



TGA Consultation: Medicine Shortages and Discontinuations - Proposed Changes to Reporting Requirements

January 2025

Response to consultation survey

Issue 1: Monitoring medicine shortages

Question 1: Which is your preferred option?

Option 1

Option 2 - TGA proposal

- a. **Adding 23 registered, non-prescription medicines that are critical to the health of patients in Australia, to the Reportable Medicines Determination (as outlined in Attachment A), and**
- b. **Including a provision in the Act to require sponsors of any approved medicine to provide the TGA, on request, with detailed supply information (i.e. not limited to reportable medicines).**

Option 3

Question 2: Why is this your preferred option?

Formerly known as the Society of Hospital Pharmacists of Australia (SHPA), Advanced Pharmacy Australia (AdPha) is the progressive voice of Australian pharmacists and technicians, built on 80 years of hospital innovation that puts people and patients first. AdPha supports all practitioners across hospitals, transitions of care, aged care and general practice clinics to realise their full potential. We are the peak body committed to

forging stronger connections in health care by extending advanced pharmacy expertise from hospitals to everywhere medicines are used.

AdPha convenes over 30 Specialty Practice Groups, comprising of a network of specialist pharmacists in various specialty therapeutic areas, who promote the health and wellbeing of patients by improving medication management across all care settings.

AdPha is a member of the Medicine Shortages Action Group (MSAG) convened by the TGA. This group is essential in developing timely communication for health professions and consumers on current medicine shortages. AdPha leverages the expertise of its members across a range of Specialty Practice Groups (SPGs) to provide targeted and specialised advice. Additionally, AdPha is a participant in the National IV Fluid Response Group, which has further demonstrated the importance of collaboration and advanced pharmacy practice in addressing critical shortages.

Medicine shortages and discontinuations are increasingly frequent, severely disrupting patient care. In December 2024, the TGA listed approximately 400 medicines as being in short supply, 40 of which are facing critical shortages and discontinuations nationwide.¹ As acknowledged by parties to the First Pharmaceutical Wholesaler Agreement (1PWA), shortages have a significant impact on the health and wellbeing of Australians and, when they occur, they place pressure on other parts of the health care system, including the acute care settings.²

Despite the TGA's efforts to communicate medicine shortages and discontinuations to health professionals and consumers, this information does not always align with the realities faced by clinicians on the ground. A 2022 report revealed that 29% of shortages encountered by pharmacists are not reflected in the Medicine Shortage Report Database, highlighting a gap in real-time data reporting.³

AdPha appreciates the opportunity to provide feedback on the TGA's consultation on medicine shortages and discontinuations, and supports the TGA's focus on the Medicines Shortages Reforms Programs.

AdPha members believe that option 2 represents a pragmatic and balanced approach, considering government funding limitations while targeting critical medicines. AdPha members widely support increased visibility of shortages for critical medicines, as demonstrated by the collaborative responses enabled during recent IV fluid shortages.

To maintain a responsive framework, it is recommended that the TGA retain flexibility to add medicines to the reportable medicines list as new shortages arise. This adaptive approach would ensure that the framework can respond to future challenges without unnecessary delays.

Question 3: What impact would the TGA's preferred option (Option 2) have on your organisation?

The TGA's preferred option (Option 2) would significantly enhance our members ability to plan and implement effective contingency measures to ensure patient safety during medicine shortages. Greater visibility of shortages for critical medicines, as highlighted during the recent IV fluid shortages, enables collaborative approaches to manage supply disruptions effectively. This visibility is crucial for transitions of care – ensuring treatments initiated in hospitals are accessible in the community and preventing situations where patients cannot continue essential therapies. Patients presenting to emergency departments due to lack of access to medicines in the community were cited as a direct consequence of shortages.

Some members noted that while Option 2 is practical given the limitations of government funding and administrative resources, the proposed additions to the reportable medicines list may appear reactive. To maintain a responsive framework, it is recommended that the TGA retain flexibility to add medicines to the reportable medicines list as new shortages arise. This adaptive approach would ensure that the framework can respond to future challenges without unnecessary delays

Issue 2: Medicine discontinuations

Question 4. Which is your preferred option?

Option 1

Option 2 - TGA proposal

Update the Act to require sponsors of all reportable medicines to provide 12 months' notice of a decision to permanently discontinue the medicine (or as soon as practicable after the decision is made).

Option 3

Question 5. Why is this your preferred option?

AdPha strongly supports the proposal to require 12 months' notice for discontinuations of reportable medicines. This extended notice period is critical for patient safety, as it provides adequate time for healthcare professionals to plan safe transitions to alternative medicines and implement governance activities such as clinical consultations, formulary updates, and adjustments to policies and protocols. This extended notice period is critical for patient safety, particularly in palliative care, where medicine shortages can have severe consequences for patients at the end of life.

Members involved in procurement and medicines information services emphasise that early notice is essential to support their roles in mitigating the impacts of shortages and discontinuations. The ability to plan effectively ensures that disruptions to patient care

are minimised, and that treatment continuity can be maintained across healthcare settings.

Option 2 simplifies the reporting framework by removing the need for sponsors to assess the criticality of a discontinuation, reducing the risk of misalignment between sponsor assessments and the realities faced by clinicians and patients.

Question 6: What impact would the TGA's preferred option (Option 2) have on you or your organisation?

The TGA's preferred option (Option 2) would significantly enhance healthcare professionals' ability to mitigate the impact of medicine discontinuations. Members have reported that late or inconsistent notifications hinder their capacity to manage supply disruptions and maintain continuity of care. For example, geographical inequities in medicine distribution exacerbate challenges faced by rural and remote areas. When discontinuations are announced with insufficient notice, these areas experience even greater delays in accessing alternative therapies, leaving vulnerable patients without critical medicines.

Earlier notice provides sufficient time to safely transition patients to appropriate alternative treatments and conduct governance activities, including clinical staff consultations, formulary updates, and revisions to policies and protocols. This extended planning period is essential for ensuring patient safety, reducing disruptions to care, and minimising medication errors. Members noted that frequent switches in brands and strengths led to errors, including tenfold overdoses, highlighting risks of sporadic availability of high-risk medicines.

Additionally, the extra time will enable organisations to manage resource-intensive processes like compounding or repackaging, as seen during the recent morphine liquid shortages. These processes, while necessary to maintain care continuity, require significant planning and coordination that only an extended notice period can provide.

Members emphasised that the proposal simplifies planning and coordination by providing a clear and consistent timeline for discontinuations. This ensures health professionals have the time and information needed to respond proactively to changes in medicine availability.

By improving predictability and enabling proactive decision-making, this proposal strengthens patient care and supports continuity of treatment across healthcare settings.

If you have any queries or would like to discuss our submission further, please contact Jerry Yik, Head of Policy and Advocacy at policy@adpha.au

References

¹ Therapeutic Goods Administration (TGA). (2019). Management and communication of medicine shortages and discontinuations in Australia: Guidance for sponsors and other stakeholder bodies. TGA, Australia

² Department of Health and Aged Care. (2024). First Pharmaceutical Wholesaler Agreement (1PWA). Agreement between the Commonwealth of Australia and the National Pharmaceutical Services Association Limited. Available at: <https://www.health.gov.au/sites/default/files/2024-12/first-pharmaceutical-wholesaler-agreement-1pwa.pdf>.

³ The Pharmacy Guild of Australia, SHPA, PSA. (2022). Medicine shortages in pharmacy – a snapshot of shortages in Australia August 2022. Available at: <https://adpha.au/publicassets/246079bb-5d23-ed11-910a-00505696223b/Medicine-shortages-in-pharmacy--A-snapshot-of-shortages-in-Australia.pdf>