Response ID BHLF-TKS9-WDQC-T

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 11:02:07

Introduction

About you

What is your name?:
Dr Sarah Raphael

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:
Australian Dental Industry Association

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:
Peak Dental Industry Representative

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):

ADIA supports the release of disruption information in principle, provided the framework is risk-based, targeted to high-impact disruptions rather than applied universally and does not include the release of confidential commercial information.

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

No

a. Please explain your answer (optional):

Information should not be released publicly. Distribution should be limited to relevant government health authorities and healthcare system stakeholders responsible for managing patient care impacts.

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) :

No. ADIA does not support releasing sponsor-provided disruption information to alternative device sponsors, as this creates a risk of disclosure of proprietary commercial intelligence to competitors.

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):

Yes. ADIA's key concerns include competitor access to confidential commercial information, overly broad scope without a risk threshold, and the potential chilling effect on reporting quality if sponsors believe sensitive information will be widely distributed.

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):

No. ADIA does not support release of the full dataset as proposed. Releasable information should be limited to device identification, high-level disruption status, broad timing windows where required for planning, and sponsor contact points. Information such as product line codes used as commercial identifiers, stock levels, stock locations, supplier identities, component sourcing, or manufacturing details should be excluded.

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):

Yes. Sponsors should always be provided notice of intent to publish or distribute disruption information, including the specific data fields to be released, the intended recipient list, and an opportunity to propose redactions.

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.:

The Australian Dental Industry Association supports improved visibility of genuine, high-impact medical device supply disruptions where necessary to protect patient care. However, ADIA has significant concerns regarding the current proposal, particularly the potential sharing of commercially sensitive and proprietary information with competitors and/or alternative sponsors. Such disclosures risk undermining industry cooperation, discouraging timely reporting and creating unintended competitive harm without improving patient outcomes. Dental medical devices are primarily supplied to dental practices, which operate under different substitution and procurement dynamics than hospital systems. As such, a targeted, risk-based framework is more appropriate than a broad, universal information-sharing approach.
ADIA's Core concerns include:
1. Competitor access to proprietary information
The proposal includes potential sharing of disruption information with "Sponsors of medical devices that may be a suitable alternative." In practice, this may result in direct competitors receiving commercially sensitive information including product identifiers, supply timing, and availability details. ADIA notes that for the reporting of a shortage or

discontinuation of a medicine, the TGA recognises that '…commercially sensitive information is for 'official use only' and removed from the published report. Therefore, ADIA does not support disclosure of sponsor-submitted disruption information to alternative sponsors.

2. Over-collection and over-sharing of data

The proposed dataset includes information such as product line codes, detailed reasons for shortages, stock levels and stock locations. Much of this information is not required to manage patient safety risks and increases the likelihood of disclosure of confidential commercial information. ADIA supports limiting the releasable dataset to the minimum necessary information required for clinical continuity planning.

3. Confidentiality and data-security risks

While our members generally have confidence in the TGA's confidentiality arrangements, broader distribution to multiple stakeholders increases exposure risk and may create inconsistencies in information-handling practices. ADIA recognizes that the other agencies that information is shared with may not be able to guarantee the same level of safeguard for the commercial-in-confidence information provided to them. This could endanger the trust industry places in the TGA and potentially compromise existing processes that require information disclosure.

4. The proposed framework is not risk-based

The framework as presented does not incorporate a consideration of risk in the same way as the medicines shortage notification framework, which requires reporting only for the highest risk medicines – Schedule 4 (Prescription Only) and Schedule 8 (Controlled Drugs) medicines, and a specified list Non-Prescription medicines. The framework for medical devices should similarly require reporting for only the highest risk medical devices – Class III and AIMD, and a specified list of Class IIb devices.

ADIA's Recommended approach:

ADIA recommends the adoption of a targeted, risk-based framework including:

• Application targeted to high-risk or critical medical devices used in a hospital setting, identified through defined criteria or a predetermined list.
• A shortage protocol similar to Medicines, that is applied only to higher-risk devices, maintaining the current position of no mandatory reporting for lower-risk classes.
• Consideration of actions taken by the sponsor to mitigate the risks of shortages. For example, if a dental supplier has been able to identify and communicate with all purchasers of a product, advising of a shortage or potential shortage and identifying alternative substitutions, then this should be considered as adequate mitigation of the risk to patients.
• No sharing of sponsor-provided disruption information with any other sponsors.
• Reduction of the external dataset to the minimum necessary fields required to manage patient impact.
• Mandatory sponsor notification prior to any publication or distribution, including an opportunity to review and request redactions of confidential commercial information.
• Clear reporting triggers, definitions, and practical notification timeframes.
• Strong confidentiality, access-control, and audit provisions for any authorised recipients.
• TGA obligation to protect confidential information from unauthorised use or accidental modification, loss or release to ensure that the information is not compromised by the proposed disclosures.

ADIA recommends establishing a defined "critical medical devices" trigger framework that is risk-based, with clear definitions distinguishing shortages from discontinuations, standardised reporting templates, practical notification timeframes, and explicit confidentiality protections across all authorised recipients