Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

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>.

Section 19A application form

For approval to import or supply substitute medicines during a shortage of medicines

Guidance for applicants

This form is to assist in the application process to obtain approval to import and supply a medicine under subsection 19A(1) or 19A(2) of the *Therapeutic Goods Act 1989* (the Therapeutic Goods Act). Use a separate application form for each product for which approval is sought.

For guidance on supplying substitute medicines during a shortage of medicines, go to Section 19A: Guidance for industry.

The guidance contains details on how to submit and seek further assistance.

About section 19A

Section 19A of the Therapeutic Goods Act provides the legislative basis for the Secretary to approve the import or supply of a medicine that is not included in the ARTG[1] under either:

- **subsection 19A(1) – all** ARTG registered goods that could act as a substitute for the goods are unavailable or are in short supply; and the goods are from a country specified by the Secretary or under evaluation by the TGA to be included in the ARTG.
- **subsection 19A(1A) – all** ARTG registered goods that could act as a substitute for the goods are unavailable or are in short supply; and the goods are from a country **not** specified by the Secretary
- **subsection 19A(2) –** ARTG registered goods that could act as a substitute for the goods do not exist; and the medicine is under evaluation by the TGA to be included in the ARTG.

In either case:

- the medicine must be of a kind included in Schedule 10 to the Therapeutic Goods Regulations 1990 (the Regulations), or is specified in a legislative determination

  AND

[1] Australian Register of Therapeutic Goods

- the approval must be necessary in the interests of public health.

Additional permissions or restrictions may be imposed on the importation of the medicine through the following legislation:

- *Quarantine Act 1908*
- Customs (Prohibited Imports) Regulations 1956
- relevant state and territory legislation.

Section 1. Details of applicant

Company					
Applicant name					
Position					
TGA Client ID (if applicable)		ABN			
Address					
Suburb		State		Post Code	
Email address					
Phone number		Phone number for publication			
Alternate contact details (optional)					

Note: The company name and phone number for publication listed above may be published in the database of section 19A approvals on the TGA website. Individual names will not appear in the database of section 19A approvals.

Section 2. Application type

2.1 Specify the type of application

☐ Unavailability or short supply of critical medicines included in the ARTG. Specify:

- ☐ Medicine sourced from a country specified by the Secretary – subsection 19A(1)
- ☐ Medicine sourced from a country **not** specified – subsection 19A(1A)

☐ Early access to a medicine under evaluation for inclusion in the ARTG – subsection 19A(2)

2.2 Proposed duration of approval

Requested duration of approval (ordinarily not exceeding a period of 12 months)	
Reason for duration requested	

2.3 Has the medicine previously been approved for import or supply under section 19A?

☐ **No** – Proceed to **Section 3**

☐ **Yes** – Provide the following information for previous section 19A approvals

Reason for new application	

Details of supply of the section 19A medicine under previous approvals[2]:

Approval date	Lapsing or expiry date	Amount of product supplied

[2] If there are additional section 19A approvals, provide supply information in as an attachment to this form.

Section 3. Availability of ARTG registered goods

Registered goods that could act as a substitute for the medicine do not exist (Proceed to **Section 4**)

Complete this section if the application relates to the unavailability or short supply of medicines included in the ARTG.

3.1 Have you sought information on availability from the sponsors of the medicines included in the ARTG that are unavailable or in short supply (recommended)?

☐ **Yes**

☐ **No**

☐ **Not applicable**, I am the sponsor of all the medicines listed in section 3.2

Note: We may also contact the sponsors of the medicines that are unavailable or in short supply to confirm availability. We can ask sponsors of medicines included in the ARTG for further information on the availability of those medicines under section 31 of the Therapeutic Goods Act.

3.2 Suitable substitutes that are unavailable or in short supply[3]:

Include the medicine in short supply or unavailable and any ARTG registered goods that are suitable substitutes for the medicine for which section 19A approval is being sought, including those for which you are not the sponsor.

	Medicine 1 in short supply or unavailable	Medicine 2 in short supply or unavailable	Medicine 3 in short supply or unavailable
AUST R			
Sponsor			
Active name			
Trade name			

[3] If there are additional goods, please add them as an attachment to the form.

	Medicine 1 in short supply or unavailable	Medicine 2 in short supply or unavailable	Medicine 3 in short supply or unavailable
Strength			
Dosage form			
Quantity and container type			
Percentage of market share (if known)			
Indications			
Availability (if known)			
Reason for short supply (if known)			
Estimated date for return to normal supply			
Medicine shortage notification ID (If known)			

3.3 Potential substitute goods included in the ARTG that are not suitable[4]

Include any ARTG registered goods that match the MSII protocol categories for a substitute for the medicine for which section 19A approval is being sought but you consider unsuitable.

	Product 1	Product 2	Product 3
AUST R			
Sponsor			
Active name			
Trade name			
Strength			
Dosage form			
Quantity and container type			
Indications			
Reason why it is unsuitable			

[4] If there are additional goods, please add them as an attachment to the form.

Section 4. Medicine intended for importation or supply

4.1 Is the medicine of a kind included in Schedule 10 to the Regulations?

☐ **Yes** – Specify the part and item numbers that describes the medicine in Schedule 10

Choose a Part	Select a Part from the drop-down list
Column 1 item number	

☐ **No** – The medicine must be specified in a determination under subsection 19A(4)*. Provide details of the determination below:

Section 19A(4) determination*	

* There are currently no such determinations; contact us if you require assistance.

4.2 Details of the medicine

Active name	
Trade name	
Strength	
Dosage form	
Quantity and container type	
Indication(s) approved in the foreign country of origin (if applicable)	
Proposed indication(s)	☐ Same as Indication(s) approved in the foreign country of origin ☐ Other, please specify:

Provide a brief description of the clinically important differences between the medicine for which section 19A approval is being sought and the medicine included in the ARTG that could act as a substitute (if applicable).

4.3 Is the medicine for which section 19A approval is being sought the subject of a section 23 application for inclusion in the ARTG?

☐ **No** – For a medicine unavailability/shortage, proceed to **Section 4.4**.

(If the application is only to enable early access to a critical medicine, you are not eligible for section 19A approval. Contact us for assistance.)

☐ **Yes** – Fill in the following details of the section 23 application:

TGA submission ID	
Anticipated decision date	

Proceed to **Section 5**.

4.4 Is the medicine registered or approved for general marketing in one of the foreign countries specified under subsection 19A(3)[5]?

☐ **Yes** – Specify the country in which the medicine is registered or approved for general marketing:

Foreign country in which the medicine is registered or approved for general marketing	Select from the drop-down list
Approval reference/number	

☐ **No** – The medicine and country of registration or approval for general marketing must meet the criteria outlined in the Section 19A: Guidance for industry – When a country is not specified.

Provide the following information. For guidance, go to Section 19A: Guidance for industry – Approval status of the medicine.

Details of the regulatory system of the country of approval

Foreign country in which the medicine is registered or approved for general marketing	
Name of the foreign regulator	
Approval/reference number	
Collaborative arrangements of the foreign regulatory system	
Other information	

[5] The foreign countries currently specified under section 19A(3) are Canada, France, Germany, Netherlands, New Zealand, Sweden, Switzerland, United Kingdom, United States of America.

Details of the regulation of the medicine in the foreign country

Date of registration or general marketing approval	
Type of assessment for approval	☐ Full evaluation of the dossier by the regulatory agency in the country of registration/approval. ☐ Approval by a regulator in another country.
Has the medicine been assessed by any other regulatory authorities?	☐ No ☐ Yes. Please specify:
Is the same medicine registered or approved for general marketing in other countries?	☐ No ☐ Yes. Please specify:
Is the medicine WHO prequalified?	☐ No ☐ Yes. Please provide details:
International pharmacopeia applied to the medicine (if applicable)	
Have any safety or other issues been identified with the medicine?	☐ No ☐ Yes. Please specify:

Approval in a foreign country constitutes registration or approval for general marketing in that country. Approval for purposes other than general marketing in the nominated country (e.g. export only use) will not be accepted.

Section 5. Justification that approval is necessary in the interests of public health

Provide evidence that the medicine is necessary in the interests of public health. Go to Section 19A: Guidance for industry - Supply must be in the interests of public health, for guidance.

Patient population[6] that uses the medicine	
Impact of shortage/unavailability on the patient population	

[6] The patients using the medicine, or on whom, or in relation to whom, the medicine is used.

Are there any clinical considerations in relation to using potential substitutes that could result in health issues for that population? (specific characteristics of the patient population can be included if necessary)	
Does the medicine subject of the application have any contraindications that are different to the medicine that is unavailable or in short supply?	☐ **No** ☐ **Yes**. Please specify: ☐ **There are no medicines that are unavailable or in short supply**. Please list all contraindications:
Other factors that could influence or have an impact on public health	

Section 6. Packaging and labelling

6.1 Ensure the following requirements have been met:

☐ The medicine must be labelled with the Australian sponsor's name and address

☐ The active ingredient(s), strength and dosage form are visible and in English

Supplementary labelling of the medicine is regarded as a step in manufacture[7].

You only need to provide details of the manufacturer in **Section 8.3** if details **other than** the Australian sponsor's name and address will be included on the supplementary label.

6.2 Medicine information package insert

Provide details of any information that will be supplied with the medicine, whether contained in the package or as a Consumer Medicine Information Leaflet.

Provide details of the manufacturer in **Section 8.3** if the insert is not covered by the foreign registration or approval for general marketing.

[7] You do not have to provide details of the manufacturer if the step in manufacturing consists of adding the Australian sponsor's name and address only, as this manufacturer is exempt from requiring a manufacturing licence.

Section 7. Distribution of medicine information

7.1 Dear Healthcare Professional Letter

Provide information on the proposed distribution strategy for any Dear Healthcare Professional Letter (DHPL) that is proposed to be supplied in relation to the medicine. For guidance on content and distribution of the DHPL, go to Section 19A: Guidance for industry – Dear Healthcare Professional Letter.

7.2 Other letters

Provide details and proposed distribution of any other letters proposed to be provided to suppliers or consumers of the medicine.

Section 8. Details of manufacturer(s)[8]

8.1 Finished product manufacturer

Name of manufacturer		
Site address		
Country		
GMP Licence/ Clearance (or equivalent)	Issued by	
	ID number	
	Expiry date	

8.2 Quality control testing (if different from above)

Name of manufacturer		
Site address		
Country		
GMP Licence/ Clearance (or equivalent)	Issued by	
	ID number	
	Expiry date	

[8] If there are additional manufacturers, please add them as an attachment to the form.

8.3 Will additional manufacturing steps be conducted for supply of the medicine in Australia[9]?

☐ **No** – Proceed to **Section 9**

☐ **Yes** – Provide details below.

Name of manufacturer		
Role in manufacture		
Site address		
Country		
GMP Licence/ Clearance (or equivalent)	Issued by	
	ID number	
	Expiry date	

Provide details of the additional manufacturing steps to be conducted in Australia.

Section 9. Supporting documents

9.1 Attach the following documents to the application:

	Supplied	Not applicable
Evidence of marketing approval in the country specified in Section 4.4	☐	☐
Medicine information package insert(s) or Patient Information Leaflet(s) (PIL)	☐	☐
Product Information or equivalent	☐	☐
Product packaging and label images showing the supplementary label	☐	
Draft Dear Healthcare Professional Letter	☐	
Drafts of other letters	☐	☐
GMP evidence	☐	

[9] E.g. supplementary labelling of information other than the Australian sponsor's name and address.

☐ All documents provided with the application are in English or accompanied by a certified English translation.

9.2 If any of the supporting documents listed above are not provided, please provide the reason

Privacy information

- General privacy information is available on the TGA website.
- 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.

Section 10. Applicant declaration

Under section 137.1 of the *Criminal Code Act 1995*, it is an offence to knowingly provide information to a Commonwealth entity that is false or misleading in a material particular, or to omit any information without which the information is misleading in a material particular.

Penalty: 12 months imprisonment.

I declare that I am authorised to act on behalf of the applicant company and the information contained in this application is complete and correct.

Name			
Position			
Signature		Date	