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

Improved sharing of information about medical devices

Proposed legislative amendments to publish safety, quality or performance concerns

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.

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Overview

In 2019, the Therapeutic Goods Administration (TGA) released the *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 medical devices). The plan emphasises the need for a patient-centred approach and increasing public confidence in the regulation of medical devices through greater transparency.

Due to current legislative constraints, the TGA experienced challenges in publishing information during the COVID19 pandemic relating to the safety, quality or performance of certain medical devices. The TGA worked closely with sponsors and manufacturers and health authorities to share information where possible to support pandemic responses to occur in a timely way. These challenges with the legislative constraints still exist including where regulatory action has been undertaken.

Transparency of information has been recently outlined in the World Health Organization's Global Benchmarking framework. [1] The framework is intended to strengthen regulatory systems globally so that medical devices are safe, effective, and of assured quality, both before and after they reach the market, whilst also enabling regulatory reliance between countries. The Global Benchmarking assessment requires that national regulators have robust mechanisms for communicating and being transparent with healthcare professionals and the public.

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 make amendments to the legislation to allow the TGA to release more information about medical devices, specifically to:

- provide more information to the public following post-market reviews or investigations, particularly where review findings relate to the safety, quality, performance or use of the device.

The TGA has previously consulted separately on releasing information to support management of disruptions to the supply of medical devices. Outcomes have been published on the TGA Consultation Hub.

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 (including *in vitro* diagnostic 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

[1] World Health Organization *Global Benchmarking Tools* https://www.who.int/tools/global-benchmarking-tools

- other government authorities and entities who are engaged in healthcare sectors, and
- international regulators in other jurisdictions around the world.

Much of the information we receive about therapeutic goods is considered to be commercial-in-confidence by the sponsor of the goods. For this reason, we can only release particular information in specific circumstances. Generally, these circumstances are connected to our role in supporting public health outcomes for Australians.

Examples where we can share information include:

- using section 61 of the *Therapeutic Goods Act 1989* (the Act) which allows sharing of information in a range of circumstances including with:
    - 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
- through a valid Freedom of Information process
- in response to a subpoena from a relevant Australian court.

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 explaining 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.

We have identified that sharing information about medical device concerns would enhance our existing ability to protect public health and safety. We consider that sharing information about the medical devices that have been investigated and where no action is required will improve transparency for users including consumers of the products we have investigated and were found to remain compliant and perform as intended, as well as reduce the burden on sponsors and manufacturers. Releasing information would also limit the effort by users including consumers who currently need to seek information directly from the sponsor or manufacturer.

Post-market outcomes

Currently we are only able to release limited high-level information about post-market reviews or investigations of medical devices where a decision has been made under the Act to take regulatory action such as:

- conducting a recall
- issuing a hazard alert, or
- cancelling or suspending the medical device from inclusion in the Australian Register of Therapeutic Goods (ARTG), or
- imposing conditions on the inclusion of the medical device in the ARTG.

Additionally, post-market reviews and investigations do not always result in a regulatory decision and may lead to the identification of other regulatory concerns or voluntary sponsor actions such as updating the Instructions for Use for the device. The TGA often find that many medical devices are compliant with legislative requirements and perform as intended. In these situations, we can only provide generic information about the kind of device to the public and not provide all the positive findings for these medical devices.

Example of published information

An example of general advice and information we have issued includes information about breast implant illness experienced in individuals who have received breast implants, or our post-market reviews where we have only published information on the medical devices where we have taken regulatory action. There is a gap of publishing information on the medical devices that have been reviewed and there has not been regulatory action taken. This can be confusing and could generate questions where no information is available about our review of these devices.

In some circumstances, we have published more information that did not relate to regulatory decisions, as the information related to the safe use of those medical devices and was in the context of public health concerns, such as pandemic illnesses COVID-19 and influenza.

Our web pages for medical device post-market reviews often contains the information in blue text below in the table. We are proposing to expand this to include information on the devices where regulatory action was not taken (represented in italics):

ARTG	Sponsor	Manufacturer	Device name	Models	Status / outcome
123456	PointyDevices	PointyProducts	Surgical tool	Sharp1 Sharp2	Additional Conditions of Inclusion (COI) have been imposed on the ARTG entry. The COI requires the sponsor to provide additional information, such as additional studies, to the TGA at specified time points.
234567	BluntDevices	BluntProducts	Surgical tool	Blunt1 Blunt2 Blunt3	Blunt1 has been cancelled from the ARTG by the TGA. The sponsor provided insufficient information to demonstrate compliance with the requirements. *All other models are compliant with the requirements.*
345678	*CurvedDevices*	*CurvedProducts*	*Surgical tool*	*Curve1*	*Review complete – compliant with the requirements*

456789	*LoopedDevices*	*LoopedProducts*	*Surgical tool*	*Loop1*	*Review complete – compliant with the requirements, Training materials updated for when used with automated devices.*
567890	*InvitroDevices*	*InvitroProducts*	*Virus Test*	*Test 1 Test 2*	*Review complete – compliant with the requirements. The instructions for use for Test 2 indicate there is reduced sensitivity for the WeirdStrain Virus. Test 1 remains sensitive to all currently circulating strains of the Virus.* *OR* *Review complete – performance of test has been validated against variants A and B. No impacts identified on performance for Test1 or Test2. Compliant with the requirements.*
101112	*MrJoint*	*JointDevices Inc*	*Knee Joint*	*Mr Joint 1*	*Review complete. The review identified Mr Joint 1 has a higher-than-expected rate of revision. However, Mr Joint 1 is used for a specific cohort of patients and the overall benefits outweigh the risks associated with its use.*

Within Australia there are already measures in place under the Therapeutic Goods (Listed Medicines – Compliance Reviews) Specification 2019 allowing us to share specific information about compliance reviews conducted on listed medicines. We are proposing to amend our current legislation to allow the publication of more explicit information about post-market reviews and their outcomes to improve transparency.

This may include information:

- identifying the specific devices that were the subject of the review,
- explaining how the device(s) reviewed met the requirements for quality, safety and performance,
- the safe use or performance of the device, and
- potential limitations if the device is used in particular circumstances or by individuals who do not have explicit training in the use of the device.

Question 1

Do you agree generally to the sharing of information for the purpose of providing the public with more information about the medical devices included in a post-market review or investigation? (Yes/No)

Why/why not?

Release of information

Where a post-market review or investigation has occurred, we are proposing to share a combination of publicly-available and non-public information. Information proposed to be released will include explaining why we reviewed or investigated the medical device and what the outcomes were.

Information that is already publicly available includes, but is not limited to:

- Name or model of the medical device
- ARTG entry
- Sponsor details
- Manufacturer details
- Information about the product's intended purpose, which may include the intended user, target analyte, technology, specimen type (where applicable).

Additional information that we currently publish when a regulatory decision is made, and are proposing to extend to all medical devices in a medical device post-market review or investigation includes:

- Reason for the review or investigation
- Manufacturing information such as conformity assessment certification status or component materials (for example, whether breast implants are filled with silicone or saline, or whether thermometers contain or do not contain mercury), or if the device contains software or uses artificial intelligence, or where an in vitro diagnostic medical device has limited sensitivity (for example, where some COVID-19 self-tests are not sensitive a particular strain of circulating virus). We are not intending to publicly release commercially sensitive information (such as, detailed formulations of materials or target analytes).
- High level details of findings (including positive findings where no regulatory action was required)
- Review outcomes.

Question 2

Please select the type of information you agree would be appropriate to share publicly when undertaking a medical device post-market review or investigation?

Already public information:

- ARTG entry
- Name or model of the medical device
- Sponsor name
- Manufacturer details
- Intended purpose

Additional non-public information:

- Reason for the review
- Manufacturing and device information
- Findings including reason for regulatory action
- Review outcomes

Are there other types of information that would be of benefit to share?

Question 3

Please provide any further comments or feedback regarding this proposal.

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@health.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 late-2026.

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

This consultation closes at 23:59pm on **2 October 2026**.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration (TGA)	13/08/2026

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