Response ID BHLF-TKS9-WDQJ-1

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 2026-02-26 11:29:49

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:
Olympus Australia Pty Ltd

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

Australian Sponsor

Specify 'Other' in the box below:

Privacy and Personal Information

I CONSENT: I am okay for my response and organisation's name to be published, but not my name.

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

No

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?

Not Answered

a. Please explain your answer (optional):

It would be appropriate for the TGA to release information for the purposes of managing shortages or supply disruptions, however the scope of the requirement must be very clearly defined to include only a subset of devices for specific needs. Requiring notifications to TGA of shortages or supply disruptions for all devices supplied in Australia would require significant resourcing for all stakeholders and be of little benefit.

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

Not Answered

a. Please explain your answer (optional):

Should any amendments requiring notification and release of information proceed, the information should only be shared with specific stakeholders. These

stakeholders should be clearly defined, identified and limited to only those that are necessary.

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?

Not Answered

a. Please explain your answer (optional) :

The list of stakeholders needs to be considered in respect to the scope of the requirement.

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

Not Answered

a. Please explain your answer (optional):

The scope of the proposal is unclear and as such, Olympus has significant concerns. Requiring notifications to TGA of shortages or supply disruptions for all devices supplied in Australia would require significant resourcing for all stakeholders and be of little benefit.

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?

Not Answered

a. Please explain your answer (optional):

The release of information needs to be considered in respect to the scope of the requirement, however the list provided appears to be appropriate.

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):

Yes. Sponsors are the link between the TGA and the manufacturer and are responsible for the supply of the device in Australia. Excluding Sponsors from the process may lead to missing or incorrect information.

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.:

The information provided in this consultation is insufficient for stakeholders to understand the intent or concerns of the TGA.
Reference is made to other jurisdictions that provide supply disruption and/or discontinuation information. The US FDA notification requirement under Section 506J of the FD&C Act only requires this information for devices before or during a public health emergency (PHE). The FDA guidance1 specifies that it is required only for:
- Devices that are critical to public health during a PHE, including those that are life□supporting, life□sustaining, or intended for use in emergency medical care or during surgery; or
- Devices for which FDA determines information on potential meaningful supply disruptions is needed during, or in advance of, a PHE.
In addition, the US FDA have issued a list 2 of those devices, by US FDA product code, for which a notification is required.
Health Canada has also issued a list3 of medical devices that they require notification of shortages and have specified caveats where manufacturers do not

need to report an actual or expected shortage to Health Canada4, including where they:
- anticipate that they can meet the demand for the device (or its components, accessories or parts) within 30 calendar days after the day they anticipate or become aware of the shortage. This includes devices that are on back□order for less than 30 calendar days or

1 US FDA, Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act, Guidance for Industry and Food and Drug Administration Staff, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda□permanent-discontinuance-or-interruption-manufacturing-device-unde issued 7 January 2025, accessed 19 January 2026
2 US FDA, 506J Device List, https://www.fda.gov/medical-devices/medical-device-supply-chain-and□shortages/506j-device-list, accessed 19 January 2026 3 Health Canada, List of Medical Devices – Notification of Shortages, https://www.canada.ca/en/health□canada/services/drugs-health-products/medical-devices/shortages/mandatory-reporting.html, accessed 19 January 2026
4 Health Canada, When to report a medical device shortage, https://www.canada.ca/en/health□canada/services/drugs-health-products/medical-devices/shortages.html, accessed 19 January 2026

- are also a manufacturer of another medical device that can be readily substituted for the device in shortage and are able to meet the demand for this substitute device

The TGA has not indicated:
- the expected scope of devices that would be required to be notified to TGA, or
- the length of time of an actual or expected shortage is expected to last for it to meet reporting requirements.

Should this amendment proceed, Olympus would suggest the following:
- The scope of the requirement is limited only to devices that are relevant for managing a public health emergency.
- The scope of the requirement does not exceed that of any other jurisdiction.
- Sponsors are included in any action / proposed action.
- Communication of shortages, disruptions or discontinuations are only issued to relevant and appropriate stakeholders and include only necessary information.