Conformity Assessment Procedures for Medical Devices

Proposed Amendments

MTAA Member Response – March 2026

Table of Contents

Proposal 1 – Repeal Unnecessary Procedures 2
Proposal 2 – Require Control of Design and Development 4
Proposal 3 – Design Examination of Medium-High Risk Devices 5
Proposal 4 – Reduce Barriers for Innovation 7
Proposal 5 – Include the MDSAP in the Procedures 8
Proposal 6 – Reusable Surgical Instruments 10
Proposal 7 – Clinical and Post-Market Planning and Reporting 12
Proposal 8 – General Alignment & Transition Arrangement 21

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

Proposal 1 – Repeal Unnecessary Procedures

1. **Do you agree with repealing Part 2 Type Examination Procedures of the conformity assessment procedures?**

MTAA supports the repeal of Part 2 and Part 3 procedures, noting that these pathways are no longer widely used and are not considered state of the art. The limited historical use and absence of currently active certifications suggest their removal is appropriate.

However, this support is conditional on the repeal being explicitly limited to TGA-issued conformity assessment procedures. The TGA has indicated that EU MDR certificates, including those issued by EU Notified Bodies through Type Examination and Product Verification routes, will continue to be accepted, and that sponsors relying on these pathways will not be affected. However, it remains unclear how this assurance will be operationalised within the Regulations, creating uncertainty as to how acceptance of these EU MDR certificates will be maintained in practice.

To illustrate this concern, under the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*, a Class IIb (non-sterile) device currently has the following conformity assessment options via a TGA pathway:

- Part 1 of Schedule 3 (full quality assurance procedures), excluding clause 1.6
- Part 3 (verification procedures) in combination with Part 2 (type examination procedures)
- Part 4 (production quality assurance procedures) in combination with Part 2
- Part 5 (product quality assurance procedures) in combination with Part 2

Equivalent EU MDR routes for the same device class include:

- Chapter I of Annex IX
- Annex XI Part A (production quality assurance) in combination with Annex X (type examination)
- Annex XI Part B (product verification) in combination with Annex X

Removal of references to Part 2 and Part 3 creates uncertainty as to how these equivalent EU MDR certification pathways will continue to be recognised. Without explicit clarification, it is unclear how a manufacturer relying on these routes would be able to validly sign a declaration of conformity.

This concern is further compounded by Appendix 2 of the Consultation Paper, which lists limited conformity assessment options for certain device classes (e.g. Class IIa), without clearly reflecting the full range of applicable EU MDR pathways. It remains unclear how routes such as Annex XI (Parts A or B) in combination with Annex II and Annex III technical documentation would be accommodated, or how Appendix 2 aligns with the existing Determination.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

MTAA therefore requests that the TGA explicitly confirm, within both the Regulations and updated legislative instruments, that the repeal applies only to TGA-issued conformity assessment certification. It is also critical that the TGA provide a clear and comprehensive mapping of how all relevant EU MDR conformity assessment pathways will continue to be recognised across device classes following the proposed changes.

2. **Do you agree with repealing Part 3 Verification Procedures of the conformity assessment procedures?**

Yes, as above.

3. **Do you agree with repealing Regulation 3.13 for the assessment or verification at intermediate stage of manufacture?**

Yes.

4. **Do you agree that the 5-year certification period could be repealed? Please provide a reason for your position.**

Yes.

MTAA supports the repeal of the 5-year certification period, as this approach aligns with comparable overseas regulators and has the potential to reduce unnecessary regulatory burden and costs for both manufacturers and sponsors.

However, further clarification is required regarding the nature and scope of any additional audits that may be introduced in place of periodic recertification. In particular, where a manufacturer also holds MDSAP certification, it is unclear whether on-site audits would be conducted on a for-cause basis only, or whether routine periodic audits would still be expected. Clarification is also needed in light of developments in Europe, where there is ongoing discussion on reducing Notified Body involvement for lower- and medium-risk devices.

Greater transparency is also needed on how the TGA intends to determine “higher risk” scenarios that would trigger such audits. For manufacturers holding MDSAP certification, consideration should be given to leveraging existing audit outcomes to avoid duplication. Alignment with MDSAP would support regulatory efficiency while maintaining appropriate oversight.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

Proposal 2 – Require Control of Design and Development

5. **Do you agree with repealing Part 4 Production Quality Assurance of the conformity assessment procedures? Please provide a reason for your position (optional).**

Yes.

MTAA supports the repeal of Part 4 procedures, as this pathway appears to be infrequently used and its removal may simplify the regulatory framework and improve alignment with international approaches.

However, consistent with the concerns raised under Proposal 1, further clarification is required regarding how the TGA intends to continue recognising EU MDR and other comparable overseas regulatory approvals. In particular, it is unclear how manufacturers will be able to sign declarations of conformity where they rely on established EU MDR pathways, such as Annex XI Part A (Production Quality Assurance), if the equivalent procedure is removed from the Australian Regulations.

Clarification is also needed to ensure that the repeal does not unintentionally limit access to recognised international conformity assessment routes or create ambiguity for manufacturers and sponsors. While the anticipated impact appears limited based on current usage, broader industry consultation may be beneficial to confirm the extent of reliance on this pathway and any unintended consequences of its removal.

6. **Do you agree with repealing Part 5 Product Quality Assurance of the conformity assessment procedures?**

Yes.

7. **Do you agree that a 5-year transition, including the introduction of auditing against all clauses of ISO 13485:2016 during the transition, is appropriate?**

Yes.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

Proposal 3 – Design Examination of Medium-High Risk Devices

8. **Do you agree with updating the Australian conformity assessment pathways, specifically in relation to Part 1 Full Quality Assurance Procedures, to:**

a) Add clause 1.6 of Part 1 to the minimum requirements for Class IIb implantable medical devices?

Yes.

b) Add clause 1.6 of Part 1 for at least one representative device to the minimum requirements for Class IIb non-implantable medical devices?

Yes.

c) Add clause 1.6 of Part 1 to the minimum requirements for Class 3 IVD medical devices?

Yes.

d) Please provide reasons for your position (optional).

MTAA supports the proposed updates to Part 1, including the addition of clause 1.6 for Class IIb implantable and non-implantable medical devices, as well as Class 3 IVDs. This is supported in principle as a step toward strengthening oversight of higher-risk devices.

However, this support is contingent on ensuring that the changes remain proportionate and aligned with international regulatory frameworks. Clarification is required on several key points:

- **Scope of application** – It is understood that these requirements would apply only to devices undergoing TGA conformity assessment. Confirmation is needed that devices relying on comparable overseas approvals, such as EU MDR certification, will not be subject to additional or duplicative design examination requirements.
- **Alignment with EU MDR** – Under the EU MDR, Technical Documentation Assessment is generally applied to relevant implantable devices. The proposed Australian approach appears broader, particularly for Class IIb non-implantable devices. It is important to ensure this does not create divergence that could limit reliance on established EU MDR pathways.
- **Impact on regulatory burden, cost, and timelines** – Introducing a separate Design Examination Certificate may increase application complexity, approval timelines, and ongoing compliance obligations. While the TGA has indicated cost neutrality, this may reflect a redistribution of existing bundled assessments rather than a genuine reduction in regulatory burden. Additional considerations include:
    - Potential for increased application and maintenance costs

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

  - Additional documentation requirements
  - Ongoing updates triggered by post-market design changes

- **Interaction with existing frameworks** – It is unclear how design examination requirements will interact with existing assessment frameworks, including whether TGA will adopt sampling approaches comparable to those used under the EU MDR or introduce separate methodologies.
- **Transitional arrangements** – Greater clarity is needed on how these requirements will apply to devices already supplied under existing conformity assessment certifications, including whether a Design Examination Certificate will be required retrospectively and what transition timeframes will apply.

The introduction of additional design examination requirements must also be considered in the context of cumulative regulatory burden. In particular, sponsors are currently managing the transition for patient-matched medical devices (PMMDs), which is in effect until 1 July 2029. This transition was extended to alleviate pressures arising from EU MDR implementation and domestic reforms. Introducing Proposal 3 during this period risks reintroducing that pressure by layering a new and complex certification requirement on top of existing obligations.

The current PMMD framework already incorporates risk controls, including compliance with the Essential Principles and progression toward ARTG inclusion, representing a significant regulatory uplift. Consideration should therefore be given to sequencing reforms, including deferring implementation for PMMDs until after 1 July 2029, or reassessing the need for mandatory design examination once the transition is complete.

MTAA would support a sampling-based approach to design examination for Class IIb devices, provided that the framework is clearly defined and transparently implemented. This includes:

- Clear, published criteria for sampling, including how representativeness is determined (e.g. intended purpose, risk profile, technological novelty, clinical complexity, and compliance history)
- Confirmation that sampling is risk-based and dynamic, with defined triggers for expanded review where new risks or changes are identified
- Alignment with EU MDR practices, where sampling is applied by Notified Bodies using flexible, risk-based frameworks rather than as a uniform approach across all devices
- Transparency in how sampling decisions are made, including consistency of application and interaction with the Australian “kind of medical device” construct

Without this level of clarity, there is a risk of inconsistent application, unintended expansion of scope, and divergence from comparable international frameworks.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

Proposal 4 – Reduce Barriers for Innovation

9. **Do you agree with the proposal to design a conformity assessment procedure for medical devices that are or incorporate substance, that:**

a) recognises and leverages a TGA manufacturing licence for a medicine?

Yes.

b) includes design examination requirements?

Yes.

c) specifies the technical documentation requirements?

Yes.

d) specifies post-market requirements?

Yes.

e) Please provide reasons for your position (optional).

Further clarification is required on any additional post-market requirements the TGA intends to introduce, particularly given that medical devices are already subject to a comprehensive range of post-market obligations.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

Proposal 5 – Include the MDSAP in the Procedures

10. **Do you agree with the following proposals relating to the MDSAP, specifically amending the Regulations to:**

a) *include MDSAP certificates, that have been audited specifically against Australian regulatory requirements, in the minimum requirement options for each pathway or classification of medical device?*

Yes.

b) *manufacturers, who have used an MDSAP certification, to notify the MDSAP auditing organisation when there are substantial changes to the medical device or the manufacturing processes?*

No.

c) *Please provide reasons for your position (optional).*

MTAA supports the inclusion of MDSAP certificates, audited against Australian regulatory requirements, within the minimum evidence options for CA pathways. However, it is unclear how this proposal differs from the current framework, as the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* already references MDSAP certification for relevant pathways and classifications. Clarification is required on how and where these references will be incorporated into the Regulations.

MTAA does not support introducing a legislative requirement for manufacturers to notify MDSAP auditing organisations of substantial changes.

Under the MDSAP audit model, manufacturers are required to notify auditing organisations of significant changes, including under Chapter 2, Task 3, with these changes subsequently reviewed during routine audits. In addition, current Australian requirements (including Regulation 3.5 and Clause 1.5, Part 1, Schedule 3) already link notification obligations to changes that must be reported to the TGA. As such, the proposed amendment appears duplicative and may result in unnecessary double handling.

While notification to auditing organisations is appropriate, it should not be interpreted as requiring prior approval before implementing changes. Any requirement for auditing organisation approval would introduce delays and create Australia-specific regulatory burden for globally supplied devices. Notification alone is sufficient, allowing auditing organisations to assess changes during scheduled audits where appropriate.

Further clarification is required on how this requirement would be operationalised and enforced by the TGA, given that MDSAP auditing organisations operate within an international

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

framework. It is also unclear how this proposal would function in practice, including how it would interact with existing processes for submitting substantial changes to the TGA and whether it would impact sponsors and manufacturers relying on MDSAP alongside comparable overseas approvals.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

Proposal 6 – Reusable Surgical Instruments

11. **Do you agree with up-classifying reusable surgical instruments:**

a) to Class IIa medical devices? OR

No.

b) to a new subclassification of Class I similar to the EU?

No.

c) Please provide reasons for your position (optional).

MTAA does not support the proposed up-classification of transient use reusable surgical instruments, either to Class IIa or to a new subclassification of Class I. Both approaches would introduce disproportionate regulatory burden without a corresponding improvement in patient safety.

Lack of alignment with comparable overseas regulators
A review of international frameworks indicates that reusable surgical instruments for transient use are generally classified as low-risk devices:

- In Singapore, such devices are classified as Class A (equivalent to Class I)
- In Canada, they are classified as Class I under specific conditions for reusable surgical and dental instruments
- In the United States, the majority are Class I and often exempt from premarket notification

The proposed reclassification would therefore create divergence from comparable overseas regulatory frameworks relied upon by the TGA.

Disproportionate to risk profile and lack of safety justification
These devices are well-established, low-risk technologies with a long history of safe clinical use. The proposal does not demonstrate a clear safety benefit that would justify increased regulatory oversight. The change appears administrative in nature and would not materially improve risk management outcomes.

Significant impact on regulatory burden and market access
Up-classification to Class IIa, or the introduction of a new Class I reusable category, would create substantial challenges for manufacturers:

- Manufacturers without EU MDR or MDSAP certification may be forced into TGA conformity assessment pathways, which are unlikely to be economically viable for high-volume, low-cost products
- This may result in manufacturers withdrawing products from the Australian market

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

- A preliminary review suggests a large number of existing ARTG entries may be affected, amplifying the cumulative impact on supply

Even under a Class I reusable model, reliance on MDSAP or equivalent certification would still exclude manufacturers who do not hold such approvals, without necessarily addressing the TGA's stated objectives.

Inconsistency with EU MDR approach and evolving direction
Under the EU MDR, Notified Body involvement for reusable surgical instruments is limited, typically focusing on quality management systems and aspects related to reusability, with assessments conducted on a sampling basis rather than through full technical documentation review. Class IIa devices, by contrast, are subject to more extensive assessment.

The European Commission is actively considering reforms to simplify and rebalance regulatory requirements, particularly for well-established, lower-risk technologies. Introducing additional requirements in Australia at this time risks diverging from this direction and undermining international harmonisation.

UDI and implementation challenges
Reclassification would have significant downstream implications, particularly for UDI requirements. Sponsors and manufacturers have engaged with the TGA on the understanding that Class I devices would be exempt from mandatory UDI. Reclassifying these devices would introduce substantial operational challenges, especially for instruments supplied in high-volume configurations such as surgical loan kits.

Duplication without regulatory benefit
Under current reliance pathways, quality management system and design controls are already addressed through existing certifications (e.g. MDSAP). Reclassification would primarily introduce administrative burden, additional costs, and longer timelines without materially strengthening oversight.

Alternative approach
Where there is a need for greater transparency, such as information on reusability or number of uses, this could be addressed through targeted measures. For example, enhancements to application requirements or ARTG data fields may achieve the intended outcome without altering device classification or introducing unnecessary regulatory burden.

12. **Do you agree a 3-year period would be sufficient time to allow this transition to occur?**

No.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

Proposal 7 – Clinical and Post-Market Planning and Reporting

13. **Do you agree with updating the Australian requirements to require the following procedures and documents be included in the manufacturer's quality management system:**

a) Clinical/performance evaluation plan?

No.

b) Post-market clinical/performance follow-up plan?

No.

c) Post-market surveillance/periodic safety update report?

No.

d) Please provide reasons for your position (optional).

MTAA does not support the introduction of mandatory requirements for a clinical/performance evaluation plan, post-market clinical/performance follow-up (PMCF) plan, or post-market surveillance/periodic safety update report (PSUR) within the Australian quality management system.

Misalignment with regulatory reliance framework
The proposed requirements closely align with EU MDR-specific frameworks, which are not mandated by several other comparable overseas regulators relied upon by the TGA, including the FDA, Health Canada, PMDA, HSA, and MHRA. Aligning Australia with the most stringent jurisdiction undermines the intent of regulatory reliance, which is designed to provide flexibility across multiple trusted regulatory systems.

Many devices currently supplied in Australia via pathways such as MDSAP and FDA 510(k) do not require PMCF or PSUR documentation. Imposing these requirements would create Australia-specific obligations, limiting the practicality of these pathways and reducing access to alternative regulatory routes. In particular, manufacturers without EU MDR certification may face significant challenges in generating these EU-specific documents, as they are not required within their primary regulatory frameworks. This may create barriers to market entry and ongoing supply.

Disproportionate regulatory burden and risk to market access
These requirements would introduce significant administrative and resource burden, particularly for small and medium manufacturers and for well-established, low- and medium-risk devices. This includes:

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

- Creation of new documentation where none currently exists
- Increased workload across regulatory, clinical, and post-market teams
- Duplication of reporting across jurisdictions
- Additional infrastructure for document management and review

Experience in Europe has demonstrated that similar requirements under the EU MDR have led to increased costs and widespread product discontinuations. There is a strong risk that adopting comparable requirements in Australia would result in manufacturers withdrawing products from the market, reducing device availability for patients and clinicians.

Limited additional safety value

Current Australian regulatory requirements, including the Essential Principles, conformity assessment procedures, and post-market vigilance obligations, already provide robust oversight of safety and performance.

PSURs in particular are retrospective summaries of data that manufacturers already monitor continuously within an ISO 13485-compliant quality management system. They do not contribute to early signal detection, which is instead driven by real-time vigilance, trend reporting, and risk management processes. As such, PSURs are duplicative and resource-intensive, with limited incremental safety benefit.

Redirecting resources toward proactive, real-time monitoring would better support patient safety outcomes than introducing additional retrospective reporting obligations.

Inconsistency with evolving EU direction

While the proposal seeks to align with EU MDR requirements, these requirements are currently under active review in Europe. The European Commission has acknowledged that post-market obligations, including PMCF and PSUR, are resource-intensive and is considering reforms to improve proportionality and reduce regulatory complexity.

These discussions also highlight the challenges associated with generating traditional clinical data, which can be lengthy and costly, and signal a shift toward broader acceptance of alternative evidence sources, including non-clinical data and published literature.

Adopting these requirements in Australia at this stage risks embedding a framework that is itself being reconsidered.

Need for global alignment and evidence-based approach

As a member of the International Medical Device Regulators Forum (IMDRF), Australia has demonstrated leadership in promoting globally harmonised, risk-based regulatory approaches. Member feedback strongly supports continued alignment with IMDRF and WHO principles for post-market surveillance, rather than adopting prescriptive requirements from a single jurisdiction.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

It is recommended that the TGA undertake a comprehensive gap analysis comparing clinical and post-market evidence requirements across key comparable overseas regulators to ensure any reforms are proportionate, evidence-based, and consistent with international best practice.

Scope and application
Clarification is required on whether these requirements would apply only to devices undergoing TGA conformity assessment, or also to devices relying on comparable overseas approvals. These requirements should not be duplicated where equivalent evidence has already been assessed by another recognised regulator. A more appropriate approach would be to strengthen existing risk-based post-market systems rather than introduce prescriptive documentation requirements.

14. **If the post-market surveillance/periodic safety update reports were introduced into Australia, do you agree with the proposal that manufacturers to update these, dependent upon classification:**

a) Class IIb, Class III, and Class 4 IVD medical devices to be updated annually?

No.

b) Other classifications to be updated every two years?

No.

c) Please provide reasons for your position (optional).

MTAA does not support the proposed introduction of fixed PSUR update frequencies based on device classification.

The proposal is modelled on EU MDR requirements that are currently under active review. The European Commission has acknowledged that PSUR obligations are resource-intensive and is proposing reduced update frequencies to improve proportionality. Adopting fixed reporting intervals in Australia at this stage risks embedding requirements that may soon be revised.

The proposed requirements exceed those of other major regulators relied upon by the TGA, including the FDA, Health Canada, and HSA, where PSURs are not mandated in the same manner. This creates Australia-specific obligations that manufacturers may find difficult to justify, particularly given the relatively small size of the Australian market.

Applying fixed reporting frequencies based solely on classification assumes a direct correlation between device class and post-market information needs. However, many Class IIa and IIb

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

devices are well-established, with long safety histories and stable designs. For such devices, frequent PSUR updates are unlikely to provide meaningful additional safety insights.

Introducing routine PSUR updates would:

- Create significant administrative workload for manufacturers and sponsors
- Generate large volumes of repetitive, retrospective data
- Divert resources away from proactive safety activities such as real-time vigilance and risk management

There are also concerns that increased reporting volume may place additional strain on TGA resources, potentially reducing capacity for higher-value regulatory activities.

A more appropriate approach would be risk-based and adaptive, taking into account factors such as device maturity, post-market experience, and emerging safety signals.

Requiring manufacturers to meet Australia-specific PSUR obligations may not be commercially viable, particularly for low- and medium-risk devices supplied through non-EU pathways. This may lead to product withdrawals or reduced availability of devices in the Australian market.

15. **If the post-market surveillance/periodic safety update reports were introduced into Australia, do you agree with the proposal to require the surveillance/periodic safety update reports to be provided to the TGA:**

a) Annually for Class III, Class IIb, and Class 4 IVD medical devices?

No.

b) All other classes of devices, submitted upon request?

No.

c) Please provide reasons for your position (optional).

Consistent with MTAA's responses to Questions 13 and 14, PSURs should not be mandatory in Australia due to duplication, administrative burden, and limited incremental safety value.

Requiring routine PSUR submission would introduce unnecessary duplication of existing post-market reporting obligations and create significant administrative burden for both industry and the TGA, with limited additional regulatory benefit. It also risks diverting resources away from proactive safety monitoring and timely regulatory activities.

There are also practical concerns regarding global consistency. For manufacturers operating under EU MDR, PSURs are typically developed on a global basis. Clarification would be required to ensure that globally prepared PSURs are acceptable, and that sponsors are not

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | E: mtaa@mtaa.org.au

required to generate Australia-specific reports, which would create parallel reporting systems and additional complexity.

Further, if PSUR submission requirements were introduced, it would be important to clarify how these interact with existing annual reporting obligations to the TGA, with a preference for avoiding duplication.

16. **Do you agree that a summary of the safety and performance of implantable and Class III medical devices should be required to be publicly available through the TGA website?**

a) No.

b) Please provide a reason for your position (optional).

While transparency is important, this proposal reflects an EU-specific requirement that is not adopted by other comparable overseas regulators relied upon by the TGA, including the FDA, Health Canada, and HSA. Introducing such a requirement in Australia would create additional documentation obligations without clear alignment to globally harmonised frameworks such as IMDRF or WHO.

Member feedback indicates there is limited evidence that publicly available summaries of this nature provide meaningful value to patients or clinicians. Early experience in Europe suggests limited practical use, with concerns that such documents may be more frequently used for non-clinical purposes.

There are also concerns regarding the potential for misinterpretation. Even simplified summaries may contain technical or clinical information that is difficult for the general public to interpret without appropriate context, which may lead to confusion or unnecessary concern regarding otherwise safe and effective devices.

Existing post-market mechanisms already provide appropriate transparency. Safety and performance issues are communicated through established processes such as adverse event reporting, recall actions, and other regulatory communications published by the TGA. These mechanisms are considered sufficient to address public concerns regarding device safety and performance.

More broadly, it is unclear whether the benefits of increased transparency would outweigh the additional administrative and regulatory burden introduced by this requirement.

MTAA recommends that the TGA monitor EU experience, including utilisation of EUDAMED, before considering any move toward similar public summary requirements. A more appropriate approach would focus on efficient, risk-based transparency mechanisms aligned

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

with internationally harmonised frameworks, rather than duplicating region-specific EU requirements.

17. **Do you agree that adverse event reporting for manufacturers and sponsors should include the following requirements:**

a) Manufacturers be required to report adverse events that occurred with medical devices supplied in Australia to sponsors?

Yes.

b) Manufacturers be required to report international adverse events to sponsors, where the sponsor supplies the same medical device in Australia?

No.

c) Manufacturers are required to report trends in adverse events to sponsors?

No.

d) The timeframes for manufacturers to report to sponsors be the same for sponsors to report to the TGA?

Yes.

e) Adverse events are required to be reported to the TGA, by sponsors, even after an ARTG entry has been cancelled?

No.

f) Please provide reasons for your position (optional).

MTAA supports strengthening adverse event reporting frameworks where this improves timely information exchange and patient safety outcomes. However, any new requirements must remain proportionate, avoid duplication, and align with existing global vigilance systems and sponsor–manufacturer arrangements.

Sponsor–manufacturer roles and existing processes

Adverse events occurring in Australia are typically first received and assessed by the sponsor, who is responsible for determining reportability and submitting reports to the TGA. These responsibilities, including timelines and information exchange, are already clearly defined in Quality Agreements between sponsors and manufacturers. Any new requirements should align with these established processes and avoid creating parallel or duplicative reporting

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

obligations. A focus on timely information sharing and investigation support would be more effective than prescriptive additional requirements.

There is also a need for clarity on the definition and scope of reportable adverse events to ensure consistent understanding between manufacturers and sponsors.

International adverse event reporting
MTAA does not support requiring manufacturers to routinely provide all international adverse event data to Australian sponsors. This would significantly increase data volume without improving patient safety outcomes. Large volumes of global data may obscure meaningful safety signals relevant to the Australian context, particularly given differences in reporting definitions across jurisdictions.

Sponsors already have access to relevant global safety information through existing mechanisms, including vigilance systems and regulatory reporting. A more proportionate approach would be to require sharing of international data only where it is relevant to devices supplied in Australia, impacts compliance with the Essential Principles, or indicates a potential safety signal.

Trend reporting
Trend analysis is already a core component of manufacturers' global post-market surveillance systems. Requiring routine provision of all trend data would likely create unnecessary administrative burden and dilute focus from clinically meaningful signals. A risk-based approach, where trend information is shared when relevant to Australian supply or upon request, would be more appropriate.

Timeframes
Aligning reporting timeframes between manufacturers and sponsors is supported in principle to promote consistency. However, practical implementation should recognise that sponsors may not always have direct control over upstream reporting timelines.

Reporting after ARTG cancellation
MTAA does not support mandatory reporting of adverse events after an ARTG entry has been cancelled in all circumstances. Where devices are no longer supplied in Australia, the likelihood of new adverse events is low, and maintaining records is considered sufficient. A significant example would be software-based medical devices, where cancellation of an ARTG entry typically means the product is no longer made available to users, further reducing the likelihood of new adverse events occurring.

If any requirement is introduced, it should be risk-based and limited to situations where:

- Devices have been previously supplied in Australia, and
- There remains a potential ongoing patient safety risk

Applying a blanket requirement would impose unnecessary burden without clear benefit.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

Impact on smaller sponsors
Smaller sponsors, including those relying on external regulatory support, may have limited capacity to process large volumes of additional data. Expanding reporting requirements, particularly for international events or trends, would create disproportionate administrative burden without clear regulatory value.

18. **Do you agree that manufacturers be required to provide field safety corrective actions to sponsors, including:**

a) Actions that directly relate to incidents that occur in Australia?

Yes.

b) Actions that have been raised internationally and the medical devices are supplied in Australia?

No.

c) Please provide reasons for your position (optional).

MTAA supports the requirement for manufacturers to provide sponsors with field safety corrective actions (FSCAs) related to incidents occurring in Australia, as this is critical to enable timely local risk assessment, regulatory reporting, and appropriate corrective action.

However, clarification is required regarding the scope of "directly related" incidents. Leaving this determination solely to manufacturers may result in under-reporting. A more appropriate approach would be for manufacturers to provide relevant information to sponsors, allowing sponsors to assess local impact and determine appropriate regulatory actions in Australia.

MTAA does not support the requirement for manufacturers to systematically provide all international FSCAs where devices are supplied in Australia. Such a requirement would create significant administrative burden without clear patient safety benefit. Regulatory actions, device use, and risk contexts may differ across jurisdictions, and large volumes of global information may not be relevant to the Australian context.

A more proportionate approach would be to require provision of international FSCAs only where:

- The issue is relevant to devices supplied in Australia, and
- There is a potential impact on safety, performance, or compliance with the Essential Principles

In addition, consideration should be given to whether devices have actually been supplied in Australia. Sponsors may hold an ARTG entry without active supply, in which case no local action would be required.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

Smaller sponsors may also have limited capacity to assess large volumes of international data. Requiring routine provision of all global FSCAs would therefore impose disproportionate burden without improving safety outcomes.

19. **Do you agree that the TGA should clarify that information and documents need to be provided, when asked for, for all medical devices, including those that use Part 6 and Part 7 of the conformity assessment procedures?**

a) Yes.

b) Please provide reasons for your position (optional).

MTAA supports clarifying that information and documentation must be provided upon request for all medical devices. Clear articulation of this expectation improves transparency, regulatory predictability, and preparedness during post-market reviews or investigations. However, clarification would be required regarding how this interacts with any proposed introduction of EU-aligned post-market documentation requirements, such as PSURs.

In particular, it would be important to confirm:

- Whether globally prepared documents (e.g. EU MDR PSURs) would be accepted without modification, or
- Whether Australia-specific documentation or addenda would be expected

Requiring jurisdiction-specific versions of globally maintained documents would introduce unnecessary complexity and operational burden. Member feedback highlights practical challenges, including managing multiple versions of the same document across jurisdictions, responding to updates requested by other regulators (such as EU Notified Bodies), and the risk of ongoing cycles of revisions and re-submissions to maintain alignment. This creates inefficiencies and increases the likelihood of inconsistencies across regulatory systems.

To avoid these challenges, it is important that the TGA accepts globally prepared documentation, where appropriate, without requiring Australia-specific adaptations. This would support regulatory efficiency, reduce duplication, and maintain alignment with international practices.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

Proposal 8 – General Alignment & Transition Arrangement

20. **Do you agree with the proposal to align Australian requirements with the European Regulations in the following specific areas:**

a) Manufacturers to be required to have a written agreement with the Australian sponsor(s) that specifies they meet the legislated requirements and can provide the required documents within the legislated timeframes?

Yes.

b) Manufacturers be required to have at least one person responsible for regulatory compliance who has expertise in the field of regulatory affairs or in quality management systems relating to medical devices?

Yes.

c) Increased retention period for manufacturing documentation for Class 4 IVD, Class III, and implantable Class IIb medical devices to 15 years or the lifetime of the medical device, whichever is longer, after the last device has been supplied?

Yes.

d) Increased retention period for manufacturing documentation for all other classes of medical devices to 10 years or the lifetime of the medical device, whichever is longer, after the last device has been supplied?

Yes.

e) Increased retention period for distribution records for Class 4 IVD, Class III, and implantable Class IIb medical devices to 15 years or the lifetime of the medical device, whichever is longer, after the last device has been supplied?

Yes.

f) Increased retention period for distribution records for all other classes of medical devices to 10 years or the lifetime of the medical device, whichever is longer, after the last device has been supplied?

Yes.

g) Please provide reasons for your position (optional).

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

MTAA is broadly supportive of these proposals, subject to clarification and ensuring that implementation remains proportionate, practical, and aligned with existing frameworks.

While not opposed to a written agreement between manufacturers and sponsors, clarification is required on how this proposal differs from existing requirements under sections 41FD(e) and (g) of the *Therapeutic Goods Act 1989*. Further guidance or sponsor education may be needed to ensure consistent understanding and implementation, rather than introducing duplicative obligations.

MTAA also supports the intent of ensuring appropriate regulatory oversight through the designation of a person responsible for regulatory compliance; however, flexibility is critical. Manufacturers should retain discretion in appointing this role, including where the individual is based, and requirements should remain proportionate, particularly for small and medium-sized organisations. Further clarification is required on whether alignment with the EU MDR Article 15 requirements is intended, noting that these provisions are currently under review in Europe. Adopting highly prescriptive criteria may create unintended barriers, especially for smaller manufacturers.

MTAA is not opposed to the proposed increases in retention periods for manufacturing and distribution records. However, it is important that these timeframes are applied consistently across all TGA frameworks and guidance, including recent updates to UDI requirements, to avoid misalignment and confusion.

21. **Do you agree with the proposal to adopt the intent of the following definitions as detailed in Appendix 5:**

a) Adverse event?

No.

b) Post-market surveillance?

No.

c) Information society service?

Yes.

d) Please provide reasons for your position (optional).

MTAA does not support aligning the definitions of “adverse event” and “post-market surveillance” with the proposed EU-based definitions.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

The current Australian definition of adverse event is clearer and more appropriate for post-market vigilance. The proposed EU definition appears to be derived from ISO 14155 and is intended for clinical investigation contexts. Applying this definition more broadly in Australia risks creating confusion, expanding reporting obligations beyond their intended scope, and blurring the distinction between clinical investigation and post-market surveillance frameworks.

Similarly, the proposed definition of post-market surveillance does not appear to provide additional clarity compared to existing frameworks. A more appropriate approach would be to align with internationally harmonised definitions, such as those developed by IMDRF, to ensure consistency across jurisdictions and support regulatory reliance.

MTAA supports the introduction of the concept of "information society service" in principle; however, further clarification is required on how this definition will be applied in the Australian context. In particular, it is unclear how the TGA intends to regulate activities such as direct-to-consumer services delivered online. Consideration should be given to aligning with existing Australian digital and regulatory frameworks, or adopting a simplified definition that is more readily applicable in practice.

22. **Are there other terms used in the Australian Conformity Assessment Procedures that you consider would benefit from being defined?**

a) No.

23. **Where proposals within this consultation are agreed upon, please indicate the preferred timeframe for implementation:**

a) When the current manufacturer's evidence expires or on the same date as the European Regulations, whichever is earliest?

No.

b) When their current manufacturer's evidence expires or six months later than the European Regulations, whichever is earliest?

No.

c) Immediately for new manufacturers?

No.

d) A different timeframe (please provide the suggested date and reason below)?

No.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au

e) Please provide reasons for your position (optional).

Given the breadth and complexity of the proposed changes, MTAA believes a uniform implementation approach is not appropriate. Several proposals, particularly Proposals 6 and 7, have the potential to significantly impact regulatory burden, market access, and the continued availability of medical devices in Australia. These proposals may require further consultation and careful consideration before implementation.

A more appropriate approach would be to apply phased and proposal-specific transition timelines, reflecting the level of impact and readiness of each reform. For example:

- Proposals 1–5 may be implemented earlier, subject to clarity on continued reliance on EU and other comparable overseas evidence
- Proposals with broader systemic impact, such as Proposals 6 and 7, would require longer transition periods and potentially additional consultation

There is a need for sufficient transition time for non-EU manufacturers, who may require additional time to adapt to changes that are not aligned with their primary regulatory frameworks.

Overall, implementation timelines should be proportionate, staged, and informed by the complexity and impact of each proposal, rather than applying a single approach across all reforms.

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600 | **E:** mtaa@mtaa.org.au