

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 16:44:02

Introduction

About you

What is your name?:

Prema Thavaneswaran

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:

Stroke Foundation

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

Consumer peak body or consumer or patient

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):

We agree that the TGA should release information about medical devices for the purpose of managing shortages or disruptions to supply. This will facilitate greater transparency and effective management of supply disruptions, ensuring patients have timely access to consistent, accurate information, which will build trust and reduce confusion, helping to avoid behaviours such as panic-buying and stockpiling. As a result, disruptions to patient care and risks to patient safety will be minimised. To ensure public confidence, it is critical there is a single version of truth that all health professionals (pharmacists, general practitioners and specialists) are able to refer to and communicate to patients.

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

Yes

a. Please explain your answer (optional):

We believe that in line with other comparable international jurisdictions, information about an anticipated or actual disruption to the supply of a specific medical device should be released publicly, and should not be limited to specific stakeholders only. Health professionals will play a key role in communicating relevant information on shortages or disruptions to supply to patients; however, publishing information on the TGA website in a similar manner to the medicines shortage report database ensures increased transparency, and provides health professionals with an additional, trusted information source to refer patients to. While digital communications such as announcements on the TGA website are very effective at capturing the

attention of a mass audience, it is important to understand that not all patients will be able to access digital devices or have the ability to engage with digital resources. Therefore, it is important that where appropriate, other communication formats such as posters and patient information leaflets and fact sheets are available in settings such as GP surgeries and pharmacies. It is important that this information is also available in accessible formats and in languages other than English (LOTE), to make sure people with disability, Australians that speak LOTE and First Nations Australians, do not miss out on this vital information.

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) :

As defined by the TGA, a medical device can be any product or software that works to achieve a therapeutic purpose in or on human beings, including implantable devices (e.g. pacemakers, artificial joints etc.), in vitro diagnostic devices (e.g. blood glucose meters and test strips, pregnancy test kits etc.) and personal protective equipment (e.g. medical gloves, surgical masks etc.). Therefore, in addition to the stakeholders outlined above, we suggest that information about supply disruptions should be released to the peak bodies for pharmacies and pharmacists in Australia, including the Pharmaceutical Society of Australia, which represents pharmacists, and The Pharmacy Guild of Australia, which represents community pharmacy owners.

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):

As outlined in our response to Q2, we believe that information about disruptions to the supply of a specific medical device should be released publicly, and should not be limited to specific stakeholders only. As such, where appropriate, in addition to the stakeholders outlined above, we suggest that information about supply disruptions should be released to relevant disease-specific peak bodies and patient advocacy groups. These organisations will have a number of different channels through which to communicate information on supply disruptions to their specific patient population, and their families and carers. These include online forums, websites, telephone helplines and support groups. For example, EnableMe, Stroke Foundation's recovery website, which has been co-designed with survivors of stroke, their families and carers, provides videos, podcasts and fact sheets on a wide range of topics impacting daily life after stroke, a community forum to ask questions and share experiences, and an online helpdesk to ask questions of Stroke Foundation health professionals. In addition, Stroke Foundation's StrokeLine service provides free expert information, advice, support and referral to the general public and to survivors of stroke, their families, and carers, via telephone, email, social media and EnableMe.

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):

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, sponsors of medical devices impacted by the disruption to supply, including the sponsors of devices that have been identified as viable alternatives, should be provided with a notice of intent and offered an opportunity to comment on the release of the information, to ensure that this information is accurate and up to date.

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.: