Response ID BHLF-TKS9-WDUX-K

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 16:18:03

Introduction

About you

What is your name?:
Aileen O'Connor

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:
Pathology Technology Australia

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

Other (please specify below)

Specify 'Other' in the box below:
IVD Industry Organisation

Privacy and Personal Information

I CONSENT: I am okay for my response, name and organisation's name to be published.

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):

Yes, but while adhering to a risk-based criteria.

PTA recognises the TGA's and government intentions to be informed of supply disruptions that could significantly impact Australian patients. This could be achieved on a voluntary basis if Australian sponsors are provided very clear and practical criteria guidelines, which support a patient-centric approach in the management of any supply disruptions.
Should mandatory regulations be pursued, PTA strongly recommends that reporting obligations be narrowly targeted, that is, limited to supply disruptions or discontinuations affecting sole-source or pre- identified critical IVDs, where patient risk is highest. PTA believes that adopting a risk based predetermined list like the Health Canada Model, that would identifie specific critical IVD's and the criteria in which reporting would be required, would align with PTA's core commitment to patient safety and ensuring uninterrupted access to essential IVD's.

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)

PTA is not supportive of full public release of product disruption information. A significant proportion of IVD's on the Australian market are commercialised and intended for Healthcare Professional Use only and clearly labelled as not for public use. Under current legislation, these products cannot be advertised to the general public. Publicly disclosing any supply disruption carries a risk of causing undue anxiety and unwarranted concern among general consumers who may incorrectly assume that such disruptions may affect their own health needs or the broader public health.
We recommend that release of information is limited to stakeholders who are the intended users or purchasers and/or for the purpose of identifying alternative devices and managing the impact on patients.
Additionally, to enable successful reporting even to limited stakeholders, there needs to be a suitable framework that supports the reason for the disruption, e.g. manufacturing issues, natural disasters, pandemics etc. This needs to assist stakeholders in truly understanding the nature of the supply disruption, reducing any unwarranted concern and to ensure potential actions plans are aligned and proportionate to the cause of the disruption.
Reporting processes should be standardised to ensure consistency in the reporting across sponsors and communications with TGA. Sponsors and stakeholders should adhere to predetermined protocols outlining who will receive the information and at what stage to ensure transparency of communications.

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) :

Please refer to response to Question 2 and the following paragraphs for additional detail.
Reporting processes should be standardised to ensure consistency in the reporting across sponsors and communications with TGA. Sponsors and stakeholders should adhere to predetermined protocols outlining who will receive the information and at what stage.
Even with limited stakeholder reporting, there must be data security and privacy provisions in place to protect sensitive information. Information that is requested by TGA to understand the cause of the disruption may have commercial or contractual restrictions for sponsors. Data security and privacy provisions must be clearly understood and adhered to by all stakeholders. Clear protocols pertaining to the use and distribution of the information would need to be established, as it is vital that this data supplied is used for the disruption in question and no other purpose.
PTA is not supportive of the provision of supply disruptions being provided to an alternative sponsor. This provision of sensitive commercial information by the TGA to alternative sponsors could lead to unfair competitor activities and/or reputational risk for the impacted sponsor.
There must be an ability for the sponsor to be able to vet proposed information to be shared and request a reduction in information supplied to stakeholders, depending on the issue and stakeholders in question.

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):

PTA has several concerns regarding the general principles of this data sharing:
1. Commercial Sensitivity: As detailed in response to Question 3.
2. Lack of defined event criteria and terminology: it is important to distinguish

between temporary shortages and permanent discontinuations, as well as the events that caused them.
3. Data security/privacy provisions: We request greater clarity on the protocols that TGA and their identified stakeholders would implement to ensure information shared did not disadvantage sponsors commercially or reputationally

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):

Yes - subject to the conditions outlined below.

PTA is supportive in principle of this proposal as described in the consultation “not all information will be released to all the stakeholders identified - information will be released to stakeholders on an “as needed” basis for the purposes of managing the impact of the device disruption”. However, PTA urges consideration of a targeted, proportionate, and risk-based framework that reduces reporting complexity and protects patient safety without compromising commercial confidentiality

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):

It is essential that sponsors are provided with a notice of intent.
The sponsor must be able to retain the ability to review proposed stakeholder communications and, where appropriate, be able to limit the level of detail, based on the nature of the disruption and the stakeholder involved if they have sufficiently met the reporting requirements to TGA. This safeguards the accuracy of information released and ensures that sufficient context is provided to the relevant stakeholder to avoid misunderstanding. Effective collaboration between the sponsor, TGA and stakeholders, aligned around the risk to patients, is essential

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.:

PTA recognises the government’s intention to be informed of supply interruptions or product discontinuations that could significantly impact Australian patients. However, members have substantial concerns regarding the extent of commercially sensitive information proposed to be shared across multiple government bodies with little detail on:
• Event criteria (manufacturing versus natural disasters or pandemics)
• Reporting requirements and timelines for the sponsor
• Ongoing obligations placed on the sponsor post reporting
• The selection criteria on Commonwealth departments and non-government and professional bodies as identified stakeholders
• Robust data security and privacy provisions for all identified stakeholders
• Right of reply mechanisms for the Sponsor to notice of intent
• Rationale for sharing additional information pertaining to the product that is not currently required to be publicly available on the ARTG.
While there is not complete alignment with all proposals, there are aspects of this proposal where PTA do align. PTA acknowledges the work the TGA have contributed to this consultation and as always are appreciative of the opportunity to provide feedback and comments on behalf of the IVD Industry.