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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 2026-02-16 20:19:14

Introduction

About you

What is your name?:
Chris Helms

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:
Australian College of Nurse Practitioners

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

Health professional or practitioner or peak body

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):

The Australian College of Nurse Practitioners (ACNP) supports the release of information regarding the management of medical device shortages or supply disruptions. Transparency and public awareness are essential, particularly when care may be delayed or alternative products need to be sourced. Providing this information gives clinicians advance notice to discuss any necessary changes with patients during appointments, helping to prevent further delays and informed decision making.

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

Yes

a. Please explain your answer (optional):

The ACNP agrees with Option 1. Information could be published on the TGA website in a manner similar to the Medicines Shortage Report database. This enables a clear, consistent, and transparent approach and helps prevent the spread of misinformation.

Medical device shortages directly affect patient safety, clinical outcomes, informed consent, and equity of access. Without early disclosure, clinicians are forced into last-minute substitutions, often with unfamiliar or inferior alternatives. Furthermore, proactive transparency supports proactive preparedness rather than a reactive response.

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) :

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):

The ACNP have concerns around commercial or confidentiality issues, for example some information about device suppliers or manufacturing processes may be commercially sensitive and could conflict with confidentiality obligations. Releasing detailed information about device shortages could inadvertently disclose sensitive commercial information, such as proprietary supply chain arrangements, manufacturing processes, or contractual relationships between suppliers and distributors. This may affect competitive dynamics in the market, potentially disadvantaging some suppliers or creating opportunities for stockpiling or price increases. Additionally, manufacturers may be reluctant to provide timely information if they fear commercial or reputational repercussions, which could reduce the accuracy and usefulness of the data provided to clinicians and the public. Clear guidance on what information can be safely disclosed, without breaching commercial confidentiality, is therefore essential.
Example: If a particular brand of hip prosthesis used widely in public hospitals experiences a manufacturing delay and the TGA were to publicly release detailed information about the shortage, including the supplier's name, production site, or contract details, it could inadvertently reveal commercially sensitive information. Competitors might use this information to adjust pricing or marketing strategies, and hospitals might rush to secure limited stock, potentially creating inequities in access. Additionally, the manufacturer might become hesitant to report future delays promptly, fearing reputational damage or market disadvantage, which could ultimately reduce transparency and compromise patient care.

Potential for inequity – Publicly released information may lead to some providers or regions securing alternative supplies faster, creating temporary inequities in access.

Misinterpretation by clinicians or the public – Without clear explanations about a device shortage, clinicians or consumers may misjudge its severity or expected duration, potentially leading to inappropriate changes in care. Additionally, public reporting of shortages may cause unnecessary concern if the information is not appropriately contextualised or accompanied by clear guidance on contingency planning and alternative care options.

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):

Example 1:

During the COVID 19 pandemic, global and Australian healthcare systems experienced significant Personal Protective Equipment (PPE) supply disruptions, driven by unprecedented global demand, constrained manufacturing capacity, and international supply chain issues. The World Health Organisation (WHO) documented severe shortages of PPE for frontline workers worldwide, and Australian reports described challenges in sourcing PPE for rural health services and aged care, as well as difficulties ensuring timely distribution to all eligible groups. These disruptions placed healthcare workers and patients at increased risk of infection and other adverse outcomes due to the use of substandard or improvised protective equipment.10 In addition, the lack of timely and transparent information contributed to anxiety, reduced confidence in the health system, and a loss of trust among both healthcare workers and the public. These experiences highlight the critical need for improved transparency, planning, and resilience in medical supply chains to safeguard workforce and patient safety during periods of disruption.11

Example 2:

During the TGA's review and reclassification of transvaginal surgical mesh implants, many devices were removed from the Australian Register of Therapeutic Goods because they did not meet upgraded safety and quality standards. This significantly reduced the number of approved devices available for women requiring surgery for pelvic organ prolapse or stress urinary incontinence. Clinicians reported that the limited options created challenges in providing safe and timely care, and patients faced delays, reduced choice, and increased anxiety about the safety of available devices. This example highlights how changes in device availability, whether due to supply issues or regulatory action, can directly impact patient safety, treatment access, and confidence in the healthcare system.12

The examples above illustrate that withholding information about supply disruptions can directly compromise healthcare workers' and patients' safety and increase healthcare costs.

Timely and transparent communication from the TGA regarding medical device shortages would:
• Allow hospitals and clinicians to plan appropriately

• Minimise avoidable substitutions and associated clinical risks
• Support informed decision-making and continuity of care for patients
• Reduce system-level downstream costs

For these reasons, we support the release of information by the TGA in the event of medical device supply disruptions.

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):

The ACNP believes that timely and transparent communication regarding disruptions to the supply of medical devices is critical for patient safety. Providing sponsors with notice and an opportunity to comment ensures that any released information is accurate, complete, and does not inadvertently compromise patient care. However, the primary consideration must always be the safety and continuity of care for patients. Rapid access to reliable information allows clinicians, consumers, and healthcare organisations to make informed decisions, mitigate risks, and plan appropriate alternatives, particularly in cases where device shortages could impact ongoing treatment, surgical procedures, or the management of chronic conditions.

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 ACNP commends the insightful consideration that our member NPs bring to our consultation processes. We highlight the critical need to address the ongoing limited awareness amongst the public, government agencies and health professionals regarding the existence, capabilities, scope of practice, and contributions of Australian NPs.