



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Medicine shortages in Australia

Consultation on challenges and opportunities

Version 1.0, February 2024



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Overview

Medicines are essential for the health and wellbeing of Australians. Medicine shortages can occur for various reasons. Unfortunately, some are unavoidable and can cause significant impact.

Through our mandatory reporting scheme, the Therapeutic Goods Administration (TGA) is responsible for receiving and publishing reports of shortages and discontinuations of prescription and certain over-the-counter medicines. We work closely with our stakeholders to respond to shortages and limit their impacts.

Medicine supply chains are complex global systems involving many parties. There are numerous points in the supply chain where problems can cause a national medicine shortage, each requiring a different response. We need the cooperation of all stakeholders in the medicine supply chain to develop solutions to better prevent, manage and communicate shortages.

Although many improvements have been made, medicine shortages continue to impact on the health and wellbeing of people in Australia, and the health professionals who support them. A strategic workplan for the future is required, to further reduce the impact of medicine shortages and discontinuations in Australia.

Why your views matter

We want to better understand the nature, extent and urgency of problems impacting the supply of medicines, including shortages and discontinuations of medicines in Australia. We also want to hear about possible opportunities to address these challenges, in continued collaboration with the broad range of stakeholders responsible for medicine supply and utilisation in Australia.

Your feedback will give us insights into different perspectives on the medicine supply chain, and inform recommendations on medicine shortages priorities for future improvement.

Please contact us at shortages.strategy@health.gov.au if you have any issues with completing this survey.

Give us your views

Collaborating to improve how medicine shortages are managed in Australia

The last 5 years since the introduction of mandatory reporting of medicine shortages have highlighted new and existing supply challenges, and provided an opportunity for various parties in the supply chain to come together with a common goal - to better manage medicine shortages in Australia.

Better partnerships

We expanded our medicine shortages leadership and coordination role and listened to our stakeholders to solve specific shortage issues, streamline processes, and introduce broader long-term improvements to the framework.

Examples of our partnerships include:

- **Medicine Shortages Working Party:** This group comprised key organisations in the medicine supply chain, including pharmacy, medical, wholesaler and sponsor peak bodies. The group played an important part in establishing the medicine shortages mandatory reporting scheme that played a critical role in our response to shortages during the COVID-19 pandemic. In 2020-2021, the TGA held regular working party meetings to share information about supply chain issues and collaborate to rapidly develop solutions. Although this working party no longer meets regularly, the relationship between these members and the Department of Health and Aged Care continues through various forums and mechanisms used to address supply chain challenges.
- **Medicine Availability Working Group:** In 2021 we established this group of state and territory health department representatives to share information, model availability of important medicines used in hospitals, and make recommendations about conservation measures.
- **Medicine Shortage Action Groups:** These groups bring together relevant pharmaceutical companies, health professionals and patient groups to discuss specific shortages and develop consistent messaging and clinical and conservation advice. Advice is published on the TGA website as shortage [alerts](#) to minimise the impact of a shortage.
- **Medicine Shortage Communication Champions:** A group of patients, health professionals, special interest groups and pharmaceutical companies formed to better share consistent shortage information through their communication networks.
- **Data sharing:** We rely on data from the supply chain to help us detect and manage shortages. We now receive regular voluntary reports from wholesalers on medicines in high demand. We are also developing a new way to dynamically forecast supply of medicines in the hospital setting, with supporting data-sharing policy principles.

We continue to collaborate with many other organisations to better understand and respond to medicine supply problems as they emerge.

Legislative and regulatory changes

In response to feedback from our stakeholders, including our 2021 consultation on [Building a more robust supply of medicines](#), we implemented regulatory changes to medicine shortages. These include:

- amendments to the *Therapeutic Goods Act 1989* (the Act), allowing pharmacists to dispense substitute medicines under a [Serious Scarcity Substitution Instrument](#). This amendment provided a nationally consistent approach to substitution and formalised the Serious Shortage Substitution Notices implemented at the height of the pandemic.

- legislative changes in 2023 that enabled us to approve an overseas-registered version of a medicine that was no longer on the Australian Register of Therapeutic Goods (ARTG). Previously, cancelling or removing a medicine from the ARTG also removed the ability for the TGA to approve the overseas version in response to a shortage or discontinuation. Further information on these improvements is at [Medicine shortages – recent amendments to the Therapeutic Goods Act 1989](#).
- clarifying requirements in the Act for pharmaceutical companies to report any changes to when they believe a medicine shortage will end and if it has been resolved. Further information for medicine sponsors and manufacturers on reporting medicine shortages is at [Manage a medicine shortage](#).

We also publish a [list of medicines](#) that have been in repeat or long-term shortage to encourage registration. Further information about the process for registering a prescription medicine is at [Registration of prescription medicines to manage shortages](#).

What the TGA does to assist with medicine shortages and discontinuations

What the TGA can do

Wherever possible, the TGA proactively manages medicine shortages to reduce the impact on patients.

We publish information in the [Medicine Shortage Reports Database](#) about when individual medicine shortages are expected to resolve. This information is supplied by pharmaceutical companies - also known as sponsors - and may be subject to change. We also send out shortage information, including through social media, TGA webpages and [alerts](#).

Depending on the cause of the shortage, we can take a range of management actions, including:

- working with pharmaceutical companies and other industry stakeholders to manage inventory, including supporting the fair distribution of stock within Australia
- collaborating with health professional and consumer groups to provide guidance on managing demand during a shortage, including issuing guidance on prioritising prescribing for certain conditions
- approving the supply of [overseas-registered alternative products](#) under section 19A of the Act
- allowing pharmacists to dispense certain identified substitute medicines when a medicine is in shortage, by making a [Serious Scarcity Substitution Instrument](#)
- working with pharmaceutical companies to expedite regulatory processes that may otherwise delay the supply of medicines
- working with state and territory health department representatives to model supply of medicines at risk of significant shortages and manage supply of hospital medicines.

Further information about what the TGA does to assist with a medicine shortage or discontinuation is on the [TGA shortages](#) website, including general information for consumers, health professionals and industry, specific information on major shortages, and guidance on how to access alternative products.

What the TGA cannot do

The TGA does not have the regulatory power to:

- obligate pharmaceutical companies to manufacture medicines in Australia
- manage how medicines are distributed globally to avoid shortfalls in medicine availability
- redistribute medicines to specific locations or patients in Australia
- decide how much a medicine costs, including whether it is subsidised under the Pharmaceutical Benefits Scheme
- obligate health practitioners to prescribe medicines in a certain way.

About you

Privacy and your personal information

A copy of all responses received will be published on the TGA Consultation Hub, unless you request it be kept confidential. Any text within your responses that you want to remain confidential must be clearly marked 'IN CONFIDENCE'.

In publishing these responses, we will only include your name if you consented to it being published as part of your response.

The TGA collects your personal information in this survey to:

- contact you if we need to clarify issues raised in your feedback or to check whether you are happy for the information that you provided to be made publicly available
- help provide context about your feedback, such as determining whether you are a consumer or a director of a company, or representing an interest group
- seek your feedback about how the survey was run.

Personal information means information or an opinion about another person whose identity can be easily guessed based on the information provided.

Please do not include personal information about other people in your feedback. The TGA will not publish personal information without consent unless authorised or required by law.

Responding to the questions in this consultation is optional. The only questions that need a response to allow your feedback to be submitted are specific questions about you and whether you consent to have your feedback published. These questions are clearly marked as 'required'.

Questions

1. What is your name? [Prof Raj Puranik CSANZ Board](#)
2. Please provide your email address if you consent to us contacting you with consultation updates (separate to receiving a copy of your submission). Email: rajesh.puranik@sydney.edu.au
3. Which of the following best describes you? (Required)
 - a. Medicine sponsor/manufacturer/wholesaler representative organisation
 - b. Health professional representative organisation**
 - c. Consumer representative organisation
 - d. Government agency

- e. Research/academia/media
 - f. Individual sponsor/manufacturer/wholesaler/retailer
 - g. Individual health professional, please specify type
 - h. Individual consumer/general public/community member
 - i. Other, please specify
4. Organisation name: CSANZ
5. Size of organisation: Small (20 employees and under), medium (20-199 employees), large (over 200 employees). LARGE
6. Have you been affected by a medicine shortage or discontinuation in the last 12 months?
Yes/No/Unsure YEST
7. If yes, please list which medicine shortage(s) and/or discontinuation(s). WARFARIN

Planning for medicine shortages and discontinuations

Medicine shortages and discontinuations occur for many reasons and, despite best efforts, they are sometimes unavoidable. We would like to explore how you proactively plan for shortages and discontinuations and the effectiveness of these measures. Planning activities are those undertaken by individuals and organisations to monitor and forecast changes in medicine supply, prescribing and use. These also include other forms of emergency planning, such as preparing contingency plans.

Questions

8. What do you do to plan proactively for a medicine shortage or discontinuation? Select all that apply:
- a. **monitor medicine availability (supply, demand)**
 - b. **seek out information about shortages and discontinuations**
 - c. manage stock levels
 - d. plan for alternative treatments in case of shortage
 - e. change the way medicine is prescribed/dispensed/taken (e.g. rationing)
 - f. other, please specify
9. Please explain in more detail how you plan proactively for a medicine shortage or discontinuation, including any barriers or challenges you experience.
10. [Pharmaceutical companies only] What measures do you use to monitor and predict medicine supply including disruptions and increases in demand? Are there any barriers or challenges?

Responding to medicine shortages and discontinuations

Every medicine shortage and discontinuation is unique and there is no 'one-size-fits-all' approach when responding to a shortage. A response is what you do when you find out that a medicine may not be available. It can include trying to access more stock, changing prescriptions or giving/seeking advice.

We would like to explore how you respond to a medicine shortage or discontinuation and potential challenges or barriers that may be blocking the effectiveness of your response, such as whether there are any information gaps or policies that make it difficult for you to respond to a shortage.

Questions

11. Please outline how you respond to a medicine shortage or discontinuation, including any barriers or challenges you experience. [INFORM OUR MEMBERSHIP AND WORK WITH PHARMACEUTICALS](#)
12. Please describe in detail where any of the following have helped you to respond to a medicine shortage or discontinuation:
 - a. Seeking support or advice (including from whom)
 - b. Policies or legislation
 - c. Access to information/data
 - d. Technology
 - e. Other. [TGA WEB PAGE](#)

Communicating about medicine shortages and discontinuations

Effective and timely communication is very important when responding to a medicine shortage or discontinuation.

We would like to explore the challenges, gaps and opportunities for improving the way medicine shortage information is communicated.

Questions

13. Where do you get information about a medicine shortage or discontinuation (select all that apply):
 - **health professional organisations**
 - patient organisations
 - industry organisations
 - the TGA and other federal government agencies
 - state and territory government agencies
 - the media, including social media

- other sources, please specify.

14. What information or updates about a medicine shortage or discontinuation do you find most helpful and from where? ACUTE SHORTAGES URGENTLY COMMUNICATED

15. What challenges do you face when receiving information about medicine shortages or discontinuations? UNDERSTANDING THE TIMING OF RESOLVING THE SHORTAGE TO GUIDE ON CHANGES TO CLINICAL CARE

16. What challenges do you face when sharing information about medicine shortages or discontinuations? DISTRIBUTION OF INFORMATION TO THE COMMUNITY

17. What do you think about the information on the TGA website about [medicine shortages and discontinuations](#)? WELL SET OUT

18. Do you have any suggestions to improve the TGA's communication of this information?

Impact of medicine shortages and discontinuations

Medicine shortages and discontinuations can impact our community in many ways. We want to explore how medicine shortages and discontinuations affect you, and the extent of these impacts.

Questions

19. Over the past 12 months, how much time did you spend on medicine shortages or discontinuations? What activities took the most time? A FEW HOURS

20. What were the most challenging activities and why?

21. Tell us about the health-related impacts of medicine shortages or discontinuations. HIGHLY COMPLEX PATIENTS MISSING KEY THERAPIES

22. Are there other impacts of medicine shortages and discontinuations that you would like to mention? CSANZ SEEK TO BE A KEY STAKEHOLDER IN THE COMMS REGARDING CARDIAC DRUGS

Improvement opportunities

We want to better understand the nature, extent and urgency of medicine shortage problems and challenges currently experienced in Australia, particularly by consumers, health professionals and industry.

We also want to hear about possible opportunities to address these issues, in continued collaboration with the broad range of stakeholders responsible for medicine supply in Australia, including various levels of government, pharmacists, prescribers, medicine wholesalers, sponsors and manufacturers.

Questions

23. What is the biggest problem within the following areas that you want fixed, and why:

- medicine shortages COMMUNICATION OF INFORMATION, UNDERSTANDING SUPPLY CHAIN AND ENHANCING LOCAL PRODUCTION
- medicine discontinuations

c. the broader medicine supply chain.

24. What do you think of the current TGA regulatory framework around medicine shortages and discontinuations?

25. Do you have any suggestions about how to improve medicine shortages and discontinuations in Australia (i.e., what does good management of medicine shortages and discontinuations look like for you)?

26. Do you have any further comments about medicine shortages and discontinuations in Australia?

Consent

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Questions

27. I consent to the collection, use or disclosure of my personal information as set out in the privacy notice and select the following option regarding the publication of my submission (Required):

- Publish my response, including both my name and organisation's name.
- Publish my response, without my name but including my organisation's name.
- **Publish my response, without my name or my organisation's name (anonymously).**
- Do not publish my response.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medicine Shortages Strategy Section / Pharmacovigilance Branch	February 2024

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Reference/Publication D24-331961