Response ID BHLF-TKS9-WDQH-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 2026-02-26 11:08:32

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:
AusBiotech

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

Medical device industry organisation or peak body

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):

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

Not Answered

a. Please explain your answer (optional):

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) :

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):

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):

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?

Not Answered

a. Please explain your answer (optional):

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.:

AusBiotech welcomes the opportunity to respond to the consultation about improved sharing of information about medical devices, and in particular proposed amendments relating to transparency of disruptions to supply of a medical device.

In general terms, we are supportive of activities designed to protect public health and safety. Further, our preference, where it makes sense to do so, is for regulatory consistency between medical devices and therapeutics, and for alignment with peer nations globally.

However, based on feedback from some of our members, there may be situations where the release of information about shortages of medical devices to the public may raise unnecessary concern – particularly as many medical devices, unlike most medicines, are not patient-administered, but used in the hospital settings, pathology etc. In such cases, it may be preferable to disclose the information with a defined set of stakeholders (e.g., healthcare professionals) who are skilled in translating medical information into language that is accessible for their patients and who also have the knowledge to discuss alternatives to the device that is in short supply.

Finally, to help ensure the accuracy of any information to be shared - either publicly or with a certain group of stakeholders - and to minimise the potential impact on patient care, AusBiotech recommends that sponsors of medical devices impacted by disruption to supply should have the opportunity to comment before any information is shared.