Section 19A vs Section 14/14A: a practical approach to reducing the impact of medicine shortages

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Session overview

- Section 14 vs section 19A
- TGA's role in mitigating shortage impacts
- Overview of section 19A and section 14 pathways
- Statistics
- Considerations – section 19A vs section 14
- Which pathway to choose?
- Q and A

Section 14 vs section 19A

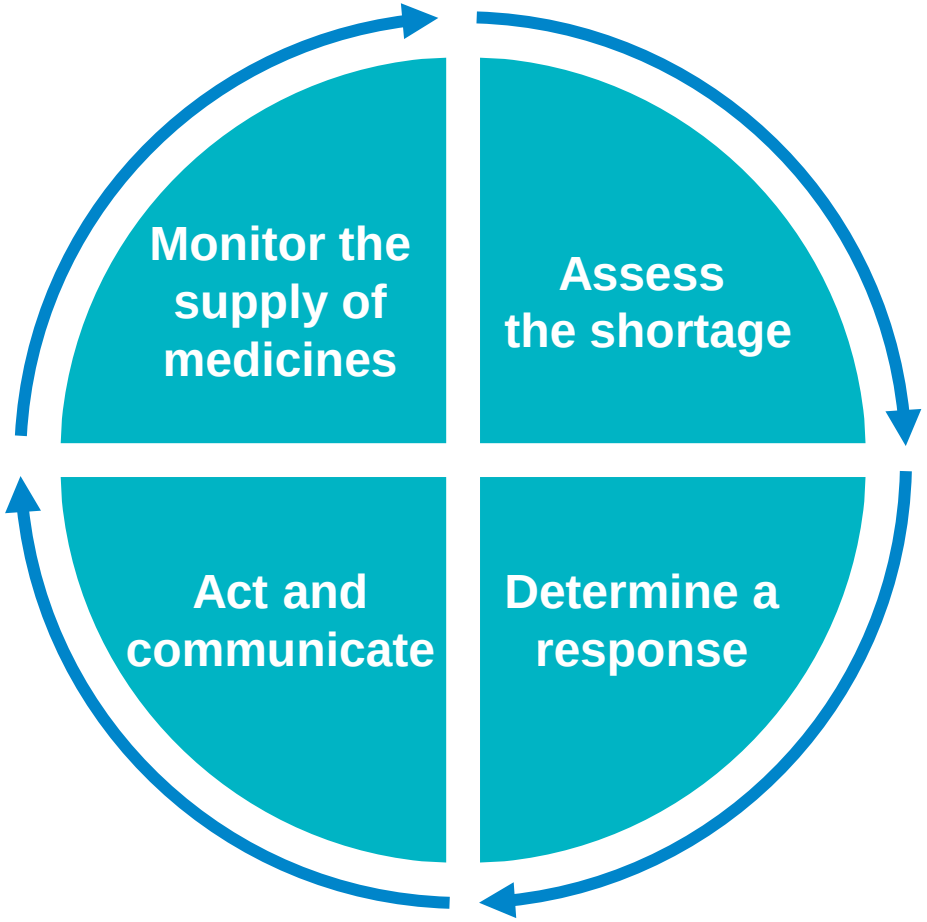
Section 14/14A	Section 19A
Applies to an ARTG-registered product	Applies when ARTG products are unavailable or insufficient
Used to address supply issues caused by non-compliance with standards	Used to import overseas-approved equivalent
Maintains supply of the **SAME** product	Introduces an **ALTERNATIVE** product
Outcome: Regulatory flexibility within ARTG	**Outcome: Temporary supply via an overseas substitute**

The role of the TGA in Medicine Shortages

Our Goal

To reduce the impact of medicine shortages for Australian consumers and health professionals.

To facilitate continual access to medicines, where possible.



What is a medicine shortage?

A medicine is in **shortage** if its supply in Australia will not, or will not likely, meet the demand for it at any time in the next 6 months, for all the patients in Australia who take it or who may need to take it.

This is different to a medicine **discontinuation** – when a medicine is no longer available in the marketplace.

- Sponsors must report shortages of **all** prescription medicines and some non-prescription medicines
- The TGA monitors the supply of important medicines at a **national** level

Section 19A

Enables time-limited approval for the importation or supply of an overseas product when certain criteria are met.

Approval must be necessary in the interests of public health.

19A Approvals where unavailability etc. of therapeutic goods

(1) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:
- (a) registered goods that could act as a substitute for the goods:
  - (i) are unavailable or are in short supply; or
  - (ii) may, in the reasonably foreseeable future, become unavailable or be in short supply; and
- (b) either:
  - (i) the goods that are the subject of the application are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3); or
  - (ii) an application under section 23 has been made for registration of the goods and the application has passed preliminary assessment; and
- (c) the goods are of a kind:
  - (i) included in Schedule 10 to the *Therapeutic Goods Regulations 1990*; or
  - (ii) specified by the Secretary in a determination under subsection (4); and
- (d) the approval is necessary in the interests of public health.

(1A) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:
- (a) registered goods that could act as a substitute for the goods:
  - (i) are unavailable or are in short supply; or
  - (ii) may, in the reasonably foreseeable future, become unavailable or be in short supply; and
- (b) either:
  - (i) the goods that are the subject of the application are not registered or approved for general marketing in any of the foreign countries specified by the Secretary in a determination under subsection (3); or
  - (ii) the goods that are the subject of the application are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3), but are not readily available for importation into, and supply in, Australia; and
- (c) the goods are registered or approved for general marketing in a foreign country; and
- (d) the manufacturing and quality control procedures used in the manufacture of the goods are acceptable; and
- (e) the goods are of a kind:
  - (i) included in Schedule 10 to the *Therapeutic Goods Regulations 1990*; or
  - (ii) specified by the Secretary in a determination under subsection (4); and
- (f) the approval is necessary in the interests of public health.

(2) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:
- (a) registered goods that could act as a substitute for the goods do not exist; and
- (b) an application under section 23 has been made for registration of the goods; and
- (ba) the application has passed preliminary assessment; and
- (c) the goods are of a kind:
  - (i) included in Schedule 10 to the *Therapeutic Goods Regulations 1990*; or
  - (ii) specified by the Secretary in a determination under subsection (4); and
- (d) the approval is necessary in the interests of public health.

(2A) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of

Specified countries

The Therapeutic Goods (Foreign Countries) Determination 2016 outlines which overseas countries are **preferred sources of medicines** considered for importation and supply **under section 19A**.

These "**specified countries**" provide a high level of confidence in quality, safety and efficacy standards, **comparable to Australian-registered products**.
There are currently 9 specified countries:

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

Products sourced from unspecified countries have additional legislative requirements for acceptable GMP evidence.

Types of section 19A approvals

Subsections

19A(1): Substitute goods are from a country specified by the Secretary

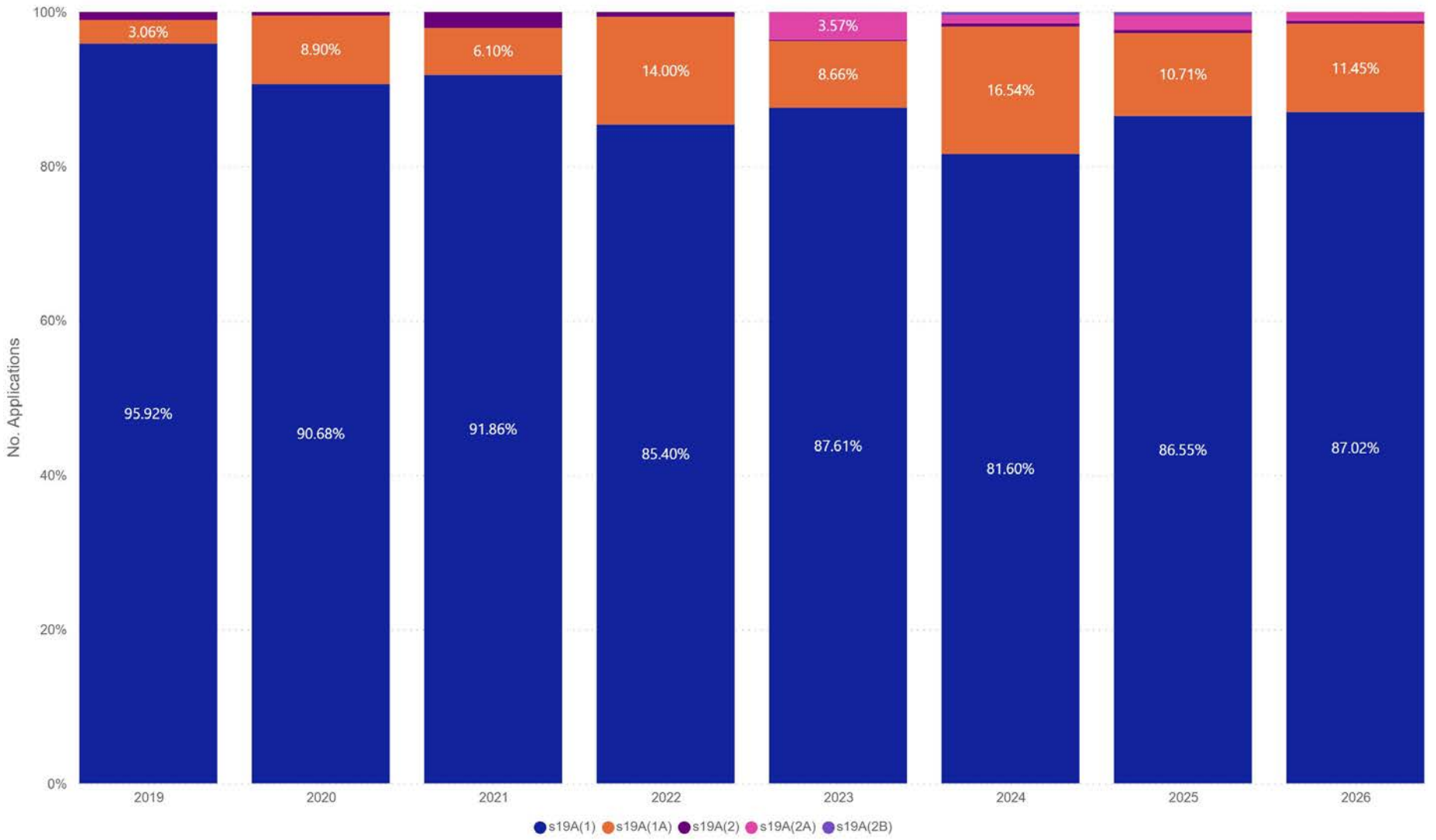
19A(1A): Substitute goods are NOT from a country specified by the Secretary

19A(2): Medicines under evaluation by the TGA for inclusion in the ARTG and registered goods do not exist

19A(2A) and (2B)

- Previously registered medicines
- Substitute goods from a specified country (2A)
- Substitute goods NOT from a specified country (2B)

Section 19A applications by type

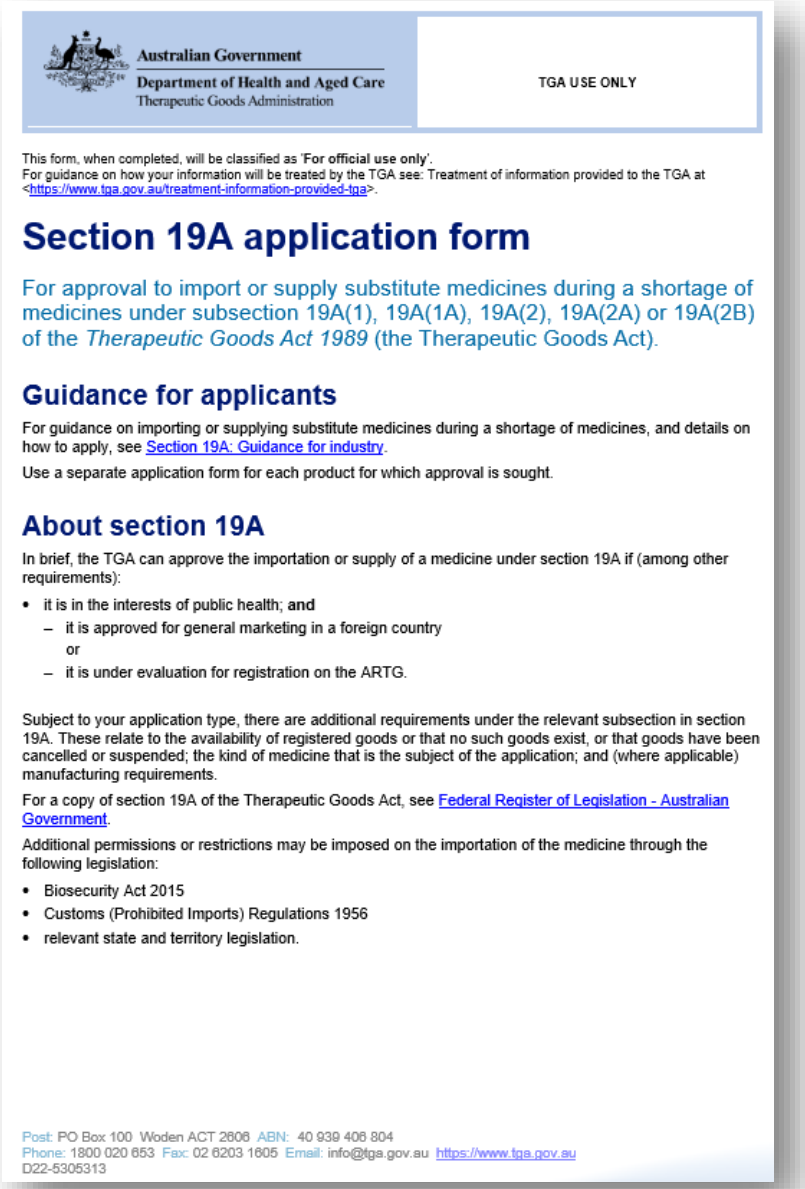


How to apply

Section 19A application form available online

- Any person can submit a section19A application – *no fee*
- Select the correct application type
- Ensure legislative criteria are met
- Complete all mandatory fields
- Prepare supporting documents
- For repeat applications, info on previous approvals
- Submit completed application and supporting documents to:

  Section19ASubmissions@health.gov.au



Australian Government
Department of Health and Aged Care
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 under subsection 19A(1), 19A(1A), 19A(2), 19A(2A) or 19A(2B) of the *Therapeutic Goods Act 1989* (the Therapeutic Goods Act).

Guidance for applicants

For guidance on importing or supplying substitute medicines during a shortage of medicines, and details on how to apply, see Section 19A: Guidance for industry.

Use a separate application form for each product for which approval is sought.

About section 19A

In brief, the TGA can approve the importation or supply of a medicine under section 19A if (among other requirements):

- it is in the interests of public health; **and**
  - it is approved for general marketing in a foreign country
    or
  - it is under evaluation for registration on the ARTG.

Subject to your application type, there are additional requirements under the relevant subsection in section 19A. These relate to the availability of registered goods or that no such goods exist, or that goods have been cancelled or suspended; the kind of medicine that is the subject of the application; and (where applicable) manufacturing requirements.

For a copy of section 19A of the Therapeutic Goods Act, see Federal Register of Legislation - Australian Government.

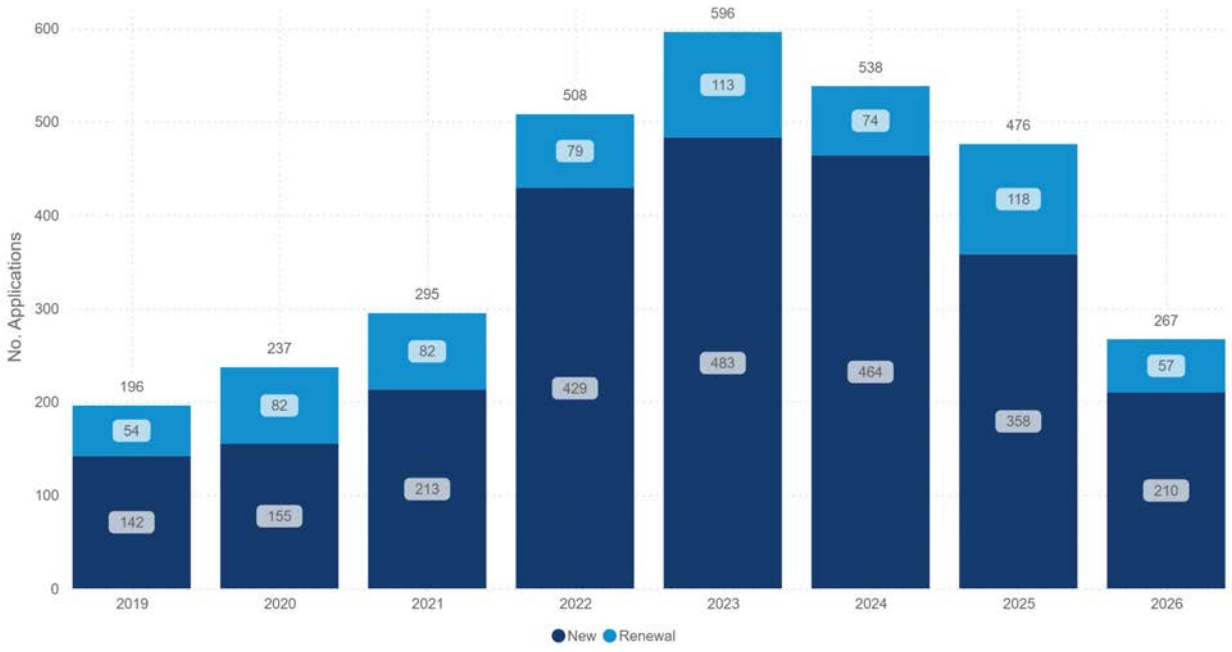
Additional permissions or restrictions may be imposed on the importation of the medicine through the following legislation:

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

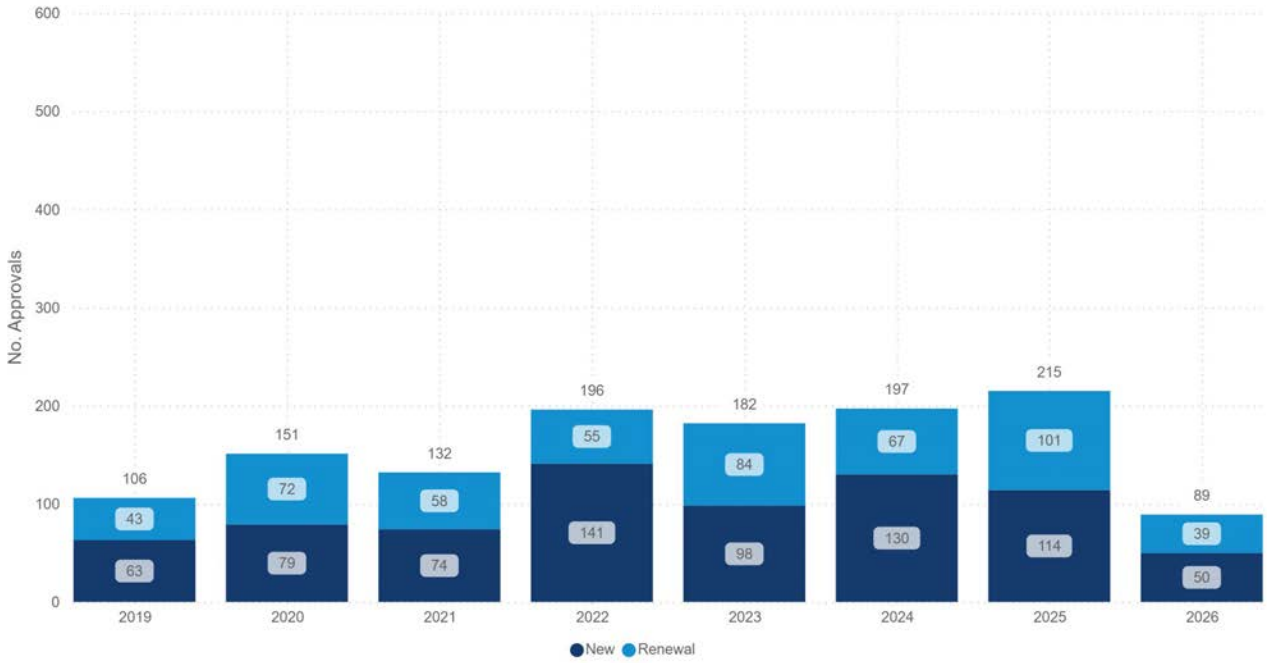
Post: PO Box 100 Woden ACT 2606 ABN: 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au https://www.tga.gov.au
D22-5305313

Applications vs approvals

Applications received



Approvals granted



Triaging section 19A applications

Risk-based prioritisation framework

Availability of Australian registered alternatives?

- Market assessments
- Clinical assessments

Public health impact?

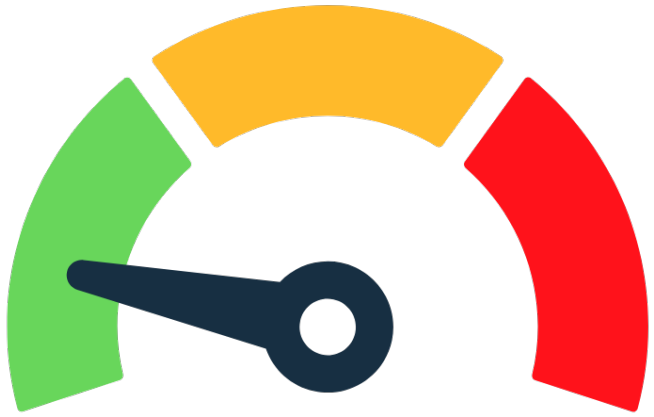
- Medicine usage, ease of switching
- Vulnerable patient groups

Suitability of the overseas product?

- Regulatory status
- How closely it matches the ARTG product: indications, formulation, pack size

When multiple applications are received:

- Applications from the ARTG sponsor or applicants working with the ARTG sponsor
- Application type
- Supply chain logistics: lead time, quantities, availability
- Only complete applications progress to assessment



Further considerations

Determining the length of a section 19A approval

- Aligned with the expected length of the medicine shortage or supply disruption – typically 1-2 months after shortage end date
- For s19A(2), the approval would align with the section 23 application decision date
- The duration of a section 19A approval generally does not exceed 12 months, but there are exceptions for long-term shortages and discontinuations

Lapsing a section 19A approval before the end of the approval period

This can occur if the approval conditions no longer apply or have been contravened.
For example:

- The medicine included in the ARTG is no longer unavailable or in short supply
- A condition of approval has been breached (GMP issues)
- A decision has been made about whether to include the medicine in the ARTG

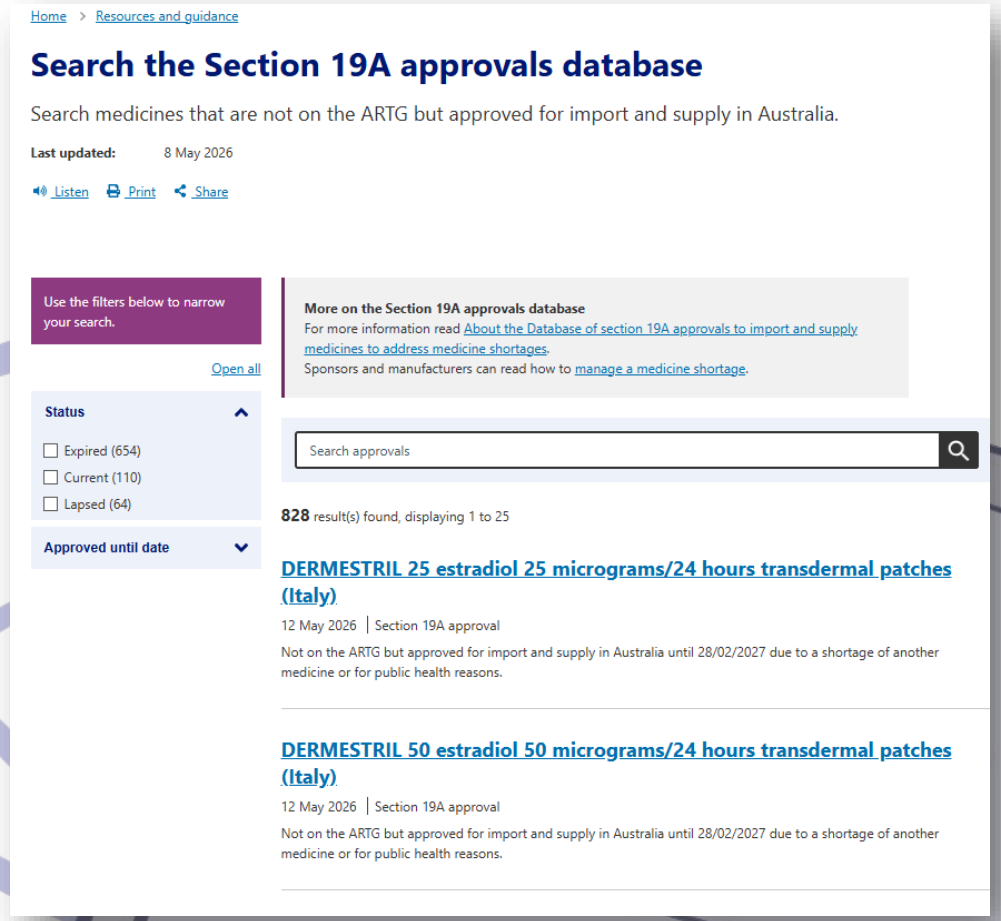
A lapsing notice is sent to the approval holder.

Approval conditions

The following conditions apply:

- Report adverse events
- Notify the TGA about any interruptions to supply, shortages or delays with importing and supplying the substitute medicine
- Periodically report supply data to the TGA
- Adhere to GMP requirements
- Distribute a Dear Healthcare Professional letter and any other communications outlined in the Notice of Approval
- Supplementary labelling

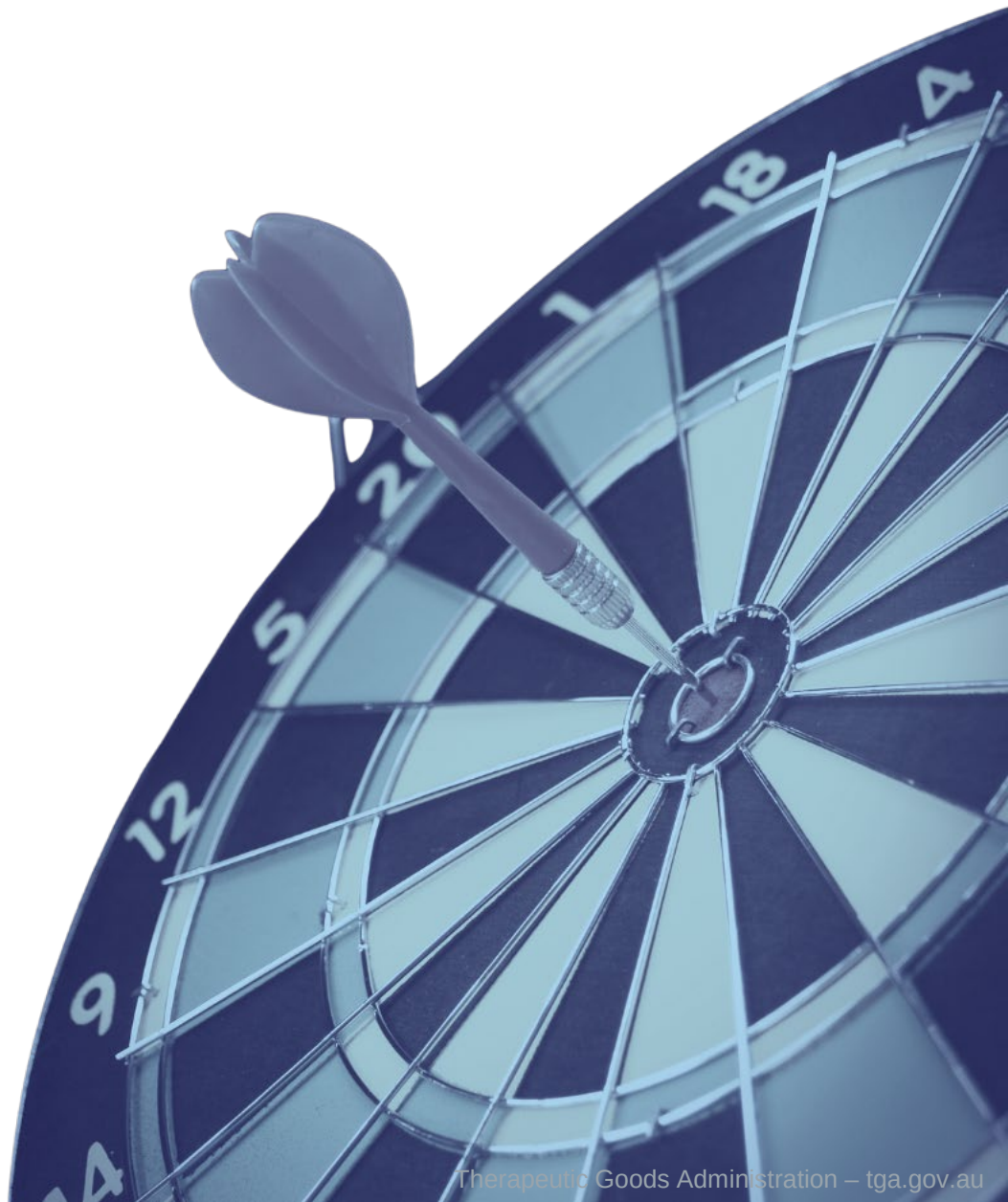
Section 19A Approvals Database



What we aim for

- Smooth transition between the product in shortage and section 19A access
- Section 19A product is readily accessible
  - Pharmacist awareness and confidence in accessibility
  - Patients can access with existing scripts and no lengthy ordering time
- PBS listing, where relevant

- Early reporting of anticipated disruptions
- For long-term approvals, consideration of ARTG registration:
  - ✓ Desmopressin 10 mcg nasal spray
  - ✓ Carbimazole 5 mg tablets
  - ✓ Phenelzine 15 mg tablets
  - ✓ Glyceryl trinitrate 300 mcg sublingual tablets



Continuous improvement activities

Legislative proposals

Minor amendment to the Act to enable earlier approval of section 19A applications and their communication

In effect from 5 September 2025

Non-legislative proposals

Improvements to the form and guidance for section19A applications

Pilot underway 2 February to 30 June 2026

Legislative instrument review

Sunsetting review of the *Therapeutic Goods (Foreign Countries) Determination 2016*

- Overseas countries that are preferred sources of medicines considered under the section 19A pathway.
- Includes targeted consultation proposal to add Singapore to the list of specified countries.

When a section 19A application is not suitable

- Suitable Australian registered alternatives are available.
- The overseas substitute is not suitable because:
    - it does not meet regulatory standards
    - its regulatory status is unverified
    - there is insufficient GMP assurance.
- Limited public health need.

Consent to import, supply or export therapeutic goods that do not comply with standards

When section 19A is not an option…

Is the product manufactured with the identical process to the Australian product?

NO → S14/14A is not the right path – a temporary variation may be an option – reach out to the relevant area's inbox

YES

Does the product meet Australian Standards as per section 10 of the Act?

NO

Section 14/14A consent to supply is an option

Standards under the Act

A standard for this purpose is one that is constituted by the matters in an order made by the Minister under section 10 of the Act.

These include:

- Therapeutic Good Orders
- a monograph in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary
- a standard published by Standards Australia.

Common standards – Therapeutic Goods Orders

- Therapeutic Goods Order No. 91 – *Standard for labels of prescription and related medicines;*
- Therapeutic Goods Order No. 92 – *Standard for labels of non-prescription medicines;*
- Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017 (TGO 95)
- Therapeutic Goods Order No. 100 - Therapeutic Goods (Microbiological Standards for Medicines) Order 2018
- Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019
- Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019
- Therapeutic Goods (Medicines - Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021
- Therapeutic Goods (Standard for Biologicals - Labelling Requirements) (TGO 107) Order 2021
- Therapeutic Goods (Standard for Human Cell and Tissue Products - Donor Screening Requirements) (TGO 108) Order 2021
- Therapeutic Goods (Standards for Biologicals- General and Specific Requirements) (TGO 109) Order 2021

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Section 14/14A considerations: What is not a standard under Section 10 of the Act

Registration number (AUST R) – Regulation 15 of the *Therapeutic Goods Regulations 1990* outlines the requirements for including the AUST number on a medicine label.

- Section 19D of the *Therapeutic Goods Act 1989* permits the Secretary (or their delegate) to consent to the importation or supply of a TGA-approved medicine without the relevant AUST number on the primary pack label.
- Consent for a medicine on the ARTG to be imported or supplied without the AUST number on the label will only be considered in extraordinary circumstances.

Signal words and cautionary statements – This information is required to be on labels in a prescribed format per the Poisons Standard (sections as 16, 17 and 18). The Poison Standard is a Legislative Instrument and not a standard under Section 10 of the Act.

Continued next slide…

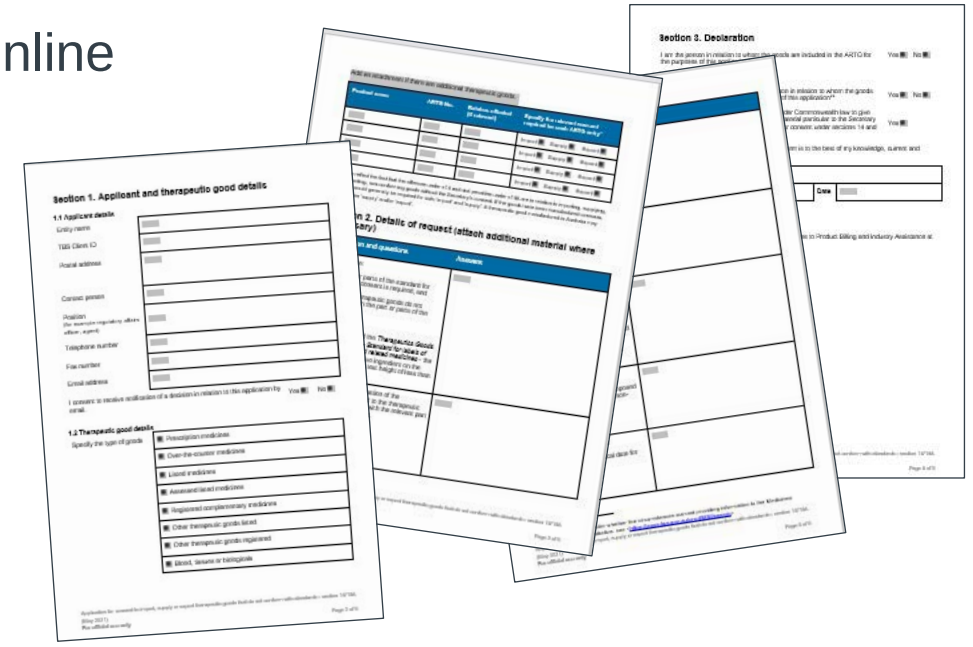
Section 14/14A considerations: What is not a standard under Section 10 of the Act

Changes to registered product details: changes to tablet markings or capsule colours, and to the manufacturing process, cannot be assessed under the section 14/14A pathway. Changes to this information may be open to variation applications, depending on the circumstances.

Formulation: Any formulation differences cannot be considered under section 14/14A.

How to apply for consent to import, supply or export goods that do not comply with standards – section 14/14A

- Determine if you meet the requirements – that you are applying for consent to not comply with a standard
- **If you are not sure, please contact us before applying – you can message the relevant reviewing area's inbox, and/or the Medicine Shortages Section, if appropriate**
- Complete the application form which is available online
- Submit the form and payment as described

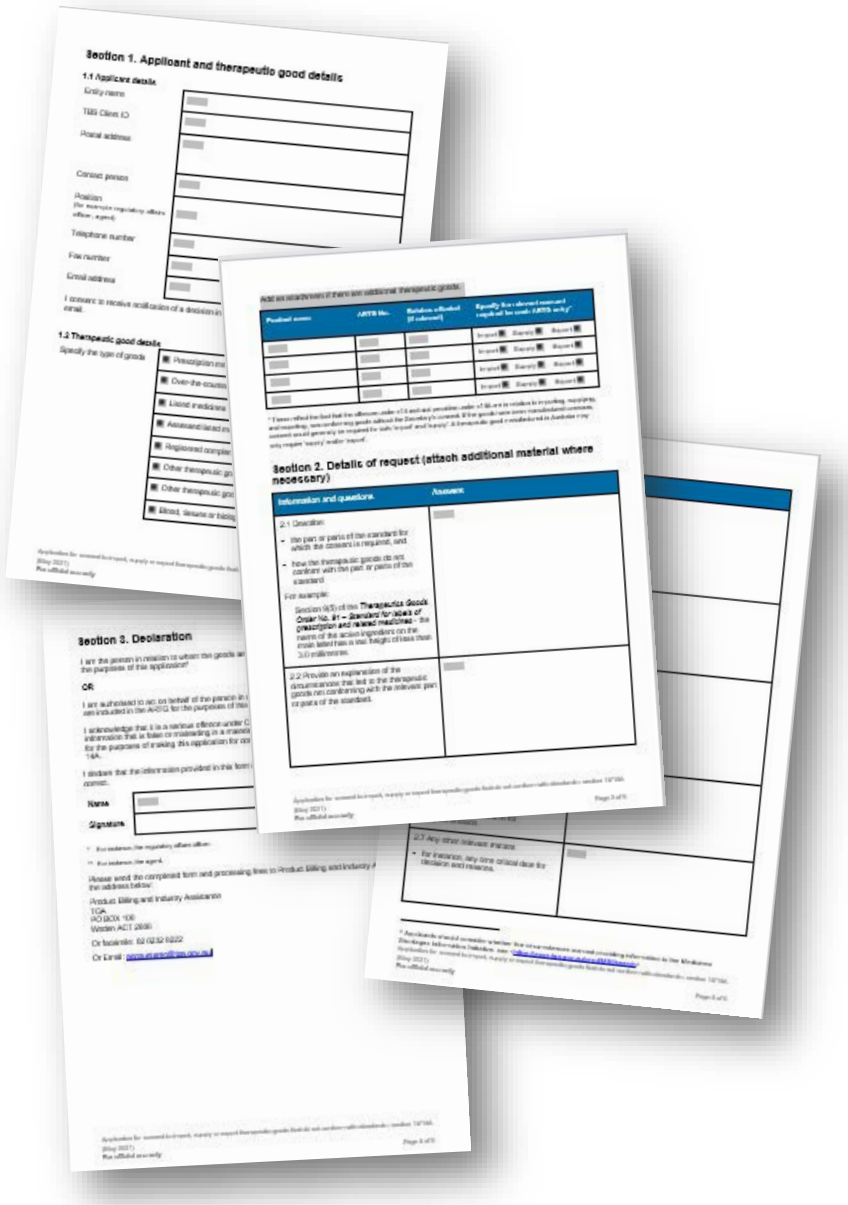


What to provide with a section 14/14A application

- If there are different labels, include these
- Details of any over-stickers to be used for labels: include mock-ups of these and at least an indication of where they will be included on the label
- Copies of any Dear Healthcare Professional, Dear Pharmacist or Dear Consumer letters.

How we process a 14/14A application

- We determine if an application is due to non-compliance with a standard.
- We assess the application, considering factors such as shortage implication, risk and consumer requirements (see next slide).
- Considering how potential risks from non-compliance can be mitigated is key – conditions may be placed on the approval to help mitigate risk.
- We consider the length of the consent, which may depend on the relevant standard and if the standard is likely to change soon, and on the expected consumption rate of the medicine in the market.



What we consider for a 14/14A application

1. Is the safety, quality and efficacy reduced?
2. Is there potential for a reduction to safe and effective use of the product?
3. Is there a clinical need for an uninterrupted supply and are suitable alternatives available?
4. Can use of appropriate conditions mitigate any risks?
5. Is it appropriate to limit the consent by reference to time and or number of batches?
6. Was the issue that caused the lack of compliance foreseeable or avoidable? What actions have been taken?

Granting permanent consents is uncommon

In the past, permanent consents were occasionally granted, but this is now uncommon.
The reasons for not giving longer consents include:

- changes to the standard the consent is for
- with respect to supplying international labels, changes to the label being supplied, which could lead to further non-compliance with the Labelling Order
- a change in the market landscape, which may mean the consent is no longer required – we have no mechanism to cancel a consent.

We normally only give 2 years to account for the points on the left (among other concerns). However, we will consider longer consents if:

- expiry of the batch in question is longer than 2 years and stock is not expected to be exhausted in that time
- a plan has been provided to show that it will take more than 2 years to resolve the noncompliance – updates on the process will need to be provided
- other justification is provided on a case-by-case basis.

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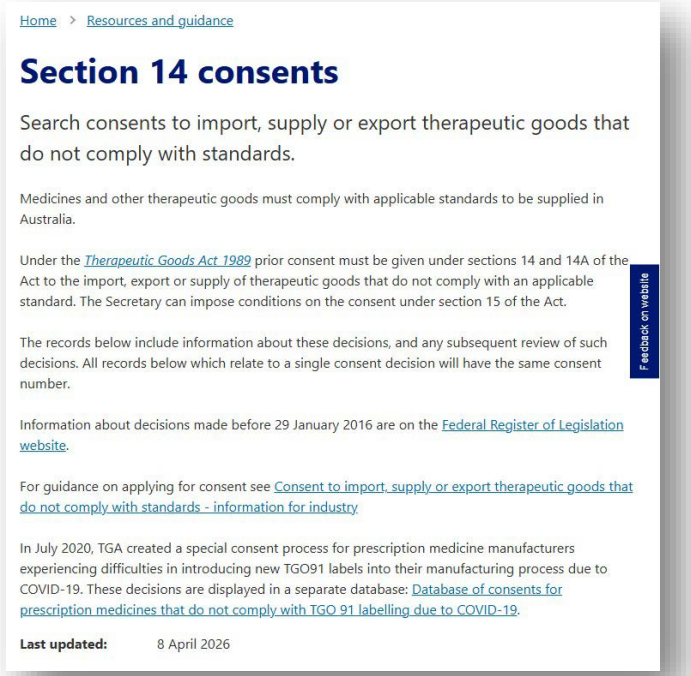
What happens next: finalising the application

- If we need more information, we will request it from the applicant.
- Our experts make a decision for the delegate to approve.
- We send out the decision letter, which will include any conditions applied.
- If consent has been given, the information will be published on the TGA website as soon as possible.
- The medicine can be supplied, so long as the conditions in the decision letter are met.



Home > Resources and guidance

Section 14 consents

Search consents to import, supply or export therapeutic goods that do not comply with standards.

Medicines and other therapeutic goods must comply with applicable standards to be supplied in Australia.

Under the *Therapeutic Goods Act 1989* prior consent must be given under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard. The Secretary can impose conditions on the consent under section 15 of the Act.

The records below include information about these decisions, and any subsequent review of such decisions. All records below which relate to a single consent decision will have the same consent number.

Information about decisions made before 29 January 2016 are on the Federal Register of Legislation website.

For guidance on applying for consent see Consent to import, supply or export therapeutic goods that do not comply with standards - information for industry

In July 2020, TGA created a special consent process for prescription medicine manufacturers experiencing difficulties in introducing new TGO91 labels into their manufacturing process due to COVID-19. These decisions are displayed in a separate database: Database of consents for prescription medicines that do not comply with TGO 91 labelling due to COVID-19.

Last updated: 8 April 2026

Feedback on website

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Over-stickering labels outside of a GMP facility

Schedule 8 of the Regulations includes *Persons Exempt from the Operation of Part 3-3 of the Act (Manufacturing of therapeutic goods).*

Item 5 allows for the application of labels or over-stickers to include a name and address and/or Registration number, while Item 6 allows for the application of the Poison Standard requirements, respectively.

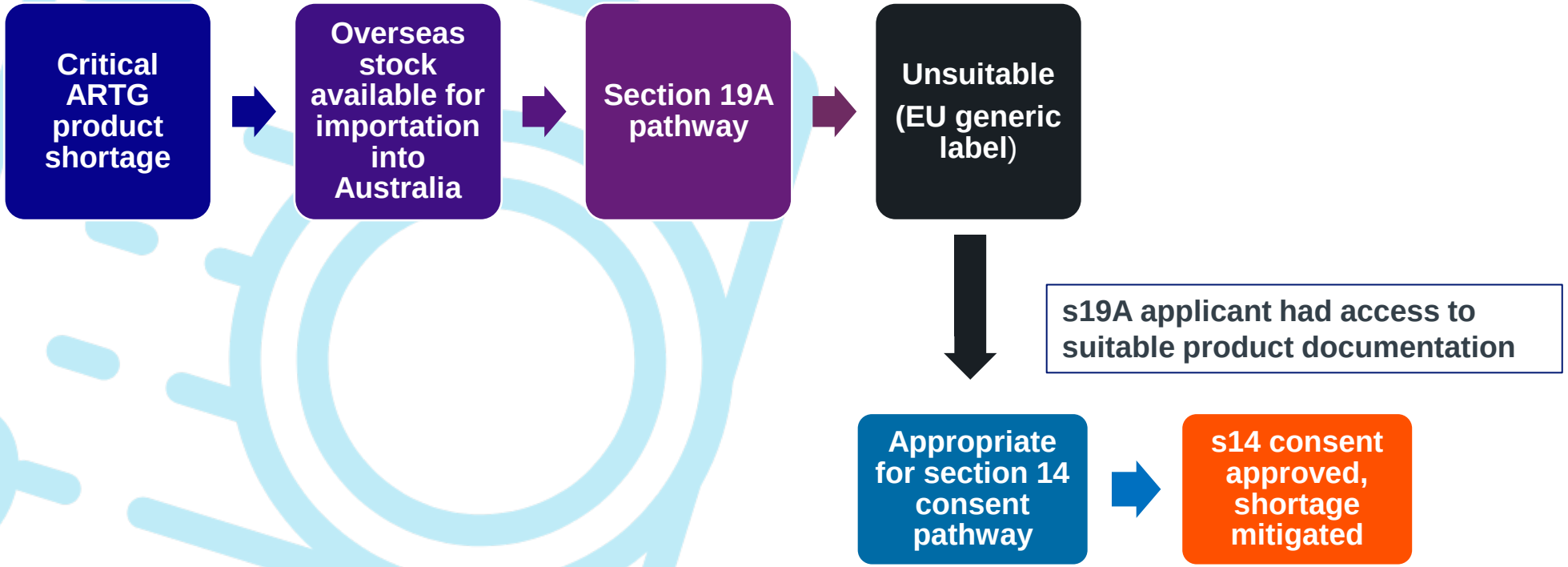
For example, if there has been a minor formulation change that has led to a new AUST R but the new packaging is not yet available.

You may be able to over-sticker existing labels to include the updated AUST R, without using a GMP facility. BUT you need to consider if the formulation changes will require any other updates to the label, as this information could not be included using the Schedule 8 provisions.

If there are shortage implications, we encourage reaching out to find a solution that best suits the scenario.

When the section 19A and 14 pathways intersect

When a product does not meet section 19A legislative requirements

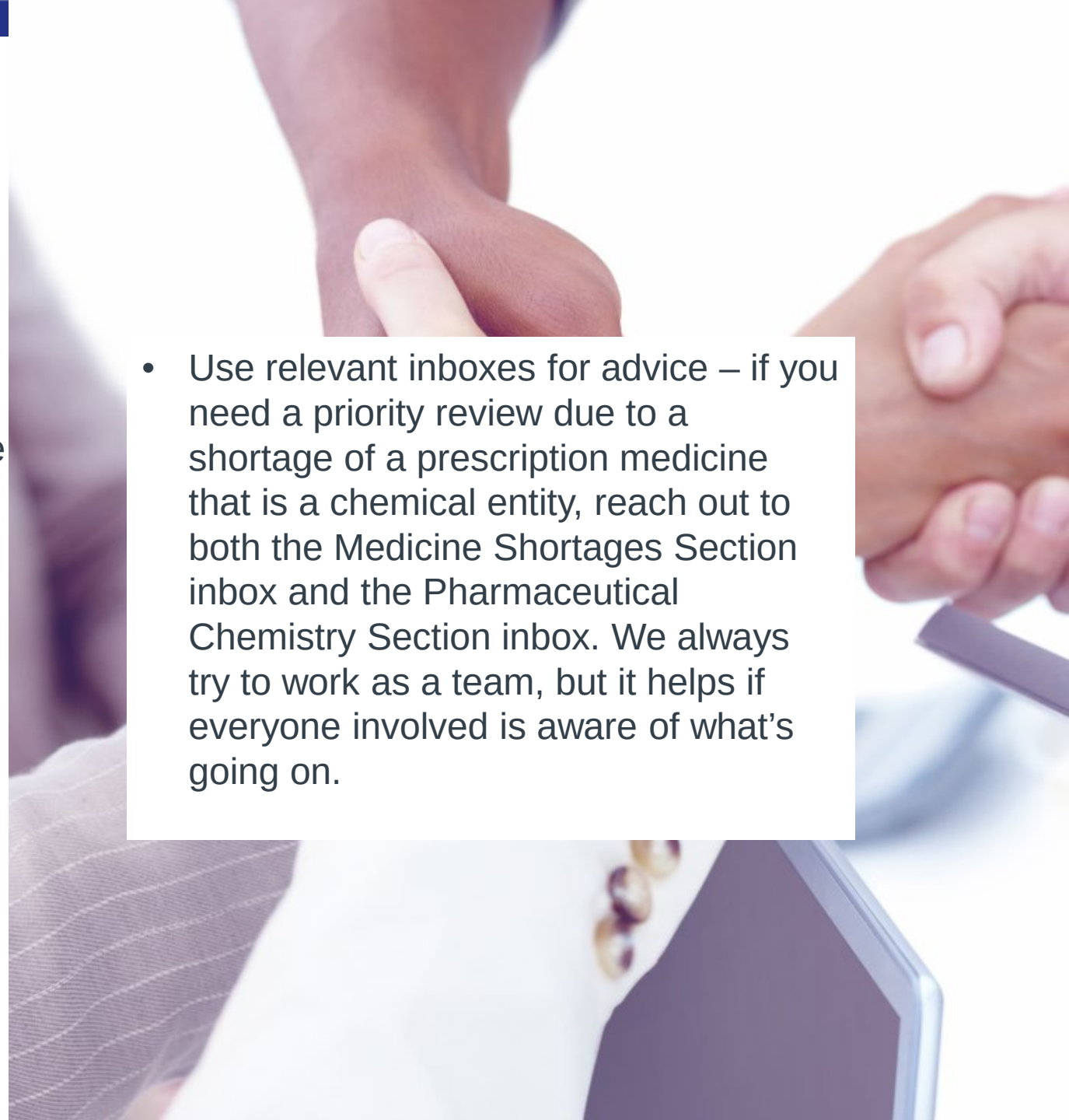


Help us help you

Teamwork makes the dream work to ensure medicine availability

- Reach out early! The more notice we have, the more time to explore options and to make sure the right application is used – be that S19A, S14/14A, a temporary 9D3 change or another option.

- Provide as much information as possible upfront – labels, standards, plans to rectify the non-compliance, corrective actions.



- Use relevant inboxes for advice – if you need a priority review due to a shortage of a prescription medicine that is a chemical entity, reach out to both the Medicine Shortages Section inbox and the Pharmaceutical Chemistry Section inbox. We always try to work as a team, but it helps if everyone involved is aware of what's going on.

Contacts

- Medicine Shortages inbox: medicine.shortages@health.gov.au
- Pharmaceutical Chemistry Section inbox: PCSinbox@health.gov.au
- Biological Science Section inbox: biological.medicines@health.gov.au
- TGA information pages:
  - Consent to import, supply or export therapeutic goods that do not comply with standards - information for industry
  - Information for sponsors: Supplying medicines during a shortage under section 19A

Questions?

www.tga.gov.au

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration