



Australian Government

Department of Health

Therapeutic Goods Administration

Management and communication of medicine shortages and discontinuations in Australia

Guidance for sponsors and other stakeholders
bodies

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TGA Health Safety
Regulation

Historical document

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Historical document

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Background

The Therapeutic Goods Administration (TGA) has implemented reforms to improve management of medicine shortages in Australia, including improving communication and increasing transparency.

Medicine shortages significantly impact the health of many Australians and have become more frequent and serious in recent years. This is due to a number of reasons, including the decrease in local manufacture of prescription medicines and the increasingly globalised nature of the medicines supply chains. Australia has only 2% of the world's medicine usage and over 90% of prescription medicines are imported.

In response to this issue, we launched the Medicines Shortage Information Initiative and associated [website](#) in 2014. This response included a voluntary notification scheme for sponsors experiencing shortages.

Since then, there has been increasing frustration expressed by many stakeholders that the information available on the Medicines Shortage Information Initiative website is neither complete nor current, and it is no longer seen as a credible source of information by health professionals or those involved in stock management in health facilities. The information is also not being published in a timeframe to allow alternative supplies, where available, to be accessed and/or to otherwise mitigate serious effects on patients when no alternative supply is available.

In response to this issue, the Australian Parliament amended the *Therapeutic Goods Act 1989* (the Act) to establish a more transparent and responsive approach to the management of medicines shortages, including those arising from discontinuation of a medicine. Through these reforms, the roles and responsibilities of relevant parties have been clarified.

Scope and definitions

This guidance provides information to sponsors and other stakeholder organisations regarding the management and communication of medicine shortages and discontinuations in Australia. It applies to the handling of all Australian registered prescription medicine shortages, not just those medicines available under the Pharmaceutical Benefits Scheme (PBS). This includes medicines for hospital use and prescription medicines, both PBS and non-PBS, available from community pharmacies. Shortages of **some** over-the-counter (OTC) medicines are also subject to mandatory reporting requirements.

This guidance also applies to any shortage that may occur as a result of a recall action of a medicine by a sponsor in accordance with the Uniform Recall Procedure for Therapeutic Goods.

From January 2019, medicine sponsors are required to report all medicine shortages to the TGA. We can mandatorily publish information about all shortages that have been assessed as having significant patient impact.

We have worked closely with industry and peak health organisations to develop these reforms and have produced this guidance and other resources to help sponsors ensure they remain compliant with these requirements. The protocols set out in this guidance document have been developed through a joint initiative of the Medicines Partnership of Australia (comprising the National Pharmaceutical Services Association, Generic and Biosimilar Medicines Association, Pharmacy Guild, Pharmaceutical Society of Australia, Australian Self Medication Industry and Medicines Australia), the Australian Government Department of Health (including the TGA), the Society of Hospital Pharmacists of Australia and the Australian Medical Association.

Through this initiative, the TGA has:

- established agreement on what constitutes a medicine shortage
- developed an improved process for communication and action regarding medicine shortages that will have potential material impacts on patients, including a national coordination and management approach for the management of shortages
- clarified the roles and responsibilities of sponsors, distributors, dispensers and government
- reached consensus on reporting requirements for current* and anticipated** shortages (and communication of information about verified shortages).



'Current shortage' means a shortage of a medicine that has commenced and is ongoing.

'Anticipated shortage' means a shortage of a medicine that is anticipated to commence at a future date.

The Medicines Watch List is a Legislative Instrument that has been established to identify medicines that have been **predetermined** as having critical patient impact. Known shortages of these medicines must be reported to the TGA within 2 working days. At this time the sponsor provides at least the minimum mandatory information about the shortage. The sponsor then has another 3 working days in which to provide the remaining required information on the shortage. All non-critical shortages need to be reported in full within 10 working days. The Medicines Watch List will be reviewed by the TGA on an annual basis.

Shortages of medicines that are not on the Medicines Watch List can still be assessed as critical by the TGA. Sponsors are also required to self-assess according to these protocols to determine whether or not a shortage needs to be reported within 2 working days.

While information about current and anticipated critical medicine shortages will always be published, publication of information about non-critical (low and medium impact) shortages through the Medicines Shortage Information Initiative is not mandatory, but is strongly encouraged in the interest of public health (see [Table 3](#)).

Early and timely engagement with health care practitioners is a priority to ensure impacts are accurately identified. Assessing the potential impacts of a particular shortage will be aided by expertise within medicine (colleges and professional organisations) and pharmacy bodies (for example, Society of Hospital Pharmacists of Australia Specialty Practice Groups) when required. State and Territory Chief Health Officers and Chief Pharmacists may also be involved in management of shortages of medicines of major importance in public health systems.

Similarly, early identification of an alternative medicine in cases of a shortage of critical patient impact is paramount. The medicine could be an alternative medicine already registered in Australia or another therapeutic alternative. It may also involve identification of suitable overseas registered products for importation and use under special provisions (for example, section 19A of the Act or the TGA's Special Access Scheme).

It is highly recommended that medicine sponsors develop effective internal procedures to ensure that they can comply with the mandatory reporting requirements, including reporting timeframes.

The internal process within the wider Department of Health for triage and coordination in response to information received by the TGA about shortages is also documented in this guidance.

[Figure 1 – Response to a reportable medicine shortage](#) schematically outlines the response to a medicine shortage.

What constitutes a medicine shortage/discontinuation?

A medicine shortage is defined in the Act as:

a shortage of a medicine in Australia at a particular time if, at any time in the 6 months before 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 may need to take, the medicine.

A shortage of a reportable medicine must be reported to the TGA within legislative timeframes.

The discontinuation of the supply of a medicine (a permanent shortage) must also be notified to the TGA as outlined in the legislation:

- (a) if the discontinuation is likely to be of critical impact:
 - (i) at least 12 months before the discontinuation is proposed to occur; or
 - (ii) if the person is unable to comply with subparagraph (i)—as soon as practicable after the decision is made; or
- (b) in any other case:
 - (i) at least 6 months before the discontinuation is proposed to occur; or
 - (ii) if the person is unable to comply with subparagraph (i)—as soon as practicable after the decision is made.

A discontinuation refers to a medicine no longer being available in the marketplace; it does not refer to the cancellation of the Australian Register of Therapeutic Goods (ARTG) entry from the Register. Information about discontinuations will be visible on the [Medicines Shortage Information Initiative website](#) for a limited time period (12 months from the deletion from market date provided by the sponsor).

What are reportable medicines?

Mandatory reporting requirements apply to **all** Australian registered prescription medicine shortages and a limited number of OTC medicines that are listed in the relevant legislative instrument.

They do not apply to any shortage that may arise as a result of a recall action of a medicine by a sponsor in accordance with the [Uniform Recall Procedure for Therapeutic Goods](#).

Reportable medicines are defined in the legislation as:

- (1) For the purposes of this Act, registered goods are a reportable medicine if:
 - (a) the goods are medicine; and
 - (b) either:
 - (i) the medicine contains one or more substances included in Schedule 4 or 8 to the current Poisons Standard; or
 - (ii) the medicine is determined in an instrument under subsection (2).

(2) The Minister may, by legislative instrument, determine medicine for the purposes of subparagraph (1)(b)(ii).

The criteria for inclusion of a non-prescription medicine are:

- the medicine is critical to the ongoing health of the patient (for example, salbutamol inhalers for asthma)
- inclusion of the medicines is critical for public health (for example, naloxone injections for opioid overdose).

The current list of reportable OTC medicines is available in the relevant legislative instrument.



Products currently on the Medicines Watch List are being included in a legislative instrument and are listed in [Appendix 1](#) of this document.

The current list of reportable OTC medicines is being included in a legislative instrument and is listed in [Appendix 2](#) of this document.

Alternative products

The process for obtaining access to alternative medicines during shortages (for medicines that are not registered in Australia) outside the Special Access Scheme has also been made more transparent and flexible. The Act has been amended to enable alternatives to medicines in short supply to be sourced from a wider range of countries.

To assist applicants (usually pharmaceutical companies or specialist suppliers) wishing to import alternative products in the context of a shortage, information, guidance and an application form have been published on the [TGA website](#). The TGA website also includes information [current section 19a approvals](#).

Responding to a medicine shortage

The components of the response to a medicine shortage are detailed in [Figure 1](#) and include:

1. Sponsor is required to report to the TGA a known medicine shortage or anticipated medicine shortage of critical patient impact (based on the sponsor's self-assessment in accordance with [Table 1](#)) within 2 working days, and within 10 working days for all other shortages.
2. The report (of an anticipated or current shortage or of a discontinuation) and its impact assessment are reviewed by the TGA to determine if the product contains an ingredient on the Medicines Watch List. Please note that, regardless of whether or not a medicine contains an ingredient that is on the Medicines Watch List, shortages with a critical patient impact are all treated in the same manner.
3. If the medicine is on the Medicines Watch List, the shortage is automatically considered a critical impact shortage, there is no requirement for the quick touch review and a Medicines Shortages Action Group may be convened (see 4b below). This Group is supported by medical and pharmaceutical professional groups and State and Territory officials, where appropriate.

4. If the ingredient is not on the Medicines Watch List, then the Medicine Shortages Section – following further input from the sponsor (if required) – undertakes a review using the assessment framework to confirm the impact level.

An agreed patient impact rating will be determined and the notification will be processed as per [Figure 1](#).

- a. Where assessed by the TGA as critical, the TGA may undertake a quick touch review within 3 working days. This review involves TGA representatives, including staff members with relevant expertise, such as medical officers, pharmacists and medicine shortages officers, as well as the impacted sponsor.

These parties will undertake these discussions in confidence, through teleconference.

- b. Where the outcome of the impact assessment (refer Table 1 – Impact assessment framework) is critical patient impact, escalation may be required to a Medicines Shortages Action Group (refer to Figure 1 – Response to a reportable medicine shortage) which may comprise:

§ a representative from the relevant medical college(s)/specialist medical society

§ pharmacist organisation (Society of Hospital Pharmacists Australia Specialty Practice Groups, and Pharmaceutical Society of Australia if the medicine is dispensed significantly in community pharmacy settings)

§ the TGA (and involving other areas of the Department of Health, for example the Chief Medical Officer / Office of Health Protection if the product shortage may have serious public health impacts or is part of the National Immunisation Program)

§ medicine sponsor who has the shortage.

In consultation with the sponsor a Medicines Shortages Action Group will prioritise use of any remaining stocks of the product in shortage and identify and communicate therapeutic alternatives for use during the period of the shortage.

These parties will undertake these discussions in confidence.

- c. If assessed by Medicine Shortages Section as medium patient impact then a 'quick touch review' may be conducted as required.

We expect sponsors to provide a copy of the communication that has been/is to be sent to relevant stakeholders. Publication of this information on the TGA website is not mandatory, but is strongly encouraged.

- d. If assessed by the TGA as low patient impact (for example, there is availability of an effective alternative), then communication from the sponsor to relevant healthcare providers only may be appropriate. Publication of information about the shortage on the TGA website is not mandatory, but is strongly encouraged.

5. A Medicines Shortages Action Group may be convened for shortages assessed to be of critical patient impact or of medicines containing ingredients on the Medicines Watch List.

6. Consultation with the sponsor will be undertaken for all medicine shortages notifications received. This will be to determine what steps, if any, the sponsor has already taken to alert health professionals and the public of the shortage. This may involve the TGA contacting other sponsors to gather information on supply status. This information will inform the action that will need to be taken. For low patient impact shortages all that may be required is the circulation of a letter advising of the nature of the shortage and the expected duration

to be sent to wholesalers. For medium patient impact or critical patient impact shortages, this step will provide information for use in the next step.

7. For medium and critical patient impact shortages, there may be a need for further engagement with the sponsor to circulate appropriate information. There may be the requirement for letters tailored to customers as well as health professionals and wholesalers.

The sponsor may also be asked more in depth information about how they intend to handle the shortage and what steps have been, or are intended to be, taken.

The TGA may then contact medical specialist colleges and other stakeholders directly to advise them of a shortage and draw their attention to the published information.

8. The TGA would then coordinate separate activities with:
 - the sponsor
 - medical specialist colleges or societies
 - the Society of Hospital Pharmacists of Australia, the Pharmaceutical Society of Australia and/or the Pharmacy Guild of Australia
 - prospective section 19A applicants.

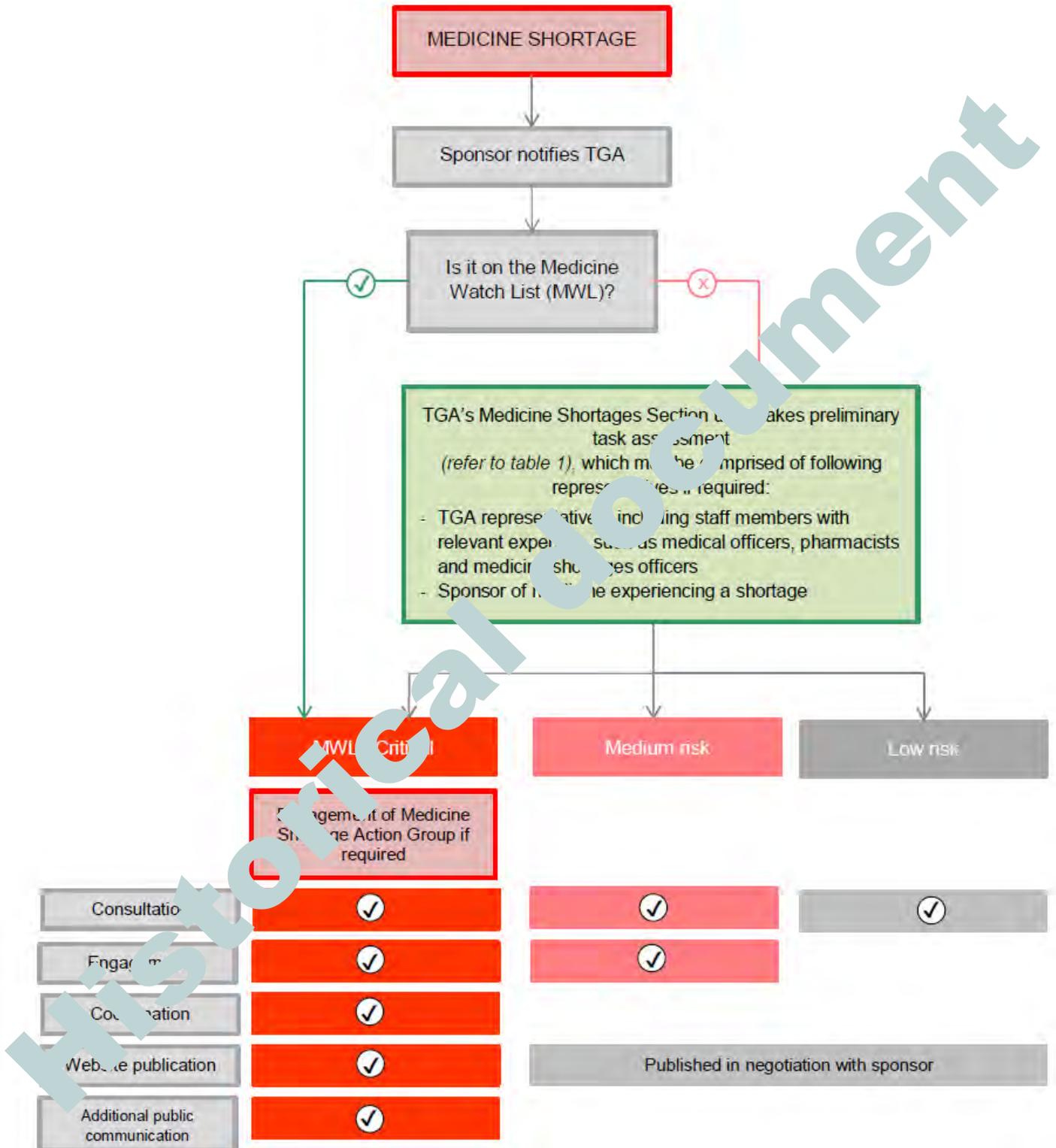
This may be undertaken to mitigate the effects of the shortage and to promote awareness of the shortage. We will work individually with the sponsor(s) to identify suitable alternative overseas products and facilitate access under the Special Access Scheme or section 19A of the Act as needed. The TGA and the sponsor will coordinate communications to enable relevant stakeholders to receive timely and consistent advice on the details of the shortage and the management activities. Steps to mitigate the shortage may be published on the Medicine Shortages website as described below.

9. The TGA will publish all medicine shortage notifications for critical impact shortages as soon as possible after receiving the initial information from the sponsor on a dedicated webpage for shortages of critical patient impact. Updates will be published as the investigation progresses and as solutions are identified.

Shortages of a medium and low impact nature are handled in accordance with Table 3 – Activities by shortage impact level. Sponsors are encouraged to publish all shortage information so that health professionals to improve awareness that alternatives may be required and to make the appropriate changes to patient treatment.

10. Further communication such as information provided by expert committees or medical specialist societies may be published if it assists in the management of the shortage. In these cases the letters or decisions will be attached to the TGA shortage management action page which will be available on the [Medicines Shortage Information Initiative](#) website.

Figure 1 – Response to a reportable medicine shortage



Steps: report, manage and communicate

Reporting a shortage to the TGA

There is a clear distinction between **reporting** to the TGA and **publication** of a medicine shortage.

Sponsors will need to report the shortage through the TGA's Business Services (eBS) portal. Further advice and instructions relating to making a medicine shortages notification will be provided in *Medicine shortages user guide – Instruction for submitting and managing information in TGA Business Services (eBS)*, which will be available to sponsors prior to implementation of mandatory reporting.

While reporting is normally done by the sponsor of the medicine, the TGA may be contacted directly (by phone or email) by a different sponsor or healthcare provider advised that the supply of a medicine is not likely to meet normal or projected demand. This information is then investigated and, if confirmed, the sponsor will be required to submit a notification to the TGA.

Mandatory reporting of shortages on a confidential basis to the TGA is necessary for all shortages of reportable medicines. For shortages of a reportable medicine that is on the Medicines Watch List, or is assessed as having critical patient impact, the sponsor must report any such known shortage to the TGA within 2 working days.

Ideally, the sponsor is able to complete the medicine shortages notification form with all the required information and submit it to the TGA within 2 working days of confirming the shortage. However, an initial report (Medicines Shortage Information Initiative notification with reduced mandatory fields) may be submitted within 2 working days containing a subset of the information that is required to be reported to the TGA. The sponsor then has another 3 working days in which to provide the remaining required information on the shortage.

The minimum information required to submit a notification form advising of a critical patient impact, current or anticipated shortage is:

- impact of the shortage
- nature of the shortage
- sponsor name (auto-populated based on the person who logs in to eBS)
- sponsor address
- Australian telephone number for public contact purposes
- medical information email for public contact purposes
- ARTG number – which will provide the ARTG name of the product in shortage
- primary contact (auto-populated based on the person who logs in to eBS) which provides contact details of someone with whom the TGA can liaise
- the date the shortage was known to the sponsor
- estimated dates for the start and end of the shortage
- availability
- proposed date of publication on the TGA website.

Minimum mandatory requirements will be identified in the eBS Notification form by the presence of red asterisks next to the required fields.

For reportable medicines that will result in a medium or low patient impact, the sponsor has 10 working days in which to notify the TGA of the medicine shortage. In this case, completion of all fields in the notification form is mandatory. The TGA will then conduct an assessment of the shortage and its impact and where required will also consult expert clinicians. The reporting process is as follows:

1. Product sponsor confidentially and mandatorily reports to the TGA of:
 - a. an anticipated shortage to facilitate early investigation with proactive forecasting and management
 - b. actual, unanticipated shortage for urgent investigation and management.
2. Information from other parties may be used to inform the TGA such as:
 - a. State and Territory health systems
 - b. health care providers (pharmacists, prescribers, hospitals) or consumers may notify shortages directly to the TGA or other parts of the Department of Health
 - c. we may obtain information about current or impending medicines shortages from international liaison activities.
3. Where possible, the Technology Assessment and Access Division within the Department of Health will provide information to the TGA to assist with the management of supply shortages.

In examples 2 and 3 above, the TGA will verify the accuracy of the reported information with the sponsor of the medicine.

The TGA is able to publish information about medicine shortages under a legislative instrument under section 61 of the Act that provides the TGA with the authority to release information to the website regardless of consent where we have assessed there is a public health interest in doing so (see [Specifications](#)).

If the sponsor anticipates that there is going to be a shortage at any time in the next 6 months, they must submit a medicine shortage notification. If unsure about whether to submit a medicine shortage, the sponsor can contact the [Medicine Shortages Section](#) for assistance.

Reporting a discontinuation to the TGA

Permanent discontinuations of reportable medicines must be reported to the TGA. Where the discontinuation is likely to be of 'critical impact', the sponsor must report the discontinuation at least 12 months before the discontinuation is proposed to occur. If the sponsor is unable to comply with this timeframe, then it must be reported as soon as practicable after the decision to discontinue is made.

Where the discontinuation is not likely to be of 'critical impact', the sponsor must report the discontinuation at least 6 months before the discontinuation is proposed to occur. If the sponsor is unable to comply with this timeframe, it must be reported as soon as practicable after the decision is made.

The long lead time for reporting a permanent discontinuation which is of critical impact is needed because in many cases the sponsor may be the sole supplier of the medicine in Australia.

The long lead time is designed to allow us to identify an alternative supplier of the product for the Australian market, which may include reviewing an application for registration of the alternative medicine on the ARTG.

Investigation – assessment and verification

What dose forms and strengths are in shortage?

The definition of what ‘medicine’ is in shortage should be further defined by molecule, strength and route of administration, rather than molecule alone, so that it is understood which formulations and strengths of a molecule are in shortage.

Sponsors, wholesalers and other stakeholders will work with the TGA to determine whether or not supply will meet demand, especially when there is more than one supplier of a product for a molecule/strength/route of administration.

The TGA will ask a sponsor to confirm and assess the availability of their product(s) suspected to be in shortage, and will ask other sponsors who sponsor a similar product about the availability of their products. The TGA will also be asking for information about therapeutic alternatives and their current status.

A risk assessment will be conducted as per the matrices in this guidance which may include undertaking a clinical review to support the management option, for example endorsing a section 19A alternative product.

How long will the product be in shortage?

Any supply disruption must be reported because it is not feasible 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 antivenoms for as little as 24 hours could be deemed critical shortages in certain circumstances.

Nature of the product in shortage

The approach outlined in Table 1 – Impact assessment framework will be used to assess the effect of the type of product in shortage on the impact of the shortage.

If the product is on the Medicines Watch List, a confirmed shortage is automatically deemed to have a critical patient impact. A risk assessment framework will be applied to all other medicines in which the nature and size of the population affected is assessed together with the availability of alternative products, before determining whether a particular shortage is of low, medium, or critical patient impact.

The Medicines Watch List is derived from a consensus review of existing State Hospital Emergency and Life Saving Drug Lists and the WHO’s Model List of Essential Medicines that are included in the ARTG. The list will be reviewed annually to ensure it remains current and appropriate.

Medicines included on the Medicines Watch List are those where lack of access in Australia could result in significant morbidity in patients, or the death of one or more patients.

The list includes antibiotics used in critically ill patients, antidotes for poisonings, some emergency and critical care products and critical vaccines included on the National Immunisation Program, as well as some anticoagulants and antivenoms.

A number of other classes of medicines have been associated with clinically serious medicines shortages, such as:

- inhaled anaesthetics, anticonvulsants, antipsychotics, antidepressants, opioids, steroids – however alternatives in these classes may potentially be interchangeable; likewise
- specific oncology medicines – which require individual patient assessment as to whether alternatives are appropriate and switching of the patient is possible.

Shortages of these medicines will be assessed on a case-by-case basis.

The assessment framework identifies the potential impact of any shortage by applying a mechanism that assesses the impact on the size of patient populations affected through measures of the prevalence of use in the population alongside the availability of alternatives (refer [Table 1](#) and [Table 2](#)).



An example of a **critical patient impact** is an unexpected shortage of heparin-based products. This product has no therapeutic alternative, and the post-surgical population group may experience life-threatening impacts if this medicine was not available.

An example of a **medium patient impact** is a shortage of an ACE Inhibitor for hypertension, where a doctor may be able to prescribe another ACE inhibitor, or other anti-hypertensive medicine. In these cases, publicly available information for doctors and pharmacists is recommended.

An example of a **low patient impact** is a shortage of a generic amoxicillin 250 mg oral product, where another generic product (either tablet or capsule) is easily substitutable with little, if any, effect on the consumer's health outcomes and where the doctor and/or pharmacist are not required to undertake significant additional effort. In this case, information is still recommended as it will inform and assist doctors and pharmacists if queries are received about availability.

For further examples, see [Appendix 3: Example scenarios for sponsors](#).

Table 1 – Impact assessment framework

Patient Population Affected	Substitute medicine ranking (refer Table 2)				
	Exact alternative available	Similar alternative available	Appropriate alternative available	Possible alternative available	No alternative available
Rare < 9 per 100,000 population	Low	Low	Medium	Medium	Critical
Uncommon > 9 and < 100 per 100,000 population	Low	Medium	Medium	Critical	Critical
Common > 100 per 100,000 population	Low	Medium	Medium	Critical	Critical

Table 2 – Assessing and ranking substitutes/alternatives

Substitute medicines or therapeutic alternative	
<p>Determined by taking into account:</p> <ul style="list-style-type: none"> 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 <p><i>Note: When ranking a substitute medicine because of a shortage, consideration is also given to the feasibility of the substitute medicine being substituted in the context of the patient population and the care setting</i></p>	<p>EXACT – same medicine (active ingredient, strength and route of administration)</p>
	<p>SIMILAR – same active ingredient but different strength</p>
	<p>APPROPRIATE</p> <p>Different active ingredient but same pharmacological class and adverse reaction profiles when administered to patient in therapeutically equivalent doses.</p> <p>OR</p> <p>Same active ingredient but different dose form that may require consideration of care setting implication.</p>
	<p>POSSIBLE – different active ingredient but comparable pharmacological class or mode of action</p>
	<p>NONE – unique pharmacology, no substitute medicine or alternative treatment options exist.</p>

Table 3 – Activities by shortage impact level

IMPACT LEVEL	ACTIVITY STEPS		
NOTIFY			
Low	Yes Mandatory reporting regardless of shortage status		
Medium	Yes Mandatory reporting regardless of shortage status		
Critical	Yes Mandatory reporting regardless of shortage status		
ASSESS			
Low	Yes by Medicine Shortages Section		
Medium	Yes by Medicine Shortages Section with 'quick touch review' if necessary (see Fig. 1)		
Critical	Yes by Medicine Shortages Section with input from Medicine Shortages Assessment Unit where necessary		
RESPOND			
Low	Anticipated communication of information through the website	Current communication of information through the website	Discontinuation communication of information through the website
Medium	Anticipated clinical guidance on substitute medicines or therapeutic alternatives linked from the website, in addition to direct communication by sponsors	Current clinical guidance on substitute medicines or therapeutic alternatives linked from the website, in addition to direct communication by sponsors	Discontinuation clinical guidance on substitute medicines or therapeutic alternatives linked from the website, in addition to direct communication by sponsors
Critical*	Anticipated Collaboration with TGA, specialists and sponsors to agree on management which may include escalation for public health responses as required	Current Collaboration with TGA, specialists and sponsors to agree on management which may include escalation for public health responses as required	Discontinuation Collaboration with TGA, specialists and sponsors to agree on management which may include escalation for public health responses as required
PUBLIC COMMUNICATION			
Low	Anticipated Optional strongly encouraged	Current Optional strongly encouraged	Discontinuation Optional strongly encouraged
Medium	Anticipated Optional strongly encouraged	Current Optional strongly encouraged	Discontinuation Optional strongly encouraged
Critical	Anticipated Yes mandatory	Current Yes mandatory	Discontinuation Yes mandatory
UPDATE			
Low	Yes regardless of Shortage status		
Medium	Yes regardless of Shortage status		
Critical	Yes regardless of Shortage status		

Investigation of alternative products

As part of the assessment and management of a shortage reported to the TGA, an investigation will be undertaken to identify products that may be available for substitution. These could be:

- the same pharmaceutical substance, dose form and strength but sourced from another supplier; or
- the same pharmaceutical substance at a different strength or different dose form; or
- a different substance but in the same therapeutic class.

In cases where no suitable products are available in Australia are identified (particularly where the same pharmaceutical substance is not available in sufficient quantities), suitable products may be sourced from overseas to address a shortage.

Following the risk assessment which includes public interest considerations determining a finding of critical impact, where there are no suitable direct or similar alternatives identified or in a situation where obtaining a substitute is delayed (such as needing to be sourced from overseas) a Medicines Shortages Action Group may be convened if required.

A Medicines Shortages Action Group will identify strategies to continue patient management that could include rationing options and alternative therapies to support management of patients affected by the shortage.

Response

When a decision has been made that the shortage has a critical patient impact, the shortage will be communicated via publication on the Medicines Shortage Information Initiative website. The sponsor and other relevant authorities will be notified of the decision by the TGA and asked to implement particular communication and management strategies.

The sponsor will be expected to undertake the following communications as appropriate:

- hospital medicines – the sponsor will notify State and Territory Health Departments; and wholesalers marketing to private hospitals; and the Society of Hospital Pharmacists of Australia
- community/retail pharmacy medicines – the sponsor will notify the Pharmaceutical Society of Australia; the Pharmacy Guild of Australia; and wholesalers and pharmacies
- PBS medicines – the sponsor will notify the Technology Assessment and Access Division, who in turn will notify Community Service Obligation Distributors
- National Immunisation Program vaccines – the sponsor will notify the Office of Health Protection
- National Blood Authority plasma components (where they are registered medicines) - the sponsor will notify the National Blood Authority and the Office of Health Protection.

For medicines of critical patient impact, the TGA's Medicine Shortages Section will notify the Deputy Secretary and Chief Medical Advisor of the Health Products Regulation Group (HPRG) and the Department of Health's Chief Medical Officer.

For shortages with medium/low patient impact, the TGA and the sponsor will notify other stakeholders as required, noting that while such shortages can be published on the Medicines Shortage Information Initiative website at the discretion of the TGA, it is expected that the

sponsor will notify those in the supply chain about the details of the shortage. For example, where a sponsor does not wish to publish their shortage but the lack of publically available information is creating significant difficulties in the community, the TGA may take the decision to publish the information on the Medicine Shortages Information Initiative website in the interest of public health. Where this occurs, the sponsor will be notified by the TGA.

We intend to notify the State and Territory Health Departments as soon as possible, most likely via an email, following notification of an imminent shortage of critical impact. This is to allow jurisdictions to begin to manage stock levels and make alternative arrangements where necessary, even if the comprehensive risk assessment has not been completed.

When notified of a shortage with **critical patient impact**, the HPRG Chief Medical Adviser (or in some cases the Department of Health's Chief Medical Officer) will work with the impacted sponsor with regard to the following activities:

- coordinate action on rationing of the products following clinical review with relevant bodies (for example Clinical Colleges, medical and pharmacy professional organisations, States and Territories, Council of Australian Therapeutic Advisory Groups)
- when there is not a supply of an alternative similar product, it may be necessary to provide advice to doctors on appropriate therapeutic alternatives or what measures need to be undertaken in view of the shortage, which can be provided by the Chief Medical Officer, States and Territories, or clinical colleges (the TGA will support the decision-making process and assist in promulgating information on alternatives)
- where appropriate, work with supply chain stakeholders on rationing of supplies and signposting to alternatives available in Australia, including different suppliers, different dose forms, or different products in the same therapeutic class
- advise of the option and relative importance of obtaining alternative products from overseas.

Communication involving multiple sponsors

It is important to note that the above discussions only occur on a voluntary, one-on-one basis between the TGA and individual sponsors (and do not involve any group or 'round table' discussions). In conversations with individual sponsors, the TGA will not pass on information about a sponsor's commercial operations (for example volumes, prices, production capabilities or difficulties) to other sponsors.

Where there are multiple sponsors supplying the market of a medicine that has fallen into shortage, the first issue for the TGA to determine is the market share of the different sponsors' products and usually the different sponsors have a good idea of their own market share. The TGA will contact sponsors individually to request this information, and information about how a shortage may affect each sponsor. A shortage might only affect one sponsor's product initially, however depending on their market share, a shortage of a particular medicine where the sponsor has a significant market share might lead to shortages of all sponsors' products and hence a shortage of the product overall.

The TGA may receive information about the different market shares and how all sponsors are affected by a shortage in the same medicine market. Communication between the TGA and each sponsor on a one-on-one basis will allow improved management of the shortage. The TGA may speak further to individual sponsors to identify if sponsors might be able to increase supply during the shortage, to minimise the effects of the shortage on patients. The same principle applies for products to be or being imported under section 19A of the Act to either enable

importation or minimise over-importation in addressing a shortage. In conversations with individual sponsors, we will not pass on information about a sponsor's commercial operations (for example, volumes, prices, production capabilities or difficulties) to other sponsors.

Other useful activities are the ability to 'ration' supply of all sponsors' products when there is a shortage to minimise stock piling of products and reduce the risk of increasing the shortage of like products. It also allows supply to those who might most need it, for example oncology drugs to finish a course rather than having new patients commence a course but not be able to complete it.

The sponsor, with the support of the TGA, will coordinate communications about confirmed shortages. This enables consistent clinical advice for communication to pharmacists, prescribers and hospitals to enable management of the shortage and mitigate risks to patient care. Where appropriate the TGA will:

- notify peak consumer organisations to manage patient expectations
- notify the Technology Assessment and Access Division who in turn will notify Community Service Obligation Distributors to ensure currency of their information
- update the Medicines Shortage Information Initiative website with management actions.

Regulatory options for sourcing medicines from overseas

The TGA regulates the import and supply of unregistered medicines for use by individual patients through the Special Access Scheme [section 19(1)] and section 19(1) of the Act] and the Authorised Prescriber scheme [section 19(5)].

The TGA can consent to the importation and supply of medicines that do not comply with a standard that are otherwise applicable ([section 14](#)).

The TGA can grant approval to a sponsor to import and supply an unregistered medicine that could substitute for a registered medicine that is in short supply (section 19A).

Information on section 19A is available on the TGA website – [Accessing medicines during a medicines shortage](#).

Coordinate communications about confirmed shortages

All shortage of critical patient impact will be published on the TGA website. These shortages will appear on a landing page on the medicine shortages website. They will be listed under one of the following sub-categories: current, anticipated or discontinued. There will also be a list of resolved critical shortages.

In certain cases, information may be published on the TGA website, including information on alternative products where appropriate. Links to other websites (sponsor, State and Territory, clinical college) will also be provided. Information on products approved to be imported under section 19A as alternative products to Australian-registered medicines that are experiencing a shortage are now available on the [TGA website](#).

While not mandatory, sponsors will be strongly encouraged to publish other (medium/low patient impact) shortages on the Medicines Shortage Information Initiative website. These will also be under one of four sub-categories: current, anticipated, resolved or discontinued and will appear on the consolidated medicine shortages page.

For critical patient impact shortages, **communication plans** need to be developed to ensure the sponsor can work effectively with a range of stakeholders, including the TGA, to conduct the following steps:

- finalise specific communication messages, channels, schedule and overall communication plan
- where appropriate, notify peak consumer organisations – to manage patient cohort expectations
- provide consistent clinical advice for communication to health care providers (pharmacists and prescribers) and hospitals to manage shortage and mitigate any patient risks
- decide on additional information for publishing on the TGA website to support patient care
- monitor and respond to shortage status changes and issues that emerge, for example, to follow up with distributors to ensure currency of their information.

For low or medium patient impact shortages, communication plans will only need to:

- sponsors to develop and implement their routine communication activities based on the impact assessment; and if applicable decide on the website publication date (that aligns with the commencement of supply chain communication) and to notify the TGA of updates as required
- the TGA to validate the assessment, and manage the publication of the shortage information if agreed (including updates) in accordance with the sponsor's nominated publication date, as well as working with the sponsor to implement any agreed regulatory response.

From time to time, health professional and public media outlets are interested in reporting on specific medicine shortages. In developing a response, sponsors and the TGA will have considered this and decided on appropriate action. It is normally the sponsor's role to discuss the details of their products and the specific reasons for the shortages with the media.

Medicines Shortage Information Initiative website

The website provides health professionals and consumers with information about medicine shortages. The site includes information about medicines that are:

- prescription medicines included in Schedule 4 or 8 to the current Poisons Standard; or
- OTC medicines determined in an instrument under section 31EH(1)(b)(ii) of the Act which include medicines such as adrenaline auto-injectors and salbutamol inhalers.

Information on availability of other OTC medicines or on medicines that are usually obtained through the Special Access Scheme or Authorised Prescriber scheme is not included.

The information available will include:

- medicines currently in shortage or anticipated to be in short supply or medicines that are to be permanently discontinued
- for critical patient impact shortages, information will be posted on the medicine shortages landing page dedicated to only critical impact shortages as well as on the consolidated list of shortages

- for low or medium impact shortages, information notified to the TGA and potentially included in the website as part of their communication and management activities, will appear in a consolidated list of shortages and discontinuations.

The information available on the website for each medicine shortage is:

- sponsor name and contact details
- product active ingredient and trade name, strength, dose form and ARTG number
- reason for the shortage
- estimated duration of the supply disruption
- status (current, anticipated, resolved, or discontinued)
- patient impact rating
- additional supply details about the medicine as appropriate
- information about substitute medicines or therapeutic alternatives as appropriate
- TGA management actions.

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

Medicine shortage information relating to medicines with a critical patient impact will be mandatorily published on the TGA website. For medium and low patient impact medicine shortages the information will normally be published on the TGA website with the consent of the sponsor.

It is recognised that there may be situations where consent is not given or is not possible. The TGA is able to publish information about medicine shortages under a legislative instrument under section 61 of the Act which provides the TGA with authority to release information to the website regardless of this consent and in cases where the TGA believes there is a public health interest in the information being publicly available (see [Specifications](#)). For example, where a sponsor has not published their shortage and the lack of publically available information is creating significant difficulties for the community, the TGA may take the decision to publish the information on the Medicine Shortages Information Initiative website.

Compliance and enforcement

Compliance measures in relation to these new reporting obligations are outlined in the [Medicine Shortages in Australia – Reporting obligations and the TGA's compliance framework](#) which is in accordance with the TGA's [Regulatory Compliance Framework](#).

We will take a risk-based approach to compliance and will develop appropriate strategies to prevent non-compliance. This will include activities to raise awareness and understanding of the new scheme, which will allow us to respond proportionally to the varied types of non-compliant behaviour.

New regulatory measures available to the TGA under the Act can be used to address breaches. These measures range from publishing the names of sponsors who do not comply with the new requirements (in accordance with s61 of the *Therapeutic Goods Act 1989*), to issuing infringement notices and, in the most serious cases or where there is repeated non-compliance,

initiating civil penalty proceedings. Civil penalties can result in maximum fines of 100 penalty units for an individual and 1000 penalty units for a body corporate.

In most cases, civil penalty action would only be used where other steps, such as awareness raising and warnings, have previously been used and there is a history of repeated non-compliance.

Roles of different stakeholder groups

TGA and Department of Health

The TGA, which is part of the Department of Health and manages the Medicines Shortage Information Initiative website, has an important role in the management and resolution of medicines shortages, but is not the sole 'manager' in these situations.

The TGA must be notified of all current and anticipated medicines shortages and of all discontinuations by sponsors once they are identified by the sponsor.

The TGA will review the sponsor's initial risk assessment of the shortage in conjunction and, as needed, convene other stakeholders (possibly a Medicine Shortage Action Group) to further consider the impact status of the shortage and communicate the shortage as needed.

The TGA can approve the temporary supply of a substitute medicine or therapeutic alternative during a medicine shortage.

The TGA may undertake additional communication activity in relation to particular medicine shortages where there are anticipated to be significant public health impacts. The TGA also consults with sponsors to streamline the notification of medicine shortages, and to enable consistent communication and management. This may include:

- escalation to a public health response such as advice from the Chief Medical Officer and advice from/ communications with State and Territory Health Departments of cases assessed as critical impact for medicine shortages and shortages of vaccines
- provision of an additional communication channel to inform health professionals and consumers about the details of the shortage (via the website)
- coordination of expert advice and information about substitute medicines and therapeutic alternatives where appropriate
- the publication of information about a medicine shortage in the public interest.

When there are significant public health impacts the Chief Medical Officer will also have a role in coordinating responses and communication.

The **Technology Assessment and Access Division**, which has responsibility for the PBS, has described the obligations under the *National Health Act 1953* of sponsors of PBS-listed medicines during a shortage above.

It is a condition of listing on the PBS that sponsors have stock available across the supply chain, and they must report any supply disruption with a PBS-listed medicine to the Department of Health (see [Appendix 4: PBS medicine supply guarantee](#)). There are legislative requirements whereby manufacturers must guarantee supply of certain medicines for up to 24 months after listing. They must notify the Technology Assessment and Access Division if they are unable to supply within this period. There are criminal penalties for non-compliance.

Where a sponsor has failed to meet their obligations under the *National Health Act 1953*, the Minister has discretion (under section 99AEH) to: delist the relevant brand, delist any of the supplier's other PBS listed brands or refuse to list a new brand from that supplier.

When a temporary supply has been granted by the TGA (section 19A), the Department is able to negotiate a price for a temporary product to ensure that it can be listed on the PBS while the registered product is in short supply or unavailable.

The reporting requirements protocol is not intended to replace the 'Guarantee of Supply' form, to be used when a 'Responsible Person' wishes to advise a failure to supply a brand of an item listed on the PBS, or a belief that a supply disruption has, or is likely to occur. Sponsors are required to complete this form and report to the Technology Assessment and Access Division.

The Technology Assessment and Access Division will be consulted during the determination of alternative sponsors as they have information on which sponsors are supplying particular products under the PBS. During confirmed medicine shortages they will also be in communication with PBS sponsors, in particular if short-term changes to listings are required due to a shortage.

Sponsors

Sponsors maintain continuity of supply for a medicine through various business processes, which may include accurate demand forecasting, maintenance of appropriate levels of safety-stock, and identification of backup supply routes. When a disruption to the supply arrangements for a medicine occurs, sponsors routinely:

- assess supply and demand gaps and develop a response:
 - implement contingency planning to reduce the supply disruption
 - assess the supply disruption to determine if and when the supply is reasonably likely to impact on consumers
 - implement management activities to secure supply including applying to the TGA for the supply of substitute medicines or therapeutic alternatives
- implement communication activities to the supply chain that are proportionate to the impact on consumers, which may include:
 - publishing of information on sponsor websites
 - activating public/health professional information hotlines
 - communicating directly with:
 - § wholesalers
 - § prescribers and pharmacists (for example 'Dear Health Professional' letters)
 - § the Australian Government Department of Health/State and Territory Health Departments
 - § State medicine information hotlines
 - § clinical colleges and health professional peak bodies (for example to discuss therapeutic options)
 - § health professional media, public media channels.

State and Territory Health Departments

State and Territory Health Departments are also involved in ensuring timely access to medicines through, for example, contractual purchasing and other procurement arrangements, and in providing advice on alternatives through therapeutics committees for hospital networks. They also have a role in coordinating responses to medicine shortages where there is a significant public health impact within their jurisdictions.

Health professionals and professional organisations

Health professionals perform roles as prescribers or dispensers across various healthcare settings including primary care and hospitals.

Health professionals can also notify the TGA of suspected medicine shortages (by email medicine.shortages@tga.gov.au or phone – 02 6232 8850).

Often it is the pharmacist who is first aware of a shortage, rather than the prescriber, as they are involved in the supply of medicine to the consumer and generally the prescriber is not. Health professionals receive medicine supply information via a range of channels including notices from the wholesaler, letters from sponsors, newsletter articles in professional media, colleagues and consumers.

When a medicine shortage occurs, health professionals are often required to identify substitute medicines or therapeutic alternatives for their patients. The dispenser has the knowledge and expertise to substitute an item that is considered to be bio-equivalent. However, they will need to refer to the prescriber for non-identical substitutes and changes to therapy. There may also be high risk cases when it is not reasonable for the dispenser or the prescriber to know about substitute medicines or therapeutic alternatives and additional information is required. In these cases, medical colleges and clinical guideline experts may become involved in providing advice on the appropriate treatment regimen.

Health professionals are then responsible for passing on information to the consumer, in an easily understood manner. With accurate information about medicine shortages, health professionals will also work to assist the consumer to manage potential problems that arise with the quality use of medicines, for example, the safety and compliance considerations needed when a substitute of different dose forms or strength is used.

Wholesalers

Pharmaceutical wholesalers distribute most medicines to retail pharmacies and hospitals.

In the case of localised or regionalised out-of-stocks or short-term shortages of PBS subsidised medicines, this is usually resolved within 24 hours due to Community Service Obligation delivery guarantee requirements, whereby Community Service Obligation Wholesalers are required to hold supply redundancy, and/or coordinate with alternative Community Service Obligation Wholesalers who may have supply immediately available in that location or region.

Exclusive-direct suppliers or distributors who are not party to the Government's Community Service Obligation do not have any formal delivery guarantee requirements, stock supply redundancy obligations or responsibilities with the Department of Health.

In the cases where shortages have the potential to be of a longer duration, sponsors may work with Community Service Obligation Wholesalers to coordinate the imposition of maximum sale

allocations on medicines that are experiencing a supply shortage, to limit the impact of possible spikes in demand driven by knowledge of a shortage.

It should be noted that the therapeutic goods legislation does not extend to the TGA having control over distributors or the distribution of medicines.

Consumer organisations

Consumers, patients and their carers require information to support their access to and quality use of their medicines from their health professional and other sources. In the case of a medicine shortage, consumer organisations, particularly disease-specific consumer groups, may have a role in supporting consumers with information and/or advising medical experts of their considerations when alternative regimens or considering substitute medicines or therapeutic alternatives.

Historical document

Appendix 1: Medicines Watch List

Antimicrobial agents

aciclovir IV
 amikacin
 amphotericin B IV (liposomal)
 ampicillin
 benzylpenicillin
 cefepime
 chloramphenicol IV
 ciprofloxacin IV
 colistin
 ethambutol
 ganciclovir
 gentamicin IV
 isoniazid
 metronidazole IV
 phenoxymethylpenicillin
 piperacillin/tazobactam
 rifampicin PO/IV
 sodium fusidate PO/IV
 trimethoprim/sulfamethoxazole IV
 vancomycin
 voriconazole

Antidotes/treatments for poisonings

activated charcoal
 desferrioxamine injection
 digoxin specific antibodies
 edetate calcium disodium injection
 ethanol injection
 folinic acid (calcium folinate) injection

fomepizole
 methylene blue IV
 n-acetylcysteine IV
 pralidoxime
 sodium nitrite IV
 sodium thiosulfate IV

Emergency/critical care

adrenaline IV
 alteplase
 amiodarone IV
 calcium gluconate
 calcium gluconate injection
 cypripentidine
 dapsone
 dextropropofol injection
 desmopressin IV
 dexamethasone IV
 diazepam IV
 glucagon injection
 glyceryl trinitrate IV
 hydralazine IV
 hydrocortisone IV
 isoprenaline
 mesna
 morphine IV
 methoxyflurane
 metoprolol IV
 neostigmine
 nimodipine PO/IV
 noradrenaline
 phenytoin IV

phosphate IV
 prednisolone PO
 protamine
 pyridostigmine
 quinine injection
 rasburicase
 salbutamol IV
 sodium bicarbonate 100mmol/100ml
 injection
 sodium polystyrene sulfonate
 suxamethonium
 terlipressin
 tenecteplase
 thiamine IV
 vasopressin
 vitamin K (phytomenadione) IV

Anticoagulants

enoxaparin
 heparin
 warfarin

Vaccines

Any vaccine on the Australian
 ADT vaccine
 BCG vaccine

Obstetrics

ergometrine
 magnesium sulfate IV
 misoprostol

Antivenoms

Brown snake antivenom
 Death adder antivenom
 Sea snake antivenom
 Taipan antivenom
 Polyvalent snake antivenom
 Stone fish antivenom
 Box jellyfish antivenom
 Tiger snake antivenom
 Red back spider antivenom
 Black snake antivenom
 Funnel web spider antivenom

Schedule 3s

adrenaline autoinjector
 glyceryl trinitrate sublingual
 naloxone injection
 naloxone nasal spray
 salbutamol inhaler

Appendix 2: Reportable Medicines Determination List (OTC medicines)

Adrenaline autoinjector

Glucagon injection

Glyceryl trinitrate sublingual

Levonorgestrel

Monobasic sodium phosphate

Naloxone injection

Naloxone nasal spray

Salbutamol autohaler

Salbutamol inhaler

Terbutaline inhaler

Ulipristal

Historical document

Appendix 3: Example scenarios for sponsors

Please note that the following examples are only representative of possible scenarios involving reportable medicine shortages. These examples are 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.

Example 1 – Manufacturing issues

Manufacturing issues are a major contributing factor to medicine shortages. For example, shortages may arise because the manufacturer ceases operation, or if there are problems sourcing the Active Pharmaceutical Ingredient (API).

If manufacturing issues occur, sponsors are required to perform an internal assessment prior to officially reporting a shortage to the TGA. Such a shortage might be current or anticipated in the near future. If the shortage is likely to occur within the next 6 months it must be reported. This internal assessment would include activities such as:

- investigating availability from another manufacturer
- assessing how long the issue will be present (duration of the resulting shortage)
- level of stock affected and market share/usage (which helps to determine impact level).

Scenario: On 1 February 2019, a sponsor of a reportable medicine that is included in the Medicines Watch List becomes aware of possible manufacturing delays. On 5 February 2019, after investigating further and obtaining information from the manufacturer, the sponsor concludes that, although the stocks of the medicine in Australia will be sufficient to meet demand for the time being, the manufacturing delays will, by early April 2019, result in the supply of the medicine in Australia not meeting or not likely to meet demand.

Outcome: As the anticipated shortfall of supply falls 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 as soon as possible or within 2 working days (in this case by 7 February 2019).

Example 2 – Unexpected increase in demand

Many medicine shortages arise due to an unexpected increase in demand, most commonly due to another sponsor of a medicine with the same active ingredient experiencing their own shortage.

When this occurs, there are a number of actions and steps that need to take place.

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

Outcome: The TGA reviews the information provided by Sponsor A. As Sponsor A has notified that they have a 50% market share, the TGA then 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. This leads to additional medicine shortage notifications from Sponsor B and Sponsor C. This may result in the TGA negotiating with Sponsor A to reassess/increase their patient impact rating. A Medicines Shortages Action Group (comprising relevant experts engaged on a case-by-case basis) is consulted in regards to proposed management actions for the shortage. The TGA continues to liaise with each of the sponsors to assess currency of information on an ad hoc basis and monitor market signals from other sources of information, such as health professionals and consumers.

Example 3 – Discontinuation of a medicine

Discontinuation of a medicine, for example for commercial reasons, creates a medicine shortage that may be subject to mandatory reporting (if it's a prescription medicine or a reportable OTC medicine).

For any discontinuation, you should notify the TGA as soon as you are aware that a product is going to be discontinued. Consideration should be given to the information that is supplied to health professionals and consumers who may be impacted by the deletion of a product from the market.

Scenario: In March 2019, the global parent company decides to shut down Australian operations and subsequently to cease supplying the Australian market from October 2019. The medicine sponsor has three items registered on the Australian Register of Therapeutic Goods which will all be discontinued in 7 months' time.

Outcome: The discontinuation will result in a shortage assessed as low patient impact. As such, the sponsor is required to report the discontinuation to the TGA at least 6 months before it is proposed to take effect (or as soon as practicable where this is not possible). If the medicine had been on the Medicines Watch List, or the shortage was assessed as being critical, it should be reported as soon as possible and at least 12 months in advance. The sponsor should begin the preparation of correspondence to relevant stakeholders, to be included in their notification to the TGA. In this scenario, the sponsor is not legally required to advise the TGA immediately, as the discontinuation is 7 months away. However, early notification is encouraged, as this gives health professionals and consumers more time to consider alternative treatment.

Example 4 – Shortage as a result of a recall

A recall of a product can result in a medicine shortage. The TGA will already be involved in the recall action, but a medicine shortage notification will also need to be made if it is a reportable medicine. Sponsor obligations pertaining to a recall are separate from sponsor 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 the TGA 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.

Example 5 – Natural disaster

Natural disasters have been known to significantly affect the availability of medicines. For example, damage caused by [Hurricane Maria in Puerto Rico in 2017](#) decreased global manufacturing productivity and led to worldwide medicine shortages for a number of lines.

Similar to instances in which a shortage is caused by a manufacturing quality issue, Australian medicine sponsors are required to perform an internal assessment confirming the likelihood of a shortage prior to officially reporting this to the TGA. Such a shortage might be current or anticipated in the near future. If the shortage is likely to occur within the next 6 months, it must be reported. This internal assessment would include activities such as:

- investigating availability from another manufacturer
- assessing how long the issue will be present (duration of the resulting shortage)
- level of stock affected and market share/usage (which helps to determine impact on supply).

Scenario: On 15 November 2019, a sponsor of a reportable medicine that is included in the Reportable Medicines Determination List (OTC medicine) becomes aware of a typhoon that has affected a manufacturing plant in Japan. On 20 November 2019, after investigating further and obtaining information from the manufacturer, the sponsor concludes that although the stocks of the medicine in Australia will be sufficient to meet demand for the time being, the damage from the typhoon and subsequent manufacturing delays will, by mid-December 2019, result in the supply of the medicine in Australia not meeting or not likely to meet demand.

Outcome: As the anticipated shortfall of supply falls within 6 months of 20 November 2019, on that date there is a reportable shortage of the medicine. In this instance, as this medicine has no generic substitutes or any alternative available, the shortage is of critical impact and the sponsor therefore must notify the TGA as soon as possible within 2 working days (in this case by 22 November 2019).

Example 6 – Local stock issues

There may be instances in which a select population of individuals in Australia may not be able to access 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). It should be noted that unless these situations were to be universal in nature and affect all patients in Australia, they would not constitute a medicine shortage.

Scenario: A rural town in Victoria has only one pharmacy servicing it. Due to the pharmacy being a relatively small business compared to its regional and metropolitan counterparts, and the volume of business conducted, it does not have commercial arrangements with all of the major available suppliers. There is an instance of a specific product being available through a specific supplier. This pharmacy does not have a commercial agreement in place or any capacity to order stock from that supplier. As a result, patients in this population have to either drive to another town or visit another pharmacy to get their prescription for the product filled.

Outcome: This would represent an unavailability of a medicine at a particular location and would not constitute a medicine shortage as per the legal definition. No regulatory obligations would be imposed on the medicine sponsor in this instance.

Appendix 4: PBS medicine supply guarantee

Granting price increases and exemptions where prices of medicines have become unviable and discontinuation of supply is planned

Under the *National Health Act 1953*, the Minister can agree a higher price for a medicine listed on the PBS. The Minister exercises this power where it is necessary to retain listing of clinically important medicines on the PBS.

In implementation of this measure, it is critical:

- that pharmaceutical companies provide accurate cost of goods and supply information to make an assessment of a reasonable price increase
- that accurate information is obtained from pharmaceutical companies about the intention to de-list if a price increase is not granted
- to strike a balance between retaining clinically needed medicines and reasonable prices where there is no economic evaluation available for those medicines

Temporary PBS listing of unregistered medicines where a registered medicine is in short supply

When temporary supply of an overseas-approved product has been granted by the TGA under section 19A of the Act, the Department of Health will negotiate a price for a temporary product to ensure that it can be listed on the PBS.

In implementation of this measure, it is critical:

- to ensure that companies are not being paid (on a longer term basis) more for temporary supply of a different brand of medicine, especially in circumstances where they are the main/sole supplier for the permanently listed PBS item
- to best evaluate how much to pay for temporary listings when there is no formal economic evaluation for that medicine
- to encourage the temporary supplier to seek permanent registration on the ARTG if the PBS medicine is permanently discontinued, to ensure that it is a temporary measure rather than an ongoing arrangement.

Requirements that manufacturers guarantee supply of certain medicines for up to 24 months after listing and that they notify the Minister's delegate if they are unable to supply

Guarantee of supply provisions are included in the *National Health Act 1953*. The purpose of the provisions is to require new responsible persons (suppliers) of F2 drugs to guarantee supply for 24 months, or until another new brand of that drug is listed, and to notify the Minister if they are unlikely to be able to supply during that initial 24 month period.

The provisions address a concern that one brand might be listed to cause a price reduction affecting competitors with no intention to supply. It was intended to deter sponsors from entering the Australian market without a viable business model able to support their long term participation in the market.

The supplier of a guaranteed brand must notify the Minister where there is an issue with supply (refer to section 99AEG of the *National Health Act 1953*). There are criminal penalties for non-compliance. In situations where a supplier has failed to meet their obligations, the Minister has discretion (under s99AEH) to: delist the relevant brand, delist any of the supplier's other PBS listed brands or refuse to list a new brand from that supplier.

It is a condition of PBS listing that a supplier agrees to the 'Assurance of Supply' arrangement including that they have sufficient stock to meet demand. There is also a 'Guarantee of Supply' form for notifying the Department if the supplier is having, or is likely to have, supply issues.

In implementation of this measure it is critical to note that the intention of the guaranteed supply provisions was not to address supply shortages. Supply shortages are most likely to take place after the 24 month period has elapsed.

Historical document

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Pharmacovigilance and Special Access Branch	23/11/2018
V1.1	Minor updates to include information about the compliance framework	Pharmacovigilance and Special Access Branch	01/05/2019

Historical document

Historical document

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

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