Response ID ANON-TKS9-WDUW-J

Submitted to Consultation: Improved sharing of information about medical devices | Proposed amendments relating to transparency of disruptions to supply of a medical device
Submitted on 2026-02-19 16:09:39

Introduction

About you

What is your name?:
[redacted]

What is your email address?:
[redacted]

Are you responding as an individual or on behalf of an organisation?

I am responding on behalf of an organisation. This means I am authorised by the organisation to convey its views, and I am only providing those views in the response.

If you are responding on behalf of an organisation, what is the name of the organisation that you represent?

Please enter your organisation name:
[redacted]

Select one (or more if applicable) of the stakeholder groups that best describes you or your organisation:

[redacted]

Specify 'Other' in the box below:

Privacy and Personal Information

I CONSENT: to my response being published but no identifying data.

Have you provided consent but there are particular questions you don't want us to publish?:

The TGA is aware that Artificial Intelligence (AI) may be used to assist in preparing responses to this consultation. It is a respondent's responsibility to ensure the accuracy of their response.

I acknowledge that I am responsible for reviewing and confirming the accuracy and completeness of my submission, accepting full responsibility for its content. I may have used AI in preparing my response; where AI has been used, I confirm that the content has been reviewed and confirmed by me.

Questions 1 and 2

1 Do you agree that the TGA should release information about medical devices for the purpose of managing shortages or disruptions to supply?

Yes

a. Please explain your answer (optional):

• Medical device shortages, supply disruptions, and discontinuations can significantly affect healthcare facilities' ability to provide health care and services, including in the public health system.
• Even if a medical device supply disruption affects a specific subset of customers/healthcare facilities, its impacts can affect the health system nationally and globally by shifting demand to other devices and reducing overall availability.
• Medical device shortages, supply disruptions, and discontinuations that affect clinical service-provision by private healthcare facilities can increase demands on the Australian public health system.
• It can be challenging for healthcare facilities and state/territory health departments to obtain clear, consistent, and reliable information from medical device sponsors and suppliers about the extent of supply disruptions, including about the range of devices affected and the anticipated duration.
• Obtaining information about potential alternatives to medical devices that are unavailable or in limited supply can also be challenging and time-consuming. This can delay healthcare facilities' sourcing of alternatives for clinical/technical evaluation and potential deployment, and thereby hinder service continuity.
• As the national medical device regulator, the TGA is well-placed to obtain and provide consistent information to state/territory health departments and healthcare facilities to assist in the management of medical device shortages and disruptions to supply.
• We appreciate the TGA's powers to compel medical device manufacturers and sponsors to provide information about medical device safety, quality, and performance. In principle, we would support strengthening these powers to include compelling medical device manufacturers and sponsors to provide information to the TGA about medical device shortages, supply disruptions, and discontinuations.

• The medical device shortage, supply disruption and discontinuation information published by the United States' Food and Drug Administration (US FDA) and by Health Canada may provide useful background for Australian jurisdictions. However, overseas data is insufficient to inform health services' assessment of the local impacts of supply disruptions.

2 Should the information be released publicly or be limited to specific stakeholders only?

Yes

a. Please explain your answer (optional):

We support either option (public release or stakeholder-specific release) in principle, providing that stakeholder-specific release would always include state and territory health departments, and that those departments retain the ability to share the information internally as needed.

If public release discourages sponsors from sharing detailed information about shortages, supply disruptions or discontinuations (particularly where the TGA cannot compel disclosure), there may be a case for preferring stakeholder specific release to ensure sponsors continue to provide fulsome information.

• Public release may increase media and public enquiries directed to state and territory health departments, creating additional administrative burden. If information is released publicly, consideration should be given to the TGA directing public enquiries to the medical device sponsor in the first instance.
• At the same time, directing a high volume of public enquiries to sponsors may divert their operational resources away from addressing the shortage, restoring supply, and providing timely, targeted updates to affected customers and health services. Any approach to public release should therefore consider the risk that increased enquiry loads, whether directed to health departments or sponsors, may slow response efforts during a disruption.
• Medical device sponsors may express concern that information about supply disruptions could be shared with competitors. However, it should be acknowledged that those same sponsors can access comparable information about their competitors, including through US FDA and Health Canada public disclosures.

Questions 3 and 4

3 If we do not make information about disruptions to supply of a medical device publicly available, do you agree that information about supply disruptions should be released to the stakeholders outlined above?

Yes

a. Please explain your answer (optional) :

• Critical stakeholders include state and territory health departments; private and public hospitals; day-hospital facilities; Commonwealth departments; the Public Health Laboratory Network; and sponsors of medical devices that may be suitable alternatives to medical devices affected by supply disruptions. Withholding information from these stakeholders would hinder healthcare facilities' and the public health system's ability to manage medical device supply disruptions and ensure uninterrupted patient care.
• It would be beneficial to provide targeted information to the Australian Medical Association, specialist medical colleges, and Professional Nursing and Midwife Association as required. These stakeholders may provide advice to the TGA and to state/territory health departments, and thereby inform the response to medical device supply disruptions.
• We would also support the TGA's ability to share information with international medical device regulatory counterparts where relevant, particularly as shortages and supply disruptions may have global impacts.

4 Do you have any concerns regarding the proposal for releasing information about disruptions to supply for a medical device?

No

a. Please explain your answer (optional):

Given medical device supply disruptions' impact on the public health system, any potential risk associated with releasing information (e.g. administrative burden of responding to enquiries) appears to be outweighed by the benefits of having data and detail to optimise the system's response.

Questions 5, 6 and 7

5 Do you agree it is appropriate for the TGA to release the information identified above in the event of a disruption to supply of a medical device?

Yes

a. Please explain your answer (optional):

• We support the TGA's proposal to notify sponsors and provide them an opportunity to comment before information is released. In principle, we also support the TGA sharing information with stakeholders on an as needed basis to support timely responses to medical device shortages.
• Providing state and territory health departments and public hospitals with access to the listed non public information would significantly improve the health system's ability to manage disruptions and reduce patient safety risks. This non public information includes, for example:
o specific product line or internal product codes,
o the nature of the shortage (for example, whether it is temporary, long term, or a full discontinuation),
o the reason for the shortage if known,

o availability information, including remaining stock levels and the locations where stock is held,
o estimated dates for when the shortage will begin, worsen, or be resolved,
o confirmation of deletion or removal from the market for discontinued items, and
o details about alternative devices and whether substitute products are currently available.
• While public information is usually straightforward to obtain, these types of non public information are much harder for health services to access. Lack of access to them can delay planning and coordination, hinder clinical and procurement decision making, and ultimately make any supply disruption more severe.

6 Should sponsors of medical devices impacted by disruption to supply be provided with a notice of intent and offered an opportunity to comment on the release of the information?

Yes

a. Please explain your answer (optional):

In principle we would not object to this, provided that the TGA's information release is not delayed by the sponsor. Any medical device supply disruptions with the potential to cause significant or national impacts should be communicated immediately.

A refined approach may be to:
i) Promptly release the information to critical stakeholders (including state and territory health departments), noting that the sponsor has been given a notice of intent and opportunity to comment and that the information may subsequently be updated; and
ii) Once the sponsor has had reasonable time to comment, release the information to additional stakeholders if required. This release could include sponsor comments.

7 Please provide any further feedback or comments you have regarding proposals to collect and share information about disruption to supply of a medical device.

Please provide any further feedback in this field.:

• We strongly support the TGA's proposal to share information about medical device shortages and supply disruptions.
• We would encourage the explicit inclusion of medical device discontinuations (as are published by the US FDA and Health Canada) in the information sought and shared.
Additional input from Supply Chain Branch:
• Vendor□led medical device supply disruptions—particularly those involving contracted products for which no clinically appropriate alternatives exist—pose a significant risk to the continuity of frontline health services.
• Where such disruptions have the potential to halt or materially compromise essential clinical operations, it is imperative that mechanisms exist to ensure access to suitable substitute devices.
• We would strongly encourage the TGA, within its legislative authority, be empowered to require sponsors to provide any known or suitable alternative medical devices which would support national consistency, mitigate critical service interruption risks, and uphold patient safety during severe or prolonged disruptions to supply.