Information session

Sharing information about the safety, quality and performance of medical devices

Dr Tania Ahmed
Acting Director
Medical Device Surveillance Branch
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Acknowledgement of Country

In the spirit of reconciliation, the Department of Health, Disability and Ageing acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

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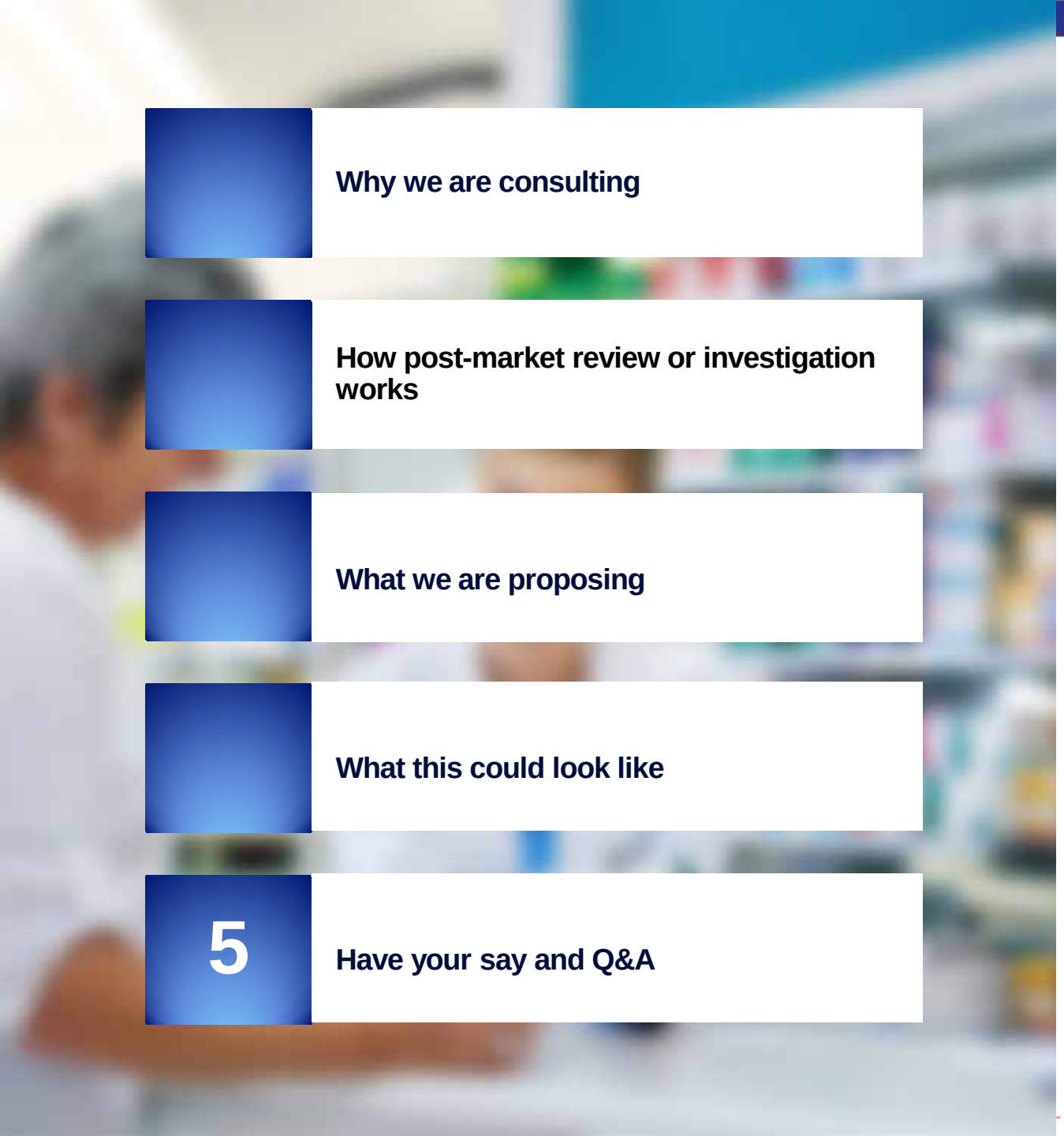


1. Why we are consulting
2. How post-market review or investigation works
3. What we are proposing
4. What this could look like
5. Have your say and Q&A

Webinar objectives & overview

A public consultation on ‘Sharing more information about medical devices’ was released on 13 August 2026

The consultation can be found: consultations.tga.gov.au/

Why are we consulting?

Consumers, healthcare professionals and other stakeholders are telling us they want more information about the safety and performance of medical devices and investigations the TGA may be undertaking.

Current legislation can limit what the TGA can publicly share about medical device post-market reviews, findings and outcomes

Why this matters

Understand what happened

Public may reasonably want to know why a device was reviewed and what the TGA found

Make informed decisions

Better information helps patients and health professionals make informed decisions

Build public confidence

Greater transparency strengthens confidence in our regulatory oversight

We are consulting on whether the TGA should be able to share more information about medical devices

What happens in a post-market review or investigation?

1

A signal or new information

Reports, data, overseas action or other signal may trigger a review

2

TGA reviews the evidence

We look at the evidence and assess its compliance for safety, quality and performance

3

We reach an outcome

The outcome depends on what the evidence shows

Possible outcomes or findings

Action needed
A safety, quality or performance signal requires regulatory or corrective action

Changes may be needed
Information, labelling, instructions for use, design or manufacturing may need to be updated to address an identified

Device is performing as intended
The review finds the device remains compliant and no regulatory action is needed

What information is publicly available?

We can usually publish high-level information when:

- A recall occurs
- A safety alert is issued
- Regulatory action is taken

What can’t be always shared publicly?

We can’t always share detailed information from a post-market review or investigation, including when:

- No regulatory action was needed
- The device remained compliant
- Detailed findings and reasons for regulatory action
- Other useful information for consumers or healthcare professionals

This means you may not always see the complete picture.

What would we like to share with you?

Device name
What we reviewed

Reason
Why we reviewed it

Findings
What we found

Manufacturing information

Review outcomes
What happened next

Information for users
Important information, where relevant

This includes the positive outcomes so you can have access to more information

We are not proposing to publicly share commercially sensitive information

Example 1: Review completed – training information updated

What could this information look like?

Device: Surgical tool

Why was it reviewed	What did the review find	What was the outcome
• The device was reviewed following concerns about how it was being used.	• The device met regulatory requirements. • Additional training information was needed.	• No regulatory action was required. • The device remained compliant. • Training materials were updated.

Example 2: Review completed – performance limitation found

What could this information look like?

Device: Virus test		
Why was it reviewed	What did the review find	What was the outcome
• Questions were raised about whether a test would detect new strains of a virus that were circulating.	• The tests were reviewed by the TGA. • One test had reduced sensitivity for a particular virus strain. • The other test remained sensitive to all currently circulating strains.	• The review was completed. • The identified performance limitation was included in the instructions for use.

Example 3: Review completed – different models

What could this information look like?

Device: Face masks		
Why was it reviewed	What did the review find	What was the outcome
• Several models of the device were included in the review.	• There was insufficient information to demonstrate that one model met the requirements. • The other models met the requirements.	• One model was cancelled from the ARTG. • The other models remained compliant.

Example 4: Investigation completed – Additional conditions of inclusion imposed

What could this information look like?

Device: Surgical tool

Why was it investigated	What did the investigation find	What was the outcome
• Concerns were identified that required further information about the device.	• Additional evidence was needed to support ongoing regulatory assurance.	• Additional conditions of inclusion were imposed on the relevant ARTG entries that required the sponsor to provide information, such as studies, at specific time points.

Example 5: Investigation completed – Device suspended

What could this information look like?

Device: Infusion pump

Why was it investigated	What did the investigation find	What was the outcome
• Increased failure rate for a device component identified in post-market monitoring.	• Concerns identified for manufacturer's Quality Management System (QMS) where critical quality checks of the affected component were not adequately performed before installation.	• The ARTG entry was suspended due to QMS deficiencies • A recall was not required as devices already supplied could be fixed by replacing the affected component.

What are we asking you?

1 Share more information?

Do you agree generally to sharing of information for providing the public with more information about the medical devices included in a post-market review or investigation?

2 What should be shared?

What information would be useful to share, such as:

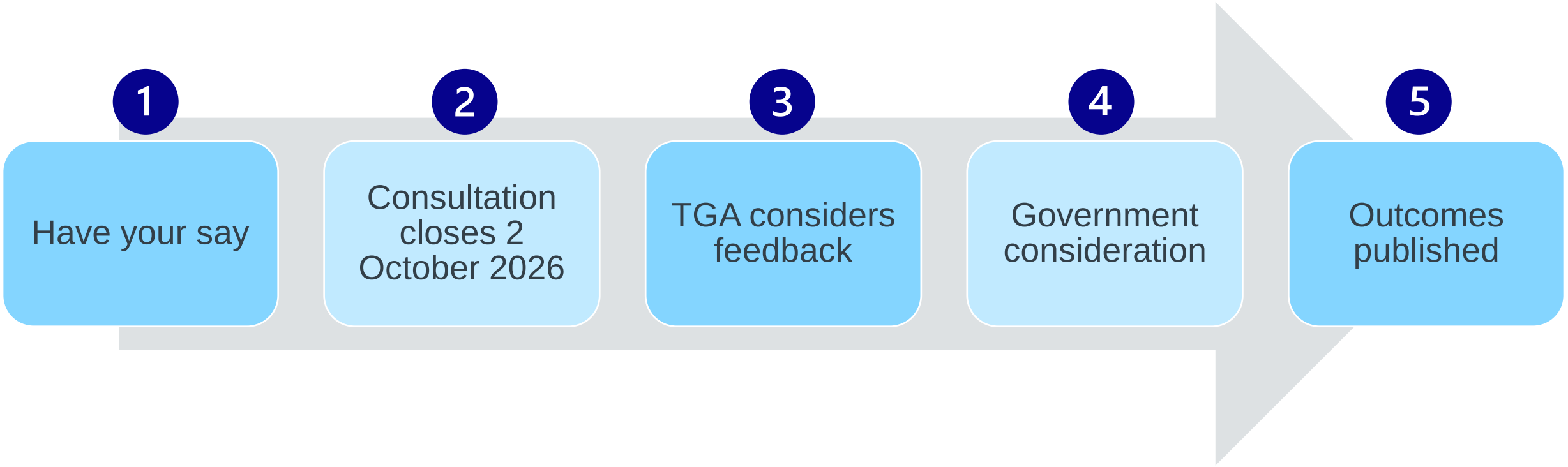
- ✓ The reason for review/investigation
- ✓ Information about the device or manufacturing
- ✓ Findings
- ✓ Outcome

3 Anything else?

What other comments or feedback should the TGA consider about the proposal?

Have your say | Consultation closes | 11.59pm (AEST), 2 October 2026

Next steps


1
Have your say
2
Consultation closes 2 October 2026
3
TGA considers feedback
4
Government consideration
5
Outcomes published

Questions?

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Mariel Bartley
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Key messages

Three things to remember from today:

1. **The TGA monitors devices after they reach the market.**
   A post-market review can identify a problem, clarify information, or confirm that no regulatory action is needed.

2. **We can’t always share the full picture.**
   Current legislation can limit what we can publicly share about reviews, findings and outcomes.

3. **We are consulting on sharing more information.**
   We want your views on what information would be useful to share.

Have your say | Consultation closes | 11.59pm (AEST), 2 October 2026

Contact us

Email: devices@tga.gov.au

Phone: 1800 141 144

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration