Response ID ANON-TKS9-WDP9-F

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 2026-01-16 17:47:32

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:
Queensland Health

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

Government agency

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?:

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):

Information from Manufacturers/Suppliers/Sponsors can be sporadic, variable, as their principal objective is likely to manage/protect their commercial outcomes, rather than the TGA/Healthcare system's priority to protect the patient. Some supply disruptions can become critical, pose a serious risk to clinical service delivery and/or patient outcomes, for which often the knowledge of the disruption is only provided when suppliers cannot supply (Leaving no time for mitigation activities to be effectual). Strengthening the TGA's role to enable greater advance notice and transparency of disruptions can only improve a system wide response and subsequently minimise clinical impacts. Also, Sponsors that cover many manufacturers [redacted]

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

Yes

a. Please explain your answer (optional):

Publicly. Having transparency of supply disruptions shouldn't be limited, as that will create a risk of exclusion or an administration burden to manage the specific stakeholder list. Sponsor/supplier push back is likely to prevent reputational harm, or again commercial interests. The public publishing transparency could also elevate Australia to a priority for multinational companies that likely mitigate solutions to markets where their commercial risks are highest.

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) :

For the reason stated before, managing the stakeholder distribution that is likely to change daily, is too burdensome for the TGA - public release prevents this, and ensures that stakeholders who haven't been identified can access the information.

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):

If the release is limited, stakeholders may miss out. If the information does not contain UDI or other identifiers, (e.g. limited to sponsor or ARTG entry information - without product codes - this information will need to be completed through extensive multiplication across the system.

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?

No

a. Please explain your answer (optional):

They can certainly provide comment - but delaying release to await their comment is a significant risk. Release the information, and have a section for sponsors to update as further information is obtained. As per previous answers - Sponsors that cover many manufacturers [redacted] likely would be unable to respond in the timeframes required to prevent clinical disruptions.

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.:

I strongly support this initiative, to ensure commercial interest do not take priority to patient safety, and the value the TGA can play through reduction of duplicated activities, is a system wide benefit.