



This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<https://www.tga.gov.au/treatment-information-provided-tga>>.

Application for approval to import/export unapproved therapeutic goods for experimental purposes in humans

Therapeutic Goods Act 1989

Privacy information

- For general privacy information, go to <<https://www.tga.gov.au/privacy>>.
- The TGA is collecting personal information in this form in order to:
 - Assess the application and issue approval if applicable
 - Contact the applicant and discuss the application where necessary

Email completed form to: eps@tga.gov.au.

Please read the following notes before completing this form:

Under sections 19(1)(b) or 32CK(1) or 41HB(1) of the *Therapeutic Goods Act 1989*, approval in writing may be granted for the importation, exportation or supply of a specified unapproved therapeutic good, for use solely for experimental purposes in humans.

This form is to assist in the application process to obtain approval to import clinical trial goods for subsequent export or to export clinical trial goods manufactured in Australia. The application form and necessary attachments should be emailed as a single file (pdf or Microsoft Word). The timeframe for processing the applications is approximately fifteen business days.

Approvals are usually issued for the duration of twelve months for multiple consignments, for distribution to the countries specified in the approval. If further countries are added to the trial, a subsequent application to include the additional countries would need to be submitted. An approval is subject to any conditions that are set out in the approval or imposed under the therapeutic goods legislation. One of the conditions of approval under the Therapeutic Goods Regulations 1990 is that a report detailing the quantity of goods that have been exported to each clinical trial site must be submitted to the TGA every six months.

Additional restrictions may be imposed on the importation and exportation of unapproved therapeutic goods through the following legislation:

Quarantine Act 1908

Customs (Prohibited Imports) Regulations 1956 & Customs (Prohibited Exports) Regulations 1958

You should contact the relevant regulatory authority(ies) in the destination country(ies) for any importation requirements.

Section 1. Details of applicant

Name of person and company applying to import and/or export clinical trial goods from Australia.

Name:		Position:			
Company:		Client ID:			
Address:					
Suburb:		State:	Select State	Post Code:	
Email address:					
Phone number:					

Section 2. Application type

New application Additional country(ies) Renewal

Previous approval number
(if applicable)

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Applying for approval to:

- Import for subsequent export to clinical trial sites in specified countries
- Import for subsequent export to a distribution centre
- Export only to clinical trial sites in specified countries
- Export only to a distribution centre

Import from country(ies):
(Leave blank if manufactured in
Australia)

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Other details:

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Section 3. Trial details

Protocol number:

Trial sponsor:

Title of study:

Short description of trial:

Section 4. Details of goods to be exported

The form has space for five products. For more than five, attach details of additional goods in the same format (i.e. additional copies of this page). For the **Active name**, enter the active ingredient name. If no AAN, BAN or USAN has been assigned, a code name or chemical name may be given. **Presentation** is quantity per dosage unit e.g. number of tablets per bottle or vials per pack.

Active name or device name	Trade name	Strength	Dosage form	Presentation

Section 5. Details of manufacturer(s)

If importing goods from overseas, provide details of the manufacturer in the country where the goods will be imported from. If manufactured in Australia, provide details of the Australian manufacturer. The form has space for one manufacturer. For more than one, attach details of additional manufacturers in the same format (i.e. additional copies of this page).

Company:	
Address:	
Country:	
TGA GMP certificate No.: (if applicable)	

I provide assurance to the Therapeutic Goods Administration that the goods have been manufactured in accordance with GMP standards.

Do any manufacturing steps occur within Australia? Yes No

(If **yes**, please attach a copy of the Certificate of GMP Compliance of a Manufacturer issued by the TGA for the site)

Section 6. Details of export destination(s)

Country(ies)

Include list of country(ies) to which goods are being exported. The form has space for six countries. For more than six, attach details of additional countries in the same format (i.e. additional copies of this page).

Country:	
Country:	
Country:	
Country:	
Country:	
Country:	

Section 7. Attachments

Please attach the following documents to the application:

Trial sponsor assurances:

A signed and dated letter on identifiable company stationary providing written assurance from the sponsor of the trial, or the chief investigator that:

- i. the trial will be conducted in accordance with ICH Guidelines on Good Clinical Practice (CPMP/ICH/135/95); and
- ii. that they will comply with requests for information regarding the conduct of the trial, if made by the TGA;

This assurance may be given by the global sponsor of the trial as they have ultimate responsibility for the manner in which the trial is conducted.

GMP certification:

If any manufacturing steps occur in Australia, the manufacturing facility would require a GMP licence, unless otherwise exempt. Please provide a copy of the certificate of GMP compliance issued by the TGA or details of a relevant exemption.

Six month reports:

If renewing or adding countries please ensure that six month reports have been submitted previously or are attached with the application.

Customs permits:

If the goods captured under the Customs (Prohibited Imports) Regulations 1956 or Customs (Prohibited Exports) Regulations 1958, please attach a copy of the relevant permits.

Section 8. Applicant declaration

- I declare that the products will be imported (if applicable) and exported only for use in the abovementioned clinical trial and that the information contained in this application is current and correct.

Name:

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Signature

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Date:

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