# Response ID ANON-TKS9-WDUE-Z

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 2026-02-18 15:18:19

## Introduction

### About you

What is your name?:
Martina Cecconi

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:
Resmed

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

Manufacturer (Australian), Manufacturer (Overseas), Australian Sponsor

Specify 'Other' in the box below:

### 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):

Yes , with a proportionate, risk-based framework.
We support the objective of improving transparency where supply disruptions may affect patient safety, clinical decision-making, or continuity of care. However, transparency mechanisms should be risk-based and aligned with international regulatory models to ensure proportionality and avoid unnecessary reporting of minor or short-term supply fluctuations. International comparators such as the European Union (MDR Article 10a) and Canada have adopted targeted approaches that focus on clinically meaningful disruptions( interruption /discontinuation could result in serious harm or a risk of serious harm OR included in a list of critical devices) .TGA should avoid a blanket requirement across all ARTG entries and align with risk-based or critical-device-list approaches.

### 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 made publicly available as a default. It should be limited to competent authorities and directly impacted stakeholders (E.g, Sponsors, distibutors Healthcare institutions (HIs) and healthcare professionals (HCPs) directly supplied by the sponsor and impacted by the disruption). This approach aligns with the European Union model under Article 10a MDR, where the manufacturer’s notification obligation is directed to competent

authorities and relevant supply chain actors rather than the general public.
Unrestricted public release of all supply issues creates “noise” that dilutes the signal of genuinely critical shortages (misinterpretation of routine supply variability by the general public) and can interpret commercial strategy as a safety issue.

## 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) :

We support structured and timely communication to relevant stakeholders who are directly responsible for ensuring continuity of patient care and managing the impact of the shortage or disruption on patients and consumers.

Supply continuity is most effectively managed by those directly responsible for procurement, clinical substitution and inventory planning, including healthcare institutions, healthcare professionals, distributors, and relevant health authorities. These stakeholders are best positioned to act on the information about supply disruptions.

Targeted sharing ensures that information is directed to those who can take meaningful action. It also minimises unintended market impacts, avoids unnecessary public concern, and reduces the risk of misinterpretation of temporary or low-impact supply fluctuations.

### 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):

It depends on which information are released, to who and in which timeframe.
As per point above the main concerns are unnecessary public disclosure that creates regulatory “noise”, misinterpretation by the general public and market disruption and risk of premature or inaccurate information . Forecasts about timing and cause of interruptions are inherently uncertain. Public publication of preliminary estimates could mislead clinicians and purchasers if revised frequently, and impose unfair penalties for good-faith forecast change, also may force manufacturer/sponsors to reveal strategic commercial information (manufacturing capacity, global allocation decisions, commercial rationalisation).

## 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):

Conditionally. As discussed in Q2 and Q3, our preferred model is that notification be limited to specified stakeholders that are responsible for procurement decisions, substitution planning, and direct patient management. They are best positioned to assess local impact and communicate appropriately with affected patients. This approach aligns with the European framework, where initial notification obligations are directed to competent authorities and supply-chain actors rather than the general public. Should the TGA determine that public notification is necessary, the proposed combination of publicly available and non-public information may represent a balanced approach. However, public disclosure must be meaningful and contextualised.Without contextual information about the nature and practical implications of the shortage, public notification may provide limited value. In most cases, patients will ultimately rely on their healthcare professional (hence preference for limiting communication to relevant stakeholders) to determine whether a change in therapy or device is necessary. Public disclosure without sufficient explanatory context risks generating confusion without improving patient outcomes.

### 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):

Given these existing obligations for sponsor , it is both appropriate and necessary that sponsors be provided with notice of intent prior to public release of shortage or discontinuation information. Sponsor shall also be responsible to update AusUDID, including status changes such as devices no longer in commercial distribution.

### 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 support the policy intent but highlight several important considerations to enssure clarity, proportionality and alignment.

CLEAR DEFINITIONS: “Anticipated disruption”, “Interruption”, “Discontinuation”, “Shortage”
DURATION THRESHOLD (Critical Recommendation): The framework should focuses on interruptions than can actually result in supply disruption rather than all temporary supply fluctuations. Short-term logistical delays or brief supply interruptions should not generally considered reportable events. We recommend that TGA incorporate a minimum duration threshold in allignement with the EU framework (e.g., disruptions expected to exceed 60 days ) before mandatory notification is triggered. Without such a threshold, the framework may capture routine shipment delays, minor inventory fluctuations,short transition periods between product generations.This risks overwhelming both manufacturer/sponsors and the TGA with low-risk notifications and diluting focus from clinically significant shortages.
AVAILABILITY of SUITABLE ALTERNATIVE (Critical Recommendation): Under the EU model, where a manufacturer supplies a suitable successor or alternative device an interruption would not typically trigger notification.We strongly recommend that the Australian framework incorporate similar exemptions.