Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Improved sharing of information about medical devices

Proposed amendments relating to transparency of disruptions to supply of a medical device

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

Overview

In 2019, the Therapeutic Goods Administration (TGA) released the *An Action Plan for Medical Devices* (Action Plan), a 3-part strategy designed to strengthen Australia's regulatory framework for medical devices (including *in vitro* diagnostics). The plan emphasises the need for a patient-centred approach and increasing public confidence in the regulation of medical devices through greater transparency.

Section 61 of the *Therapeutic Goods Act 1989* (the Act) facilitates the release of information in certain circumstances. This consultation seeks feedback on proposals to expand our ability to release information about medical devices lawfully to:

- aid in monitoring, assessing, and responding to potential and actual supply disruptions, and
- provide more information to the public following post-market reviews or investigations, particularly where review findings relate to the performance or use of the device.

Background

As a part of the Department of Health, Disability and Ageing, the TGA regulates therapeutic goods including medicines, medical devices and biologicals. We receive information about therapeutic goods from a wide range of sources to assist with assessing and monitoring the safety, quality and performance/effectiveness of therapeutic goods.

The primary source of information about medical devices are sponsors, who are required to provide us with access to certain documents and information to support our role in assessing, approving and monitoring the safety, quality and performance of the medical device. We also have powers to compel information about medical devices from sponsors, particularly when the information relates to the quality, safety and performance of the medical device. This information may be held by the sponsors, or they may obtain it from the manufacturer of the medical device.

In addition to the manufacturers and sponsors of medical devices, we receive information from other sources including:

- consumers and users of medical devices
- stakeholders involved in the supply and use of medical devices including health professionals and healthcare facilities
- other government authorities and entities who are engaged in healthcare sectors, and
- international regulators in other jurisdictions around the world.

Where there is a need to release information, including to the public, we typically do so under section 61 of the Act. Section 61 outlines the specific circumstances and information that can be released. Generally, these circumstances are connected to our role in securing positive public health outcomes for Australians.

Examples include releasing information to:

- the World Health Organization (WHO) for use in the development of policies relating to therapeutic goods regulation or (in confidence) for proceedings of committees
- other Australian government entities (including states and territories) that have functions relating to therapeutic goods to support those entities with the performance of their own functions
- other therapeutic goods regulators in other countries for the purposes of supporting them in their functions or furthering international co-operation in the regulation of therapeutic goods

- Australian and international law enforcement authorities
- the public where the information relates to the market authorisation status or safety of a therapeutic good.

The problem

Currently the circumstances where we can release information to external stakeholders that are not the manufacturer or the sponsor of a medical device are set out in various parts of the Act and more particularly under section 61. Limitations on the sharing of information under section 61 means information about medical devices generally can't be shared unless:

- a legislative instrument has been made specifying the information that can be shared,
- a regulatory decision about a specific medical device has been made, or
- the information is required to facilitate the safe use of a medical device.

There are 2 further circumstances where the ability to share information about medical devices would enhance our existing ability to protect public health and safety:

1. Disruption to supply of a medical device
2. Device performance concerns.

This consultation paper only focuses on disruption to supply of a medical device. A further consultation paper will be released relating to device performance concerns.

Disruptions to supply of a medical device

Where a decision is made by the TGA to release information about an anticipated or actual disruption to supply of a specific medical device, there are 2 proposed options for releasing the information:

1. Information may be published on our website in a similar manner to the medicines shortage report database.

   OR

2. Information is not made public but release is limited to specific stakeholders who can advise on, or who are responsible for:
   - identifying alternative devices that could be suitable substitutes, and
   - facilitating appropriate management of the impact of the shortage/supply disruption on patients/consumers.

International jurisdictions that currently publish supply disruptions and/or discontinuations on their websites include: the US FDA and Health Canada.

Question 1

Do you agree that the TGA should release information about medical devices for the purpose of managing shortages or disruptions to supply? (Yes/No)

a. Please explain your answer (optional)

Question 2

Should the information be released publicly or be limited to specific stakeholders only? (Yes/No)

a. Please explain your answer (optional)

If information about disruptions to supply for a medical device is not released publicly, we are proposing to release information to stakeholders who:

1. may be able to provide advice about suitable alternative devices that could be used to limit the impact of the shortage or disruption, and/or
2. will be responsible for managing the impact of the shortage or disruption on patients and consumers.

These stakeholders may include:

- States and territory health departments
- Private and public hospitals
- Day-hospital facilities
- Commonwealth departments, including:
  - Department of Industry, Science and Resources (DISR)
  - Australian Centre for Disease Control
- Non-government bodies and professional bodies, including:
  - Public Health Laboratory Network
  - Australian Medical Association
  - Australian Health Practitioner Regulation Agency
  - Specialist medical colleges
  - Professional Nursing and Midwife Association
  - Sponsors of medical devices that may be a suitable alternative to the affected medical device.

Question 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/No)

a. Please explain your answer (optional)

Question 4

Do you have any concerns regarding the proposal for releasing information about disruptions to supply for a medical device? (Yes/No)

a. Please explain your answer (optional)

Where a decision has been made to release information about an anticipated or actual shortage, or disruption to supply of a medical device, we are proposing to release a combination of publicly available and non-public information. Information released will include an explanation that there is, or

may potentially be, a shortage or disruption to supply for a particular medical device. Other information that may be provided includes:

- Information that is already publicly available including (but not limited to):
  - Name or model of the medical device
  - Australian Register of Therapeutic Goods (ARTG) entry
  - Unique Device Identification (UDI)
  - Information about the product's intended purpose including the intended user, target analyte, technology, specimen type (where applicable)
  - Sponsor details
  - Manufacturer details
- Information that may not be publicly available including (but not limited to):
  - Product line or code
  - The nature of the shortage (short term, discontinuation, etc)
  - Reason for the shortage if known
  - Availability (including information about the existence and location of known stock levels)
  - Estimated current or anticipated dates for shortage or disruption
  - Deletion/removal from market for discontinued goods
  - Information about any alternative medical device and the availability of that device including where it is available.

Under this proposal 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.

Question 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/No)

a. Please explain your answer (optional)

Question 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/No)

a. Please explain your answer (optional)

Question 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.

What we invite you to do

In your submission, we ask you to consider and respond to the questions outlined above and to provide any comments on the proposed changes.

How to submit your feedback

Your feedback will help inform advice to the Australian Government regarding any proposed changes to the medical devices regulatory framework. In addition to the scope of the consultation, we welcome your feedback on the consultation process.

You can review the consultation on our consultation hub and submit your feedback by using our online survey tool or email your response to devicereforms@tga.gov.au.

Participation and feedback provided during this consultation is greatly appreciated. Following internal review of feedback received, the consultation outcomes will be published on our website. This is expected to occur in 2026.

Please direct any queries via email to devicereforms@tga.gov.au.

This consultation closes at 23:59pm on 20 February 2026.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration (TGA)	7 January 2026

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication # D25-5189581