Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Export of medicines from Australia

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Contents

About this guidance

This guidance is to assist entities and individuals planning to export medicines (including prescription, over-the-counter and complementary medicines) either for commercial supply, or for non-commercial purposes (for example, 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 guidance replaces all previous guidance about the export of medicines from Australia. We will review and update this guidance in line with future feedback and potential legislative and policy changes in the coming months.

The guidance provides information about:

- export regulation
- exporting medicines for commercial supply, including:
  - Export Only medicines
  - exporting medicines that are authorised for sale in Australia
  - export certification for medicines
- non-commercial export.

Before you export a medicine for any reason, make sure you understand the requirements set out in this guidance.

If you have any feedback or would like more information please contact Exports.

This information is provided for guidance only and should not be relied on to address every aspect of the relevant legislation.

You should seek your own independent legal advice to ensure that all of the legislative requirements are met.

Export regulation

The *Therapeutic Goods Act 1989* (the Act) regulates the export of therapeutic goods from Australia. The Therapeutic Goods Administration (TGA) is responsible for administering the Act, which provides a uniform national framework for the import, manufacture, supply and export of therapeutic goods. The Act is supported by the *Therapeutic Goods Regulations 1990*, the *Therapeutic Goods (Medical Devices) Regulations 2002* and other legislative instruments.

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

We are committed to:

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

Export regulation supports the development and manufacture of Australian products and ensures that medicines exported from Australia meet appropriate safety and quality standards to support public health.

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.

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.

Contact the importing country to ensure you meet their importation requirements.

Other legislation applicable to export

When preparing to export medicines for commercial supply, you need to comply with other applicable Australian or state and territory legislation, such as:

- *Corporations Act 2001*
- *Criminal Code Act 1995*
- *Customs Act 1901*
- *Narcotic Drugs Act 1967*
- *Industrial Chemicals Act 2019*
- *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*.

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

Exporting medicines for commercial supply

The Act generally requires therapeutic goods to be included in the Australian Register of Therapeutic Goods (ARTG) before they can be imported into, manufactured, supplied in or exported from Australia unless they are exempt.

Generally, any medicine that is being exported for commercial supply must be either:

- listed in the ARTG as an Export Only medicine

  OR

- registered or listed in the ARTG and authorised for supply in Australia.

ARTG registration or listing is required before export

If you intend to export a medicine from Australia for commercial supply that is not included in the ARTG, you will need to submit an application to include the medicine in the ARTG.

To list an Export Only medicine refer to Applying for a new Export Only listing

To register or list a medicine refer to Overview of applying for market authorisation.

Exemptions to ARTG registration or listing (in relation to Export Only medicines)

Some therapeutic goods are exempt from the requirement to be included in the ARTG and can be exported without being in the ARTG. In some cases, the exemption may be subject to compliance with certain conditions. For a list of exempt therapeutic goods refer to Schedules 5 and 5A of the *Therapeutic Goods Regulations 1990*.

Examples of therapeutic goods for export that are exempt under Schedules 5 and 5A include:

- goods exported that are not for commercial supply, do not contain a substance the exportation of which is prohibited under the *Customs Act 1901*, and are not intended for use in a clinical trials on humans (item 2, Schedule 5)
  - goods imported into Australia that are held under the direct control of the sponsor and exported (item,1(e), Schedule 5A)
  - homeopathic preparations, unmedicated acne preparations, medicated insect repellents, disinfectants, sunscreen preparations, anti-dandruff lotions and shampoos, and nappy rash creams - of a type described in items 8, 8A and 8B of Schedule 5.

Who can export medicines for commercial supply

To export a medicine for commercial supply, you must be either:

- the person (generally, this is the sponsor of the good) in relation to whom the medicine is registered or listed in the ARTG

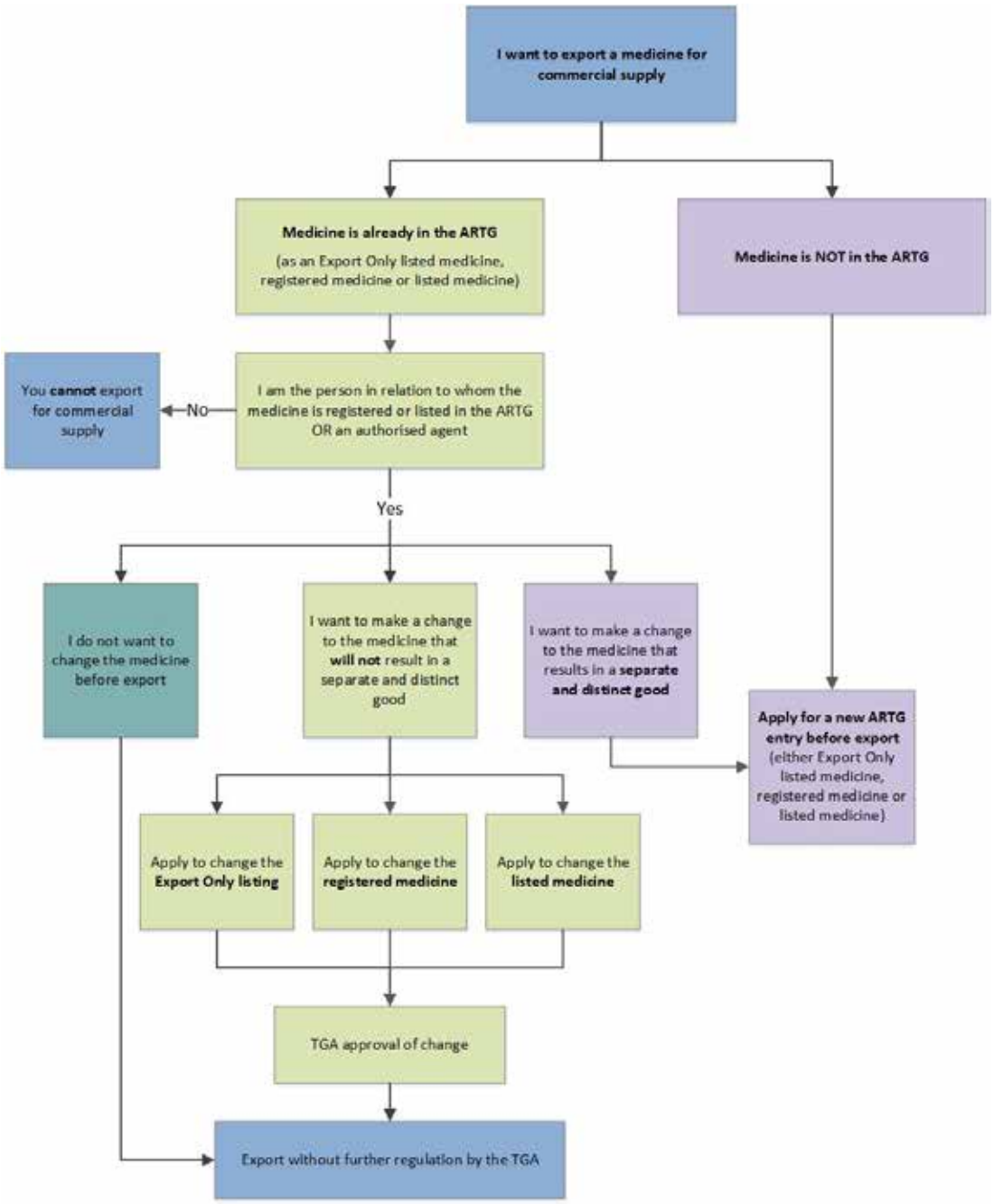
  OR

- an agent authorised to act on behalf of the person in relation to whom the medicine is registered or listed in the ARTG.

The export of a medicine for commercial supply will breach section 19B and/or contravene section 19D of the *Therapeutic Goods Act 1989* in cases where:

- the medicine is exported by someone other than a person in relation to whom the medicine is registered or listed in the ARTG (or other than someone authorised to act on that person's behalf)
- the medicine has not been registered or listed in the ARTG and is not an exempt or excluded good.

Figure 1 – Overview of exporting medicines for commercial supply



Export Only medicines

Export Only medicines **must** be listed in the ARTG (under section 26 of the Act) and **cannot be supplied in Australia**, including Australian duty free outlets.

Export Only medicines:

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

Advertising provisions of the Act are also relevant to Export Only medicines

Section 42DKB of the Act provides for the Secretary to give a person responsible for an advertisement a notice preventing the advertising from containing a specified representation that is false or misleading.

Sections 42DLA and 42DLC of the Act provide for criminal and civil penalties where a notice under section 42DKB is contravened.

Assessment criteria

All Export Only medicine listing applications undergo a manual assessment by the TGA against criteria set out in section 26 of the Act to establish product safety and quality.

Compliance with international standards

Therapeutic Goods (Standard for Export Only Medicines) (TGO 114) Order 2024. It requires Export Only medicines to comply with the current versions of the following standards that relate to product quality:

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

Manufacturing requirements

Export Only medicines must be manufactured in accordance with Good Manufacturing Practice (GMP) as outlined in the Manufacturing principles for medicinal products.

All steps of manufacture **must** meet requirements equivalent to Australian regulatory guidelines for the specific medicine type.

Mandatory requirements for Export Only medicines:

- Australian manufacturers must have a current manufacturing licence issued by the TGA

- overseas manufacturers must have a current 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 (item 1, Schedule 4 of the *Therapeutic Goods Regulations 1990*). The step(s) of manufacture must align with the manufacturing licence conditions.

For ingredients that are Schedule 4 and 8 in the Poisons Standards (the SUSMP) the Active Pharmaceutical Ingredient (API) manufacturers must be identified in the application.

Your application will be rejected if you do not meet the manufacturing requirements.

Formulation ingredients

Individual ingredients, including active ingredients and excipients, must have an Australian Approved Name (AAN) for therapeutic substances. For further information, refer to Approved names for ingredients.

Therapeutic claims

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

Product presentation

We assess product presentation for safety of intended purpose.

Section 3(1) of the *Therapeutic Goods Act 1989* provides a definition of the term 'presentation' in relation to therapeutic goods. The presentation of a medicine includes matters relating to the name, label, packaging, package inserts, and any advertising or other information associated with the goods. This may include information regarding dosage form and indications. Section 3(5) is also applicable.

For example, 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 include all the active ingredients.

Product label and name

Product labels for Export Only medicines should meet the requirements of the importing health authority**.**

Finished product labels for Export Only medicines need to:

- include all active ingredients
- reflect the formulation and product specification.

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

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

If a non-English Export Only label is included with the application, an English translation of the label **must** also accompany the application.

Proposed product names need to be distinct from other product names in the ARTG and acceptable (including product names used in the Special Access Scheme)

Goods exported as bulk product

Export Only medicines (when in final dosage form) may also include medicines exported in bulk to be packaged and labelled overseas.

Bulk shipper labelling

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

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

Confirmation of willingness to accept the goods by the importing country

Export only medicines that are new to an importing country may require a confirmation from the importing country of their willingness to accept the goods. Evidence from the relevant overseas regulatory authority may be required and used in the assessment of an application to list a product as an Export Only medicine. This may be requested, particularly in relation to a new and/or unapproved product.

Applying for a new Export Only listing

The Export Only application form is available online. Before applying for an Export Only medicine, you will need:

- a TGA client identification number
- access to TGA Business Services (TBS) portal.

TGA Business Services: getting started with the TGA provides information about TGA business services.

A user guide is available within the TBS portal to assist when applying for or changing an Export Only medicine listing.

Mandatory documentation

Three mandatory documents must be submitted with your application:

- the finished product specification (including formulation)
- the medicine label, including any package inserts and the Product Information (PI) if applicable
- Approved forms for notification or certificate under subsection 26B(1) of the *Therapeutic Goods Act 1989*

- this is a mandatory form for all new Export Only medicine listing applications and provides notification to the Secretary of the Department of Health that a certificate under subsection 26B91) is not required in relation to the application.

What to expect

Once the online application is submitted, you will receive an invoice. The Schedule of fees and charges and refund policy are on the TGA website.

Generally, we aim to process applications for Export only listings in 30 working days. However, this is subject to the circumstances of the case.

The TGA uses the submitted material to assess the application against the assessment criteria, including the acceptability of the medicine's safety for the intended purpose of use, and the acceptability of the presentation of the medicine. Should further information be required, we may request it under section 31 of the Act.

Incorrect or incomplete applications

Applications may be rejected if they are incorrect or incomplete.

For example, if the:

- manufacturing requirements are not met
- application does not meet the assessment criteria

We may give an applicant up to 6 months (depending on the circumstances) to resolve issues.

Changing an existing Export Only listing

To change an existing Export Only listing refer to the Export Only medicine change table below, which details the type of change and corresponding application type. For any changes not listed in the Export Only medicine change table contact Exports.

There are 2 application types:

- a **grouping** application allows you to **change** a currently supplied good under the Groups Order (for example, adding an export only name to an existing product in the ARTG)
- a **variation** application allows you to make a **minor change** to a product's details (for example, making a manufacturing related change to an existing product in the ARTG).

Some changes will require you to submit a new Export Only application.

A user guide is available within the TBS portal to assist when applying for or changing an Export Only medicine listing.

Table 1a: Export Only medicine change table

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

Type of Change	Application type
Addition of therapeutic indications	Grouping application
Directions for use	Grouping application
Addition or deletion of fragrance, flavour or colouring	Grouping application
Change in Shelf life	Variation application
Change in source of animal ingredient	Variation application
Manufacturing related changes	Variation application
Change of wording of indications (intent must remain the same)	Notification
Removal of some or all indications	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 1b: Specific changes to product label

Change to product label	Application type
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 1c: Specific changes to product specification

Change to product specifications	Application type
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 of medicines authorised for supply in Australia

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

- you are the person in relation to whom the medicine is included in the ARTG, or an agent authorised to act on behalf of that person in relation to the exportation

  AND

- the medicine is unchanged to the one authorised for supply in Australia.

Any change must be approved before export

Generally, any change to a medicine authorised for supply in Australia, including a change for the purpose of export, must be approved by the TGA prior to export. This is a condition of registration or listing in the ARTG (section 28(5)(aaa) of the Act). Failure to comply may give rise to suspension or cancellation from the ARTG, or other penalties.

If you intend to change an Australian supplied medicine for export purposes, make sure you understand the requirements **before commencing export.**

Adding an export name

If you want to export a medicine that is already authorised for supply in Australia under a name not included in the ARTG, you must submit a grouping application to add the proposed export name(s):

- for registered medicines, submit a Grouping application form to add an export name to a registered medicine
- for listed medicines, submit a grouping application through TGA Business Services.

The ARTG number will stay the same.

Applying for a change other than an export name

The process to apply for a change other than adding an export name depends on the:

- type of medicine

  AND

- proposed change.

For the relevant guidance refer to Table 2 below.

Table 2 – Guidance to assist applying for changes to medicines authorised for supply in Australia

Medicine type	Relevant guidance
Prescription medicines	Refer to Varying an ARTG entry topic in the ARGPM BETA
Over-the-counter (OTC) medicines	Process to change a registered OTC medicine Changing an OTC medicine: using the Changes Tables
Complementary medicines	Changing a listed or assessed listed medicine – Application types and change tables Changing a registered complementary medicine – RCM application levels and changes tables

Changes that result in a separate and distinct good

Some changes to a medicine may result in a medicine being classified as a separate and distinct good from the medicine currently included in the ARTG (as a result of section 16 of the Act).

If you want to export a medicine that is separate and distinct to a medicine already authorised for supply in Australia, you must apply for a new ARTG entry before export.

Registered medicines

A registered medicine authorised for supply in Australia, is separate and distinct (under subsection 16(1)) if it has a different:

- formulation, composition or design specification
- strength or size (disregarding pack size)
- dosage form or model
- name
- indication (except for variations to indications under section 9D(2) of the *Therapeutic Goods Act 1989*)
- directions for use
- container type (disregarding container size).

Listed medicines

A listed medicine authorised for supply in Australia is separate and distinct (under subsection 16(2) and regulation 11) if it has a different:

- active ingredient (or quantity of this)
- dosage form
- name
- indication
- excipient
- quantity of a restricted ingredient that is an excipient, or concentration of a restricted ingredient, or directions for use in relation to the recommended single or daily dose of a restricted ingredient.

Exporting medicinal cannabis

There are specific requirements under the *Therapeutic Goods Act 1989* and *Narcotic Drugs Act 1967* that need to be considered before exporting medicinal cannabis products. The requirements are set out in:

Therapeutic Goods (Standard for Medicinal Cannabis TGO 93) Order 2017.

Medicinal cannabis products imported into and supplied/manufactured in Australia must conform with TGO 93. TGO 93 is a standard that specifies minimum quality requirements for medicinal cannabis products.

The TGA may also request information relating to manufacturing, API, supply pathways and labelling for Export Only medicinal cannabis product applications.

The Office of Drug Control (ODC) is responsible for administering the licensing and permit scheme that regulates the cultivation of cannabis plants and cannabis resin, the production of cannabis or cannabis resin and the manufacture of narcotic drugs.

Export of medicinal cannabis – Guidance for cultivators and manufacturers of medicinal cannabis.

In addition, ODC require medicinal cannabis products for export to be registered or listed in the ARTG before a licence and permit can be issued under the Customs (Prohibited Exports) Regulations 1958.

Further guidance in relation to exporting medicinal cannabis will be published in the coming months. If you require clarification of a particular requirement, please contact TGA Exports or ODC.

Export of unapproved medicines

'Unapproved' medicines have not been approved for use in Australia. 'Unapproved' medicines must be manufactured according to Good Manufacturing Practice (GMP) and other manufacturing requirements.

Clinical trials

Where appropriate, the TGA may grant approval (in writing) for the export of 'unapproved' medicines for use overseas for experimental purposes in humans under section 19(1)(b) of the *Therapeutic Goods Act 1989*.

Requirements for exporting therapeutic goods for use in clinical trials overseas

You will need to apply for TGA approval to export therapeutic goods overseas for use in clinical trials.

Approvals are usually granted for **multiple consignments** for export to **one or more countries** for a period of twelve months. A new application is required to renew an approval after this twelve month period.

Application form

The application form and further information is available on the *Import/export of unapproved therapeutic goods for experimental purposes* page of our website.

Six monthly reports

A report detailing the quantity of goods that have been exported to each clinical trial site must also be submitted to the TGA every six months.

The six monthly report template and further information is available on the *Import/export of unapproved therapeutic goods for experimental purposes* page of our website.

For guidance on conducting clinical trials, refer to the Australian clinical trial handbook.

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 export 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
- assist Australian medicines to be accepted in the international marketplace.

To apply for export certification you **must** be the person in relation to whom the medicine is included in the ARTG or an agent authorised to act on behalf of that person.

Australia's medicine 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.

World Health Organization (WHO) Certification Scheme

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 the issuing authority for Certificates of Pharmaceutical Product (CPP) under the WHO Certification Scheme on behalf of Australia.

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 WHO Certification 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 by 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.

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 CPP is an internationally recognised certificate issued under the WHO Certification Scheme.

The CPP provides 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 CPP for an Export Only medicine is issued under the WHO Certification Scheme for a product that is listed as an Export Only medicine in the ARTG and is permitted to be exported from Australia. An Export Only medicine cannot be supplied in Australia.

Certificate of Listed Product (CLP)

The CLP is similar to a CPP. It is **not** issued under the WHO Certification Scheme however. A CLP can be issued for a single product listed as a complementary medicine in Australia, and it includes a comment specifying that the product is **permitted for free sale (in that it can be legally supplied) in Australia**.

The TGA understands that some products which are classified as therapeutic goods/medicines in Australia are regulated as health/dietary/food supplements in the importing country. As these products are regulated as medicines in Australia, they must be accompanied by TGA export certificates. The CLP is widely accepted in international jurisdictions in place of a Certificate of Free Sale.

Specific CLP requirements for Vietnam

CLP requirements for products being exported to Vietnam and which are regulated as health/dietary/food supplements by the Vietnam Food Authority (VFA), will require the following:

- Inclusion of schedule 2 (manufacturing details) – please ensure you select this option during the application process and select the manufacturer of the dosage form for your product as a minimum
- Inclusion of a supporting Word document (see template at Attachment 2) stating a sponsor comment to be included in the CLP regarding the product category for Vietnam 'health supplement/dietary/food supplement'. This will be used to capture the requested sponsor comment in the CLP.

Please note that the TGA cannot advise on which product category should be listed on the CLP. It is up to the applicant to include the current comment/product category (as required by Vietnam) on what is acceptable or appropriate.

In circumstances where the product is not considered a medicine in Australia (i.e. not included in the ARTG), a Certificate of Free Sale can be obtained from the appropriate regulatory authority such as the Department of Agriculture, Water and the Environment (DAWE),- external site the Australian Chamber of Commerce and Industry (ACCI)- external site or other relevant agency depending on the nature of the product.

Please note: A Certificate of Free Sale issued by the TGA is ONLY available for medical devices and NOT listed/registered medicines.

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

The BCPP for biological medicines is issued under the WHO Certification Scheme. 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 please contact vaccines@health.gov.au.

To apply for a blood product BCPP please contact 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 submit a separate application for each product.

TGA regulatory status comments

The CPP and CLP contain a TGA regulatory status comment.

Table 3: TGA comments for certification type

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 has been approved by the TGA and is permitted to be exported from Australia
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

Sponsor's comment

You can request to include a sponsor's comment on the CPP (for example, why the medicine is not currently supplied in Australia).

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

Providing a sponsor's comment is optional and **is included at the TGA's discretion as the certifying body.**

Before submitting your certificate application

Before applying for an export certificate, you need to:

- ensure you are the sponsor of the medicine or an authorised agent 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 an export certificate

Submit an online application using TGA Business Services to apply for a Certificate of Pharmaceutical Product (CPP) or a Certificate of Listed Product (CLP).

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

Once the online application has been submitted, you will receive an invoice. Your application will not be processed until the invoice is paid. The current fee for export certification can be found on the TGA's Schedule of fees and charges webpage under **Export**.

We aim to process export certification applications in approximately 15 working days. However, this is dependent on the circumstances.

A user guide is available within the TBS portal to assist when applying for export certification for medicines.

Sponsor status

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

Schedules

The TGA generates two schedules to accompany all CPPs and CLPs. You may use the TGA generated schedules or provide your own schedules. All information contained in the schedules must reflect the **exact** information contained in the ARTG entry for the product.

Schedules include the certificate number and the official Australian Government Department of Health logo.

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

Schedule 1 – Formulation (mandatory)

CPPs and CLPs are accompanied by a formulation schedule, referred to as ‘schedule 1’. This schedule contains the formulation of the medicine as it appears in the ARTG.

Schedule 2 – Manufacturers (optional)

We confirm GMP as part of the application process.

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

Sponsor-provided schedules

You may use the TGA-generated schedules or provide your own version of these schedules.

Schedules c**annot** include information that is not in the ARTG or TGA approved.

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

- 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 in the ARTG or approved by the TGA.

Sponsor-provided schedules must be single-sided A4 documents.

Order of schedules

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

The TGA does not mandate the order of subsequent schedules. However, there can be no gap between schedules. For example, if there is no manufacturing schedule, the next schedule is schedule 2.

Page numbers of schedules

Number each page of a schedule.

Start each subsequent schedule from page 1.

Declaration for sponsor-provided schedules

Some importing countries require a declaration on all sponsor-provided schedules. You should check with the importing country for their requirements for declarations.

The declaration can only be signed by the sponsor or an authorised agent of the sponsor. The declaration should state:

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

Submitting schedules

You may provide electronic or hard copy (paper) schedules based on the requirements of the importing country.

Electronic schedules

Upload your schedules as part of the Electronic supporting attachment list.

Hard copy schedules

Post hard copy schedules to:

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

The TGA does not provide advice regarding importing countries' requirements.

Attachments

An importing country may request documentation that cannot be certified under the WHO Certification Scheme. These are referred to as attachments. Attachments are not verified by the exports team.

Attachments are limited to:

- certificates of analysis
- methods of analysis
- product specifications
- raw material specifications.

If an importing country requests an attachment, email Exports for further information.

Applications that do not meet requirements

You will not be issued a certificate if:

- you are not the person in relation to whom the medicine is included in the ARTG or an agent authorised to act on behalf of that person
- the manufacturers involved in the manufacture of the medicine do not have a current TGA issued manufacturing licence or GMP clearance
- you have included a 'kit' incorporating more than one registered or listed product.

Applications put on hold

If your application is put on hold, you have 3 months to resolve the problem or you will not be issued a certificate.

Receiving your certificates

Certificates are posted via Express Post envelope to the applicant, at an authorised address listed in the TGA Business Services portal.

We cannot provide an update regarding the arrival date of your certificate once it has left the TGA.

Non-commercial export

Exporting for personal use, family or friends

Before exporting a medicine, you should contact the appropriate authority in the destination country to confirm their requirements.

If you are exporting medicines for non-commercial use, ensure:

- the medicine is in the Australian Register of Therapeutic Goods (ARTG) unless exempt
- the medicine is not for commercial supply
- the medicine does not contain prohibited substances under the *Customs (Prohibited Exports) Regulations 1958*
- the medicine is not for use in a human clinical trial
- the quantity does not exceed 3 months continuous supply
- medicines are in original packaging
- prescription medicines are accompanied by a valid prescription from an Australian doctor
- prescription medicines include their pharmacy label.

Controlled substances can only be exported with an appropriate license or permit from the Office of Drug Control.

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

Exporting medicines for donation

The TGA recommends that a person intending to export therapeutic goods for donation consider the following:

- the WHO webpage Donations of medicines and medical devices
- World Health Organization (2010): Guidelines for medicine donations
- Australian Pharmaceutical Advisory Council (2000): Australian guidelines for drug donations to developing countries

The export of therapeutic goods for donation falls within the exemption in item 2 of Schedule 5 of the *Therapeutic Goods Regulations 1990*, which stipulates that the goods:

- 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

All medicines must be manufactured according to Good Manufacturing Practice (GMP) and other manufacturing requirements, including medicines that are not for commercial supply.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication. Replaces all previous guidance about the export of medicines from Australia.	Application Entry, Support and Export Section and Regulatory Guidance Team	June 2021
V1.1	Inclusion of additional information for CLP requirements for Vietnam	Application Entry, Support and Export Section and Regulatory Guidance Team	May 2023
V1.2	Replacement of the details and link regarding compliance with international standards, specifically TGO 114 which replaced TGO 70C	Application Entry, Support and Export Section and Regulatory Guidance Team	October 2024

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