Response ID BHLF-TKS9-WDUD-Y

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 2026-02-25 16:23:56

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):

The scope should be limited to specific products using a risk-based approach. For example, Health Canadas “List of Medical Devices - Notification of Shortages”. https://www.canada.ca/en/health□canada/services/drugs-health-products/medical-devices/shortages/mandatory-reporting.html The reporting will result in increased workload for both sponsors and the TGA. We also have a concern that the scope may expand beyond initial reporting requirements to other medical devices.

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

Yes

a. Please explain your answer (optional):

Yes, limited to specific stakeholders only.

Information should be limited to the intended users of the products e.g., consumers or health professionals.
For products supplied to health professionals we have the following concerns about information

being released publicly.
• Panic buying/stockpiling — disclosure of availability could worsen shortages.
• Commercial sensitivity — release of stock levels or reasons could harm competitiveness.
• Reputation risk — public “shortage” listings may make sponsors look responsible even when they are not.
• Misinterpretation — supply issues could be mistaken for safety problems.
• Loss of control over messaging — TGA may frame the issue differently to sponsors.
• Alternatives listed by TGA — concern about incorrect or unfair competitor suggestions. This can also put pressure on supply of competitor alternatives, leading to further shortages in the market. This is often due to insufficient time or warning being provided to the alternative manufacturer to increase supply/availability.

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?

No

a. Please explain your answer (optional) :

This approach may cause panic and confusion. We often experience this with market actions when recall state coordinators are involved – the letter is sent to all departments including those that are not affected by the market action.

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

Yes

a. Please explain your answer (optional):

See response to Questions 1 , 2 & 3.

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?

No

a. Please explain your answer (optional):

We agree Information that is already publicly available may be released. We do not agree with the release of information not publicly available. The reasons we do not agree are listed in our response to Question 2 (e.g., reputation risk, commercial sensitivity).

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):

This is an important step to ensure the information being provided is accurate and does not misrepresent the disruption.

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.:

1) Limited guidance has been provided on what will be the criteria to trigger a market notification i.e. duration of disruption, volume used in the market, clinical criticality, limited availability of alternatives in the market etc.
[redacted]
2) Contractual obligations exist between the sponsor and customer (hospital). Within sales contracts there is often a requirement to provide similar notifications directly to the tender board and/or customer.
3) Most disruptions are temporary therefore how will this be managed and displayed on the

database?
4) What is the process of updating stakeholders with regards to the supply disruption?