

Response to the Therapeutic Goods Administration (TGA) consultation on 'Improved sharing of information about medical devices - Proposed amendments relating to transparency of disruptions to supply of a medical device'

Questions 1 and 2

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:

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

OR

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](#).

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

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
- No

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

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.

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

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
- No

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 and 6

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.

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

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
- No

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.