Response ID ANON-TKS9-WDU6-H

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 15:47:32

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:
[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?:

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?

Yes

a. Please explain your answer (optional):

Yes, [redacted] would be supportive of releasing limited information to appropriate stakeholders to manage the impact of the shortage and supply disruption, rather than to the general public.
However, rather than this be a blanket approach across all devices, it should be dependant on a risk based approach and the intended use of the medical device as well as on the potential impact of the medical device shortage to the end-user/patient, ie only if the shortage gets classified as having a critical impact (which would require defining, similar to how the Medicines Watch List has been established to set out a list of known critical medicine ingredients). In doing so, consideration should be given on the value of reporting anticipated/realised shortages for lower risk devices (e.g., Class I) when weighing the benefit of market impact to the work required by all relevant stakeholders in complying with reporting requirements . Medical devices and the manner in which they are entered on the ARTG means that for many devices a single ARTG record may cover multiple variants in scope. As the shortage may link to only some SKU's under the ARTG record which cannot be defined by model number or UPI, releasing information directly to the public may cause more confusion and panic. Further, Some medical devices are available on pharmacy shelves and public notification can increase panic buying and only further exacerbate the supply disruption or management of the shortage. We also ask that the TGA carefully consider the procedures and processes which will need to be put in place be clear and not resource intensive or cumbersome as many device sponsors may be distributor companies with limited regulatory personnel. It is also important to acknowledge that regular communication and reporting impose a resource burden on distributors, sponsors, supply chain partners, internal and external to companies, as well as the TGA . Communication responsibilities should be proportionate and practical.

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

No

a. Please explain your answer (optional):

Please see response to Q1 above.

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) :

Please see response to Q1 above.

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):

Please see response to Q1 above.

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):

Please see response to Q1 above.

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):

Sponsors should be notified in advance to verify accuracy and context, and to raise any commercial or patient safety concerns, before decision is made to disclose the information of broader stakeholders. This would potentially help prevent resource-intensive retractions or clarifications post-release, and contributes to efficient, accurate communication for devices supplied in the Australian market.

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.:

TGA need to consider the broad diversity of medical devices and their distinctions from prescription medicines in the Australian context.

Prescription medicines in Australia require a valid script and involve formal communication between pharmacists and prescribers to authorise any substitution when a product is unavailable without a direct alternate. This process helps ensure appropriate care but can also delay patient access to necessary treatment. As such the medicine shortage reporting framework for prescription medicines can provide some assistance for pharmacists and prescribers via structured oversight.

In contrast, medical devices encompass a very wide range of products, from commonly available consumer items to highly specialised, critical devices used in healthcare settings. Most medical devices do not require a prescription or formal verification for substitution, allowing consumers or clinicians to access alternatives without the same requirements that exist for prescription medicines.
Experience with mandatory reporting and public disclosure of prescription medicine shortages through the TGA shortage database, has shown that publishing medicines shortages or notices of limited supply can lead to unintended consequences of panic buying and stockpiling. This can exacerbate supply pressures and delay equitable access. It also has been demonstrated to impact demand forecasting for both the affected product and alternative therapies in the Australian market. This creates additional burdens for medicine sponsors in terms of accurate forecasting, and if additional medicine shortage notices are required.

Given these considerations, [redacted] would like the TGA proposals for medical device supply disruption reporting to consider the following before reaching a decision:

Take a risk-based and differentiated approach, focusing resources on critical or high-impact devices without easy alternatives, rather than applying uniform requirements across all devices.

Recognise the lower level of regulatory substitution control for most medical devices. Any reporting and communication measures should reflect this practical flexibility.