

Response ID BHLF-TKS9-WDU3-E

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 09:52:32

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?:

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?

Yes

a. Please explain your answer (optional):

Disruptions to supply of medical devices affect procedure planning and scheduling, patient care, bed flow, and overall service delivery. Proactive communication allows surgical services to implement contingency plans, identify alternatives, ensure appropriate patients consent is gained and reduces the risk of last minute cancellations or rescheduling of procedures.

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

Yes

a. Please explain your answer (optional):

Yes, to all stakeholders, in a manner similar expected drug shortages. Information released should include details about the item, the expected duration of the disruption, the reason/s for the supply chain disruption, details regarding equipment failure or operational issues and the anticipated remediation plan

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) :

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):

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):

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. However, sponsors should be notified only if doing so does not delay informing stakeholders

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.: