Australian Government
Department of Health
Therapeutic Goods Administration

Export of medicines guidance

Recent updates

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Agenda

- Background
- Public consultation
- About the guidance
- Export basics/legislation
- Export Only medicines
- Export Only medicines (authorised for supply in Australia)
- Export of medicinal cannabis
- Export of unapproved medicines
- Export certification for medicines
  - Updates about specific requirements when exporting medicines to Vietnam
- Export certification for medical devices
- Export of unapproved medicines for clinical trials
- Pipeline

Background

- Guidance material about exporting therapeutic goods from Australia was originally published on the TGA website in 2002-2007 and was in need of an update.
- The Export Guidance Project was undertaken to account for significant changes since then. The purpose of the Project was to develop user-focussed guidance that aligns with current legislation, policy and business operations.
- The project is being done in stages:

Stage 1

  - removal of all previous export guidance material on the TGA website
  - publication of key information in frequently asked questions, as an interim measure until the new guidance material was produced
  - publication of new guidance and forms relating to the export of human substances.

Background

Stage 2

The development and publication of new guidance has incorporated the consultation feedback into the new guidance material where possible.. Specifically we have:

- included an export overview flowchart in the Export of medicines from Australia guidance
- clearly identified who can export for commercial supply
- restructured the guidance material to assist with clarity
- clarified the differences between EO medicines and exporting medicines authorised for supply in Australia.

In relation to the Export of medicines from Australia guidance:

- ‘Solely for Export’ content was removed noting this practice ceased in 2014
- ‘Certificates for Exempt Products (CEPs)’ content was removed noting this practice ceased in 2019
- amendments to legislation have been incorporated, specifically section 28(5)aaa of the Act

Public consultation

Stage 2 of the Export Guidance Project was the subject of a public consultation that closed in February 2020. Stage 2 guidance material addresses out-of-date and inaccurate information that was previously publicly available.

The TGA sought comments from stakeholders on draft guidance material for the:

- Export of medicines from Australia
- Export certification for medical devices

Seventeen submissions were received from government agencies, industry, peak bodies, sponsors and manufacturers. There were 79 comments received.

Summary of public consultation received

Number of comments	Relevant stage the comment is addressed in	Nature of comments received
46	Stage 2	• Changes allowable prior to exporting a medicine already supplied in Australia • Removal of change tables related to specifications, label and PI variations • Re-arrange sections and make the guidance clearer especially form new or smaller sponsors • Addition of hyperlinks to forms and user guides and flowcharts • Clarity on page numbering of schedules, who can export from Australia, translating documents, • Changes allowable when exporting an Australian supplied product • Removal of old guidance and a lack of access to these documents for reference • Consistent use of “export only” and “solely for export”
1	Stage 3	• Resolution on differing Certificate of Pharmaceutical Product (CPP) requirements by importing countries, specifically Vietnam. • Practical solution to assist exporters to comply with the Apostille convention administered by DFAT for attachments not verifiable by the TGA and or allowable under the CPP Who Scheme
29	Not applicable/ out of scope or NFA	• General comments about the usefulness of the documents, suggestions to take steps to accept electronic export certificates into the future • TGO 70
3	Case by case basis	• Cessation of Certificate of Exempt Products

Recent changes affecting export certification

- Export certification to be discussed in detail later in the presentation
- Industry feedback was received by the TGA about the difficulties experienced by exporters of medicines to Vietnam
- The TGA became aware that other agencies were inadvertently issuing export certification/approval for medicines that are regulated as foods/dietary/health supplements in Vietnam.
- This practice was ceased in October 2021 and the TGA are the only authority that can issue export certification for medicines.
- Over the past few months the TGA have been liaising with the Vietnamese regulatory authority (the Vietnam Food Administration) about their requirements and reached a workable solution. This will be covered in later slides.

About the guidance

- Published in September 2021 after industry consultation in early 2020
- Industry feedback was used to improve the guidance with further clarification, use of flowcharts, tables and additional paragraphs added where required
- The guidance replaces the outdated Export guidance with up to date clarification on TGA policy
- The purpose of the guidance is to assist entities and individuals planning to export medicines (including prescription, OTC and complementary medicines for commercial and non commercial purposes)
- Future updates are planned to incorporate more recent changes to export requirements and processes.
- Tranche 2 updates are currently in review and the updated guidance will be published in the coming weeks.

Export basics

- The export of medicines is regulated by the TGA and 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.
- To export medicines you must meet certain regulatory requirements as set out in therapeutic goods legislation, in addition to other Commonwealth and state or territory legislation criminal and civil penalties apply if you do not meet these legal requirements.

Export legislation

Export regulation

- *Therapeutic Goods Act 1989* (the Act), supported by the *Therapeutic Goods Regulations 1990 (the Regs)*, *Therapeutic Goods (Medical Devices) Regulations 2002* and other legislative instruments.

Controlled substances

- The Office of Drug Control (ODC) regulate and provide advice on the export of controlled substances from Australia. Controlled substances are prohibited for export without a licence and permit under *Customs (Prohibited Exports) Regulations 1958*.
- Contact ODC if you are exporting products with controlled substances

Other applicable legislation

- Compliance with other applicable Australian or state and territory legislation including: *Corporations Act 2001, Criminal Code 1995, Customs Act 1901, Narcotic Drugs Act 1967 etc*

Exporting medicines for commercial supply

- The Act requires that goods be included in the Australian Register of Therapeutic Goods (ARTG) before they can be imported, manufactured, supplied in or **exported** from Australian unless exempt (Schedule 5 and 5A of the *Therapeutic goods Regulations 1990)*.
- The exported medicine must either be listed in the ARTG as an Export Only medicine OR registered (AUSTR) or listed (AUSTL) in the ARTG (authorised for supply in Australia).
- To export there must be a person (generally this is the Sponsor) in relation to whom the registered or listed medicine in the ARTG or an authorised agent to act on behalf of the person in relation to whom the medicine is registered or listed in the ARTG.
- One or more step of manufacture must take place in Australia (item 1, schedule 4 of the Regs) for all Export only medicines.
- A flowchart (Figure 1,page 9) was added as an overview of exporting medicines for commercial supply.

Export only medicines

Export only medicines must:

- Be listed in the ARTG (under s26 of the Act) before export
- Safe for their intended purpose
- Manufactured according to manufacturing principles for medicinal products
- Be of acceptable presentation (section 3(1) of the Act defines the term ‘presentation’)
- Comply with the required quality and safety standards
- Not be supplied in Australia (including duty free outlets)

Note – Export only medicines are subject to the advertising provisions in the Act.

Export only medicines - Assessment criteria

- Assessment criteria include:
- **Compliance with international standards (TGO70C)**
- **Manufacturing requirements**

  Australian manufacturers must have a current licences issued by the TGA and overseas manufacturers must have a current GMP clearance issued by the TGA in the Sponsor's name)
- **Formulation ingredients**

  Each ingredient including active and excipient must have an Australian Approved Name (AAN). Visit approved names for ingredients or contact TGA Names.
- **Therapeutic claims**

  The Sponsor must hold evidence to support any therapeutic claims made in relation to the medicine.
- **Product presentation**

  As per section 3(1) of the Act, presentation includes matters relating to the name, label, packaging, package inserts, advertising other information such as dosage form and indications.

Export only medicines - Assessment criteria

- **Product presentation (Label and name)**

Export only product labels need to meet the importing health authority requitements, and include all active ingredients, reflect the formulation and product specification.

Finished product labels for export only medicines do not need to comply with the TGO 91 or 92 or include the AUSTL number.

Non English labels included with the application require a translated label to accompany the application.

Proposed product names need to be distinct from other ARTG names and be acceptable (this include product names and Special Access Scheme)

- **Goods exported as bulk product**

Export only medicines with in final dosage form can include medicines exported in bulk to be packaged and labelled overseas. A bulk shipper label is required for these applications (product name, batch number, storage, export and Sponsor/manufacturer details)

- **Importing country requirements and willingness to accept the goods.**

Evidence of acceptance can be requested during assessment.

Application for a new export only listing

- Form is available online via TBS (need a TGA client number and access to TBS portal)
- User guide on how to complete the form available in TBS
- Mandatory documentation
    1. Finished product specification
    2. Medicine label (including package inserts, PI and any translations if label is in another language)
    3. Correctly completed approved form notification or certificate under subsection 26B(1) of the Act
- After the online application is submitted, you will receive an invoice
- Aim is to process application with 30 working days
- Should further information be required a section 31 request may be made during assessment.
- Incorrect/incomplete application may be refused

Change an existing export only listing

- Refer to change table in guidance. Changes are captured by either a grouping, variation or a notification. Some changes require a new listing application.
- Generally any changes in the dosage form, addition/deletion of an active or excipient (excluding flavour, fragrance or colour) will require a **new** application.
- Changes to an excipient amount, product name, addition of an export name, indications and directions for use are captured via a **grouping** application.
- Changes to shelf life, animal ingredient source, and manufacturing changes (adding or deleting manufacturers), changes to dosing instructions, some product specification changes (less restrictive test limits and addition of tests other than appearance or identification) with are captured via a **variation** application.
- Variations can be made when submitting a grouping application.
- Changes to label layout, fonts, colours, deletion of country specific warnings, language, more restrictive tests, addition of tests on appearance and identification are notifiable to the TGA via email request to tga.exports@health.gov.au

Export of medicines authorised for supply in Australia

- Adding an export name to a registered or listed medicine
  - For registered medicines, submit a grouping application (form/guidance on the TGA website, Exports landing page)
  - Listed medicines, submit an application via TGA Business Services
  - ARTG number will remain the same
- Any other change must be approved before export (condition of registration section 28(5)(aaa) of the Act)
  - Prescription medicines – refer to ARGPM BETA (Varying an ARTG entry)
  - OTC medicines – refer to process to change a registered OTC medicine and associated change tables
  - Complementary medicines – refer to changing a listed, assessed listed or registered medicine – application types and change tables)
- Some changes result in a separate and distinct good (section 16 of the Act).
  - Registered medicines – different formulation, strength, dosage, name, indication etc
  - Listed medicines – different active (including quantity), dosage form, name, indication, excipients etc

Exporting medicinal cannabis

- Therapeutic Goods (standard for Medicinal Cannabis TGO 93) Order 2017
  Currently the TGA is consulting with industry on the new TGO 93 draft.

- The TGA may request additional information in relation to manufacturing such as the source of API, supply pathways, importing country details and labelling.

- ODC administers the licencing and permit scheme for the cultivation of cannabis plants , cannabis resin, the production of cannabis resin, and narcotic drugs. ODC often require medicinal cannabis products to be in the ARTG before a licence and permit can be issued under *Customs (Prohibited Exports Regulation 1958.*

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.
- 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 Act.
- An application can be made to export unapproved therapeutic goods for use in clinical trial overseas using the application form on the TGA website. Approvals can be granted for multiple consignments to one or more countries over a period of 12 months. An approval can be re-newed after this 12 month period.
- A six monthly report must be submitted to the TGA with details of the quantity of exported goods. The template and instructions are also on the TGA website.
- Refer to the Australian clinical trial handbook

Export Certification for medicines

- Export certification is used to facilitate export of medicines that are registered or listed in the ARTG (under section 58 of the Act). The certification provides regulatory support to overseas authorities and enhances the confidence of these authorities about the quality and safety of medicines both for supply in Australia and intended for export.
- Australia is a Member State for the purposes of the World Health Organisation (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. The TGA is the only issuing authority of Certificate of Pharmaceutical Product (CPP) under this Scheme. The Scheme requires that the certifying country (in this case Australia) to the receipt country that:
  - a specific pharmaceutical product is authorised for marketing in Australia
  - the manufacturing facilities and operations conform to GMP as recommended by WHO

Types of export certification

- The TGA issue four types of export certificates:
  - Certificate of Pharmaceutical Product (CPP) – internationally recognised certificate issued under the WHO Scheme
  - Certificate of Pharmaceutical Product (CPP) for an Export Only medicine - internationally recognised certificate issued under the WHO Scheme
  - Certificate of Listed Product (CLP) – Similar to the CPP, but **not** issued under the WHO Scheme
  - Batch Certification of Pharmaceutical Products (BCPP) - internationally recognised certificate issued under the WHO Scheme

- The TGA is the only issuing authority for export certification for medicines
- Products need to be in the ARTG before export certification can be issued
- The TGA does not issue a Certificate of Free Sale (CFS) for medicines

TGA regulatory status comments

- The CPP and CLP contain a TGA regulatory status comment
- Differences between comments relate to whether the product is:
  - evaluated
  - Approved
  - supplied in Australia
  - approved for export or
  - permitted for free sale (in that it can legally be supplied) in Australia.
- TGA regulatory comments can not be altered

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 comment

- A Sponsor comment is permitted on export certification by request and is optional*
- The request to make comment differs depending on the certificate type.
- All comments must be verifiable against the ARTG and are at TGA's discretion to be included in the certificate.
- Only certain comments are allowable on the CPP which complies with the requirements of the WHO Scheme.
- Sponsor comments relating to product category in Vietnam are allowable on a CLP

Export certification - Specific country requirements

- Some products which are classified as therapeutic goods/medicines in Australia are regulated as health/dietary/food supplement in the importing country.
- As these products are regulated as medicines in Australia, they must be accompanied by TGA export certification.
- A CLP is widely accepted by international authorities in place of a Certificate of Free Sale (the TGA regulatory status comment refers to this)
- CLP requirements for products exported to Vietnam which are regulated as health/dietary/food supplement by the Vietnam Food Authority (VFA) will require:
  - Inclusion of schedule 2 (manufacturing details). Please select this option during the application process (minimum is the manufacturer of dosage form)
  - Inclusion of a supporting Word document with the Sponsor comment to be included in the CLP regarding the product category

Proposed template – Sponsor request for comment on importing country product category on CLP

SPONSOR COMMENT REQUEST for Certificate of Listed Product (CLP)

Please include the following Sponsor comment(s) as you would like them to appear on the relevant CLP(s):

Application ID	**Sponsor comment**
Example EX-2022-EX-001100-1	*Health Supplement*

- One word document can be used for multiple applications and upload as a supporting document with each application.
- Insert additional rows if required.

Export certification - Application process

- Before submitting – ensure you are the sponsor or an authorised agent of the medicine, all the details in the ARTG are correct and up to date, check the importing country requirements.
- Applications are online via the TGA Business Services.
- An invoice is generated after the online application is submitted and the application will not be processed until the invoice is paid.
- The current fee for export certification in available on the TGA's Schedule of fees and charges webpage.
- Target processing timeframe is 15 working days.
- User guide available within TGA Business Services to assist applicants.

CPP and CLP schedules

- The TGA generates two schedules to accompany all CPPs and CLPs. You may use the TGA generated schedules or provide your own schedules (A4 single sided, page numbered and either supplied electronically or hard copies send to Exports).
- 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 and can not include information that is not in the ARTG or TGA approved. The order of schedules are:
    - Schedule 1 – Formulation (mandatory)
    - Schedule 2 – Manufacturers (optional)*
    - Additional schedules that can be included: TGA approved product label, PI, CMI and shelf life.

Note – some importing countries require a declaration on sponsor-provided schedules.

CLP and CPP Attachments

- An importing country may request documentation that can not be verified under the WHO Scheme. These are referred to as attachments and 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 or has other requirements, contact the Exports team in the first instance.

Receiving export certification

- Certificates are posted via Express Post envelope to the applicant, at an authorised address listed in the TGA Business Services portal.
- Ensure contact people/agents are authorised in TGA Business Services.
- We cannot provide an update regarding the arrival date of your certificate once it has left the TGA. We can provide the Express Post tracking number.

Export certification for medical devices

- If you plan to export a medical device from Australia, you must meet certain regulatory requirements set out in the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Medical Devices) Regulations 2002*, in addition to other relevant Commonwealth and state or territory legislation.
- If you intend to export a medical device, you need to have either a current ARTG inclusion that allows a medical device to be supplied in Australia and exported OR a current Export Only ARTG inclusion.
- The only exception is if those goods are exempt medical devices (refer to Therapeutic Goods (Medical Devices) Regulations 2002) or excluded medical devices (some low-risk products are excluded from the TGA's regulatory framework and should not be included in the ARTG)
- Medical devices need to comply with the regulatory requirements in the importing country.
- Export certification for medical devices in not a requirement of the Australian Government.
- Application is via a form from the TGA website and payment is made to accounts.

Pipeline - Export of food to China

- In 2021 China issued a number of decrees requiring that foods imported into China had to be registered in the General Administration of Customs of China (GACC) database and endorsed by the competent authority in the country of origin, in order to be able to be exported from January 2022.
- The goods captured by the decrees are largely foods, for which Department of Agriculture, Water and Environment is the competent authority. However, a number of the goods are regulated in Australia as listed medicines (e.g. functional foods, bee products) - for these, the TGA is the competent authority.
- For listed medicines in scope of the decrees, the TGA will endorse the sponsor of the medicine, as they are the entity legally responsible for the overall manufacture of the goods in Australia.
- In 2021 a number of sponsors currently exporting listed medicines to China provided their details to be included in a pre-registration list.
- These sponsors have now been issued a GACC account and are required to provide documentation to the GACC to complete their registration process.
- The TGA has been working with sponsors to understand and help facilitate the process and we now have a number of successful GACC registrations

Pipeline

- A new export pathway for Biologicals is being developed. The TGA have finished the public consultation with the sector, and we are reviewing responses and currently formulating a pathway to be recommended to government.
- Updated export guidance to include the importing country requirements and process for Vietnam, publication over the coming weeks
- Clarification on how TGO 110 applies to export only listing applications for vaping products.

Australian Government

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