

# Medicine Shortages Update:

Recent amendments to medicine shortage reporting obligations and the supply of overseas medicines

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Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

## Outline

- **TGA's role in managing medicine shortages**
- **Importance of sponsor supply information**
- **New changes to:**
  - **reporting obligations for medicine shortage notifications**
  - **supply of overseas medicines when a product is cancelled from ARTG**

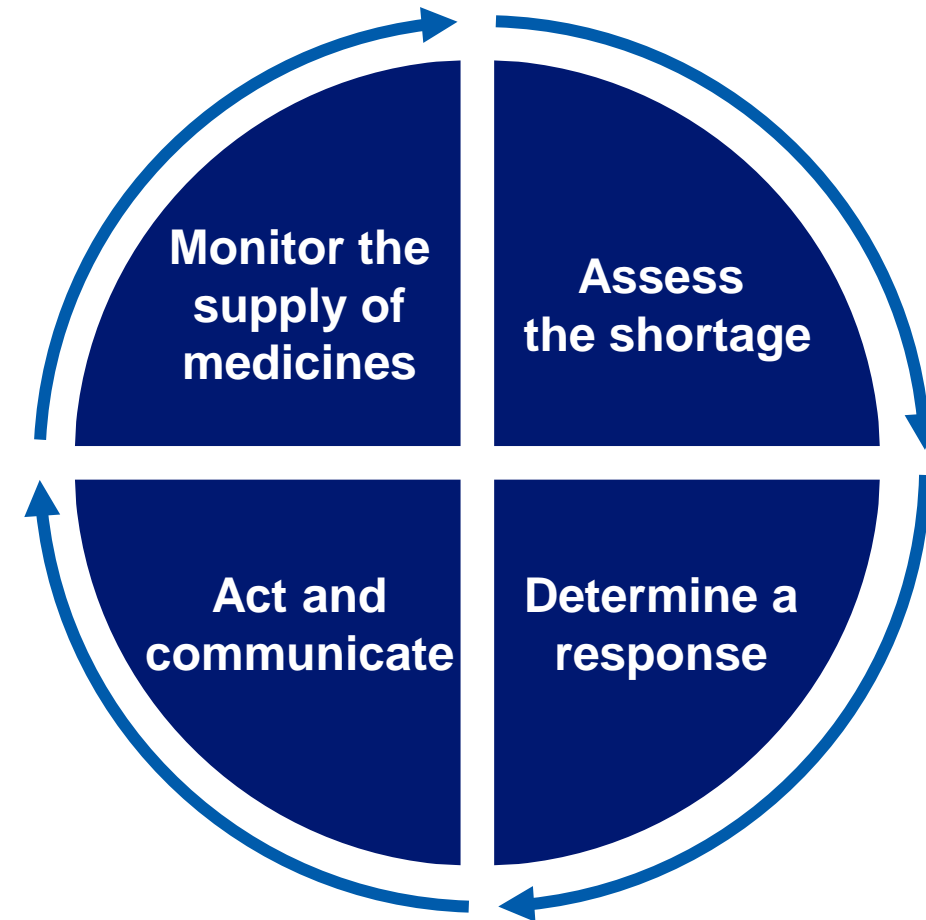


# The role of the TGA in medicine shortages

## Our Goal

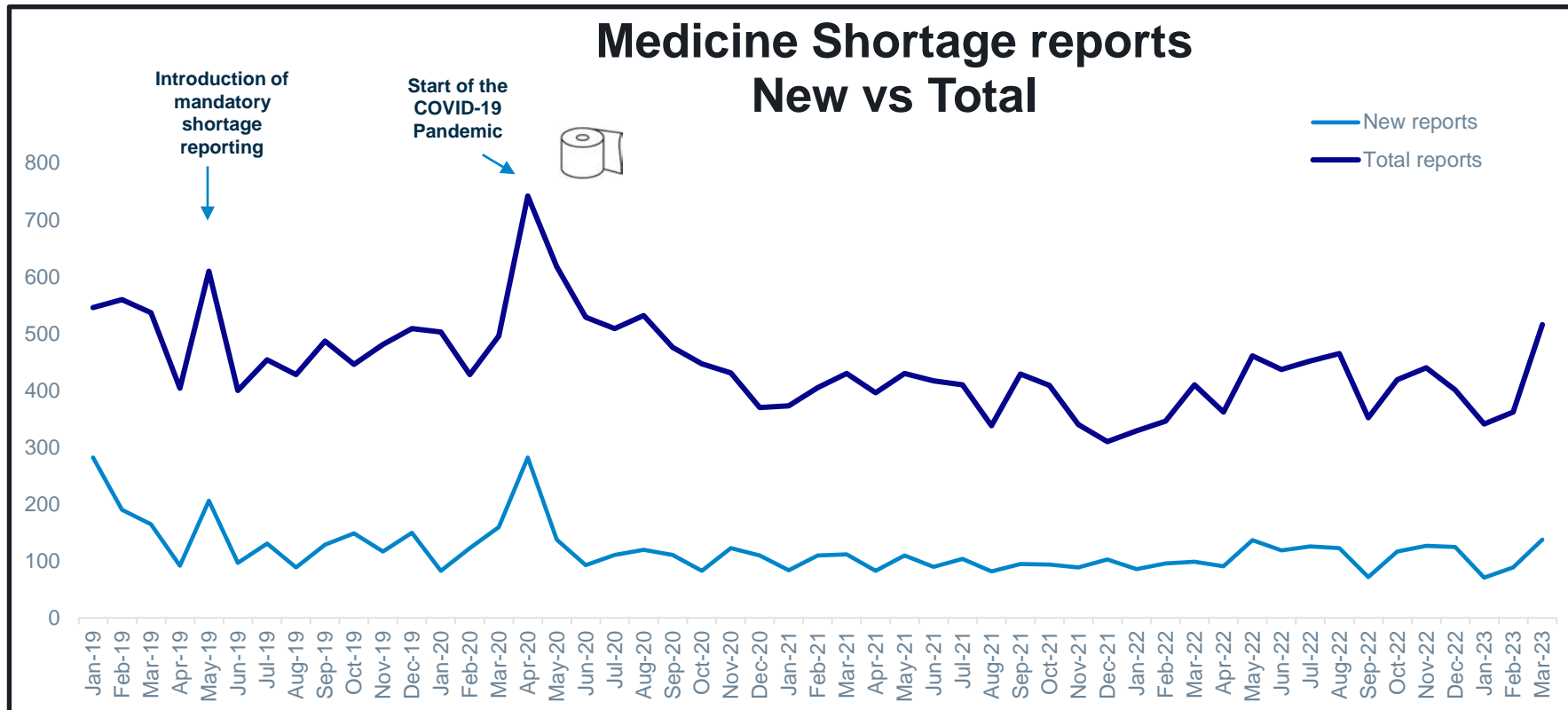
To reduce the impact of medicine shortages for Australian consumers and health professionals

To facilitate continual access to medicines, where possible



# Impact of COVID-19 on medicine shortages

The COVID-19 pandemic has highlighted supply chain issues and changed the way signals are received and shortages are managed



- **Consistent** number of new and total reports
- **Increased** complexity of shortages
- **Increased** supply monitoring
- **Increased** engagement
- **Increased** methods used in managing shortages

# Why does the TGA ask for supply information and how is it used?

Therapeutic Goods Administration | eBusiness Services  
Medicine Shortage Notification

Notifier ARTG Entry **Details** Impact Shortage Action Supporting Information

\* Indicates information that must be completed

When was the shortage known to the sponsor?

Nature of the shortage:  Anticipated  Current  Discontinued

Shortage reason:

Shortage reason - further information:

Estimated period supply will be affected at wholesaler points: From:  To:

Availability: Available  Date of processing  Deferred publication

Indicate preference for date of publication:  Yes  No

Is this shortage related to other medicines within the same Therapeutic class?  Yes  No

Is this shortage specific to Australia?  Yes  No

Estimated normal demand volumes for Australia:  units / month

Estimated percentage share of the Australian market:  %

Estimated current stock at sponsor / manufacturing level in Australia:  units

Estimated current stock at wholesaler / distributor level in Australia:  units

Explain what is meant by 1 unit in this context:

e.g. 1 unit = 1 bottle x 30 tablets or 1 unit = 5 x ampoules of injection or 1 box of 10 x 100mL bags etc.

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**Your  
important  
supply  
information  
is used to:**

- Detect supply gaps
- Determine suitability of management actions
  - Ask other sponsors to bring orders forward
  - SSSIs
  - Section 19A approvals
  - Wholesaler supply constraints
  - Do nothing?
- Model availability
- Timing of management actions
  - Urgency/frequency
- Other shortage information
  - Identify vulnerable population groups
  - Communication to HPs

# Your supply information ultimately helps US to help YOU and consumers

Accurate and  
timely supply  
information

TGA can implement  
suitable  
management actions

Reduces the  
impact of the  
shortage for health  
professionals and  
consumers

# Recent amendments to the *Therapeutic Goods Act 1989*

- Changes to medicine shortage reporting obligations
- Changes to the import or supply of overseas medicines



# Changes to medicine shortage reporting obligations

## What is the change

1. Must specify the **period of the shortage** (duration)
2. Must notify **changes to the duration of the shortage**
3. Must confirm that **the shortage has resolved**



## When will it be enforced

On **22 September 2023**

From 22 September, for medicine shortage notifications with an end date **on or after 22 September 2023**

*Sponsors must report changes within 2 or 10 days, in line with the status and reporting timeframes of the initial shortage notification*





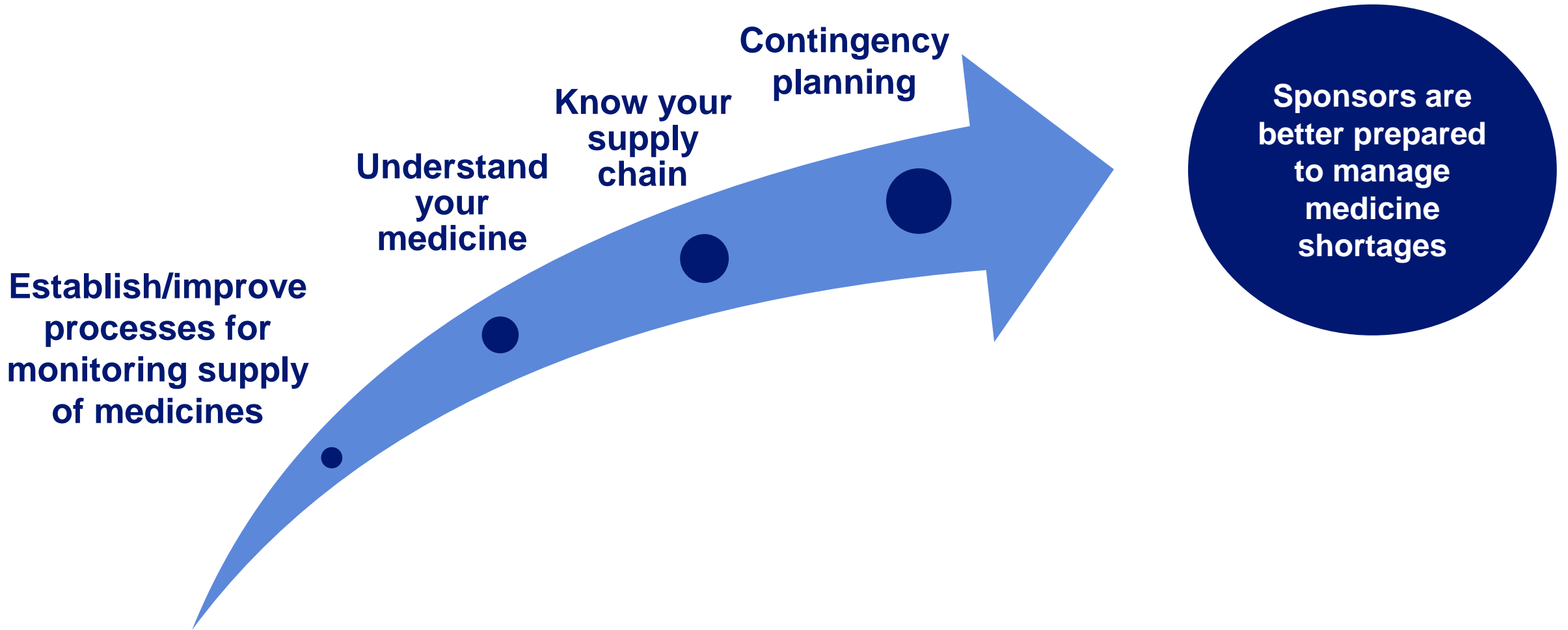
## Why has this change been made?

### Changes to notification requirements will:

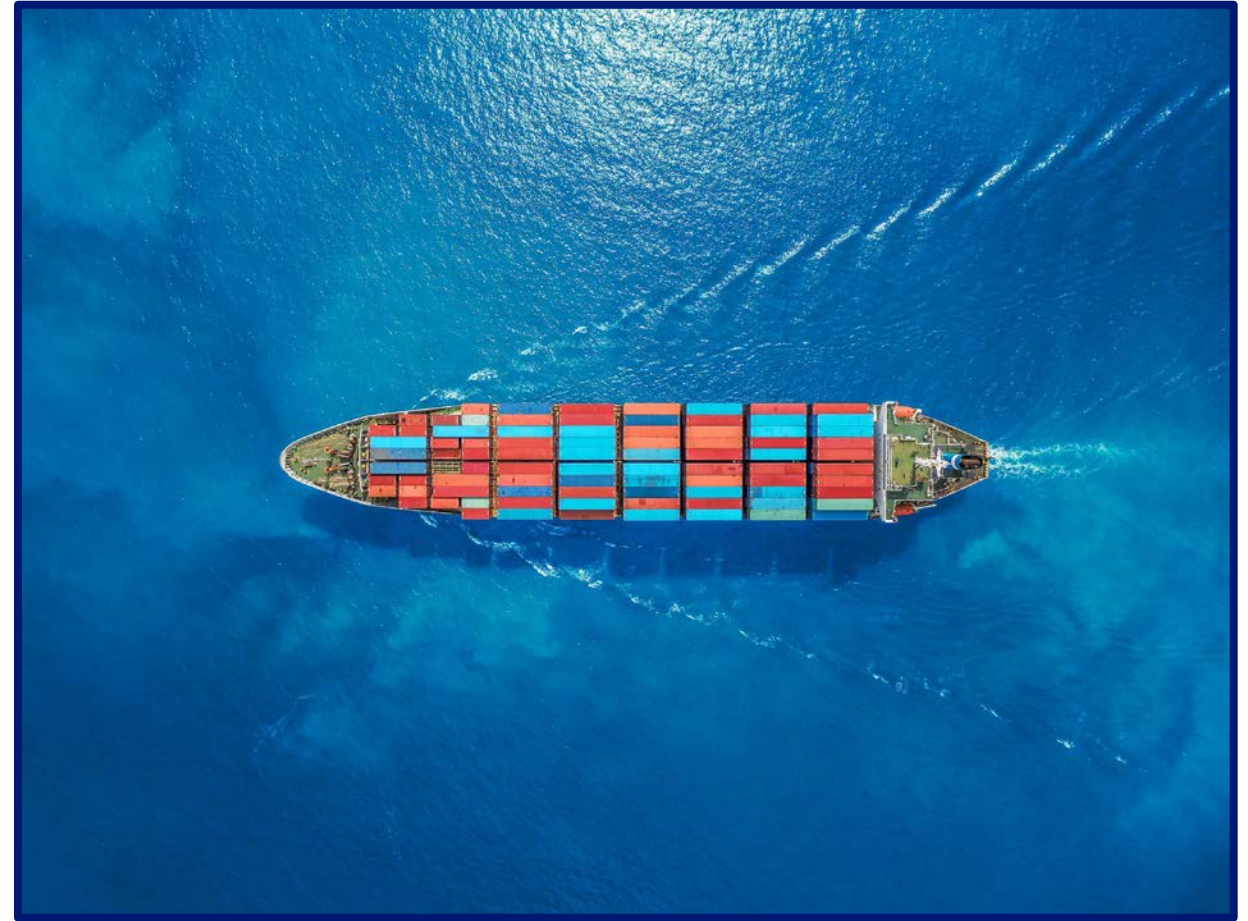
- **Improve accuracy** of information on the TGA Medicine Shortage Reports Database
- Assist with **better management** of shortages for everyone
- **Reduce the impact** of medicine shortages on patients

# What does this change mean for sponsors?

Sponsors must update their medicine shortage notification if there are changes to the **shortage duration** and when the **shortage has resolved**



**Changes to the import or supply  
of overseas medicines under  
section 19A when a medicine is  
cancelled from the ARTG**



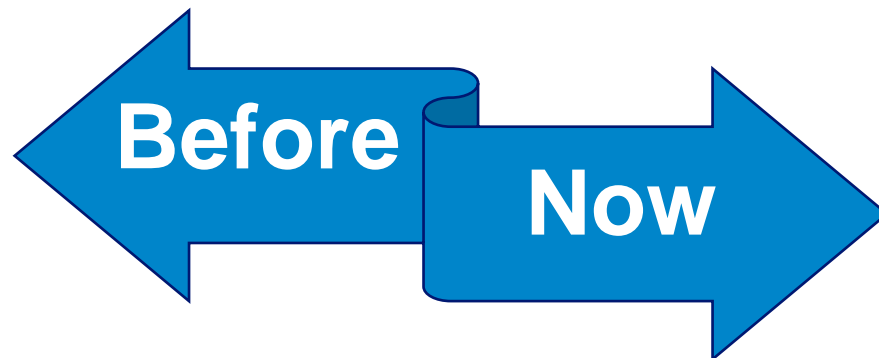
# Changes to the import or supply of overseas medicines

22 March 2023

Section 19A (1)

Section 19A (1A)

Section 19A (2)



Section 19A (1)

Section 19A (1A)

Section 19A (2)

Section 19A (2A)

Section 19A (2B)

	19A(1)	19A(1A)	19A(2)	19A(2A)	19A(2B)
<b>Registered goods</b> that could act as a substitute for the goods are unavailable or are in short supply	✓	✓	✓	✗	✗
<b>Previously ARTG registered goods</b> could act as a substitute for the goods but are <b>cancelled</b> or <b>suspended</b>	✗	✗	✗	✓	✓

# What is the reason behind the section 19A amendments?

To bridge the access gap for clinically important medicines that are cancelled or suspended from the ARTG

Section 19A(2A)  
Section 19A(2B)

Clinically important  
medicine cancelled  
from the ARTG

Continued care for  
patients when a  
medicine is  
cancelled



# What does this section 19A amendment means for sponsors

- Sponsors no longer need to maintain an ARTG entry for a discontinued medicine to allow supply under s19A.
- The existing section 19A framework and all related processes continue to apply.
- Import and supply must still be in the interest of public health.

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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*).

### Section 2. Application type

#### 2.1 Specify the type of application

**Updated application form**

[Section 19A: Guidance for industry – About section 19A](#)

**Medicine sourced from a specified country: subsection 19A(1)** – e.g., 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.

**Medicine sourced from a country that is not specified: subsection 19A(1A)** – e.g., 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.

**Early access to a medicine under evaluation for inclusion in the ARTG: subsection 19A(2)** – e.g., 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.

**Medicine previously registered on the ARTG (or suspended) sourced from a specific country: subsection 19A(2A)** – e.g., previously ARTG registered goods could act as a substitute for the goods but are cancelled (or suspended); and the goods are from a country specified by the Secretary.

I am the sponsor of the medicine cancelled or suspended from the ARTG.

I am not the sponsor of the medicine cancelled or suspended from the ARTG.

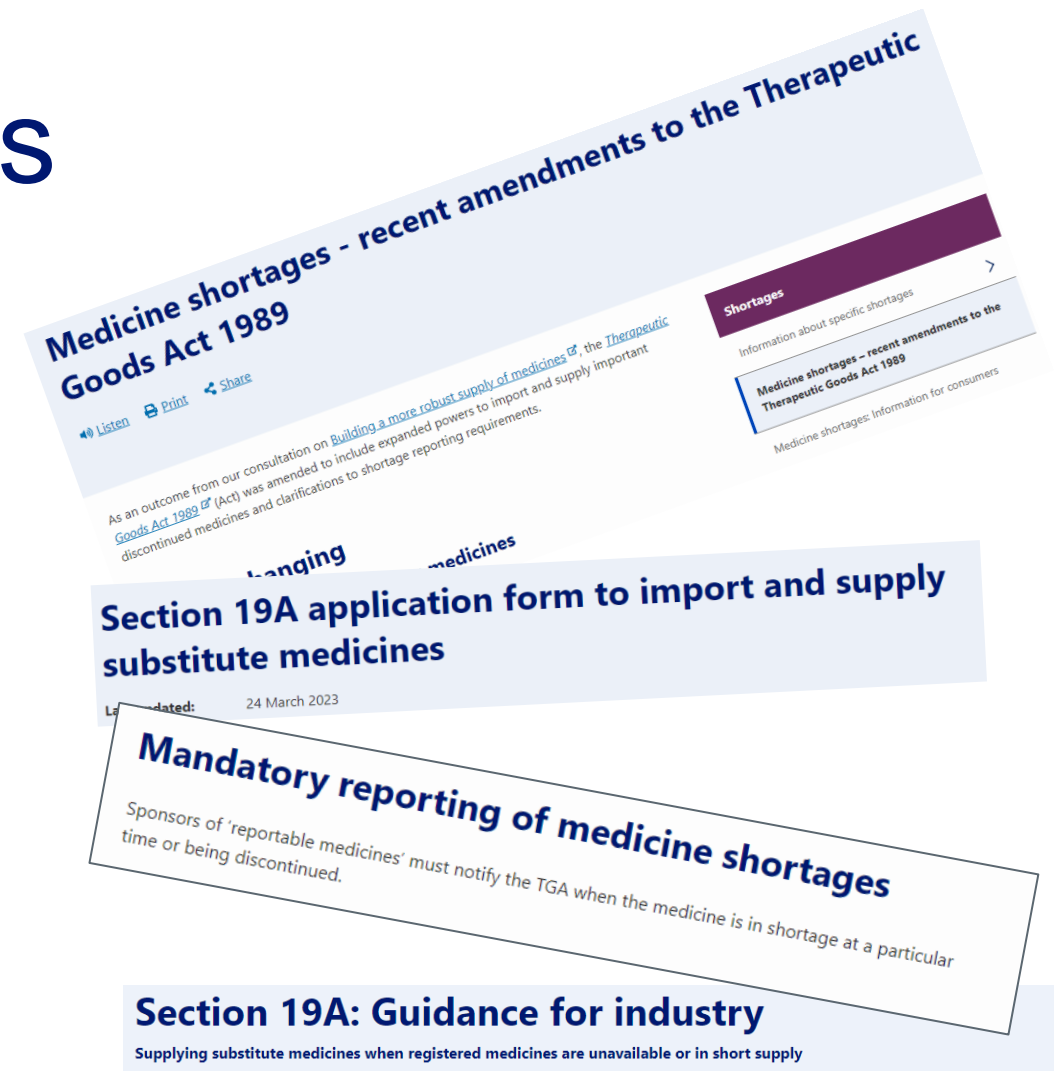
**Medicine previously registered on the ARTG (or suspended) sourced from a country that is not specified: subsection 19A(2B)** – e.g., previously ARTG registered goods could act as a substitute for the goods but are cancelled (or suspended); and the goods are from a country not specified by the Secretary.

I am the sponsor of the medicine cancelled or suspended from the ARTG.

I am not the sponsor of the medicine cancelled or suspended from the ARTG.

# Visit our updated pages

- [Recent amendments to the Therapeutic Goods Act](#)
- [Section 19A guidance](#)
- [Section 19A application form](#)
- [Information for sponsors and suppliers - reporting requirements](#)
- [Reporting obligations and the TGA's compliance framework](#)



# Summary of changes

## Changes to medicine shortage reporting obligations

On 22 September 2023, sponsors must report changes to the **shortage duration** or **end date** and when the **shortage is resolved**

## Prepare now for supply disruptions

- Know your medicine and supply chains
- Optimise processes
- Consider contingencies

## Changes to section 19A approvals

### **section 19A(2A)** and **section 19A(2B)**

Approval to import or supply of overseas medicines under section 19A for medicines that are cancelled/suspended from the ARTG





**Australian Government**

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**Department of Health and Aged Care**  
Therapeutic Goods Administration