Response ID ANON-TKS9-WDU7-J

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 18:51:14

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:
[redacted]

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

[redacted]

Specify 'Other' in the box below:

Privacy and Personal Information

I CONSENT: to my response being published but no identifying data.

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 — where release is risk□based, proportionate, and targeted.

We support proactive information sharing where it improves patient access and system□level planning without generating unnecessary signal noise. Timely, structured transparency enables jurisdictions and healthcare networks to plan substitution and mitigation for genuine, high□risk disruptions before patient harm occurs.
Any reporting or disclosure framework should remain non□mandatory and narrowly scoped, focused on sole□source or clinically critical medical devices where disruption would materially increase patient risk. Broad, indiscriminate reporting risks overwhelming regulators and stakeholders with low□value data and diverting effort away from shortage mitigation.
This approach aligns with TGA's existing risk□based decision logic, where supply impact, criticality, essentiality, and likelihood of patient harm are assessed together, rather than treating all backorders or discontinuations as equal.

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

No

a. Please explain your answer (optional):

A tiered (hybrid) approach is recommended.

A two-tier model balances transparency with responsible information management and shortage prevention:

Public layer: High-level, contextual information only (device name/model, ARTG entry, general description of disruption, anticipated timing).
Controlled layer: Operational and planning data (product codes, availability windows, substitution considerations) restricted to authorised stakeholders directly involved in mitigation.

This structure reduces the risk of public misinterpretation, panic purchasing, and demand distortion, while ensuring that healthcare systems and sponsors can coordinate effectively.
Consistent with a risk-based framework, any disclosure obligation should remain non-mandatory and limited to sole-source or clinically critical devices, avoiding disproportionate reporting across thousands of low-risk products.

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) :

The proposed stakeholders — state and territory health departments, hospitals, professional bodies, and sponsors of alternative devices — are best positioned to make evidence-based allocation and substitution decisions, in collaboration with sponsors.

Targeted information sharing enables:

Rapid clinical planning for sole-source or clinically critical devices.
Coordinated mitigation across networks where disruption poses meaningful patient impact.

Importantly, this approach recognises that shortage identification and mitigation are shared supply-chain responsibilities, not solely sponsor-driven activities.

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 — concerns relate to implementation, not intent.

Key concerns are manageable with appropriate safeguards:

Demand distortion or hoarding if granular stock data are public.
Mitigation: Restrict detail to controlled channels; apply a “minimum necessary” disclosure standard.

Data accuracy and update burden, particularly where shortages are dynamic or mitigated before escalation.
Mitigation: Structured update intervals, clear thresholds for reportability, and validation windows for sponsors.

Commercial sensitivity of SKU-level manufacturing and logistics data.
Mitigation: Limit scope to sole-source or clinically critical devices, consistent with risk-based decision criteria.

Risk of misinterpretation as a recall or safety action.
Mitigation: Maintain explicit separation between supply disruption communications and safety-related regulatory actions.

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 — within a tiered, risk-based release framework.

We support TGA publicly releasing high‑level contextual information only, including:

Device name and model
ARTG entry and UDI
Intended purpose
Sponsor details
High‑level description of the disruption

We support releasing operational detail only to authorised stakeholders, including:

Product codes
Nature, cause, and expected duration of the shortage
Availability windows
Alternative device considerations

These elements should apply only where disruption meets defined thresholds of clinical criticality or sole‑source dependence, ensuring that disclosure remains proportionate and actionable.

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):

Yes — with an expedited but realistic timeline.

A short notice period (e.g. ~7 days) allows sponsors to:

Validate factual accuracy
Align with global supply communications
Provide mitigation context (e.g. alternative SKUs, phased deliveries, local rework)

Given the proposed framework should be non‑mandatory and limited to high‑risk devices, a brief pre‑publication review materially improves accuracy without undermining timely system awareness.

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.:

We recommend that the framework for supply disruption transparency be:
• Non mandatory and risk based, with obligations targeted only to sole source or clinically critical medical devices where disruption materially impacts patient care.
• Structured using a two tier model:
o Public high level notifications
o Controlled stakeholder access for operational detail
• Standardised across sponsors, with defined terminology, disruption categories, and substitution guidance.
• Supported by update SLAs and formal closure notes, ensuring accuracy over time.
• Clearly differentiated from recall or safety related actions to avoid misinterpretation.
• Flexible for sponsors, allowing confidential annexes where sensitive operational detail is required for health system planning.
This approach maximises patient benefit, minimises unnecessary administrative burden, and ensures that the regulatory framework remains risk proportionate and aligned with TGA's existing criticality based decision logic.