Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Reporting medicine shortages and discontinuations in Australia

Guidance for sponsors

Version 2.1, March 2023

Contents

About this guidance

This guidance is for sponsors of reportable medicines, which include:

- Schedule 4 (Prescription Only) medicines
- Schedule 8 (Controlled Drug) medicines
- over-the-counter medicines included in the Therapeutic Goods (Reportable Medicines) Determination.

'**Reportable medicines**' are defined in the Therapeutic Goods Act 1989 (the Act), see section 30EH.

This guidance describes the mandatory requirements for reporting current and anticipated reportable medicine shortages and discontinuations in Australia.

This guidance should be read in conjunction with Medicine shortages/discontinuations – Electronic notification form: User guide.

Reporting a shortage to the TGA

You must notify us of all current and anticipated shortages and discontinuations of reportable medicines.

Information that you need to report includes, but is not limited to:

- impact of the shortage
- nature of the shortage
- duration of the shortage
- dosage forms and strengths in shortage
- estimation of current stock levels
- availability of alternative products
- supply management options

This information is important as it helps us assess the extent of the shortage and develop strategies to manage it. Notifications are published on the TGA website but commercially sensitive information is for 'official use only' and removed from the published report.

For information on what we publish, please see 'What information is published'.

If a health professional or another sponsor advises us that supply of your medicine is unlikely to meet normal or projected demand, we will investigate. If confirmed, you will be required to submit a notification to us.

There are penalty provisions under the *Therapeutic Goods Act 1989* that can be applied to sponsors who do not comply with the mandatory reporting obligations.

Information on compliance measures in relation to your reporting obligations is available at: Medicine Shortages in Australia: Reporting obligations and the TGA's compliance framework

Medicine shortages and discontinuations

A **medicine shortage** occurs when the supply of a medicine is not likely to meet the normal or projected consumer demand within Australia at any point during the next **6 months**.

A **discontinuation** refers to a medicine no longer being available in the marketplace. It does not refer to cancellation of an Australian Register of Therapeutic Goods (ARTG) entry.

Section 30EI of the Act defines **medicine shortage** as:

> There is a shortage of a medicine in Australia at a particular time if, at any time in the 6 months after that particular time, the supply of that medicine in Australia will not, or will not be likely to, meet the demand for the medicine for all of the patients in Australia who take, or who may need to take, the medicine.

Mandatory reporting timeframes

If you are the sponsor of a reportable medicine, you must notify us of any shortage or discontinuation of your product(s) within legislated timeframes. You must also update us with any changes in duration, and confirm the resolution of your shortage. Timeframes differ depending on the impact of the disruption.

Information to help you assess the impact rating is included later in this guidance. Timeframes for reporting shortages:

- **Critical impact shortages**

  You must report known shortages of critical impact to us within **2 working days**.

  At this time you must provide at least the minimum mandatory information about the shortage.

  You have a further **3 working days** in which to provide the remaining required information about the shortage. The same timeframes apply for reporting updates, including confirming shortage resolution.

- **Non-critical shortages**

  You must report all non-critical shortages (those of low and medium impact) to us in full (that is, completion of all mandatory fields in the notification form) within **10 working days**. The same timeframes apply for reporting updates, including confirming shortage resolution.

- **Anticipated shortages**

  You must submit a medicines shortage notification if you anticipate that there is going to be a shortage at any time in the next 6 months.

Timeframes for reporting discontinuations:

- **Critical impact discontinuations**

  You must report discontinuations of critical impact medicines at least **12 months** before the discontinuation is to occur or, if this is not possible, as soon as practicable after the decision.

  The long lead time for reporting a permanent discontinuation that will have critical impact is necessary as your brand may be the only version of the medicine on the ARTG.

- Non-critical discontinuations

You must report non-critical discontinuations at least **6 months** before the discontinuation is to occur or, if this is not possible, as soon as practicable after the decision.

You must report **all** discontinuations even if you are replacing the product with a new entry on the ARTG.

If you are unsure about whether to submit a medicine shortage notification, you can contact the Medicine Shortages Section for assistance.

For details of legislated reporting timeframes, see section 30EF of the Act.

Impact ratings

Do I need to self-assess the impact rating?

If your medicine is not on the Medicines Watch List, you need to self-assess the shortage impact rating.

Shortages of medicines included on the Medicines Watch List are **automatically** deemed to have a critical shortage impact rating.

Assessing the shortage impact rating

In determining the shortage impact, you need to consider the:

- nature and size of the population affected
- prevalence of use in the population
- availability and type of alternative or substitute medicines.

To help you self-assess the impact of your shortage, refer to Table 1 and Table 2 below. Your reportable medicine shortage will have a **critical** shortage impact rating if EITHER of the following applies:

- at the time of the shortage or decision to discontinue, there are no Australian-registered goods that could reasonably be used as a substitute for the medicine in question, or
- if there are suitable substitutes available, they would likely not be available in sufficient quantities to meet demand

AND

- the shortage or discontinuation has the potential to have a life-threatening impact, or a serious impact, on the physical or mental health or functioning of, persons who take or who may need to take, the medicine in question.

Table 1 – Impact assessment framework

Substitute medicine ranking (refer Table 2)					
Patient Population Affected	Exact alternative available	Similar alternative available	Appropriate alternative available	Possible alternative available	No alternative available

Substitute medicine ranking (refer Table 2)					
Rare < 9 per 100,000 population **Uncommon** > 9 and < 100 per 100,000 population	Low	Low	Medium	Medium	Critical
Common > 100 per 100,000 population	Low	Medium	Medium	Critical	Critical

Table 2 – Assessing and ranking substitutes/alternatives

Substitute medicines or therapeutic alternatives	
Determined by taking into account: • Types of substitute medicines or therapeutic alternatives that exist • The approved indications for the substitute medicines or therapeutic alternatives • Likelihood of available substitute medicines or therapeutic alternatives being available in quantities to meet demand **Note:** When ranking a medicine shortage, consideration is also given to the feasibility of the medicine being substituted in the context of the patient population and the care setting	**EXACT** – same medicine (active ingredient, strength and route of administration) **SIMILAR** – same active ingredient but different strength **APPROPRIATE** Different active ingredient but same pharmacological class and adverse reaction profiles when administered to patient in therapeutically equivalent doses. OR Same active ingredient but different dose form that may require consideration of care setting implication. **POSSIBLE** – different active ingredient but comparable pharmacological class or mode of action **NONE** – unique pharmacology, no substitute medicine or alternative treatment options exist

See sections 30EF and 30EG of the Act for information about assessing critical impact shortages and discontinuations.

We will review your notification to confirm the impact status. If it is not correct, we will contact you and you may be asked to vary the notification.

Additional resources

- Decision tree - What is the patient impact of my medicine shortage and do I have to report it to the TGA?
- Case studies

Completing the shortage notification form

Nature of the shortage

You must tell us what type of shortage is occurring. Shortages can be:

- Current – they are happening now
- Anticipated – they will happen at a future date
- Discontinuations – products will no longer be supplied to the Australian market
- Resolved – supply of a medicine that was in shortage has returned to normal (you cannot identify a shortage as 'resolved' if you haven't already reported it to us)

Once you have sufficient stock to meet demand, the shortage is resolved and you must vary your existing notification to reflect this.

Duration of shortage

You must report any supply disruption, regardless of the expected duration.

It is not feasible for us to prescribe a standard minimum period of inability to supply that will

not be of significant consequence to patients.

For example, inability to supply an antibiotic used in life-threatening situations or particular anti-venoms for as little as 24 hours could be deemed to be of critical impact in certain circumstances.

Dosage forms and strengths in shortage

When identifying what is in shortage, you must further define the medicine (or molecule) by active ingredient(s), strength and route of administration.

This information allows us to assess the shortage against alternative formulations and strengths, when there are other suppliers of similar medicines.

Stock levels

When reporting a shortage or discontinuation, it is important that you provide us with an estimation of the current stock levels in Australia at both:

- sponsor/manufacturer

AND

- wholesaler/distributor.

This information assists us in assessing the extent of the shortage and what strategies are needed to manage it.

In some situations the amount of stock held at a distribution centre, considered in conjunction with what the sponsor holds, can affect whether or not there is a medicine shortage.

Alternative products

Sourcing alternative products from overseas

Where there are no suitable alternative Australian-registered medicines, you can apply to import and supply overseas-approved medicines under section 19A of the Act.

Medicines approved under section 19A for import and supply to assist during a medicine shortage are included in a database on the TGA website.

For more information, refer to Information for sponsors: Supplying medicines during a shortage under section 19A

Temporary PBS listing of section 19A approved medicines

Where we have approved temporary supply of an overseas-approved medicine, you can apply for listing of the section 19A medicine on the Pharmaceutical Benefits Scheme (PBS). No fees apply for the temporary listing.

For more information refer to PBS Frequently Asked Questions.

Special Access Scheme

You also can import stock for use by certain health practitioners under the Special Access Scheme (SAS).

Consent to import and supply medicines that do not comply with standards (under section 14 of the Act)

In exceptional circumstances, you can also apply for consent to import and supply Australian-registered medicines that do not comply with applicable standards (for example, a particular therapeutic goods order or pharmacopoeial monograph).

Requesting priority review

To mitigate a shortage of a reportable medicine, you can request **priority review** of an application for section 14 consent. You must have submitted a medicine shortage notification before seeking priority review.

For more information refer to:

- Consent to import, supply or export therapeutic goods that do not comply with standards – information for industry
- Database of consents to import, supply or export therapeutic goods that do not comply with standards

Supply management options

To assist us in coordinating communications and shortage management in parallel with you, you need to advise us of what supply management actions are planned or have been undertaken to help address the shortage.

- Actions that you can consider include, but are not limited to:
- constrained supply to prevent stockpiling
- working to expedite the next shipment
- supply of a substitute medicine approved under section 19A
- hold emergency stock for patients
- import medicines for use under the Special Access Scheme

Submitting a shortage notification

You must submit a medicine shortage notification through the TGA Business (TBS) portal within the mandated reporting timeframes.

Detailed instructions for completing and submitting the electronic medicine shortages notification form is available at: Medicine shortages/discontinuations – Electronic notification form: User guide.

Contact us

- If you have any questions relating to the notification form or on medicine shortages, please contact the Medicine Shortages Section.
- If you have any questions about TGA Business Services (TBS) or require help setting up an account or creating a medicine shortage notification, please contact the Help Desk.

Minimum information required to submit a notification to TGA

The minimum information you must provide us within the mandated timeframes depends on the impact of the shortage you are reporting.

Critical impact notifications

If you are submitting a notification advising us of either a current or anticipated **critical impact** shortage, you have **2 working days** to submit the following minimum information:

- impact of shortage
- nature of the shortage
- sponsor name – auto-populated based on the person who logs in to the TGA Business Services (TBS) portal
- sponsor address
- Australian telephone number for public contact purposes
- medical information email for public contact purposes
- Australian Register of Therapeutic Goods (ARTG) number – this will provide the ARTG name of the product in shortage
- primary contact (auto-populated based on the person who logs in to TBS) which provides contact details of someone with whom we can liaise

- the date the shortage was known to the sponsor
- estimated dates for the start and end of the shortage
- availability.

You have a further **3 working days** in which to provide the remaining required information about the shortage.

The minimum mandatory reporting requirements are identified in the TBS Notification form by the presence of red asterisks (*) next to the required fields.

Non-critical impact notifications

If you are submitting a notification for a reportable medicine that will result in a medium or low patient impact, you have 10 working days in which to notify us and completion of **all** mandatory fields in the electronic notification form.

Updating shortage information

You are required to update the shortage details as soon as you have new information on duration or shortage end date, including confirming that the shortage has resolved. Do not wait until the existing shortage notification is due to be updated or resolved.

- For medicines first notified with critical shortage impact rating the notification must occur as soon as possible , but no later than 2 working days after discovering the change to the shortage period or end date
- In any other case the change is required to be notified before the end of 10 working days beginning on the first day the person knows, or ought reasonably to have known, of the change to the period or end date.

Your nominated end dates can be extended or the shortage identified as ‘resolved’ earlier, as required. Information on how to vary a notification is available in Medicine shortages/discontinuations – Electronic notification form User guide.

Maintaining up-to-date information about the shortage is essential to help health professionals and patients manage during the disruption and inform sponsors of suitable alternatives of the impact of your shortage on their supply.

New notifications for products previously in shortage

Sometimes, when you are trying to create a new medicine shortage notification, you will not be able to submit even when all mandatory fields are filled. This happens when there is a previous notification still in the system. Resolved notifications remain in the system for 3 months after you report the resolved shortage.

Please contact us so we can **archive** the previous notification immediately. This will allow you to submit the new notification within a couple of hours.

You cannot vary a resolved notification. If your product goes back into shortage after it was resolved, you must create a new notification.

Publication of shortages on the TGA website

All medicine shortages and discontinuations of reportable medicines are published on the Medicine Shortage Reports Database on the TGA website.

The database is the key tool for delivering consolidated information to support health professionals and consumers when there is a temporary or permanent disruption to the supply of a medicine in Australia.

By subscribing to the alert service, subscribers can elect to receive email or RSS feed notification of new and updated medicines shortage information.

Publication timeframes

We publish **all current shortages and discontinuations** immediately after our review of the notification. This helps ensure timely and consistent communication to all our stakeholders.

For **anticipated** shortages and discontinuations, you can provide a justification asking us to consider delaying publication. We need to publish these as soon as possible to allow sufficient time for health professionals and consumers to prepare in advance but we will consider a request to delay publication if there is a strong public health justification.

Acceptable reasons could include:

- allowing sponsors to determine if the shortage is likely to eventuate
- allowing time for sponsors to manage remaining supply
- allowing time for sponsors to prepare communications

If your justification is not in the interest of public health, we will tell you of our decision and publish **immediately**.

If we agree with your justification to delay publishing, we will publish on your nominated date or contact you to discuss an alternative date.

The **final decision** about the publication date will be at our discretion.

What information is published

The information published on the Medicine shortage reports database will include:

- sponsor's name
- sponsor's nominated public contact details
- ARTG number
- ARTG name of medicine (includes name, active ingredient(s), strength, dosage form and container)
- dosage form
- active ingredient(s)
- therapeutic class description
- nature of the shortage
- availability
- reason for the shortage

- estimated shortage dates for current or anticipated shortages
- deletion from market date for discontinued products

The sponsor's nominated website will only be published if it contains information that relates to the sponsor's management of the shortage

Any relevant management action taken by the sponsor or the TGA can also be published.

Availability of shortage notifications on the TGA website

Anyone can view published information in the Medicine Shortage Reports Database on the TGA website. The length of time for which a shortage is included in the Database varies depending on its status.

- A published anticipated shortage remains under the 'Anticipated' tab in the Database until it is resolved or becomes current
- Current shortages notified to the TGA can be found under the 'Current' tab
- Once the notification has been updated to show that it's resolved, it can be viewed under the 'Resolved' tab for a further 3 months
- All discontinuations can be viewed from the date of publication until 1 year after the nominated 'Deletion from market' date

Communication of shortages

We publish information about medicine shortages to help patients and health professionals manage treatment during the supply disruption. It is important that medicine sponsors also actively communicate directly to anyone affected. This can include communication strategies and activities such as letters to health professionals, patient groups and wholesalers.

You should include the following details when communicating about shortages:

- name of the medicine in shortage
- its ARTG number
- duration of the shortage/expected discontinuation date
- your contact details, such as a phone number
- any alternative arrangements for supply during the shortage period, for example, section 19A approvals
- confirmation that the TGA has been notified
- where can patients find further information, for example the TGA website or your company's website

Sponsor communication of shortages

If you think your medicine may require significant management or conservation, please contact us before you communicate details of your shortage to others.

You must contact all known points in your supply chain to inform them of a supply disruption.

If your medicine is affected by a critical shortage or discontinuation, you must also contact the following entities, as appropriate. This can occur after the notification has been published on the Medicine Shortage Reports Database.

- **hospital medicines** – notify State and Territory Health Departments, wholesalers marketing into private hospitals and the Society of Hospital Pharmacists of Australia
- **community/retail pharmacy medicines** – notify the Pharmaceutical Society of Australia, the Pharmacy Guild of Australia and wholesalers and pharmacies
- **PBS medicines** – notify the Australian Department of Health's Technology Assessment and Access Division, who in turn will notify Community Service Obligation Distributors. You may have reporting obligations under the *National Health Act 1953*.
- **National Immunisation Program vaccines** – notify the Australia Department of Health's Office of Health Protection and Response
- **National Blood Authority plasma components** (where they are registered medicines) – notify the National Blood Authority and the Office of Health Protection and Response.

Case studies

Scenarios are set out below to assist your understanding of your obligations to report shortages and discontinuations. The examples include situations which may not seem to fit the usual circumstances but the list is not intended to be exhaustive or comprehensive.

Every potential medicine shortage needs to be assessed and managed based on its specific circumstances and in accordance with the requirements determined by the Act.

Manufacturing issues

Scenario: On 1 February 2019, a sponsor of a reportable medicine included in the Medicines Watch List becomes aware of possible manufacturing delays.

The sponsor investigates mitigation strategies such as using an alternative manufacturing site and assesses the extent of the problem (both in duration and the amount of affected stock). On 5 February 2019, the sponsor concludes that, although the stocks of the medicine in Australia will be sufficient for the time being, the delays will mean that demand won't be met by early April.

Outcome: As the anticipated shortfall will occur within **6 months** of 5 February 2019, on that date there is a reportable shortage of the medicine.

As the medicine is included in the Medicines Watch List, the shortage is of **critical impact** and the sponsor therefore must notify the TGA within **2 working days** (in this case by 7 February 2019).

Unexpected increase in demand

Many medicine shortages arise due to an unexpected increase in demand, most commonly due to another brand with the same active ingredient already being in shortage.

When this occurs, a number of actions are needed. This can often involve liaison with the TGA.

Scenario: Sponsor A has a 50 per cent market share for a specific medicine, while Sponsor B and Sponsor C each have 25 per cent. Sponsor A reports a shortage of their brand to the TGA. The impact level is assessed by Sponsor A as being **medium** and they notify the TGA within **10 days**.

Outcome: The TGA reviews the shortage notification and publishes it. As Sponsor A has notified that they have a 50 per cent market share, the TGA contacts Sponsor B and Sponsor C individually to inform them of the shortage and collect information relating to their current supply status, market share and whether they anticipate any shortages in the next **6 months**.

Sponsor B expects a shortage due to the increased demand caused by Sponsor A's shortage. Sponsor C is unsure and is asked by the TGA to investigate further. Upon further investigation,

Sponsor C also anticipates a shortage due to increased demand. Both companies submit anticipated shortage notifications.

As a consequence, the TGA may negotiate with Sponsor A to reassess/increase their shortage impact rating.

The TGA continues to liaise with each sponsor to assess currency of information and monitor market signals from other sources of information, such as health professionals and consumers. In these situations, it is common for the TGA to develop mitigation strategies such as approving temporary supply of overseas-registered medicines.

Discontinuation of a medicine

Scenario: In March 2019, the global parent company decides to shut down Australian operations and cease supplying the Australian market from October 2019. The medicine sponsor has three products registered on the ARTG that will all be discontinued in **7 months**.

Outcome: The sponsor assesses the discontinuation as being of low impact and therefore has 1 month to notify the TGA (to be within the **required 6 month** reporting period).

However, to allow affected patients and health professionals as much time as possible to identify alternative treatments, the sponsor should inform the TGA as soon as possible.

Discontinued medicine is replaced with a new medicine

Some changes made by sponsors to their medicines will result in the need for a new entry on the ARTG. This is because under the Australian legislation, the goods have become 'separate and distinct' from the original entry. However, in some instances, the new medicine can be 'grouped' with the existing medicine and the AUST R number remains the same.

Scenario 1: A product will be discontinued in **6 months**. The sponsor has registered a new product, considered therapeutically identical but with a new AUST R number, but it will not in supply for another **9 months**.

Outcome: A **discontinuation notification** is required for the original product, noting the actual deletion from market date. There will be **3 months** where there is effectively no registered product available.

To help patients during the disruption in supply, the sponsor should provide details of the replacement medicine so we can include this information on the published discontinuation notification.

As the new product has not been supplied, there is no shortage of this medicine in the 9 month period and **no** requirement to notify the TGA of lack of supply. The sponsor should confirm if they must notify the TGA of commencement of supply as this is usually a condition of registration for new prescription medicines.

Scenario 2: A product will be discontinued in **6 months**. The sponsor has registered a new product, considered therapeutically identical but with a different AUST R number, and it will be available in the marketplace before the end of the 6 months.

Outcome: There is a requirement for a **discontinuation notification** to be submitted for the original product. When submitting this notification, the sponsor should include in the supplementary information that it is being replaced with another medicine, providing all relevant details.

We will include this information in the published notification to inform customers of the change. The sponsor can also inform health professionals and consumers using a Dear Healthcare Professional/consumer letter(s).

Scenario 3: A product will be discontinued in **6 months** but the sponsor has a new product registered which retains the AUST R number of the product being discontinued. Manufacture of the new product has been delayed for **9 months**.

Outcome: As both products have the same AUST R number, an **anticipated** shortage notification should be submitted for the 'new product' for a period of **3 months** with the shortage period beginning in **6 months**. The sponsor does **not** submit a discontinuation notification.

Shortage as a result of a recall

A product recall can result in a medicine shortage. The TGA will already be involved in the recall action, but, if it is a reportable medicine, the sponsor must also submit a medicine shortage notification.

Sponsor obligations for a recall are separate from the obligation to report a medicine shortage.

Scenario: Through its standard quality assurance processes, a sponsor discovers that the majority of batches for one of its medicines are contaminated. This is reported to the TGA and advice provided recommends an immediate consumer-level product recall.

Outcome: In addition to the recall related activities, the sponsor also notifies the TGA that this will result in a shortage of that product for about **3 months**. This is the period of time the sponsor estimates it will take to get alternative batches of stock into Australia in sufficient quantities to resolve the shortage.

Local stock out issues

There may be instances where a sub-population in Australia may not have access to a certain medicine at a particular point in time. This could be due to a number of reasons including limitations in delivering to a particular region or cohort (for example, a town in which only a pharmacy depot exists or due to specialised commercial arrangements between wholesalers and pharmacies). These situations are known as 'stock outs' and are not managed by the TGA as medicine shortages.

Scenario: A rural town has only one, relatively small pharmacy. Due to the volume of business conducted, it does not have commercial arrangements with all of the major available suppliers.

A patient in the town is prescribed a medicine that is not stocked by the pharmacy's supplier, so the local pharmacist cannot dispense the medicine. The patient must drive to another town to get their prescription filled.

Outcome: This would represent an **unavailability** of a medicine at a particular location and would not constitute a medicine shortage under the TGA's legislation. No regulatory obligations would be imposed on the medicine sponsor in this instance.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Pharmacovigilance and Special Access Branch	23 November 2018
V1.1	Minor updates to include information about the compliance framework	Pharmacovigilance and Special Access Branch	May 2019
V2.0	Re-write and update following enhancements to the TBS portal form and Medicine Shortage Reports Database	Pharmacovigilance and Special Access Branch/ Medicine Shortages Section and Regulatory Guidance	May 2021
V2.1	Minor updates including clarifications on legislative requirements for updating shortage notifications.	Pharmacovigilance Branch	March 2023

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