29 September 2026

Medical Devices Surveillance Branch
Therapeutic Goods Administration
Department of Health, Disability and Ageing

Via email to: devicereforms@tga.gov.au

To whom it may concern,

Re: Response to Public Consultation on Sharing More Information About Medical Devices

Assistive Technology Suppliers Australia welcomes the opportunity to respond to the Therapeutic Goods Administration's consultation on sharing more information about medical devices.

ATSA is Australia's national peak body representing assistive technology suppliers, manufacturers, importers, distributors, retailers, service providers and technicians. Many products supplied and supported by ATSA members are regulated as medical devices. Assistive technology users may depend on these devices for mobility, communication, personal care, independence and safety. ATSA therefore supports greater transparency where it provides consumers with accurate and useful information without unnecessarily disrupting access to devices that remain safe to use.

Consultation 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? Why or why not?

Yes.
ATSA supports providing the public with more information about medical devices included in post-market reviews or investigations.

ATSA supports a targeted amendment to the legislative framework to address the current restrictions on releasing information. In particular, the TGA should be able to publish the outcome of a completed review where a device was found to be compliant or no regulatory action was required; including where no formal regulatory decision has been made.

This aligns with the expectations around transparency and communication described in the World Health Organization's Global Benchmarking Tool, *GBT+MD, for evaluation of national regulatory systems* of medical devices.

Greater transparency about the safety, quality, performance and use of medical devices will help consumers, health professionals, suppliers and service providers make informed

decisions. It should also reduce uncertainty and the direction of unnecessary enquiries to sponsors and manufacturers.

Published information should clearly distinguish a review that is underway from confirmed non-compliance, voluntary action, formal regulatory action, a finding of compliance or a finding that no regulatory action was required. The mere existence of a review does not establish that a device is unsafe or non-compliant.

Consultation 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. Is there any other information that would be beneficial to publish?

ATSA supports publication of all categories proposed in the consultation paper, including:

- The Australian Register of Therapeutic Goods entry
- Device name or model
- Sponsor and manufacturer details
- Intended purpose
- Reason for the review
- Relevant manufacturing and device information, and
- Findings and review outcomes.

ATSA supports publication of relevant high-level manufacturing and device information, such as:

- Conformity assessment status
- Relevant component materials
- Whether the device contains software or uses artificial intelligence, and
- Identified performance limitations.

Detailed technical, proprietary or commercially sensitive information that is not necessary to explain the findings or support safe use should not be published.

Other information that would be beneficial

Where relevant, the TGA should also publish:

- The status of the review and relevant dates
- The specific models, versions, components or configurations covered
- A plain English explanation of the findings and their significance
- Whether the device was compliant or regulatory action was required
- Any voluntary action or limitations applying to particular users, configurations or circumstances
- Practical advice for consumers, health professionals, suppliers and technicians

Information should identify affected products as precisely as possible. Many assistive technology products are adjusted, programmed or combined with other components for an individual user. A concern may apply to a particular component, accessory, software version, configuration or condition of use rather than every device sold under the same product name.

Providing appropriate context

Where reported incidents or safety data are published, the TGA should explain

- Their nature and seriousness
- Any limitations in the evidence, and
- Whether the device was established to have caused or contributed to the outcome.

Incident numbers should not be presented without this context.

Findings should also distinguish between a concern with the device and an issue arising from product selection or prescription, sizing, configuration, installation, training, servicing, repair, maintenance, modification, software, accessories, telecommunications or power failure, or use outside the intended purpose. This will help consumers understand the actual risk and reduce the likelihood that a safe and effective product is unnecessarily discontinued.

Where published findings draw on information or action from an overseas regulator, the TGA should identify the relevant jurisdiction and explain whether the same findings or regulatory action apply in Australia.

Information published during a review

Detailed information about a post-market review should generally be published after the review has been completed and its findings established. Publishing information earlier may cause unnecessary concern, reputational harm or disruption to the supply and use of a device before the facts have been determined.

An exception should apply where the TGA reasonably considers that earlier publication is necessary to protect public health or safety. Any interim information should:

- Be clearly identified as preliminary
- Explain why publication before completion of the review is necessary
- Distinguish matters under investigation from confirmed findings
- Describe any immediate action consumers or other stakeholders should take
- Avoid identifying a broader range of products than the available evidence supports.

The TGA should update interim information promptly. Once the review is complete, the final outcome should be given the same or greater prominence and linked clearly to any earlier information.

Consultation question 3: Please provide any further comments or feedback regarding this proposal.

Fair processes for sponsors and manufacturers

Except where urgent publication is required to protect public safety, sponsors should have a reasonable opportunity to check information for factual accuracy before it is published. This should allow sponsors to:

- Correct factual errors
- Confirm the products covered
- Provide relevant technical or clinical context, and

- Identify genuinely commercially sensitive information.

The purpose of this process would not be to override the TGA's findings, prevent publication or delay urgent safety communication. It would aim to improve accuracy and recognise that an Australian sponsor may need to obtain information from an overseas manufacturer.

The TGA should also provide clear guidance on commercial sensitivity and establish a timely process for correcting inaccurate or outdated information. Standard timeframes, coordinated information requests and a nominated TGA contact would significantly improve the experience of sponsors without reducing consumer protections.

Supporting consumers and the supply chain

Suppliers and technicians may be the first point of contact for consumers following publication of a safety concern, even where they are not the sponsor. Public information should therefore identify the action expected of consumers, health professionals, sponsors, suppliers and technicians. Where supply-chain action is required, sponsors should receive reasonable advance notice wherever practicable so that consistent information can be distributed, without delaying urgent safety communication.

Where a person relies on a device for daily safety or independence, advice should consider the risks of abruptly discontinuing its use. It should explain whether the device can continue to be used, whether precautions, corrective action or an alternative arrangement are required and who the user should contact.

Telecommunications-dependent medical devices

For devices that depend on telecommunications connectivity, published information should identify any network, compatibility, power or backup requirements affecting safe operation. It should distinguish a device defect from a problem caused by network availability, configuration or an external outage and explain any action users, suppliers or technicians should take.

Accessibility and implementation

Information should be published through one authoritative and searchable source, written in plain English and available in accessible HTML rather than PDF alone. Users should be able to search by device name, model, manufacturer, sponsor and Australian Register of Therapeutic Goods entry. An email alert or subscription option should also be considered.

Before implementation, the TGA should consult consumers, sponsors, manufacturers and relevant industry bodies on the publication framework, standard terminology, factual verification process and correction mechanism. The process should be proportionate and avoid unnecessary administrative burden.

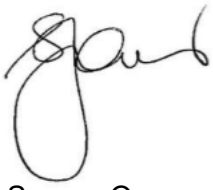
Concluding comments

ATSA supports the proposed changes outlined in the consultation paper, subject to the safeguards outlined above. A carefully designed publication framework will give consumers

access to more complete and useful information while ensuring that sponsors, manufacturers, suppliers and technicians are treated fairly and can communicate effectively with device users.

ATSA would welcome the opportunity to contribute to the development of the supporting guidance. For further information, please contact Lauren Henley, Director of Policy and Advocacy, at lauren.henley@atsa.org.au.

Yours Sincerely,



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