Australian Government
Department of Health
Therapeutic Goods Administration

Section 19A: Guidance for industry

Supplying substitute medicines when registered medicines are unavailable or in short supply

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TGA Health Safety Regulation

Contents

Introduction

This document provides guidance and information to those who wish to supply a substitute medicine in place of a registered medicine that is unavailable or in short supply – including where that medicine is not marketed – where the supply of the substitute medicine is necessary in the interests of public health.

Generally, prescription and over-the-counter medicines[1] must be included in the Australian Register of Therapeutic Goods (ARTG) before those medicines can be marketed in Australia.

Occasionally, the availability of a registered medicine is affected by a medicine shortage or unavailability. In these circumstances, there is provision under section 19A of the *Therapeutic Goods Act 1989* (the Therapeutic Goods Act) to facilitate the availability of medicines not currently included in the ARTG, in place of a registered medicine that is unavailable or in short supply.

Note: This guidance is designed to cover the majority of cases where section 19A approval is granted; that is when there is a medicine shortage. Contact us if you require further assistance to determine if your medicine is eligible for section 19A approval after reviewing the information on eligibility for section 19A approval.

Follow the Medicine Shortages Information Initiative protocol if you become aware that there may be a current or future issue with the supply of a medicine included in the ARTG, for which you are the sponsor, if the unavailability or short supply of the medicine will have a negative impact on public health.

About section 19A

Section 19A of the Therapeutic Goods Act provides the legislative basis for the Secretary of the Department of Health (the Secretary) to approve the import or supply of a medicine that is not included in the ARTG 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
- **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.

The Secretary, or their delegate, can grant approval:

- for a specified period of time

  AND

- subject to any relevant conditions

  PROVIDED

[1] As defined in Schedule 10 to the *Therapeutic Goods Regulations 1990*

- the approval is necessary in the interests of public health.

Before approval can be granted, the applicant must provide evidence that all of the following criteria apply to the medicine by submitting a section 19A application form:

The medicine must be:

- of the kind included in Schedule 10 to the *Therapeutic Goods Regulations 1990* or specified in a determination made by the Secretary under subsection 19A(4) of the Therapeutic Goods Act
- needed in the interests of public health
- not able to be substituted with a medicine included in the ARTG because either:
  - all suitable substitutes are unavailable or in short supply

    OR
  - there are no suitable substitutes presently included in the ARTG

  AND either:
- registered or approved for general marketing in a foreign country – only when it is a substitute for a medicine included on the ARTG that is unavailable or in short supply.

  OR
- under evaluation for inclusion in the ARTG – when:
  - it is a substitute for a medicine included on the ARTG that is unavailable or in short supply

    OR
  - a substitute does not exist (i.e. when there is an unmet clinical need).

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.

The Therapeutic Goods Administration (TGA) publishes details of section 19A approvals associated with medicine shortages on its website to inform consumers, health professionals and industry. Medicines approved for import and supply under section 19A are subject to the same advertising restrictions and pharmacovigilance activities (such as adverse event reporting and recalls) as those included in the ARTG.

It is an offence to import and supply, or manufacture and supply, medicines that are not included in the ARTG without the prior approval of the Secretary, or subject to an exemption under the Therapeutic Goods Act.

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

- *Biosecurity Act 2015*
- *Customs (Prohibited Imports) Regulations 1956*
- relevant state and territory legislation.

Eligibility for section 19A approval

The unavailability or short supply of a particular medicine included in the ARTG will ordinarily not have a significant impact on public health where there are other medicines available on the market that may be supplied in its place. Other medicines included in the ARTG that may be suitable substitutes include those medicines that are:

- the same in all relevant respects to the medicine that is unavailable or in short supply, but available from another manufacturer or supplier

  OR

- closely related to the medicine that is unavailable or in short supply and may be used safely in its place.

However, if there are no suitable substitutes included in the ARTG, or all suitable substitutes are also unavailable or in short supply, the unavailability or short supply of the registered medicine may have a negative impact on public health.

In these circumstances, the Secretary or their delegate can grant approval to import and supply a substitute medicine that is not included in the ARTG in place of the medicine that is unavailable or in short supply under section 19A of the Therapeutic Goods Act. Generally, only one section 19A approval is granted for each shortage, go to When TGA receives multiple applications for more information.

The following sections provide a general guide to determine if a medicine is eligible for such approval. These considerations are also summarised in a flowchart at the end of this section.

Products must be medicines

Section 19A only applies to medicines, of the kind included in Schedule 10 to the *Therapeutic Goods Regulations 1990*, or where the goods have been specified in a determination made by the Secretary under subsection 19A(4).

Note: To date, the Secretary has not made any determinations under subsection 19A(4) to allow products, other than those included in Schedule 10 to the Therapeutic Goods Regulations 1990, to be supplied under section 19A.

Supply must be in the interests of public health

The Secretary, or their delegate, uses the information provided at Justification that approval is necessary in the interests of public health, and any other relevant information, to determine whether approval of an application is in the interests of public health. Generally, the following matters will be considered:

- the availability of other treatments for the disease or condition
- whether other available treatments meet the therapeutic requirements of the patient population
- the suitability of substitutes for the intended patient population
- the consequences of discontinued treatment or changing treatment
- any additional health risks associated with the medicine that is the subject of the application
- the projected demand for the product above that which the current supply can meet.

Suitable substitutes

As part of a section 19A application, the applicant should consider whether there are suitable substitutes already included in the ARTG.

The applicant should identify and assess the suitability of all potential substitutes included in the ARTG that are exact, similar, appropriate or possible, as defined in the Medicines Shortages Information Initiative protocol, which includes the medicine that is unavailable or in short supply.

Suitable substitutes may also include goods that are therapeutic devices. However, this is relatively unlikely in practice. For convenience, this guidance predominantly references substitute medicines.

In some cases, suitable substitute medicines may be included in the ARTG, but at the time of the application, are unavailable or in short supply.

For an application to be approved, all potential substitutes must be found to be unsuitable to meet the public health need, or all suitable substitutes must be unavailable or in short supply.

Applicants should identify all potential substitutes whether or not those substitutes are available at the time an application is made under section 19A. Any approval granted under section 19A will lapse if a suitable substitute becomes available during the course of the approval – go to Lapsing of approvals for more information.

Determining suitability

To determine suitability, the Secretary, or their delegate, will consider:

- how close the substitute is to the medicine for which section 19A approval is being sought, including the approved indications
- how feasible it is to use the substitute in the context of the patient population and the associated care setting
- how appropriate it is to use the substitute in the intended patient population, including consideration of contraindications
- how appropriate the dosage form of the substitute is in treating the proposed indications of the medicine for which section 19A approval is being sought.

Further consideration of potential substitutes

Sometimes, patients may be on a medicine included in the ARTG that is about to become unavailable or in short supply. In such circumstances, the transition from one medicine to another is an important consideration. The transition to the medicine for which section 19A approval is being sought should be compared with the transition to any potential substitute, having consideration to the following matters:

- changeover requirements for patients, such as wash-out, weaning or lag time prior to commencement of the new medicine and the clinical effect
- whether one medicine provides a more stabilised course of treatment
- whether the medicine for which section 19A approval is being sought may be in the interests of patient care and safety even though there is a potential substitute included in the ARTG.

Early access to medicines under evaluation

If there is no medicine presently included in the ARTG for the treatment of a specific indication, approval can be granted under subsection 19A(2) of the Therapeutic Goods Act to allow early access to a medicine that is currently under evaluation for inclusion in the ARTG.

The Secretary, or their delegate, must be satisfied that:

- there are no registered goods that would be a suitable substitute for the medicine

  AND

- an application for inclusion in the ARTG (under section 23 of the Therapeutic Goods Act) has been made to the TGA.

Note: For early access to a medicine that is under evaluation, section 19A(2) approval lapses when a decision has been made on the relevant section 23 application. If the medicine remains unavailable or in short supply for a period following the registration of the medicine, a new application must be approved under subsection 19A(1) of the Therapeutic Goods Act to continue the import and supply of a substitute medicine. Go to Lapsing of approvals for more information on requesting a new approval to change from subsection 19A(2) to 19A(1) following the inclusion of a medicine in the ARTG.

Specified foreign countries

If the medicine for which section 19A approval is being sought is not under evaluation for inclusion in the ARTG, it may be registered or approved for general marketing in a country specified by the Secretary in a written determination under subsection 19A(3) of the Therapeutic Goods Act.

The current specified countries are:

- Canada
- France
- Germany
- Netherlands
- New Zealand
- Sweden
- Switzerland
- United Kingdom
- United States of America.

Prior to submitting an application, applicants should check the Therapeutic goods determinations web page for any changes.

When the country is not specified

In rare cases, the only medicines that are available globally to address a shortage are not available in any of the countries that the Secretary has specified. The Secretary or their delegate may grant section 19A approval in this circumstance if the following criteria are met:

- the medicines that are needed are not registered or approved for general marketing in any of the countries specified by the Secretary in a legislative instrument under subsection 19A(3), or if they are approved in such a country, they are not readily available for importing into Australia, but are registered or approved for general marketing in another country

  AND

- the manufacturing and quality control procedures used in the production of the medicines are acceptable

AND

- the approval is necessary in the interests of public health.

The decision to grant approval under section 19A(1A) is complex and the Secretary will make a decision balancing:

- the robustness of the regulatory system in place in the foreign country in which registration or approval for general marketing of the specific therapeutic good proposed for supply under section 19A has been granted

AND

- the history of regulation and manufacture of the particular medicine

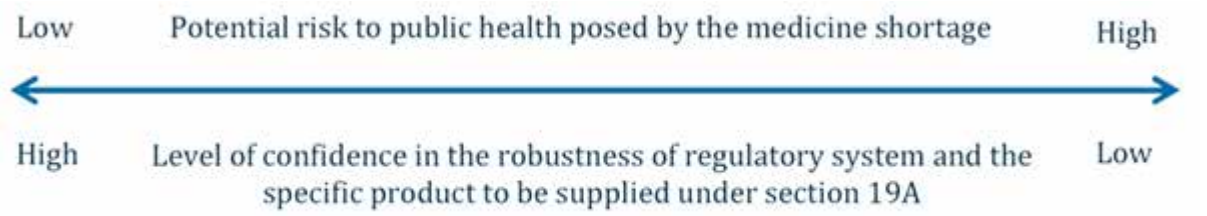
AND

- justification that the medicine is needed in the interests of public health.

The outcome may differ depending on the strength of each consideration. A shortage that potentially poses a very high level of risk to public health (in the sense that patients are likely to die if they are not able to access the medicine for the period of the likely shortage) may require the Secretary to consider section 19A approval to allow the supply and/or import of a particular medicine from a specific country even if the relevant regulatory system is not as robust as Australia or the medicine does not have a long history of safe use in that market.

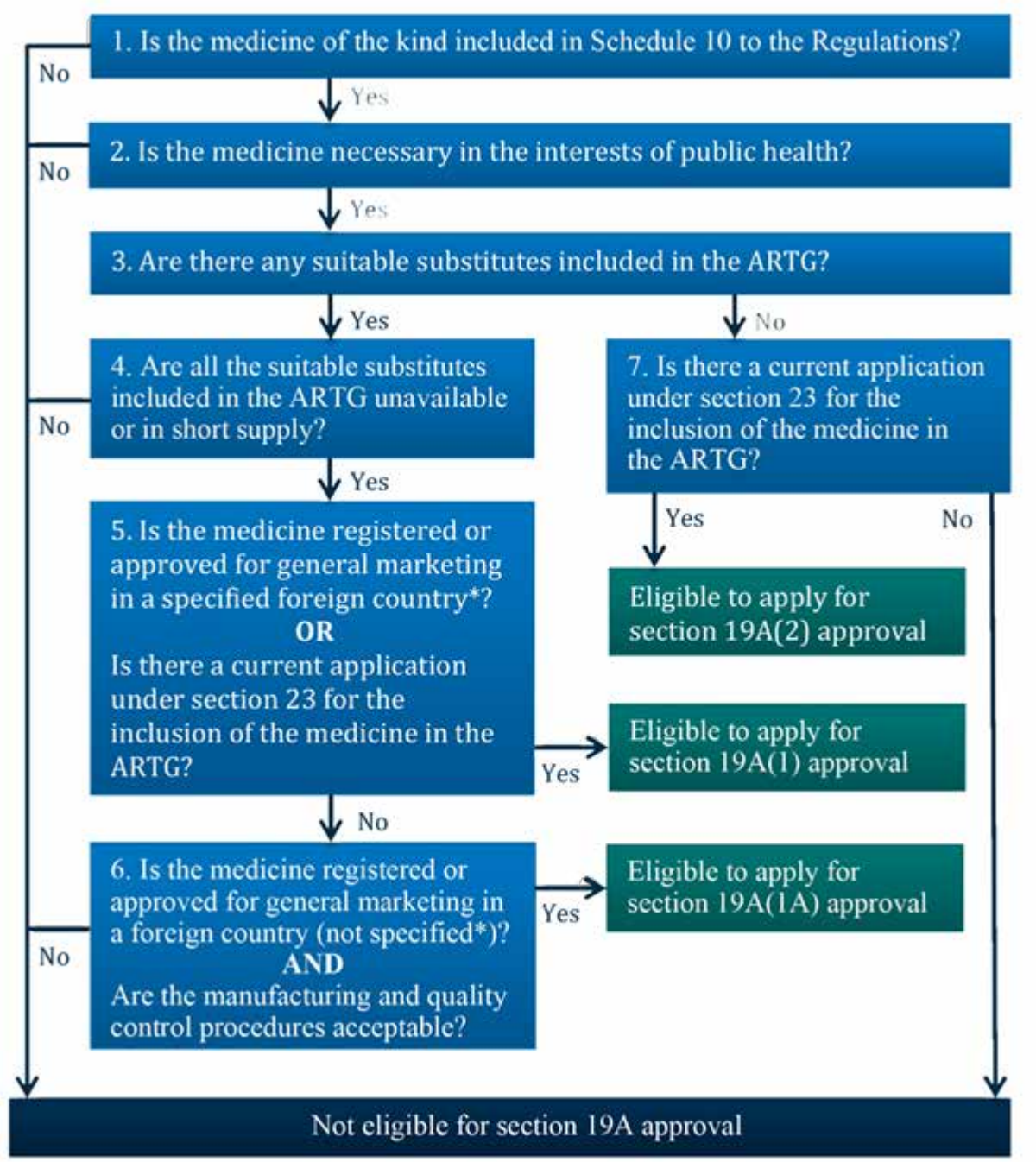
If the shortage does not potentially pose such a significant risk to public health then the Secretary may consider that the potential benefit to public health from the medicine would be outweighed by the potential risk of approving the import and supply of a medicine from a country whose regulatory system is not as robust as Australia or without a long history of safe use of that medicine.

The following illustration demonstrates the consideration between the balance of potential risk and level of confidence.



Summary of considerations for section 19A approval

The following flowchart summarises the considerations for section 19A approval to import and supply medicines that are not included in the ARTG.



Who can make a section 19A application

Any person can make an application to import and supply medicines that are not included in the ARTG in the interests of public health to:

- address a medicine shortage or unavailability of a medicine included in the ARTG

  OR

- allow early access to a medicine under evaluation for inclusion in the ARTG.

Note: You do not need to be the sponsor of the medicine that is unavailable or in short supply to make an application. However, you do need to be in a position to advise the TGA about the availability of the medicine included in the ARTG.

Once approval has been granted, the section 19A approval holder is the sponsor of that medicine and is required to adhere to the obligations of sponsors. Ensure that you are capable of adhering to these obligations before applying for approval to import and supply medicines under section 19A.

Generally, it will be sufficient for the Secretary to grant only one person a section 19A approval to address a specific medicine shortage.

For more information go to When we receive multiple applications.

Making an application

The Section 19A application form sets out the information needed to obtain approval, including:

- details of the medicine to which the application applies
- details of the medicine(s) included in the ARTG for which there is a supply issue (if applicable), including details of an actual shortage and the relevant Medicine Shortages Information identification number
- justification that the approval is in the interests of public health
- evidence that any likely conditions of approval will be met, including details of:
  - proposed packaging and labelling of the medicine
  - information to be provided to health professionals and consumers
  - manufacture of the medicine.

All documentation provided with the application must be in English or else accompanied by a English translation. We will accept translations provided the applicant is prepared to make a declaration that it is a true translation from an accredited translator. It does not need to be certified unless the applicant feels that this is necessary. If one of the languages in a bilingual document is English, a translation is not required.

The TGA provides a template to assist you with your preparation of a Dear Healthcare Professional Letter.

Section 1 – Details of applicant

Provide details of the person (company) applying to import or supply the medicine in Australia, including contact details of the individual responsible for preparing the application under section 19A.

Note: The company in whose name the approval is sought, email address and phone number may be identified in the Section 19A approvals database on the TGA website if approval is granted.

Section 2 – Application type

Identify whether the application is for the approval of a specified medicine, on the basis that:

- all substitute medicines included in the ARTG are unavailable or in short supply and:
  - Medicine sourced from a country specified by the Secretary– subsection 19A(1)
  - Medicine sourced from a country not specified – subsection 19A(1A).

  OR
- there is no substitute medicine included in the ARTG but an application for inclusion in the ARTG (registration) has been made in relation to the specified medicine – subsection 19A(2).

Duration of approval

Propose the duration of approval (this should not normally exceed 12 months).

For unavailability or short supply, the proposed duration should not exceed the expected duration of the unavailability or shortage.

Provide justification for the duration requested, considering the following:

- expected duration of the medicine shortage (if applicable), including:
  - whether the issue leading to short supply has been identified and whether appropriate steps are being taken to rectify the problem
- expected approval date for the section 23 application (if applicable)
- period of Good Manufacturing Practice (GMP) evidence.

Note: Section 19A approvals may lapse before the period of approval has expired – go to Lapsing of approvals.

For unavailability or short supply: Applicants will need to provide the reason why a medicine included in the ARTG will remain unavailable if the total duration of the medicine shortage has exceeded, or is expected to exceed, 12 months.

Determining amount to import

Approval under section 19A only allows for the import and supply of the medicine and does not permit you to export the medicine. Therefore, only import the amount of medicine that you need to supply.

When determining the volume of stock you import under section 19A, consider that:

- an approval under section 19A can lapse before the end of the nominated period - for example, in the situation where a medicine shortage ends earlier than expected (for more information and examples, go to Lapsing of approvals)

  AND

- excess stock cannot be supplied after lapsing or expiry of the approval.

Repeat applications

Provide information on any previous section 19A approvals granted to you in relation to the medicine. Include details of:

- the reason for proposing repeat approval under section 19A
- the date on which each of the previous section 19A approvals will expire, or has expired or lapsed
- supply of the medicine under previous section 19A approvals.

Section 3 – Availability of ARTG registered goods

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

If there is no medicine included in the ARTG that could act as a substitute for the medicine for which section 19A approval is being sought, proceed to Medicine intended to be imported or supplied.

Provide details of:

- Potential substitutes included in the ARTG, including substitutes that are not presently available

  AND

- Potential substitutes that are unsuitable.

Potential substitutes included in the ARTG

Provide details of any medicines included in the ARTG that could act as a substitute for the medicine for which section 19A approval is being sought, including those for which you are not the sponsor[2]. For guidance, go to Suitable substitutes. Note the following definitions for terms used in the application form:

- **quantity and container type:** quantity per pack – e.g. number of tablets per bottle or blister pack; vials per pack; or if supplied as a kit, a description of the contents – and the type of container used for the medicine
- **availability:** an estimate of how much stock is currently available at the sponsor, distributor, hospital and retail levels (if known)
- **reason for short supply:** an explanation of the reason for the unavailability or shortage (if known), for example:
  - increased demand
  - manufacturing delays
  - cessation of supply
  - recall of stock
  - lack of raw material
  - delay in supply
  - other reasons – provide details.

Confirm availability

If you are not the sponsor of one or more of the relevant medicines included in the ARTG, we recommend that you seek information from the sponsors on the availability of their medicines. We understand that obtaining information on availability is dependent on the cooperation of the sponsors of medicines that are in short supply or unavailable.

[2] Sponsor: The person in relation to whom the goods are included in the ARTG.

We use this information to assess how the unavailability or short supply has been determined, and how restoration of supply will be managed. Provision of this information in your application may enable TGA to reduce the time for processing the application.

We may also contact the sponsors of the medicines that are in short supply or unavailable – go to Processing your application.

Potential substitutes that are unsuitable

Provide details of any potential substitute medicines you identified (go to Suitable substitutes) that you assessed as unsuitable. Note the following definitions for terms used in the application form:

- **Quantity and container type of the unsuitable substitute:** quantity per pack – e.g. number of tablets per bottle/blister pack or vials per pack; or if supplied as a kit, a description of the contents – and the type of container used for the medicine
- **Reason why the apparent substitute is unsuitable:** provide a brief justification as to why you consider that the apparent substitute is unsuitable – for guidance go to Suitable substitutes.

Section 4 – Medicine intended to be imported or supplied

Kind of goods (medicine)

Provide details of the kind of goods (medicine) included in Schedule 10 to the *Therapeutic Goods Regulations 1990*.

Details of the medicine

Provide details of the medicine for which section 19A approval is being sought, noting the following definitions for terms used in the application form:

- **Quantity and container type of the medicine:** quantity per pack – e.g. number of tablets per bottle/blister pack or vials per pack; or if supplied as a kit, a description of the contents – and the type of container used for the medicine
- **Indication(s) approved in the foreign country of origin:** provide the indication(s) for which the medicine is registered or approved for general marketing in the foreign country specified in Approval status of the medicine (if applicable)
- **Proposed indication(s):**

  Where there is a section 23 application under evaluation by the TGA:

  – the proposed indication(s) should be the indication(s) sought for inclusion in the ARTG.

  Where the medicine is being sourced from a foreign country, the proposed indication(s) depend on the nature of the substitution to the medicine included in the ARTG that is in unavailable or in short supply:

  – **exact substitute[3]:** use the Australian indication(s), unless there is a clinical reason to restrict the indication(s)

  – **not an exact substitute:** generally, only the indication(s) common to both medicines will be approved for use under section 19A.

[3] Exact substitute means same active ingredient, strength, route of administration and dosage form.

If applicable, provide a brief description of any 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.

Approval status of the medicine

Specify whether the medicine is:

- the subject of a current application for inclusion in the ARTG (under section 23 of the Therapeutic Goods Act).

  OR, if the medicine included in the ARTG is unavailable or in short supply:

- approved for general marketing in at least one of the foreign countries specified by the Secretary.
  - **Note:** The medicine that is the subject of the application must be same goods that are registered or approved for general marketing in the foreign country specified by the secretary under section 19A(3) of the Therapeutic Goods Act.

  OR

- Not available in any of the specified foreign countries, but meets the criteria at When the country is not specified.

When the country of registration or approval is not a specified foreign country, provide the following information regarding the substitute medicine and the country where it is registered or approved for general marketing. This is a guide only; we may consider other matters and request additional information if necessary.

Details of the regulatory system of the country of approval

- Name of the country where approval for general marketing has been granted.
- Name of the authority that regulates medicine in the foreign country.
- Approval reference or number issued by the regulatory authority.
- Details of the country's collaborative arrangements that may provide greater confidence in their regulatory system, for example:
  - Pharmaceutical Inspection Cooperation Scheme (PIC/S)
  - the European Union or the European Free Trade Association (EFT) and the European Economic Area
  - International Medical Crisis Response Alliance (IMCRA) member
  - International Generic Drug Regulators Programme (IGDRP) member
  - membership of any other collaborative arrangement related to medicines put in place with TGA.
- Other information about the regulatory authority that you consider important to support your application, for example:
  - established Good Manufacturing Practice and Good Clinical Practice inspection program

- established pre- and post-marketing responsibilities and capabilities, including a pharmacovigilance system that is capable of detecting safety signals
- adopted international guidelines for quality, safety and efficacy (for example, International Conference on Harmonisation guidelines)
- capacity of the regulatory framework and its history in regulating medicines to a high standard
- track record of approving safe and effective medicines.

Details of the regulation of the medicine in the foreign country

- How long has the product been registered or approved and marketed in the country of approval?
- Specify the type of assessment for registration or approval. For example whether the approval was based on:
  - full evaluation of the dossier by the regulatory agency in that country
  - approval by a regulator in another country
- Has the same medicine been assessed by any other regulatory authorities?
- Is the same medicine also registered or approved for general marketing in other countries?
- Is the medicine WHO prequalified?
- Have any international pharmacopeia been applied to the medicine (for example, the European Pharmacopeia, British Pharmacopeia and United States Pharmacopeia for medicines)?
- Have any safety or other issues been identified with the medicine?

Section 5 – Justification that supply is in the interests of public health

Provide the following information to demonstrate that the supply of the medicine is in the interests of public health:

- information relating to the patient population that uses the medicine, including details such as the size of the population and the particulars of use - for example, whether there is widespread use, intermittent widespread use, or emergency use
- information relating to whether the health of the population that uses the medicine would be particularly disadvantaged if the medicine was not available, including the specific characteristics and/or disadvantages for any subgroup
- information identifying any potential substitutes for that medicine included in the ARTG and information relating to whether those substitutes are available for that population (or subgroup), including details of their actual availability (as specified under Section 3)
- information as to whether there are any specific clinical considerations in relation to using potential substitutes that could result in health issues for that population (or subgroup), including details of those considerations and potential health issues. If specific characteristics of the patient population (e.g. allergy related matters) are a factor, this can be included

- contraindications relating to the medicine(s) that are different to the medicine that is unavailable or in short supply
  - include all contraindications if there is no medicine that is unavailable or in short supply
- any other factors that could influence or have an impact on public health.

Section 6 – Packaging and labelling

All medicines supplied under section 19A are required to carry the approval holder's name and address. The label should allow health professionals and consumers to easily identify the active ingredient(s), strength and dosage form.

For medicines sourced from a foreign country, supply the medicine in the packaging from that country, with supplementary labelling applied as appropriate.

To supply medicines under section 19A:

- label the package with your company's name and address
- ensure the package text is in English, or apply a supplementary label with an English translation of the active ingredient(s), strength and dosage form

  AND

- ensure the active ingredient(s), strength and dosage form are visible on the package.

Any label applied over the approved packaging from the country of origin is supplementary labelling. If the supplementary label contains details other than the approval holder's name and address, the manufacturer responsible for labelling must have evidence of GMP.

Provide images of the packaging and labels as supporting documents. One or more of the images you provide may be published on the TGA website. These images may vary depending on the type and approval status of medicine and may include (but not limited to) one or more of the following examples:

- an image of the packaging approved in the country of origin
- an illustration of the placement of supplementary labels
- an illustration of the package design.

Medicine information package insert

Provide details of the type and source of the information insert to be included in the packaging for the substitute medicine with an indication of the date of last review by the national authority. For example:

- Product Information (PI)
- Consumer Medicines Information (CMI)
- Patient Information Leaflet (PIL)
- an equivalent information document from another country
- supplementary information for users.

For unavailability or short supply, indicate the source of the proposed information insert to be included with the substitute medicine. This is usually the insert supplied with either:

- the medicine included in the ARTG that is unavailable or in short supply
- the section 23 application for inclusion in the ARTG
- the medicine registered or approved for general marketing in the foreign country.

Provide evidence of GMP in section 8 for any medicine information package inserts that are not covered in the foreign registration or approval for general marketing.

Section 7 – Distribution of medicine information

When you supply a medicine under section 19A, you need to provide information as appropriate to:

- relevant health professionals
- suppliers
- consumers.

Dear Healthcare Professional Letter

Supply a draft Dear Healthcare Professional Letter to ensure safe use of the medicine with the application.

All letters should:

- advise that the medicine has not been approved for general marketing by the TGA and is being supplied under a section 19A approval
- outline any contraindications
- describe any potential safety risks
- advise recipients to report adverse events to you or to the TGA
- provide your contact details.

Where the approval is associated with the unavailability or short supply of a medicine included in the ARTG, the letter should also:

- identify the medicines that are unavailable or in short supply that the section 19A approved medicine is intended to replace
- provide the reason the medicines are unavailable or in short supply
- clearly outline the differences between the medicines that are unavailable or in short supply and the medicine approved under section 19A
- identify the changes to practice that healthcare professionals may need to make, or changes consumers may need to make, compared with the medicines that are unavailable or in short supply.

An example Dear Healthcare Professional Letter is provided. This example relates to an application to supply a substitute medicine due to shortage of a medicine included in the ARTG.

The letter is also available as a template.

Distribution of the letter

You will need to provide the Dear Healthcare Professional Letter to the health professionals you supply with the medicine.

- **Where there is no substitute medicine included in the ARTG**

  The Dear Healthcare Professional Letter may only be provided to medical practitioners at their request or with supply of the medicine approved under section 19A. Mass distribution of a Dear Healthcare Professional Letter is not permitted because this may be considered as advertising a therapeutic good not included in the ARTG (section 42DL(1g) of the Therapeutic Goods Act).

- **Where the medicine is being supplied to cover the unavailability or short supply of medicines included in the ARTG**

  We will consider a request from you to distribute the Dear Healthcare Professional Letter to inform relevant health professionals who have not been supplied with the medicine of the availability of a substitute medicine to address the unavailability or shortage of a registered medicine. However, if you have applied to the TGA for inclusion of the substitute medicine in the ARTG, please ensure that the letter cannot be regarded as advertising.

Provide a list of the recipients or groups of recipients to whom each of the letters are to be distributed.

The distribution of the Dear Healthcare Professional Letter for repeat section 19A approvals should be similar to the original approval. Consider whether any additional recipients would be appropriate.

Other letters

Sometimes you need to provide information about the medicine supplied under section 19A to other suppliers and users. Consider whether the following letters are appropriate:

- **Dear Wholesaler Letter**, when you need to provide information to wholesalers. For example:
  - information relating to the medicine shortage
  - other supply information.
- **Dear Patient or Customer Letter**, when you need to provide information to the patient or customer. For example:
  - confirmation as to whether the medicine information package insert will be provided separately to the medicine
  - information relating to the appearance or use of the medicine, particularly information that is different from the patient's current treatment
  - any other specific information relevant to the patient or customer.

The other letters usually contain information similar to the Dear Healthcare Professional Letter, but with appropriate language for the recipient.

We will also consider whether any other letters are needed. We will contact you if we consider that additional letters, other than those you provide in your application, are needed.

Section 8 – Details of manufacturer(s)

Provide the details for all manufacturers associated with the substitute medicine, including the final product manufacturer and the manufacturer responsible for release for supply.

Evidence of Good Manufacturing Practice

Provide details of the evidence of GMP as supporting documents for all manufacturers involved in the steps of manufacture, including (but not limited to):

- finished product manufacturer
- quality control testing (if different from the finished product manufacturer)
- supplementary labelling:
  - only provide details of the manufacturer responsible for labelling if the supplementary label includes details other than the approval holder's name and address, as manufacturing certification is required
  - you do not need to provide the details of the manufacturer if the step in manufacturing consists of adding the approval holder's name and address only, as it is exempt from the requirement of GMP under item 5 of Schedule 8 to the *Therapeutic Goods Regulations 1990*
- medicine information package inserts not covered by foreign country registration or approval for general marketing.

Acceptable sources of GMP evidence may be obtained from:

- the TGA:
  - manufacturers can print GMP certificates issued by the TGA by accessing their account at TGA Business Services.
- a country that has a Mutual Recognition Agreement (MRA) or equivalent with the TGA.

We will consider other sources of GMP evidence on a case-by-case basis, including (but not limited to):

- Medsafe – when the manufacturer is located in New Zealand.
- FDA – when the manufacturer is located in USA:
  - a copy of the GMP certificate is not required for FDA certifications – compliance will be checked in the FACTS database.
- Health Canada – when the manufacturer is located in Canada.
- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) – when the manufacturer is located in the country where certification has been granted.

Clearly state the expiry period for all GMP evidence. Section 19A approval is not given for a period exceeding the date of expiration of any GMP compliance for relevant manufacturers.

Australian manufacturing steps

Provide details of any manufacturing steps that will occur in Australia following importation, including evidence of GMP. For example:

- secondary packaging
- supplementary labelling
- medicine information package inserts.

If the supplementary label only includes the sponsor's name and address, you do not need to provide details of the manufacturer responsible for supplementary labelling.

Section 9 – Supporting documentation

Provide supporting documentation in English. For more details, go to Making an application.

- **Evidence of registration or general marketing approval in the relevant foreign country:**

  If applicable, provide documented evidence that the medicine has been registered or approved for general marketing by the national authority in the relevant foreign country.

- **Medicine information package insert or Patient Information Leaflet:**

  Provide a copy of:

  – the medicine information package insert or PIL that will be provided with the medicine

  AND

  – if different from above, the medicine information package insert or PIL approved in the foreign country where the medicine is registered or approved for general marketing. (if applicable).

- **Product Information or equivalent**

  If applicable, provide the Product Information or equivalent that is approved in the foreign country where the medicine is registered or approved for general marketing.

- **Product images**

  Provide true size, colour images of the packaging and labels for the container, primary packaging and intermediate packaging to be placed on the section 19A medicine. Show the placement of supplementary labels.

  Please provide images that have sufficient resolution to ensure that all text is legible, as we may publish one or more images on the TGA website.

- **Evidence of GMP**

  Provide evidence of GMP for relevant manufacturing site(s).

- **Draft Dear Healthcare Professional Letter and other letters**

  Provide drafts of the proposed Dear Healthcare Professional Letter and any other letters to be supplied with the goods to ensure safe use of the product.

Submitting an application

Send your application form and relevant attachments to the Medicines Shortages Section by:

- **email (preferred):** medicine.shortages@tga.gov.au
- **post:** Medicines Shortages Section, Pharmacovigilance and Special Access Branch, TGA PO Box 100, Woden ACT 2606, Australia
- **courier:** Medicines Shortages Section, Pharmacovigilance and Special Access Branch, TGA 136 Narrabundah Lane, Symonston ACT 2609, Australia.

Include a list of attachments so that we can verify that the full application has been received.

Emails should not exceed 20Mb; please provide attachments as a zip file or in multiple emails if needed.

We will send you an email to confirm that your application form and attachments have been received.

Send us an email or phone **+61 2 6232 8850** if you are unable to supply all requested information, or if you have questions regarding your submission.

When the TGA receives multiple applications

We usually only grant one approval if we receive more than one application in relation to the same medicine shortage or unavailability. We will only grant approval to subsequent applications if demand is likely to exceed what can be supplied under the initial approval.

Applicants who have the ability to manage the supply chain during a shortage are preferred. Therefore, preference will be given to effective applications in the following order:

1. sponsor of the medicine that is unavailable or in short supply
2. applicants with arrangements in place with the sponsor of the medicine that is unavailable or in short supply
3. other applicants.

An effective application is one that:

- has been completed in full
- provides all relevant attachments

  AND

- meets the criteria for approval.

Fees

No fees are payable for applications to import and supply medicines under section 19A in the interests of public health.

Processing your application

Timeframe

There is no statutory timeframe for making decisions on applications made under section 19A of the Therapeutic Goods Act. However, we process such applications as quickly as possible, because these requests are made in the interests of public health. Providing accurate and detailed the information will allow the TGA to assess the application and make a decision more efficiently.

If you have any questions regarding your request please contact us.

Assessing applications

We review the available evidence in order to be satisfied that the medicine is suitable for approval under section 19A. We use the flowchart at Summary of considerations for section 19A approval to make an assessment of eligibility for approval under section 19A. This includes a clinical evaluation conducted by medical experts at the TGA.

We also work with you if it is necessary to impose any additional conditions of approval.

Confirming availability of substitutes included in the ARTG

We contact the sponsors of medicines that are unavailable or in short supply, to confirm availability and investigate whether other suppliers of the substitutes are able to increase supply to cover the shortfall.

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.

Approval

If we are satisfied that the criteria for section 19A approval are met, we will approve the importation and supply of the medicine and impose relevant conditions on that approval. We provide you with a notice of approval that outlines the conditions of approval. You must adhere to all conditions listed in the notice.

The period of approval will be specified in the notice of approval. The medicine approved under section 19A must not be imported or supplied after the expiry date or after the approval has lapsed. You must submit a new application if the medicine needs to be supplied in the interests of public health beyond the specified period.

We publish section 19A approvals on our website when they are associated with a medicine shortage.

Rejection

You will be notified in writing if the application is not approved. We do not publish rejections.

Conditions of approval

A number of conditions are likely to be imposed on any section 19A approval. For example, conditions relating to:

- good manufacturing practice

- effective communication strategy
- adverse event reporting
- reporting on supply.

We may also apply other conditions, depending on the nature of the medicine and the circumstances of approval.

You are not permitted to advertise medicines that are approved under section 19A.

Reporting on supply

Generally, it will be a condition that you provide information about the supply of the medicine approved under section 19A:

- where the approval is granted for a period of less than six months, reporting will be required on the total amount of product supplied in the period of approval until its expiration or lapsing ('the reporting period')

  OR

- where the approval is granted for a period of more than six months, reporting will be required on the total amount of product supplied in the first six month period following approval ('the first reporting period') and the amount of product supplied in the period following the first six month period until the expiration or lapsing of the approval ('the second reporting period').

The reports must be submitted within 28 days of the conclusion of each reporting period, and should be emailed to medicine.shortages@tga.gov.au. A report template will be provided with the notice of approval.

Consequences of not complying with conditions

If you do not comply with a condition of a section 19A approval, the Secretary can notify you under subsection 19A(9) of the Therapeutic Goods Act that the approval has lapsed (that is, it has been cancelled). Following any such cancellation, you would be prohibited from supplying or exporting surplus stock.

It is also an offence under subsection 22(7) of the Therapeutic Goods Act to breach a condition of a section 19A approval.

Publication of section 19A approvals

We publish information on section 19A approvals to import and supply medicines on the TGA website when they are associated with the unavailability or short supply of a medicine. Approvals are usually published within five working days after the approval holder has been notified. The following information is included where applicable:

- details of the medicine covered by the section 19A approval:
  - active ingredient, trade name, strength, dosage form, indications and an image
- details of the medicine included in the ARTG that is unavailable or in short supply:
  - active ingredient, trade name, strength, dosage form, ARTG number

- name of the person to whom the approval is granted under section 19A (company name only)
- period of the approval (expiry date) and information relating to the period of any previous approval granted under section 19A in relation to the medicine (including the reason for its lapsing)
- additional information relating to supply – such as where there is a delay between section 19A approval and the supply of that medicine
- related medicine shortage information.

The Medicines Shortage Information Initiative (MSII) also includes a link to the section 19A approvals database.

Lapsing of approvals

An approval under section 19A can lapse before the end of the nominated approval period in the following circumstances:

- any of the specific criteria for approval no longer apply, for example:
  - a decision has been made about whether or not to include the medicine in the ARTG
  - the medicine included in the ARTG is no longer unavailable or in short supply
- a condition of approval has been breached – go to Consequences of not complying with conditions.

We will notify you in writing:

- if the approval lapses before its expiry, and we will provide information on the reason for lapsing

  OR

- within eight weeks before the expiration of the approval, as a matter of courtesy.

If you want to continue supplying the medicine after the expiration or lapsing of an approval, you must make a new application under section 19A.

The lapsing of an approval or the expiry of the nominated approval period does not prevent another approval being granted under section 19A before the lapsing of the first period. Any subsequent approval may be expressed to take effect on the expiry of that period.

However, where the period has expired prior to a new approval being granted, you are prohibited from importing and supplying the medicine for the period between the two approvals.

Where a new approval is requested to change from subsection 19A(2) to 19A(1) or 19A(1A) following a successful section 23 application to include the medicine in the ARTG, approval cannot take effect until the date of inclusion in the ARTG of the medicine. The TGA may assess a subsection 19A(1) or 19A(1A) application prior to the section 25(3) decision. However, the decision letter can only be provided on or after the section 25(3) decision date.

Making an appeal

The TGA internal review guidelines apply to the following 'initial decisions' made regarding an application or approval to import and supply medicines under section 19A of the Therapeutic Goods Act:

- approval, including conditions of approval
- refusal to approve
- lapsing.

Further assistance

Contact the TGA's Medicine Shortages Section for more information on:

- determining if your medicine is eligible for section 19A approval
- completing the section 19A application form
- importing or supplying medicines that are not included in the ARTG.

Example Dear Healthcare Professional Letter

[Section 19A applicant company letterhead]

[Date]

Dear Healthcare Professional

Shortage of [registered medicine] Aust R [XXX] and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*

The Australian registered medicine, [registered medicine AUST R XXXXX], sponsored by [Australian sponsor], is [unavailable/in short supply] due to [reason for short supply/unavailability]. Supply of [registered medicine] is expected to resume [date, if known].

[Applicant company] has been able to arrange supply of an alternative product [section 19A approved medicine] on a temporary basis. This product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until [expiry date of the notice of approval] for the following indication(s):

· [Indication(s) specified in the notice of approval]

[Section 19A approved medicine] is registered and marketed in [one of the specified countries].

Please note the following information regarding differences between [section 19A approved medicine] and [registered medicine AUST R XXXXX]. [Provide information on the Quantity and container type, strength, dosage form, indication(s), formulations, description, scheduling, labelling and other relevant comparisons/differences between the products. Include any contraindications and potential safety risks].

Please refer to the Australian Product Information [prescribing information] for [recommended dosing, adverse reaction profile].

[For CMI/Patient leaflet in a foreign language] Patients should be advised to disregard the CMI/patient leaflet for [section 19A approved medicine] contained within the pack and refer to the Australian Consumer Medicines Information available from [pharmacist, website, pack].

PBS Reimbursement

[Provide information on PBS reimbursement if applicable.]

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with [section 19A approved medicine] should be reported by healthcare professionals and patients to the [applicant company] on [phone number] or by email [email address]. Alternatively, this information can be reported to the TGA.

Please forward this information to relevant staff members in your organisation.

For further information, please contact [applicant company name] on [phone number] or email [email address].

Yours sincerely

[Name/Position]

[Applicant company]

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Pharmacovigilance and Special Access Branch (PSAB) and Regulatory Guidance Section	October 2017
V1.1	Biosecurity Act 2015 replaced Quarantine Act 1908	PSAB	January 2018

Therapeutic Goods Administration

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https://www.tga.gov.au

Reference/Publication #