Response ID ANON-TKS9-WDUS-E

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 13:35:37

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:
Roche Products Pty Ltd

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

Australian Sponsor

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?

Yes

a. Please explain your answer (optional):

Roche supports a patient-centred approach in management of supply disruptions to medical devices with the goal of minimising patient impact. However, we advocate for a refined, risk-based approach rather than applying mandatory reporting to all products included on the ARTG.

We suggest adopting a predetermined list, analogous to the concept of Therapeutic Goods (Medicines Watch List) Determination 2018 for prescription medicines or the Health Canada model that identifies specific critical IVDs or devices that meet criteria for high patient risk should a disruption occur.

Risk based mandatory reporting will enable consistency of reporting and clarity regarding supply status which will support resolution efforts. Device inclusions on the ARTG do not provide specificity regarding the exact clinical situation where the device is used. It will therefore be especially important that clear definitions and mechanisms are in place to facilitate identification of “high patient impact” devices and potential alternatives. It is also important that companion diagnostics are considered, specifically where an IVD is required to identify which patients are clinically appropriate for a targeted medicine. In this case a supply disruption of an IVD has the potential to affect the ability for health care providers to appropriately select patients who can receive a given medicine with consequential potential detrimental impacts to clinical management of patients .

Clear definitions and terminology distinguishing potential / anticipated and temporary shortages from permanent discontinuations are also required. Without this clarity, information release may hinder rather than help supply chain management.

Roche has experience in working with TGA in the management of shortages of prescription medicines, including those of high impact during the Covid-19 public health emergency. Our experience with management of shortages of critical medicines has demonstrated that effective management should ideally include early intervention including managing stock inventory and analysing patient impact, collaboration with external and internal stakeholders and a patient-centred approach. These general principles also apply in the context of medical device shortages, particularly those of a critical nature. The overarching goal of reducing patient impact must remain paramount, ensuring any response is proportionate to the duration and magnitude of impact of the shortage for all stakeholders, without enduring unintended consequences of any mitigation to ongoing supply and sustainable access.

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

No

a. Please explain your answer (optional):

Roche advises against full public release of all disruption information. To prevent unnecessary public concern or "panic buying" which can exacerbate supply issues, information should be targeted. We recommend that release is limited to stakeholders who are directly responsible for identifying alternative devices and managing the impact on patients. This could potentially include targeted patient advocacy groups.

Crucially, there must be a transparent framework governing this release, which includes
Sponsor Consent: A mechanism for the Sponsor to confirm agreement with the release and the intended audience
Purpose: Clarity regarding the specific intended purpose of the release to each stakeholder group.
Assurance: Mechanisms to ensure data is used strictly for the agreed scope and confidentiality is maintained.
Data Lifecycle: Notification to the sponsor that the information has been deleted or destroyed once the shortage is resolved.

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 refer to response to question 2.

Sharing with State/Territory health departments and hospitals is logical for mitigation and preparedness and allows for a coordinated approach between States. However, this agreement is contingent upon the implementation of robust data security and privacy provisions.

We seek further clarity on the rationale for sharing data with broader Commonwealth agencies, such as the Department of Industry, Science and Resources (DISR). While we understand the role of the Office of Supply Chain Resilience, it is vital that information is used strictly for managing the specific disruption and not for commercial benchmarking or other unintended purposes. The Sponsor must retain the ability to provide input on the nature and extent of data shared during these cross-stakeholder discussions.

Based on Roche's experience with management of prescription medicine shortages,the role of TGA in convening and facilitating discussion between relevant stakeholders is valuable towards the overall goal of minimising patient impact. The Sponsor of the medical device should have the ability to determine the nature and extent of data shared with other stakeholders.

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):

Roche has concerns regarding the governance and principles of this data sharing:
1. Commercial Sensitivity: The proposal implies sharing potentially commercially sensitive material (e.g. manufacturing details). We are concerned that wider dissemination increases handling and disclosure risks ,particularly through Freedom of Information (FOI) frameworks.
2. Lack of Legislative Detail: The absence of a draft legislative instrument makes it difficult to assess the precise safeguards and limits of the proposed arrangements.
3. Use of Information: We request greater clarity on the "preparedness" application of this data sharing to ensure it does not commercially disadvantage sponsors.

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):

Roche is supportive in principle of this proposal as described in the consultation “not all information will be released to all the stakeholders identified - information will be released to stakeholders on an “as needed” basis for the purposes of managing the impact of the device disruption”. Further definition and clarity of this proposal is required including the ability for the Sponsor to provide input and agreement prior to release of information.

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):

It is essential that sponsors are provided with a notice of intent. This ensures that the information being released is accurate, provides context that may prevent confusion, and allows the Sponsor to flag commercially sensitive data that may not be relevant to the immediate public health response. Experience from management of critical medicine shortages supports the principle of collaboration between stakeholders and coalescence around a common patient-centric goal as being of critical importance. During cross-stakeholder discussions, the Sponsor of the medical device should have the ability to determine the nature and extent of data shared with other stakeholders.

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.:

This response reflects the combined position of Roche Diagnostics Australia Pty. Limited and Roche Products Pty. Limited. Both entities are Sponsors of device inclusions on the ARTG.

In summary, Roche is supportive of the principle of information sharing to enhance health emergency preparedness and patient safety and recognises the value of transparency in mitigating the impact of supply disruptions on the Australian healthcare system.

However, given the inherent complexity of global medical device supply chains and the multi-stakeholder impact of these proposals, we urge the TGA to conduct further consultation on the specific legislative drafting and operational specifics.

We look forward to collaborating with the TGA to refine these details to ensure the framework achieves its public health goals without imposing disproportionate risks on industry.