessible by consumers in Australia, including social media advertising. There are criminal offence and civil penalty provisions under the Act that apply to those responsible for advertising export only medicines if false and/or misleading representations are made.

Assessment criteria

All export only medicine listing applications undergo a manual assessment by the TGA against criteria defined in Section 26 of the *Therapeutic Goods Act 1989*.

We assess criteria for all Export only medicine listing applications to establish the safety and quality of the product.

If these criteria are met, the product will be listed in the ARTG with conditions imposed for the duration of its inclusion in the ARTG.

Compliance with international standards

Export only medicines must comply with recognised international standards, which determine product quality. These standards are outlined in:

- Chapter 3 Part 3-1 of the *Therapeutic Goods Act 1989*
- Therapeutic Goods Order (TGO) No. 70 - Standards for Export Only Medicine.

TGA recognised standards for export only medicines

We assess the product specifications against:

- British Pharmacopoeia
- European Pharmacopoeia
- United States Pharmacopoeia
- Japanese Pharmacopoeia

If the product does not meet an applicable standard, you may apply for consent to import, supply or export goods that do not comply with standards - section 14/14A.

Manufacturing requirements

All steps of manufacture **must** meet requirements equivalent to Australian regulatory guidelines for the specific medicine type. The medicine must be manufactured in accordance with **Good Manufacturing Principles (GMP)** as outlined in the manufacturing principles for medicinal products.

Mandatory requirements for export only medicines:

- Australian manufacturers must have a valid manufacturing licence issued by the TGA
- overseas manufacturers must have a valid GMP clearance issued by the TGA **in the name of the sponsor**

One or more steps of manufacture must take place in Australia for all Export only medicines. The nominated steps must be reflected on the manufacturing licence. This includes medicines imported into Australia and held prior to export, refer to Importing therapeutic goods for export purposes.

If the manufacturing requirements listed above are not met, your application will be rejected.

Formulation ingredients

Individual ingredients, including active ingredients and excipients, must have an Australian Approved Name (AAN) for therapeutic substances. Further information can be found on Approved names for medicine ingredients.

For all human or animal derived materials included in a product for export, sponsors need to provide details including animal source and country of origin.

Therapeutic claims

The sponsor must hold evidence to support any therapeutic claims made in relation to the product.

Product presentation

We assess product presentation to make a decision on the acceptability of the medicine's presentation and safety for intended purpose of use.

Section, 3(1) of the *Therapeutic Goods Act 1989* provides a definition of the presentation of therapeutic goods. The presentation of a medicine includes the name, label, packaging, package inserts, dosage form and indications.

The TGA will **not** approve a medicine if the presentation:

- is misleading, confusing or false
- implies it is a treatment for a serious disease where there is insufficient evidence of efficacy
- has a dosage form that may be confused with toys, food or confectionary
- does not reveal all the active ingredients

Any product material physically added after the product has been exported from Australia is not subject to regulation by the TGA.

Product label

Finished product labels for Export only medicines should meet the requirements of the importing health authority, including any applicable warning statements.

Finished product labels for Export only medicines do **not** need to:

- comply with Therapeutic Goods Orders No. 91 and 92 for labelling of goods for supply in Australia
- include the AUST L number

If a label is provided in a non-English translation, it **must** be accompanied by an English translation of the label text.

Shelf life and stability studies

The product shelf life is the time period during which a therapeutic good is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label.

Product shelf life is assessed based on the stability data held by the sponsor for each product. We will request stability data for the product when required.

Goods exported as bulk product

Export only medicines also include medicines exported in bulk to be packaged and labelled overseas.

Bulk products may include:

- goods already approved for supply in Australia that are being exported in bulk for further packaging and labelling overseas
- goods specifically intended for bulk export overseas

Bulk shipper labelling

A bulk shipper label must be supplied with your application. The following information must be on the label:

- product name
- batch number
- storage conditions
- expiry details
- sponsor and/or manufacturer name

Applying for an export only medicine listing

To apply for an Export only listing, the sponsor of the medicine must have a TGA Business Services account. After logging into the portal, the sponsor can apply for an export only listing using the online application form. Refer to:

- User guide to apply for an Export only medicine listing.

Mandatory documentation

There are three mandatory documents that must be included as part of a new export only application which will be assessed to determine the product's eligibility for listing in the ARTG:

- the product specification
- product label and any other information packaged with the product prior to export from Australia
- notification that 26B(1) certificate is not required (patent certificate)

What to expect

Once the online application has been submitted you will receive an invoice. The applicable fees and charges can be found on the TGA website.

We aim to process applications for export only listings in **thirty** working days.

The TGA uses the submitted material to make a decision on the acceptability of the medicine's presentation and safety for the intended purpose of use. Should further information be required, the sponsor may receive a request under Section 31 of the *Therapeutic Goods Act 1989*.

Incorrect or incomplete applications

Your application will be rejected if:

- the manufacturing requirements are not met
- the application is incomplete or incorrect
- the application does not meet assessment criteria

If your application is put on hold, you will have a maximum of **six** months to resolve the issue or it will be rejected.

Changes to existing export only medicine listings

There are three types of changes that can be made to an existing Export only listing. For a specific list of allowable changes to your export only medicine, see product change tables.

Some changes will require submission of a new application.

Grouping

- a change permitted under the *Groups Order* and the goods are intended to replace the current supplied goods
  - an application fee equivalent to a new product is payable
  - the existing AUST L number is maintained

Variation

- a minor change to a product's details
  - an application fee is payable
  - the current AUST L number is maintained

Notification

- a very minor change to the product's details that does not change the ARTG record
  - an application fee is not payable
  - the current AUST L number is maintained

Product change tables

The following tables describe the application type required.

Table 1 – Type of application you will need

Type of Change	New application	Grouping	Variation	Notification
Change in dosage form	New application			
Addition or deletion of an active ingredient	New application			
Change in the amount of an active ingredient	New application			
Change in type of container	New application			
Change in the amount of an excipient		Grouping		
Change to product name		Grouping		

Type of Change	New application	Grouping	Variation	Notification
Addition or deletion of an export only name		Grouping		
Addition of therapeutic indications		Grouping		
Directions for use		Grouping		
Addition or deletion of fragrance, flavour or colouring		Grouping		
Change in Shelf life			Variation	
Change in source of animal ingredient			Variation	
Change in manufacturer			Variation	
Change of wording of indications (intent must remain the same)				Notification
Addition or deletion of pack size				Notification
Change to Product Information (not reviewed by the TGA – must be already approved by the importing health authority)				Notification

Table 2 – Specific changes to product label

Change to product label	Variation	Notification
Change to dosing instructions	Variation	
Change to font/colour/layout		Notification
Addition or deletion of country specific warning		Notification
Change to distributor details		Notification
Marketing authorisation number		Notification
Language		Notification

Table 3 – Specific changes to product specification

Change to product specifications	Variation	Notification
A less restrictive limit within an already given range	Variation	
Addition of tests other than 'Appearance' or 'Identification'	Variation	
A more restrictive limit within an already given range		Notification
Removal of country specific tests		Notification
Addition of tests regarding 'Appearance' or 'Identification'		Notification

Export certification for medicines

To facilitate export, the TGA issues export certification for medicines that are registered or listed in the Australian Register of Therapeutic Goods (ARTG) under Section 58 of the *Therapeutic Goods Act 1989*. Export certification is **not** a requirement of the Australian Government.

We issue these certificates to:

- provide appropriate and useful regulatory support to overseas authorities
- enhance the confidence of overseas authorities in the quality and safety of medicines authorised for supply in Australia and/or intended for export
- be accepted in the international market place and to authorities in export destinations

To apply for export certification you **must** be the sponsor of the medicine or an authorised agent acting on behalf of the sponsor.

Australia's export certification process

The TGA promotes the quality and safety assurance provided by Australia's therapeutic goods regulatory system.

We provide export certification to promote confidence in the quality and safety of medicines authorised for marketing in Australia and/or intended for export.

To facilitate export certification for medicines, Australia is a World Health Organization (WHO) Member State for the purposes of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. The TGA is an issuing authority for Certificates of Pharmaceutical Product (CPP) under the WHO Scheme on behalf of Australia.

World Health Organization (WHO) Scheme

Australia participates in the World Health Organization (WHO) *Certification scheme on the quality of pharmaceutical products moving in international commerce*. The WHO Certification Scheme is an international voluntary agreement to provide assurance to participating countries about the quality and safety of pharmaceutical products moving in international commerce.

The Scheme requires a participating Member State (acting as the certifying country) to certify to the authority of another participating Member State (the recipient country) the following:

- a specific pharmaceutical product is authorised for marketing in the certifying country
- the manufacturing facilities and operations conform to Good Manufacturing Practice (GMP) as recommended by the WHO

Good Manufacturing Practice (GMP)

Good Manufacturing Practice (GMP) is confirmed as part of the application process. All manufacturers included on the export certificate have current GMP. The dosage form manufacturer is included on the first page of the certificate unless requested otherwise.

To request a notarised copy of a TGA licence or certificate, refer to request for certificates or notarised copies of TGA licences and certificates.

Types of export certificates

The TGA issues four types of export certificates for medicines:

- Certificate of Pharmaceutical Product (CPP)
- Certificate of Pharmaceutical Product (CPP) for an Export only medicine
- Certificate of Listed Product (CLP)
- Batch Certification of Pharmaceutical Products (BCPP)

We are unable to provide a copy or a sample of export certification.

Certificate of Pharmaceutical Product (CPP)

The Certificate of Pharmaceutical Product (CPP) is an internationally recognised certificate issued under the *World Health Organization (WHO) Certification scheme on the quality of pharmaceutical products moving in international commerce*.

The CPP provides a snapshot of the regulatory status of a single pharmaceutical product.

The CPP is used by overseas authorities to verify information such as:

- product details including the name, formulation and dosage form
- compliance with Good Manufacturing Practice (GMP)

Certificate of Pharmaceutical Product (CPP) for an export only medicine

The Certificate of Pharmaceutical Product (CPP) for an Export only medicine is issued under the WHO Scheme for products that are listed as Export only medicines and are not available for supply in Australia.

Certificate of listed product (CLP)

The Certificate of Listed Product (CLP) is similar to a CPP however is not issued under the WHO Certification Scheme.

We issue CLPs for a single product listed as a complementary medicine in Australia that may have a different regulatory status overseas. This includes herbal products, vitamins and minerals that are regulated as 'foods' or 'dietary supplements' in the importing country.

Batch Certification of Pharmaceutical Products (BCPP) for individual batches of biological medicines

The TGA provides Batch Certification of Pharmaceutical Products (BCPP) for biological medicines. The BCPP is a batch specific certificate for influenza vaccines and blood products manufactured by Australian manufacturers for products included in the ARTG.

To apply for a Vaccine BCPP, submit batch documentation and an application form to vaccines@health.gov.au.

To apply for a blood product BCPP, submit batch documentation and an application form to biochemistry@health.gov.au.

The TGA does **not** issue export certification for 'kits' containing one or more individual registered or listed products. You will need to a submit separate application for each product.

TGA regulatory status comments

The CPP and CLP certificates contain a TGA regulatory status comment. The TGA comments vary based on the type of certificate requested.

Certification type	TGA Comment
Certificate of Pharmaceutical Product for a registered medicine	This product has been evaluated and approved by the TGA and is permitted to be supplied in Australia
Certificate of Pharmaceutical Product for a listed medicine	This product has been approved by the TGA and is permitted to be supplied in Australia
Certificate of Pharmaceutical Product for an Export Only Medicine	This product is listed on the Australian Register of Therapeutic Goods as an export only medicine
Certificate of Listed Product	This product has been approved by the TGA and is permitted for free sale (in that it can be legally supplied) in Australia

Optional sponsor's comment on CPPs

For Certificate of Pharmaceutical Product (CPP) applications, you can request to include a sponsor's comment on the certificate.

All comments **must** be verifiable against the ARTG.

Providing a sponsor's comment on the CPP is optional and it **is included at the TGA's discretion**.

Before submitting your certificate application

Before applying for a TGA export certificate you need to:

- ensure you are the sponsor of the medicine or an authorised agent acting on behalf of the sponsor
- ensure all of the details in the ARTG record are correct and up-to-date
- contact the relevant embassy, high commission or consulate to check the country's importation requirements

Application process

How to apply for a TGA export certificate

You need to submit an online application using TGA Business Services to apply for a Certificate of Pharmaceutical Product (CPP) or a Certificate of Listed Product (CLP). Refer to:

- User guide to apply for export certification for medicines

All information contained in the application **must be accurate**. The TGA is unable to make changes on your behalf.

Once the application has been submitted to the TGA and the invoice paid, the application will be processed. We aim to process export certification applications in fifteen working days.

Sponsor status

The sponsor status of the product refers to the role the sponsor is taking in relation to the manufacture of the product.

The application will ask you to select one of three options for the product:

a. Manufactures dosage form

   – select option (a) if the sponsor manufactures the dosage form

   – if option (a) is selected, the sponsor will be listed as the dosage form manufacturer on the certificate

b. Packages and/or labels dosage form manufactured by independent manufacturer

   – select option (b) if the sponsor is involved in some of the manufacturing step(s), including packages and/or labelling or release for supply, and the product has been manufactured by an independent manufacturer

   – if option (b) is selected, you will be asked if you wish to **display dosage form manufacturer**

c. Is involved in none of the above

   – select option (c) if the sponsor is not involved in any manufacturing of the product

   – if option (c) is selected, you will be asked if you wish to **display dosage form manufacturer**

Display dosage form manufacturer

The selections are:

- **Supress details from the certificate.** This option will not display the manufacturing details on the certificate.
- **See schedule 2 for manufacturing details.** This option will display selected manufacturing details on the manufacturing schedule which will be identified as schedule 2.
- **One of the manufacturers recorded against the AUST L/R number selected.** This option will display the selected dosage form manufacturer's name and address on the first page of the certificate.

Schedules

The TGA generates two schedules to accompany all CPP and CLP. A sponsor may use the TGA generated schedules or may submit their own copy of the schedules. All information contained in schedules must reflect the **exact** information contained in the ARTG entry for the product.

All information included with the CPP and CLP applications will be verified.

Schedule 1 – Formulation details

CPP and CLP are accompanied by a formulation schedule, referred to as 'schedule 1'. This schedule contains the formulation of the product as it appears in the ARTG.

Schedule 2 – Manufacturing details (optional)

Manufacturing information is confirmed to ensure a TGA issued manufacturing license or GMP clearance is in place.

You can indicate if you wish to include the manufacturing schedule in your application form.

Sponsor provided schedule requirements

Sponsors may include the following additional schedules to accompany their CPP or CLP application as requested by the importing country, **provided they have been approved by the TGA**:

- Product label that has been approved by the TGA
- Product Information that has been approved by the TGA
- Consumer Medicine Information that has been approved by the TGA
- Shelf life that has been approved by the TGA

All of the information contained in a schedule **must** be approved by the TGA.

Sponsor provided schedules must be:

- submitted via post
- single-sided A4 documents

Number each page of the schedule.

Ordering of schedules

There can be no gap between the numbering of schedules.

Formulation details must be labelled schedule 1. Manufacturing details, if included, are schedule 2.

Following this, the TGA does not mandate the order or number of the schedules. If there is no manufacturing schedule, the next schedule must be labelled schedule 2.

Declaration for sponsor supplied schedules

Some importing countries require a declaration and an original signature of the sponsor on all sponsor provided schedules. Due to this, we require each schedule supplied by the sponsor to contain a declaration and an original signature.

The declaration that accompanies your schedule should state:

> I, [your name], on behalf of [your company's name] declare the information provided in this schedule is current and correct.

This needs to be **signed** and **dated** by the sponsor or an authorised agent acting on behalf of the sponsor.

Post the hard copy schedules to:

Therapeutic Goods Administration
Attn: Exports
PO Box 100
Woden ACT 2606
Australia

Attachments to a certificate

Additional information requested by an importing country, which cannot be verified by the TGA, can be included as an attachment. Attachments are **not** certified by the TGA.

Examples of acceptable attachments include:

- Product Information, Consumer Medicine Information or product labels that have not been approved by the TGA
- certificates of analysis
- methods of analysis
- product specifications
- raw material specifications

Incorrect or incomplete applications

Your application will be withdrawn if:

- the application is incorrect or incomplete
- you are not the sponsor or an authorised agent acting on behalf of the sponsor
- the manufacturers involved in the manufacture of the medicine do not possess valid GMP
- you have included a 'kit' incorporating more than one registered or listed product

If your application is put on hold, you will have a maximum of **six** months to resolve the issue or it will be withdrawn.

Receiving your certificate

Once the online application has been submitted you will receive an invoice. The applicable fees and charges can be found on the TGA website.

We aim to process export certification applications in **fifteen** working days.

The certificate will be posted to the applicant at an authorised address listed in the TGA Business Services portal.

You may supply a self-addressed express post envelope to the exports team to expedite the shipping of your application.

We cannot provide an update regarding the arrival date of your certificate once it has left the TGA. Please wait a minimum of six weeks after your application status has changed to 'completed' in TGA Business Services before contacting the exports area.

Non-commercial export

Exporting for personal use, family or friends

You need to meet certain conditions to export medicines overseas for non-commercial use.

- The medicine must not be for commercial supply, must not contain a substance prohibited under the *Customs Act 1901* and must not be for use in a clinical trial in humans.
- The medicine to be exported must be in the Australian Register of Therapeutic Goods (ARTG), unless otherwise exempt.
- The total quantity to be exported cannot exceed three month's continuous supply.
- Prescription medicines must be accompanied by a prescription from an Australian registered doctor.
- You must keep all medicines in their original packaging. Prescription medicines must include their pharmacy label.
- You should contact the appropriate authority in the destination country to ensure you can bring the medicine with you.

If you are travelling with a prescription medicine covered by the **Pharmaceutical Benefits Scheme (PBS)** go to How to manage your PBS medicine overseas.

Unapproved medicines for clinical trials

The TGA issues permits for the export of 'unapproved' medicines for use overseas for experimental purposes in humans under sections 19(1)(b) of the Therapeutic Goods Act 1989.

The application form is available at Import/export of 'unapproved' therapeutic goods for experimental purposes.

For further information, contact eps@health.gov.au.

Named patient program

Under Section 19(1)(a) of the *Therapeutic Goods Act 1989*, permission may be granted for approval to export an unapproved medicine for use in the treatment of a specific person overseas under the Named Patient Program.

For further information contact eps@health.gov.au.

Export of medicines for donation or humanitarian purposes

The TGA recommends that a person intending to export therapeutic goods for donation or humanitarian purposes consider the following guidelines issued by the World Health Organization and the Australian Government:

- World Health Organization (2010): Guidelines for medicine donations
- Australian Pharmaceutical Advisory Council (2000): Australian guidelines for drug donations to developing countries

The *Therapeutic Goods Act 1989* (the Act) requires therapeutic goods to be included in the Australian Register of Therapeutic Goods (ARTG), unless those goods are the subject of an exemption, approval or authority under the Act. An exemption for goods not intended for commercial supply, including those for donation or humanitarian purposes, is specified in item 2, Schedule 5, *Therapeutic Goods Regulations 1990*.

Therapeutic goods are exempt from entry into the ARTG if they are goods **for export** and they:

- are not for commercial supply
- do not contain a substance the exportation of which is prohibited under the *Customs Act 1901*
- are not intended for use in clinical trials on humans

There are offence provisions under the *National Health Act 1953* that apply to exporting prescription medicines that are subsidised by the Australian Government under the Pharmaceutical Benefits Scheme (PBS). For more information go to: **How to manage your PBS medicine overseas**.

No exemption from manufacturing requirements

There is no exemption from manufacturing requirements for medicines that are not for commercial supply. All medicines must be manufactured according to Good Manufacturing Practice (GMP).

Version history

Version	Description of change	Author	Effective date
V1.0	Publication for consultation	Application Entry, Support and Export Section	Consultation date: December 2019

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication # D19-6298171