



Medicine shortages and discontinuations: Proposed changes to reporting requirements

In January 2025, Cancer Council Australia and the Clinical Oncology Society of Australia together completed a submission to the Department of Health and Aged Care and Therapeutic Goods Administration (TGA). The *Medicine Shortages and Discontinuations* consultation aimed to investigate regulatory, digital and process improvements to the monitoring of medicine shortages and discontinuations in Australia, and to support mitigating actions. The consultation sought feedback on proposed improvements to TGA's regulatory framework for medicine shortages and discontinuations in Australia.

We agreed with the changes proposed by the TGA for monitoring medicines shortages and handling medicine discontinuations, with the submission highlighting the following areas:

- Support for the proposed 23 new additions to the Reportable Medicines Determination, including those that are used to help manage side effects of chemotherapy treatment, however regular review of this Determination is needed.
- Emphasis on the prolonged gap in access for rural patients accessing medicines exacerbates the impact of shortages and disruptions, highlighting a critical need for more equitable solutions across all regions.
- Reinforcing that improved reporting of medicines shortages does not resolve the potential for resultant increased out-of-pocket costs that are borne by Australians when a shortage occurs. More must be done to ensure that people can access alternative medicines in the event of a shortage, without additional financial or logistical burden.
- Support for the 12-month lead-time for discontinuations is favourable as it provides practitioners sufficient time to assess alternative options for their patients, helping to mitigate patient concern and anxiety.
- Calling for further consideration of sponsors providing additional information about why the medicine was discontinued, as this would be highly beneficial and would aid in medication planning, fostering greater trust in the system among healthcare providers and the public.

Information about the progress of the consultation can be found on the TGA's consultation's webpage: <https://consultations.tga.gov.au/tga/monitoring-medshortages-discontinuations/>