Response ID ANON-TKS9-WDU1-C

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 2026-02-20 11:23:15

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:
Medical Technology Association of Australia (MTAA)

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?:

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):

While in principle, MTAA supports TGA's intent to improve transparency and information sharing to better anticipate and manage medical device supply disruptions and support continuity of patient care, our members have raised significant concerns about the practicality of the proposed approach. As it is currently framed in the consultation, it may not achieve these objectives and could introduce unintended operational and commercial consequences. In particular, aspects of the proposal risk creating complexity, uncertainty, and burden without necessarily improving the ability of the health system to prevent or effectively manage shortages.

Before any decision is taken, MTAA would welcome the opportunity for direct dialogue to work through these concerns and explain the practical realities from a sponsor perspective. We believe this engagement would support development of an approach that is workable in practice, achieves the objectives of the consultation, and delivers better outcomes for patients, industry, and the broader health system.

We request clarification on:
1. Whether there is evidence demonstrating that device shortages have directly resulted in immediate patient harm, and how the proposed framework would address such risks more effectively than existing sponsor-led supply management processes. Sponsors already actively communicate with healthcare providers, hospitals, and distributors to manage supply disruptions, including forecasting, allocation, and contingency planning. It is therefore unclear what additional benefit a formalised regulatory reporting framework would provide beyond existing mechanisms.
2. The definition of temporary supply “disruptions”, including clear thresholds and duration criteria, to avoid capturing routine backorders or short term

logistical delays.
3. How the TGA and other agencies would use this information, what specific actions would be taken, and how such actions would enhance supply chain resilience or clinical continuity.

Any framework must be clearly justified, risk-based, and proportionate, and focused on scenarios where regulatory coordination would materially improve patient outcomes.

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

No

a. Please explain your answer (optional):

MTAA strongly supports limiting information release to defined stakeholders on a strictly need-to-know basis, rather than broad public dissemination. Public disclosure of supply disruptions may result in misinterpretation of supply issues as safety or quality concerns, potentially causing unnecessary alarm among patients and healthcare providers and creating unintended market consequences.

Concern was expressed regarding protection of commercially sensitive information. Information such as stock availability, supply forecasts, manufacturing constraints, and supply chain details may reveal confidential commercial strategies or operational limitations. Even where information is shared with limited stakeholders, there is a risk of further dissemination beyond the intended audience, thus any information sharing must include strict confidentiality safeguards, access controls, and clear limitations on onward disclosure.

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) :

MTAA generally supports targeted information sharing where it serves a clear clinical or operational purpose, provided robust confidentiality protections are in place. However, several practical complexities that must be addressed:

• Sponsors may not have full visibility of global manufacturing or supply chain constraints, particularly where devices are manufactured overseas. As a result, reporting obligations may require sponsors to provide estimates based on incomplete or evolving information.
• Multiple sponsors may supply the same or similar devices, and a shortage experienced by one sponsor may not reflect overall market supply availability. Without appropriate contextualisation, disclosure of sponsor-specific shortages may create confusion among healthcare providers and consumers.

We recommend that any stakeholder communication framework clearly define what information will be shared, with whom, and under what circumstances, and ensure sponsors have an opportunity to review and verify information prior to release. Greater coordination between hospitals, distributors, and manufacturers was also encouraged to facilitate redistribution and ensure devices are directed to areas of highest need.

A suggestion is to limit the framework to critical devices or confirmed discontinuations, as there are concerns about the risk of information being shared beyond the intended stakeholder group or used in a commercial context.

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):

Concerns were raised regarding scope, feasibility, and operational impact.

i. The consultation does not clearly define which devices would be subject to reporting requirements. We request clarification on whether the framework would apply to all devices or be limited to critical or high-risk products. We recommend that SaMD and lower-risk devices be excluded from scope, as supply disruptions for these products are unlikely to present significant public health risks and inclusion would impose disproportionate administrative burden without clear patient safety benefit.

ii. If SaMD is intended to be included, “disruption to supply” must be clearly defined in the software context. Unlike physical devices, disruptions to SaMD are more likely to relate to licensing, cloud or service availability, cybersecurity measures, or version transitions, rather than stock or logistics constraints. Any framework applied to SaMD should therefore be limited to circumstances where unavailability poses a genuine public health risk and should not be triggered by routine product lifecycle management, updates, or version changes.

iii. Unlike medicines, many medical devices are not readily interchangeable. For example, implantable devices such as orthopaedic implants require extensive surgeon training, established clinical workflows, and supporting instrumentation. Transitioning to alternative devices may involve significant clinical risk, additional training, and operational disruption. Similarly, software-based devices may have compatibility constraints that prevent substitution. Accessories and component shortages may not necessarily prevent continued safe use of a device for all intended purposes. Regulatory notifications that do not reflect this nuance may create confusion or misinterpretation in the market.

iv. Noting that sponsors already communicate directly with hospitals and customers regarding shortages and alternatives through established, non-TGA mandated channels – continuous reporting and updating of supply disruption information may create substantial administrative burden for sponsors, particularly where supply conditions fluctuate frequently or involve global supply chain variables outside sponsor control.

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):

MTAA suggests that release should be proportionate, limited to necessary data fields, and restricted to defined stakeholders through controlled mechanisms, such as a secure, access controlled portal.

Of particular concern to our members is disclosure of commercially sensitive information, including stock levels, supply chain constraints, and manufacturing details. Such information may have commercial implications and should not be disclosed beyond what is strictly necessary to support clinical continuity. Information regarding alternative devices should be optional, recognising that, as outlined above, suitable alternatives may not always exist or be clinically or operationally appropriate.

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):

MTAA's position is that sponsors must be provided with advance notice and an opportunity to review and comment prior to any release of information. Sponsor input is considered essential to ensure disclosures are accurate, appropriately contextualised, and reflective of the nature, scope, and clinical impact of a 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.:

The proposal may create significant administrative load for sponsors with limited practical benefit. Given the large volume of medical devices supplied in Australia, there is a risk that any database of disruptions could become overly congested and difficult to use. Reporting of temporary disruptions could be voluntary, while discontinuations or permanent withdrawals may be more appropriate for mandatory reporting.

MTAA strongly emphasises that any framework be clearly defined. Specifically, we request:
• Clear definition of what constitutes a reportable shortage or disruption, including thresholds and duration criteria
• Clarification on which device classes and product categories will be in scope, and whether a defined list of critical devices will be developed. While it is understood that the scope may be reviewed over time, MTAA requests that industry be consulted prior to any expansion and given the opportunity to provide input before additional devices or categories are included.
• Consideration of excluding lower risk devices and Software as a Medical Device
• Strong confidentiality safeguards to protect commercially sensitive information
• Recognition of the limitations sponsors face in forecasting global supply
• Confirmation whether scope will be aligned with international approaches such as the US FDA and Health Canada, which limit reporting to defined lists of critical devices.

It is also important to highlight the significant challenges members have experienced under the medicines shortages reporting framework, including ongoing administrative burden associated with continuous updates, lack of clear processes for discontinued products that remain on the ARTG, and requirements to identify replacement products including competitor products. These challenges are likely to be magnified in the medical device context, where direct substitution is often not clinically feasible. Accordingly, careful consideration must be given before applying a similar framework to medical devices, and lessons learned from the medicines model must be addressed to ensure a proportionate and workable approach.

MTAA members broadly support improved transparency objectives, provided implementation is proportionate and risk based. We would welcome the opportunity to engage further with the TGA to ensure any framework is appropriately designed and supports a balanced approach that protects patients, maintains continuity of access to medical devices, and minimises unintended impacts on industry.