Response ID ANON-TKS9-WDP6-C

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 2026-02-05 07:05:12

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:
Australasian Sleep Association

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 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):

People with obstructive sleep apnoea or chronic respiratory failure are critically dependent on CPAP devices or ventilators to assist their breathing during sleep. Any interruptions to supply could have significant consequences. For example, delaying the discharge to home of patients in hospital, needing provision of a home ventilator prior to being able to be discharged, or requiring patients who have been managed at home to be transferred to hospital for acute care while ventilation is not able to be provided at home.

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

Yes

a. Please explain your answer (optional):

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) :

In the case of CPAP machines or ventilators, this list includes the relevant groups that would need to be advised.

4 Do you have any concerns regarding the proposal for releasing information about disruptions to supply for a medical device?

No

a. Please explain your answer (optional):

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):

Sponsors may have additional information, including knowledge of alternative options or workarounds using existing devices to mitigate the impact of disruptions to supply.

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.: