Response ID BHLF-TKS9-WDQ5-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 2026-02-26 12:53:08

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:
Australian Society of Plastic Surgeons

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):

ASPS supports the proposal that the TGA should release information about managing shortages or disruptions to the supply of medical devices. Transparency in the face of supply chain disruptions is crucial for ensuring that both clinicians and patients are kept informed and can make timely, informed decisions regarding surgical options.

For example, in the event of a shortage of a particular type of implant, surgeons should have access to information about alternative products or supply timelines so that they can plan and manage patient expectations accordingly. This will allow for informed decision-making in clinical practice and improve patient outcomes.

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

Not Answered

a. Please explain your answer (optional):

ASPS recommends that the information be made publicly available, as well as shared with relevant stakeholders. Transparency helps not only healthcare providers but also patients, ensuring that they are aware of any disruptions in the availability of devices that may affect their treatment options.

Public dissemination of information ensures that patients are aware of potential delays or disruptions in supply, which could lead them to seek alternative treatment options or adjust their timelines. In addition to surgeons, other key stakeholders, such as hospital administrators, device suppliers, and regulatory bodies, should also receive the information in a timely manner to manage any ongoing impacts.

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?

Not Answered

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?

Not Answered

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?

Not Answered

a. Please explain your answer (optional):

ASPS recommends the release of detailed and clear information on the nature of the supply disruption, including the specific devices affected, the expected duration of the disruption, the potential impact on patient care, and any recommended alternatives. This is particularly important given the diversity of medical devices used in plastic surgery, many of which are procedure-specific and not readily interchangeable.

Information on the underlying causes of the disruption, such as manufacturing delays or regulatory issues (e.g. alerts and recalls), should also be included when possible. This level of detail allows for a deeper understanding of the issue and aids in strategic decision-making.

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?

Not Answered

a. Please explain your answer (optional):

ASPS believes that sponsors should be notified and given the opportunity to comment before information is released. Sponsors of medical devices, particularly those with the responsibility for the ongoing supply of breast implants, should have the opportunity to provide context, share their efforts to resolve the disruption, and offer alternatives. This collaboration helps ensure that the information released is accurate and reflects the efforts being made to address the supply issue.

However, ASPS recommends that this process should not unduly delay the release of essential information to healthcare providers and patients. The timeliness of information is crucial, particularly when supply disruptions may affect patient access to surgery in a significant way.

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.:

he Australian Society of Plastic Surgeons (ASPS) welcomes the opportunity to provide feedback on the proposed changes to improve transparency about disruptions to the supply of medical devices. ASPS represents surgeons engaged in the field of plastic and reconstructive surgery. While breast implants are among the most commonly used medical devices in plastic surgery, our specialty relies on a wide range of medical devices across reconstructive, trauma, hand, and aesthetic practice.

These include, but are not limited to: breast implants; artificial joints and joint replacement devices used in hand surgery; a variety of surgical meshes used in wound repair, abdominal wall reconstruction; artificial skin substitutes and dermal matrices; facial implants for reconstructive and aesthetic purposes; other aesthetic implants such as calf, pectoral, and buttock implants; and fixation devices and systems used in facial and hand fracture management.

As such, ASPS is particularly concerned with how proposed changes may impact the supply, continuity, and availability of a broad spectrum of essential medical devices.

ASPS Perspective:

Disruptions to the supply of any of the devices outlined above may directly affect patient access to surgery, compromise timely care, or limit appropriate treatment options.

Plastic surgery frequently involves complex, staged, or time-sensitive procedures, such as trauma reconstruction, cancer reconstruction, congenital surgery, and wound management, where device availability is critical to achieving safe and effective outcomes. Any disruption in supply may result in delays, cancellations, changes to operative planning, or the need to use less optimal alternatives.

Therefore, it is crucial that any changes in the regulation and transparency of device supply disruptions are carefully considered with regard to patient welfare, surgeon practice, and the ongoing availability of these devices in the Australian market.

ASPS strongly supports measures that enhance transparency and provide relevant information to both healthcare providers and patients during times of medical device shortages or disruptions. While breast implants are a prominent example, plastic surgeons rely on a wide array of medical devices, and disruptions affecting any of these may have serious implications for patient safety, access to care, and surgical outcomes. Clear, timely, and accurate information from the TGA will help ensure that patients continue to receive the best possible care despite potential disruptions in the supply chain.

We appreciate the opportunity to provide feedback on these proposed changes and look forward to continued collaboration with the TGA to ensure that patients and healthcare providers are adequately informed and supported during times of disruption.