Information Session - Proposed amendments to the conformity assessment procedures for medical devices

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Acknowledgement of Country

In the spirit of reconciliation, the Department of Health, Disability ad 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

Welcome

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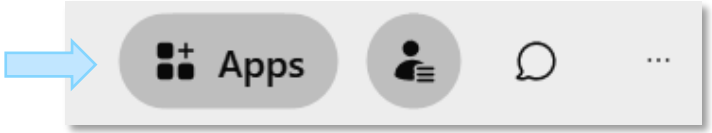

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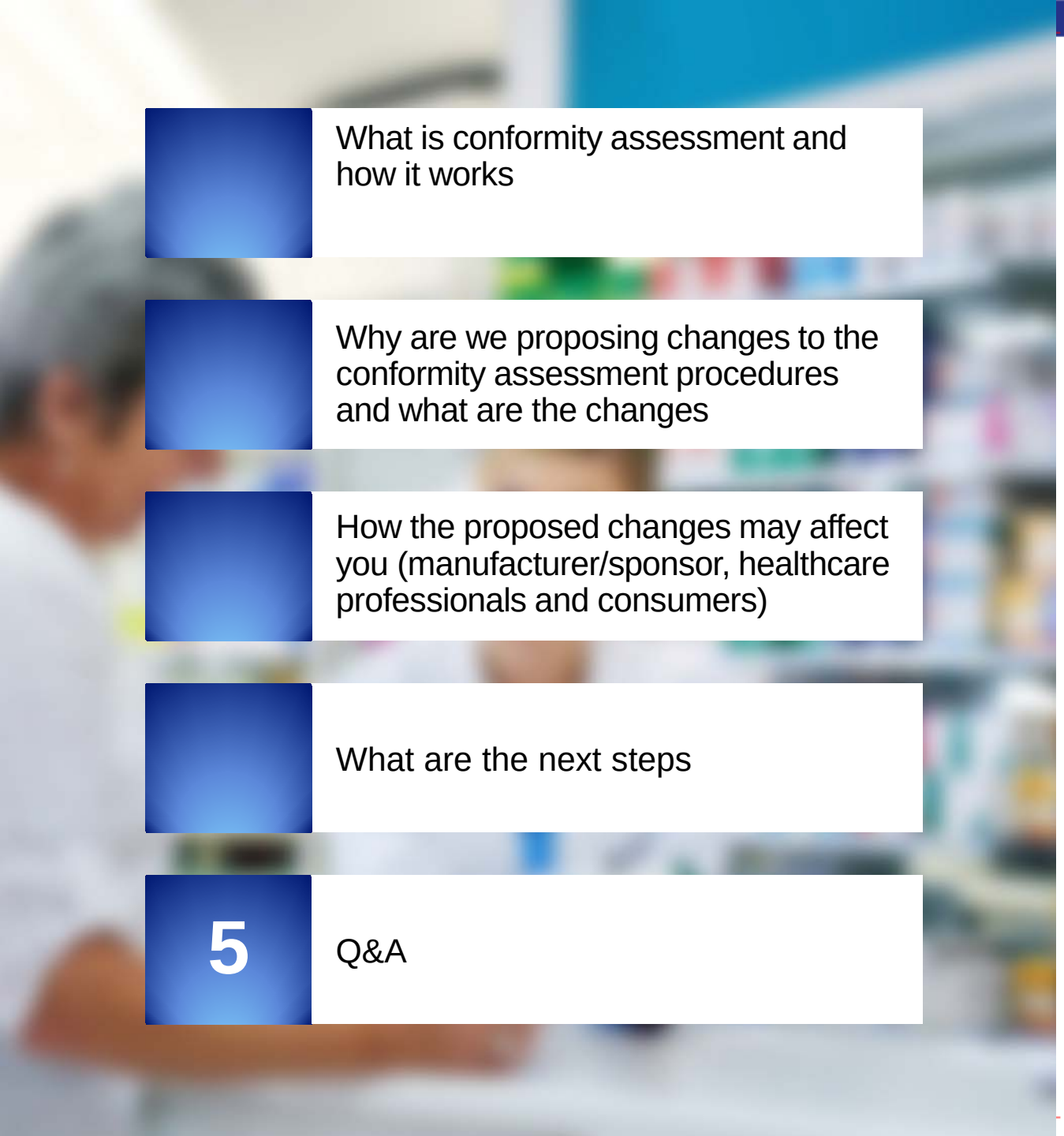


1. What is conformity assessment and how it works
2. Why are we proposing changes to the conformity assessment procedures and what are the changes
3. How the proposed changes may affect you (manufacturer/sponsor, healthcare professionals and consumers)
4. What are the next steps
5. Q&A

Webinar objectives & overview

A public consultation on ‘Conformity Assessment Procedures for Medical Devices – Proposed Amendments’ was released on 19 December 2025

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

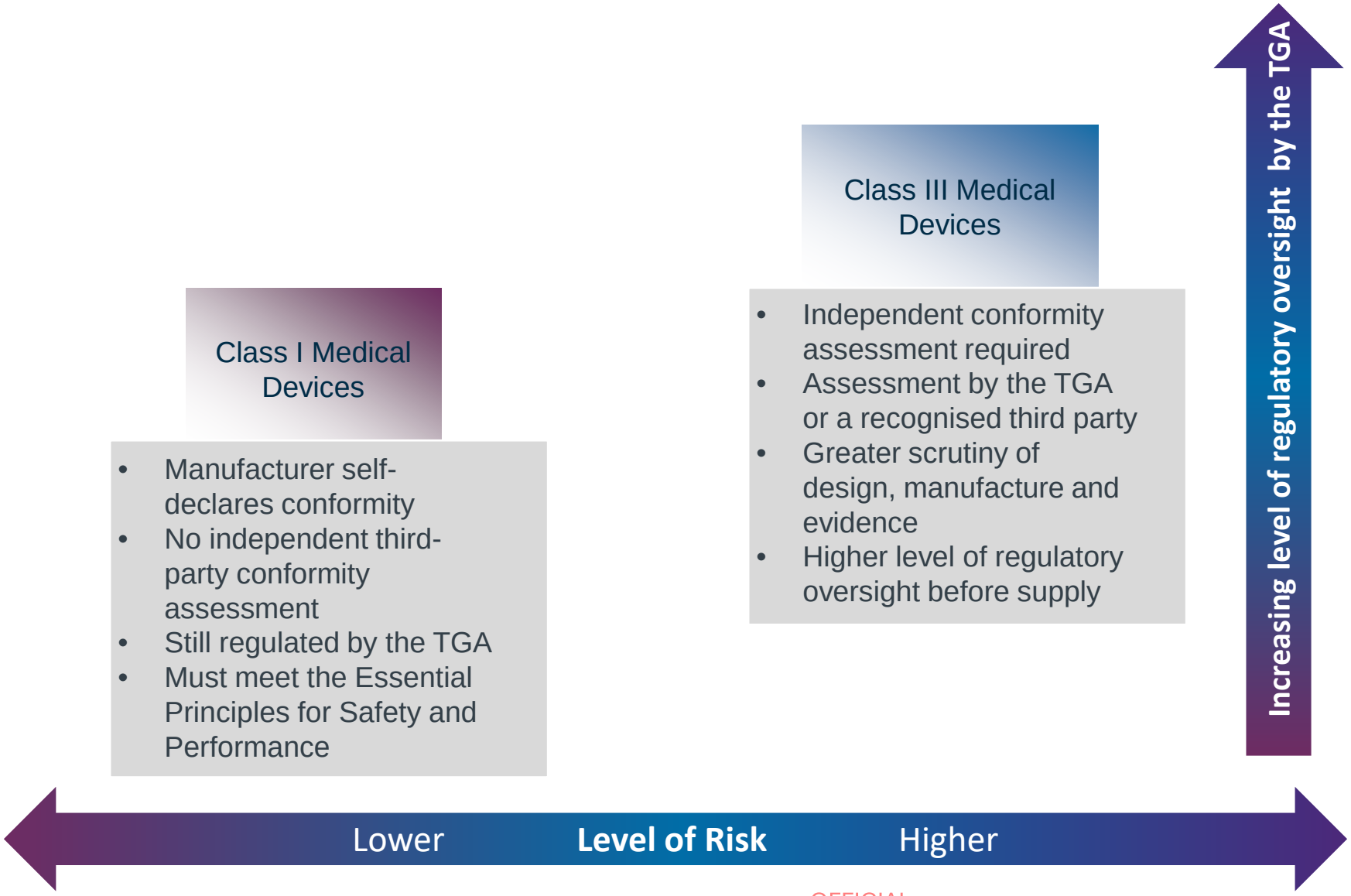
What is conformity assessment?

- Core part of Australia's medical device regulatory framework
- Processes used to demonstrate that a medical device meets the Essential Principles for Safety and Performance
- Required before a medical device can be supplied in Australia

How does conformity assessment work?

- Requirements are set out in the Therapeutic Goods Act 1989 (*the Act*) and Therapeutic Goods (Medical Devices) Regulations 2002 (*the Regulations*), which describe eight conformity assessment procedures
- Sponsors apply to include their devices in the Australian Register for Therapeutic Goods (ARTG) using conformity assessment evidence
- Conformity assessment procedures (CAPs) do not apply to comparable overseas regulator pathways.
    - Comparable overseas regulator pathways were established based on an assessment that those overseas regulatory systems provide an equivalent level of assurance
- The applicable CAP depends on the device's risk classification with higher risk devices subject to greater regulatory oversight

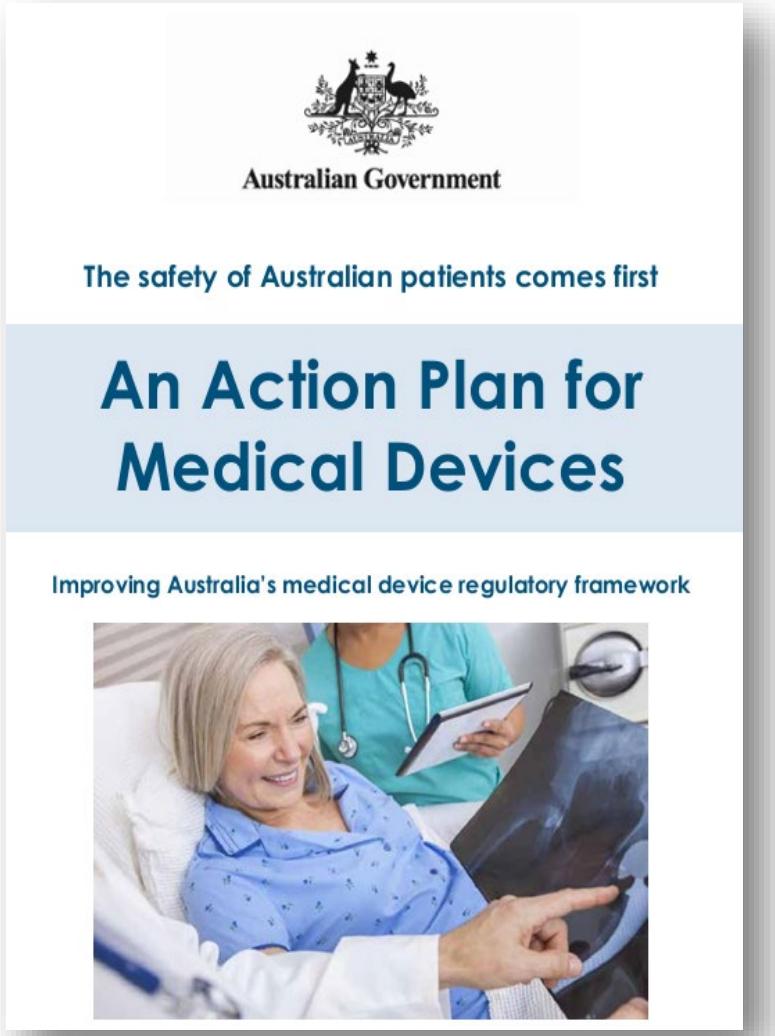
Conformity assessment: what applies by device risk



- Some devices are not required to be included on the ARTG
- These devices are still regulated by the TGA and must meet regulatory requirements

Why are we proposing changes?

- Guided by An Action Plan for Medical Devices, which prioritises patient safety and confidence
- Modern medical devices are increasingly complex in design and development
- Some conformity assessment procedures are outdated or rarely used
- Internationally align our regulatory framework (wherever possible)
- Opportunity for clearer, more consistent requirements
- Opportunity to strengthen Australia's regulatory system across the medical device lifecycle



How this consultation relates to conformity assessment pathways

Impact on COR pathways

Consultation focus: Primarily Australian conformity assessment procedures

Proposals 1 – 5

- Apply to conformity assessment certification by the TGA or by any future Australian conformity assessment body
- **DO NOT apply to COR pathways**

Proposals 6 – 8

- Applies to all medical device certifications including certifications by COR
- **No change to the recognition of COR assessments or approvals**

None of the proposals change how comparable overseas regulator (COR) pathways are recognised.

Proposal 1: Repeal unnecessary procedures

Part 2 Type Examination

Part 3 Verification

Regulation 3.13

- **Propose: Repeal these procedures**
- These procedures are rarely used and add unnecessary complexity

Potential impacts

- **Manufacturers**: Minimal impact; no effect on existing TGA certifications or COR pathways
- **TGA:** Minimal impact; removes unnecessary procedures and simplifies the framework

Fixed term certification

- **Propose: Repeal fixed term certification**
- Regulatory oversight would continue via other pathways, supported by ongoing risk-based audits

Potential impacts

- **Manufacturers:** Removes unnecessary recertification
- **TGA:** Allows resources to be focused on applications for new technologies and surveillance

Proposal 2: Require control of design and development

Part 4 Production Quality Assurance	Part 5 Product Quality Assurance

- Increasingly important for modern technologies including software based and patient-matched devices
- **Propose:**
  - **Repeal these procedures**
  - **5-year transition to Part 1 certification**

Potential impacts

- **Manufacturers**: Those using Part 4 and 5 to transition to Part 1 certification, with full compliance against the full QMS incl. design and development requirements after 5-year transition
- **TGA:** Changes to application process and greater focus on full QMS assessment under Part 1

Proposal 3: Design examination of medium-high risk devices

- Require design examination for:
  - Class IIb implantable medical devices
  - Class 3 IVD devices
- Introduce design examination of a representative sample for Class IIb non-implantable medical devices
- Strengthen scrutiny of medium-high risk devices, aligning with international approaches

Potential impacts

- **Manufacturers**: Additional design examination certification for higher risk devices, potentially cost-neutral in relation to assessment fees
- **TGA:** Increased design examination assessment activity and stronger pre-market assurance

Proposal 4: Reduce barriers for innovation

- Introduce a conformity assessment procedure for medical devices that incorporate a medicine
- Reduce regulatory barrier for Australian innovators
- Recognises existing TGA manufacturing licenses where appropriate
- Consultation seeks views on design examination, technical documentation and post-market requirements

Potential impacts

- **Manufacturers**: Leverage existing TGA manufacturing license for the medicine, reducing the need for separate device QMS certification; stakeholder feedback will inform further impact
- **TGA:** Greater reliance on existing manufacturing license inspections and cross-agency coordinated assessments while maintaining device specific review

Proposal 5: Include MDSAP in the procedures

Medical Device Single Audit Program (MDSAP)

- Sponsors may use for manufacturers' MDSAP certification as evidence
- For TGA conformity assessment, manufacturers may use MDSAP certification as QMS evidence
- **Propose:**
  - More formal recognition of MDSAP with Australian conformity assessment procedures
  - Clarifying how MDASP certification can be used to meet Australian conformity assessment requirements
  - Clarifying expectations for notification of substantial changes when manufacturers rely on MDSAP certification.

Potential impacts

- **Manufacturers**: Utilise MDSAP certification as QMS evidence, reducing the need for duplicative audits but still need to comply with product requirements
- **TGA:** Greater reliance on recognised audits for QMS assessment; focusing effort on product compliance rather than re-auditing

MDSAP certification supports Quality management system (QMS) evidence only and does not replace product conformity assessment requirements.

Questions are now open

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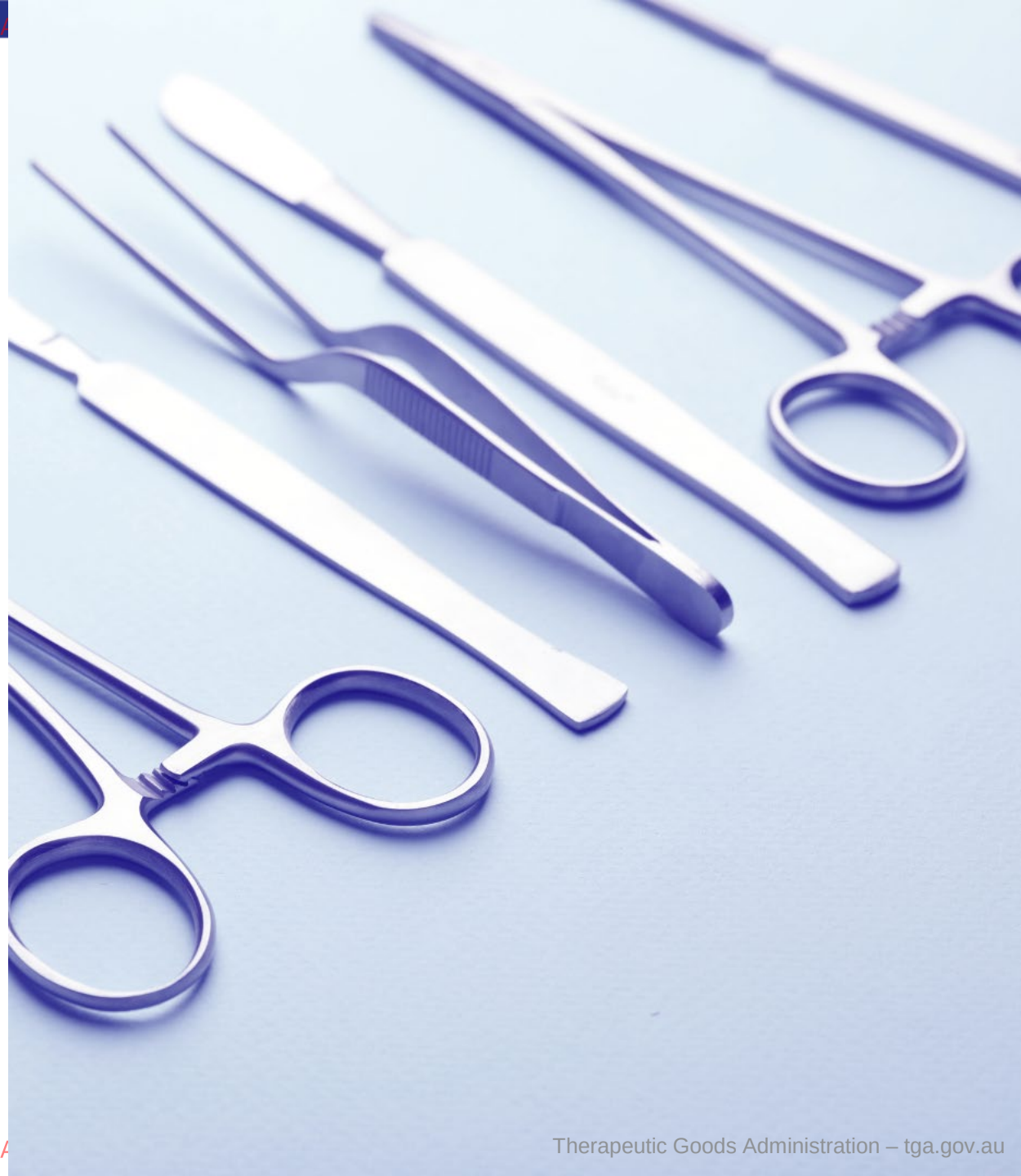
Proposal 6: Reusable surgical instruments

- Up-classify reusable surgical instruments to:
  - reflect modern manufacturing and reprocessing practices
  - ensure risk-appropriate regulatory oversight
- Propose a 3-year transition period

Potential impacts

- **Manufacturers**: Increased evidence requirements, regulatory oversight and additional certification costs (other than EU certifications)
- **Sponsors:** additional ARTG inclusion fees and ongoing annual charges
- **TGA:** Increased assessment and monitoring supporting stronger risk controls



Proposal 7: Clinical and post-market planning and reporting

- Expand clinical investigation data and literature review requirements
- Require structured plans and reports, including clinical/performance evaluation plans and post-market follow-up
- Introduce more consistent post-market surveillance including periodic safety reporting and clearer expectations for field safety corrective actions
- Strengthen adverse event reporting, including manufacturer to sponsor obligations
- Seek views on whether summaries of safety and clinical performance for higher risk devices should be publicly available

Potential impacts

- **Manufacturers/sponsors**: Additional clinical and post-market planning and reporting obligations across the device lifecycle
- **TGA: I**mproved access to clinical and post-market data to support earlier risk identification across device lifecycle; increased data analysis

Proposal 8: General alignment & transitions

Align relevant CAPs with European Regulations	Clarify certain requirements (e.g. written agreements, record retention)	Adoption of terminology	Timeframes for implementing proposals (i.e. transitions)

Potential impacts

- **Manufacturers**: Stronger governance requirements; increased document retention and expanded records to support device lifecycle traceability
- **TGA:** Improved access to long term device documentation to support post market reviews and investigations; greater regulatory alignment with international frameworks

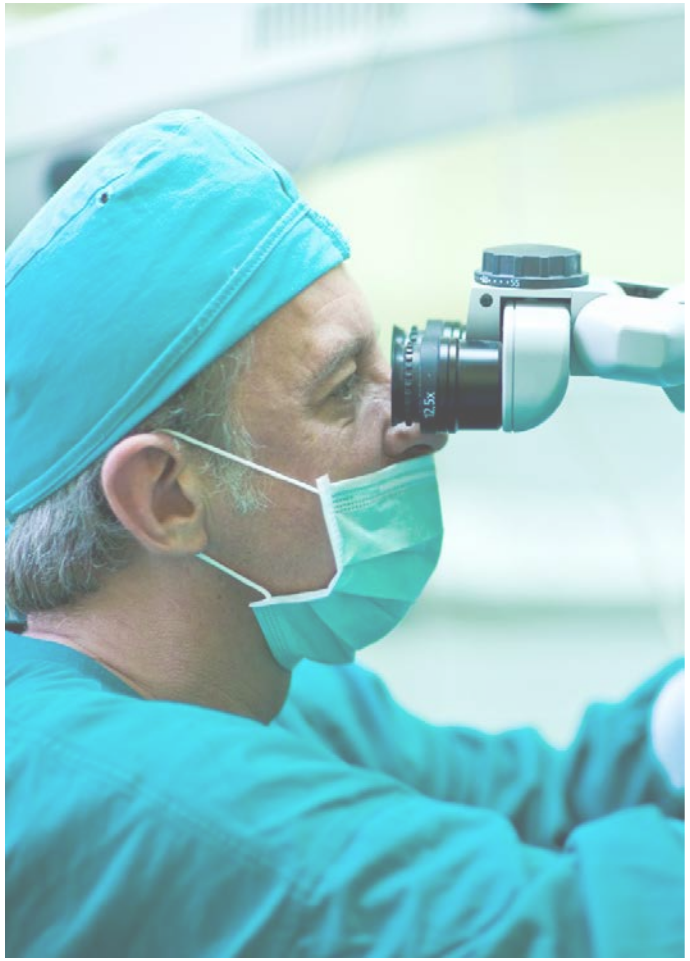
What do these changes mean for you?

I’m a manufacturer or sponsor

- Clearer pathways and expectations
- Reduced duplication, where appropriate
- Continued focus on lifecycle evidence
- Aligned with international approaches to support global consistency

What do these changes mean for you?

I’m a healthcare professional



Greater confidence in devices used

Clearer expectations for evidence and monitoring

Better support for timely regulatory action when safety concerns arise

Improved access to safety and performance information through clearer reporting and transparency

What do these changes mean for you?

I’m a consumer

- Timely access to innovative technologies, where appropriate
- Improved access to information about safety and performance concerns
- Safety or performance issues can be identified and addressed earlier
- Greater confidence in the regulation of medical devices

What are the next steps for this consultation?

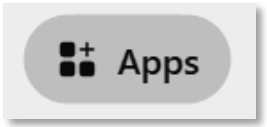
Submissions from all stakeholders are encouraged, including practical feedback on impacts, feasibility and transition considerations.

The consultation can be found:

consultations.tga.gov.au/

How did we go?

Take a moment to complete our survey, and we'll be back with your shortly for Q&A



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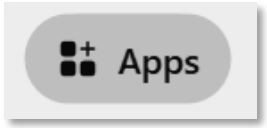

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Panel	Section
Tania Ahmed	Devices Post Market Review
Kylie Downes	Devices Applications and Triage
Tao Tan	Devices Applications and Triage
Uphar Chamoli	Devices Specialist Evaluation
Olivia Reeves	Devices Specialist Evaluation
Fiona McCormack	Devices Emerging Technology
Rebecca Bateson	Devices Emerging Technology
Shraddha Swami	Devices In Vitro Diagnostic
Blake Charlton-Fenwick	Devices Manufacturing Quality
Ankit Sharma	Devices Manufacturing Quality
Jessica Rennie	Devices Clinical Surveillance
Katie Burns	Devices Post Market Review
Kelly Tsang	Devices Post Market Monitoring

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