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

Conformity Assessment Procedures for Medical Devices

Proposed Amendments

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Introduction

In Australia, medical devices are regulated by the Therapeutic Goods Administration (TGA). The TGA considers how the medical device is meant to be used and the possible risks to individuals or public health. Since all medical devices carry some risk, the TGA uses scientific and clinical expertise to make sure the benefits outweigh the risks.

The TGA has been systematically reviewing the way medical devices are regulated. This has been guided by *An Action Plan for Medical Devices* which is a three-part strategy to strengthen Australia's regulatory system while continuing to be patient focused and have greater transparency. The Australian Government is also committed to improve how medical devices are regulated by internationally aligning our regulatory framework (wherever possible) and to participate in the Medical Devices Single Audit Program (MDSAP). This consultation is part of the ongoing reform program.

This consultation seeks views on where appropriate alignment should occur with the conformity assessment procedures of the European Regulation 2017/745 on medical devices (MDR) and the European Regulation 2017/746 for in vitro diagnostic medical devices (IVDR), collectively referred to as the European Regulations. We have reviewed the current Australian conformity assessment procedures against the European Regulations (see Appendix 1 for details of the comparison) and we propose to align with the European Regulations, where practicable.

This consultation also seeks feedback on proposed stronger alignment with the guidance published by the International Medical Device Regulators Forum (IMDRF) and the regulatory approach of countries that are members of the MDSAP. In addition to the TGA, the MDSAP members include the medical device regulators from Brazil, Canada, Japan and the United States of America (US), as well as an increasing number of observer and affiliate regulatory authority members from other countries. As a member of the MDSAP, alignment with the other participating regulatory authorities, where possible, will ensure Australia realises the full benefits of this rapidly growing program.

Conformity Assessment

The aim of the conformity assessment procedures is to provide objective evidence about the safety, performance, benefits and risks of a medical device. More formally, conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device complies with regulatory requirements. For medical devices, these are the Australian safety and performance requirements known as the Essential Principles.

Conformity assessment is primarily the responsibility of the medical device manufacturer. The TGA uses conformity assessment evidence to confirm that medical devices are safe and effective and that any quality, safety or performance problems are quickly identified and resolved.

Conformity Assessment Procedures

The conformity assessment procedures are regulatory requirements described in the *Therapeutic Goods Act 1989* (the Act), and detailed in Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Australian Regulations).

The Australian Regulations currently describe eight parts of the conformity assessment procedures (see Appendix 1 for a summary). Depending on the types of medical devices being manufactured at a location, more than one of these conformity assessment procedure parts may apply, with the regulatory oversight of the manufacturer increasing as the risk of safety of the medical device increases. The different conformity assessment procedure parts require different kinds of evidence to demonstrate that the necessary oversight was applied.

Generally, a person or company (known as the sponsor) must apply to the TGA to have a medical device included in the Australian Register of Therapeutic Goods (ARTG) to then import, export or supply within Australia. The sponsor provides information on the manufacturer's conformity

assessment with their application. The TGA considers the conformity assessment evidence to make regulatory decisions on the inclusion of the device in the ARTG.

A sponsor may provide conformity assessment documents or certificates that have been issued by the TGA, an Australian conformity assessment body (note there are not yet any Australian conformity assessment bodies), or specified comparable overseas regulators as evidence of the manufacturer's compliance with the conformity assessment requirements. Proposals 1-5 of this consultation focus mainly on the conformity assessment procedures relied upon for TGA conformity assessment certification, or certification by any future Australian conformity assessment body. Proposals 6, 7 and 8 also apply to medical devices certified by comparable overseas regulators.

None of the proposals in this consultation would change the way we recognise comparable overseas regulator approvals and assessments.

Benefits of the proposals

The proposals aim to harmonise requirements internationally, strengthen the design and performance documentation, as well as the monitoring and follow-up of devices in use. Recent incidents involving medical devices, such as transvaginal mesh and breast implants, have highlighted the need for manufacturers to have stringent post-market monitoring processes, to require or access more complete clinical performance and adverse event data, as well as rapidly share information on emerging safety issues. There is a strong focus in these proposals to more promptly identify and address threats to patient safety and to take quicker action.

We expect these proposals will:

- provide clarity and consistency for manufacturers by simplifying the requirements
- decrease regulatory compliance costs by aligning more closely with the European Regulations, the MDSAP and IMDRF guidance
- reduce the time for the benefits of new technologies to become available to Australians
- ensure manufacturers implement robust quality management systems with improved control over the design and construction and ongoing monitoring of medical devices, including medical device software, artificial intelligence, and other advanced manufacturing technologies, resulting in enhanced quality and safety of medical devices throughout their lifecycle
- minimise public health and safety risks
- increase consumer and healthcare professional confidence in the regulation of medical devices.

Proposals

Your views are sought on the following proposals.

- Proposal 1 – Repeal unnecessary procedures
- Proposal 2 – Require control of design and development
- Proposal 3 – Design examination of medium risk devices
- Proposal 4 – Reduce barriers for innovation
- Proposal 5 – Include the MDSAP in the procedures
- Proposal 6 – Reusable surgical instruments
- Proposal 7 –Clinical and post-market planning and reporting
- Proposal 8 – General alignment and transition arrangements

Proposal 1 – Repeal unnecessary procedures

At present, the conformity assessment procedures are complex to navigate due to the multiple parts which may be applied to medical devices. We are proposing to repeal the procedures that may be considered unnecessary, including Part 2 Type Examination, Part 3 Verification, and Regulation 3.13 (intermediate stage of manufacture), thereby streamlining the use of the conformity assessment procedures.

Since the conformity assessment procedures were introduced in 2002, the TGA has certified very few manufacturers under the Part 2 Type Examination and Part 3 Verification of the conformity assessment procedures (see Appendix 1 for a summary of the parts). There are currently no manufacturers certified under Part 2 or under Part 3.

Similarly, the TGA has rarely assessed the 'intermediate stage of manufacture' provision (Regulation 3.13), and it has been over 10 years since there were any current certificates for this provision.

In developing this proposal, in addition to the low volume of certifications, consideration has been given to the following:

- Part 2 is misaligned with the IMDRF guidance and the MDSAP requirements as it does not require the manufacturer to establish controls over design and development under its quality management system. Repealing Part 2 would resolve this misalignment by reverting to the requirements of Part 1 of the conformity assessment procedures, providing additional assessment of those design and development phases of manufacturing. Repealing Part 2 would thereby align our conformity assessment procedures with international guidance and the other regulatory authorities that participate in the MDSAP.
- Part 3 is misaligned with the IMDRF guidance and the MDSAP requirements as it does not require the manufacturer to establish a quality management system at all. Repealing Part 3 would resolve this misalignment by reverting to the requirements of Part 1 of the conformity assessment procedures and requiring a quality management system. Repealing Part 3 would thereby align our conformity assessment procedures with international guidance and the other regulatory authorities that participate in the MDSAP.
- Conversely, by removing Part 2 and Part 3 from the conformity assessment procedures we could appear to be misaligned with some other international regulatory agencies, including the European Union and the Medicines and Healthcare product Regulatory Agency (MHRA; the regulator in the United Kingdom). However, we propose to still accept Type Examination and Verification certificates issued by those comparable overseas regulators, so there would be no impact for those sponsors and manufacturers using those certification pathways.
- Maintaining unnecessary and obsolete pathways complicates the TGA's requirements for industry and repealing these pathways would simplify the Australian Regulations.

The TGA conformity assessment certificates are issued for up to 5 years, although the TGA may extend a certificate (only once) for up to 1 year (section 41EF of the Act). Manufacturers who want to maintain the certification must re-apply to the TGA, and the TGA must re-assess compliance before re-issuing a certificate. This approach mirrors the European Regulations, where notified bodies must recertify manufacturers every 5 years. However, the other comparable overseas regulators that the TGA recognises (US, Canada, Japan, Singapore) do not require manufacturers to periodically re-apply for approval. We seek feedback on whether the 5-year certification period could be repealed, allowing certificates to be maintained indefinitely, whilst still being subject to ongoing risk-based surveillance assessments and audits.

'Recertification' assessments divert resources from assessing applications for new technologies and manufacturers. Although the TGA takes a risk-based approach and focuses on reviewing the post-market performance of the previously assessed devices, recertification assessments take time and resources for manufacturers and for the TGA. In 2023-24, the TGA assessed 89 recertification applications in addition to post-certification reviews that are undertaken. The TGA considers that recertification assessments provide only limited additional assurance beyond its normal assessment

cycle throughout the certification period and is an unnecessary burden on both the regulator and the manufacturer. We note that this issue has also been raised in Europe, in the context of the review of the implementation of the European Regulations.

Proposal 1

1. Do you agree with repealing Part 2 Type Examination Procedures of the conformity assessment procedures? Yes/No
    a. Please provide a reason for your position (optional).
2. Do you agree with repealing Part 3 Verification Procedures of the conformity assessment procedures? Yes/No
    a. Please provide a reason for your position (optional).
3. Do you agree with repealing Regulation 3.13 for the assessment or verification at intermediate stage of manufacture? Yes/No
    a. Please provide a reason for your position (optional).
4. Do you agree that the 5-year certification period could be repealed? Yes/No
    a. Please provide a reason for your position (optional).

Proposal 2 – Require control of design and development

Proposal 1 described how the Part 2 Type Examination procedures do not require the manufacturer to establish controls over design and development under its quality management system. Similarly, Part 4 Production Quality Assurance procedures require the manufacturer to establish a quality management system, but it does not require controls over design and development. In practice, this means that clause 7.3 of the quality management system standard ISO 13485:2016, which covers design and development of the medical device, is excluded from assessment and certification. This is why Part 4, in isolation, is only allowed for lower risk medical devices (Classes Is, Im, IIa and 2 IVD medical devices) and is currently insufficient for higher risk medical devices (Classes IIb, III, 3 IVD and 4 IVD medical devices). The control of design and development is important to ensure that the product is safe and performs as intended.

Control of design and development are increasingly important for modern medical device manufacturing that relies more on complex design and development. This is particularly the case for software related products and advanced manufacturing where design and production are indistinguishable stages in product realisation. Part 4 Production Quality Assurance procedures and Part 5 Product Quality Assurance procedures only cover production and final inspection of the kind of device and do not cover fundamental processes for good software engineering from software development (including planning, requirements analysis, architectural design, system testing), as well as change processes (covering not only design changes but also changes that must be made during the development process to fix bugs and resolve problems). These are all activities that are required to demonstrate the software can meet its intended purpose.

The long-established practice of the TGA is to recommend manufacturers of software related medical devices and patient-matched medical devices to not use the Part 4 Production Quality Assurance procedures, even for lower risk class devices. The TGA operational policy has been to instead recommend that manufacturers use the Part 1 Full Quality Assurance procedures that must include

clause 7.3 of ISO 13485:2016 and include control of design and development. However, there is no basis to compel a manufacturer to do so if they are legally eligible to apply the Part 4 procedures.

Of the MDSAP participating regulatory authorities, only Health Canada allows manufacturers of Class II medical devices to exclude design and development from their quality management system audits or inspections. Repealing Part 4 would, therefore, align with the MDSAP requirements for the USA, Brazil, and Japan.

While the Part 4 procedures align with the equivalent Canadian and European requirements in both the old Medical Devices Directive Annex V and the new European Regulations, this does not mean the Australian framework needs to maintain Part 4. The TGA proposes to continue to accept Health Canada approvals and European Production Quality Assurance certificates for low-medium risk devices, under the Australian comparable overseas regulator framework (see Appendix 2 for a summary), noting the additional product assessment undertaken by notified bodies under the new European Regulations, and by Health Canada. We do not consider the Canadian or European requirements as compelling reasons to maintain Part 4 for manufacturers seeking a TGA conformity assessment certificate, and we propose to repeal this option. However, your views on any potential unanticipated consequences would be appreciated.

We propose to similarly repeal the Part 5 Product Quality Assurance procedures from the Australian framework. Like Part 4, Part 5 excludes consideration of the control over design and development under the quality management system. However, Part 5 also excludes clause 7.5.2 of ISO 13485:2016 from the assessment, which addresses production process validation. Part 5 is even more misaligned with the MDSAP requirements than Part 4, and Part 5 is similarly ill-suited to contemporary manufacturing. Health Canada does not allow clause 7.5.2 of ISO 13485 to be excluded. The new European Regulations have also removed the old Medical Devices Directive Annex VI, which was equivalent to Part 5. There is therefore a strong rationale for doing likewise in Australia to align with Europe and all MDSAP countries.

The TGA has certified relatively few manufacturers under the Part 5 Product Quality Assurance procedures. There are currently only 5 manufacturers certified under Part 5 (as of 2 December 2025). Part 4 Production Quality Assurance is more popular than Part 5 (19 certified manufacturers) but less popular than Part 1 (167 manufacturers).

If Part 4 and Part 5 are repealed, we propose to support manufacturers with those certificates to transition to Part 1 certification over the course of the next 5 years, which is the conformity assessment certification cycle. We propose to maintain our assessment fees at Part 4 or Part 5 surveillance audit levels during this transition, to minimise costs to these manufacturers. If this proposal proceeds, we would start auditing these manufacturers against all clauses of ISO 13485:2016, including clauses 7.3 and 7.5.2. However, we would only mandate full compliance with the Part 1 Full Quality Assurance procedures after the 5-year transition. We would also stop accepting new applications from manufacturers seeking certification under Parts 4 or 5.

Proposal 2

5. Do you agree with repealing Part 4 Production Quality Assurance of the conformity assessment procedures? Yes/No
    a. Please provide a for your position (optional).
6. Do you agree with repealing Part 5 Product Quality Assurance of the conformity assessment procedures? Yes/No
    a. Please provide a reason for your position (optional).

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/No

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

Proposal 3 – Design examination of medium-high risk devices

The new European Regulations require notified bodies to assess medium-high risk class devices for compliance with the general safety and performance requirements. There are sampling rules that require every model of Class IIb implantable medical device to be assessed and for representative samples of non-implantable Class IIb and Class 3 IVDs to be assessed.

Higher scrutiny of medium-high risk devices is an important feature of the new European Regulations, especially for implantable medical devices and compliance with the clinical evidence requirements.

In Australia, the TGA has always assessed compliance with clinical evidence requirements and safety and performance requirements (Essential Principles) as part of any conformity assessment certification for Class IIb or Class 3 IVD medical devices. We do so based on risk-based sampling of the technical documentation.

For Class III and Class 4 IVD medical devices, with our previous proposals, we seek to formalise the assessment and certification under the Australian Part 1.6 Design Examination procedures, by repealing Part 2 Type Examination. In this proposal we look to align with the European Regulations by formalising our current practice and specifying that the Part 1.6 Design Examination procedures must also apply to Class IIb or Class 3 IVD medical devices.

This would require a design examination certificate for every ‘kind of medical device’, as defined in Australia under Section 41BE of the Act [1] and Regulation 1.7, for Class IIb and Class 3 IVD medical devices that require a TGA conformity assessment certificate. In practice, this means assessing and certifying a representative sample device for each Global Medical Device Nomenclature (GMDN) code[2]. This aligns with assessment requirements for certification from comparable overseas regulators to include ‘kind of medical device’ assessments.

This change should be cost-neutral in relation to assessment fees since we are already recovering the costs of our assessment which addresses both the product assessment and the quality management system assessment. This proposal would essentially split these separate components.

[1] Section 41BE of the Act provides that a kind of medical device has the same sponsor, manufacturer, device nomenclature system code medical device classification, and are the same in relation to such other characteristics as the regulations prescribe, either generally or in relation to medical devices of the kind in question.

[2] Regulation 1.7 - In accordance with the Global Medical Device Nomenclature System Code, as set out in ISO 15225:2000(E), the device nomenclature system code specified for a medical device is: … for a Class 3 IVD medical device—the relevant Level 3 collective term, or if no Level 3 collective term exists, the relevant Level 2 collective term … for a Class IIb medical device—the relevant preferred term

Proposal 3

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/No

    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/No

    c. Add clause 1.6 of Part 1 to the minimum requirements for Class 3 IVD medical devices? Yes/No

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

Proposal 4 – Reduce barriers for innovation

The TGA has received anecdotal reports from industry of cases where Australian inventions went offshore for manufacturing because they were unable to source an Australian manufacturing site with appropriate certification. These cases relate to a medical device that:

- are substances introduced into the body or applied on the skin, or
- incorporates a substance that, if used separately, would be a medicine.

The reports suggest that manufacturers with appropriate licenses for manufacturing medicines in Australia were available, but those with appropriately certified quality management systems for medical device manufacturing were not as accessible.

This proposal is to reduce barriers for Australian innovations by developing a conformity assessment procedure similar to Part 6B of the conformity assessment procedures. Part 6B relates to Class 4 in-house IVD medical devices used in relation to the manufacture of blood, blood components and plasma derivatives, human cell and tissue based therapeutic goods. Part 6B.3 recognises that other TGA manufacturing licenses meet most of the quality management system requirements for medical devices and can be used as part of the evidence of compliance with the conformity assessment procedures. In practice, a TGA medical device auditor would join the TGA biologics inspection as a joint activity.

This proposal would similarly recognise a TGA manufacturing license for medicines as meeting most of the quality management system requirements. Additional requirements addressing design and development, technical documentation requirements, and post-market requirements for medical devices would be assessed either separately or by a TGA medical device auditor joining the TGA manufacturing licence inspection.

Proposal 4

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/No
    b. includes design examination requirements? Yes/No
    c. specifies the technical documentation requirements? Yes/No
    d. specifies post-market requirements? Yes/No
    e. Please provide reasons for your position (optional).

Proposal 5 – Include the MDSAP in the procedures

Sponsors of medical devices may use MDSAP certification as part of their manufacturer's evidence for inclusion in the ARTG, along with other international assessments and approvals from comparable overseas regulators. Similarly, manufacturers may choose to apply for TGA conformity assessment certification to obtain appropriate evidence of compliance with the requirements for their medical devices. When applying for TGA conformity assessment certification the manufacturer may submit, as evidence of their compliant quality management system, certification from the MDSAP.

We propose to introduce references to the MDSAP in the Regulations (such as in Division 3.2 or in Schedule 3 of the Regulations). We would reference the MDSAP requirements, auditing organisations and certification, and require manufacturers to notify substantial changes to their auditing organisation as per the MDSAP rules. We propose to recognise MDSAP certification as an acceptable way for manufacturers to satisfy obligations to have their quality management system assessed, in addition to the currently recognised options, which are conformity assessment certification by the TGA or an Australian Conformity Assessment Body (noting that there are currently no Australian Conformity Assessment Bodies). We would also clarify that the MDSAP auditing organisation must assess the manufacturer's compliance with the Australian requirements, currently specified in the MDSAP Audit Approach document, if products are supplied to Australia.

We would also clarify that the MDSAP certification does not satisfy the product compliance requirements under the conformity assessment procedures. The product compliance requirements must be satisfied by evidence of approval or certification by a comparable overseas regulator, by a TGA conformity assessment certificate or by a future Australian Conformity Assessment Body.

We are seeking your feedback and consideration on this proposal, which is intended to provide additional clarity for manufacturers and sponsors.

Proposal 5

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/No

    b. Require 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? Yes/No

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

Proposal 6 – Reusable surgical instruments

This proposal considers how reusable surgical instruments are classified. As such this proposal will have an impact on all reusable surgical instruments supplied in Australia, including those that utilise the comparable overseas regulator certification pathway for inclusion in the ARTG, as well as those that utilise TGA conformity assessment certification.

In Australia, most reusable surgical instruments are currently classified as Class I or Class Is (if sterile) medical devices. However, many reuseable surgical instruments are higher classes (Classes IIa, IIb or III medical devices) depending on the intended purpose of the device. Other regions, including Singapore, Europe, Canada, the US, take a similar risk based approach for classifying reusable surgical instruments, with various considerations, including the contact sites for instruments (for example those intended to have contact with the central nervous system or central circulatory system are classified as higher risk devices) or the degree of risk of infection as these devices are intended to be reused on multiple patients and reprocessed by health services.

The new European Regulations require manufacturers of reusable surgical instruments, no matter what their classification, to obtain certification from an EU notified body. Previously, those surgical instruments that were Class I devices did not need to be assessed by a notified body. The intent of the EU Regulations appears to be improving the quality of the instructions that manufacturers provide to health services who need to reprocess the devices after use. Manufacturers must validate the cleaning and sterilisation instructions for their reusable surgical instruments to ensure that the devices are suitable for reprocessing and reuse. The notified body plays an important role in checking that the manufacturer has appropriate evidence to support the reprocessing instructions.

Those devices that were previously Class I, nominally remain Class I in Europe but are now generally referred to as Class Ir devices. However, the European conformity assessment procedures required for these devices are equivalent to those required for a Class IIa medical device, although the notified body assessment is limited to “the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use".

We propose to align the classification of our Class I reuseable surgical instruments with Europe. The rationale is further strengthened by stakeholders (e.g. hospital infection control and sterilisation experts) raising concerns with the TGA about the risks associated with these devices and inappropriate or inadequate cleaning, disinfection, sterilization, maintenance, and device failures following multiple uses.

We consider the most straightforward way to align with the increased conformity assessment requirements being implemented in Europe and address the identified risks with reusable surgical instruments is to up-classify the Class I devices to Class IIa in Australia. This would avoid the need to create a new Class Ir category in Australia, with the associated additional costs, complexity and

system changes for the TGA and industry. Creating a new Class Ir category may risk limiting the supply of these devices to European certification only as this classification is not used in other jurisdictions.

In practice, this would mean repealing subclause 4 of classification Rule 3.2 (Schedule 2 of the Regulations) that applies to surgically invasive medical devices intended for transient use. Most surgically invasive devices for transient use are Class IIa, unless other risk factors apply, to make them a higher class. Subclause 4 is the exception that reduces the classification of reusable surgical instruments to Class I, so repealing that clause would make these Class I devices Class IIa.

By up-classifying the reusable Class I and Class Is medical devices to Class IIa, current comparable overseas regulator arrangements would not need to change. The conformity assessment certificates for Class IIa medical devices are the same as those for Class Ir medical devices in Europe, although the scope of the notified body assessment is more targeted. In Europe, manufacturers of Class Ir medical devices must obtain certification under the Full Quality Assurance or Production Quality Assurance procedures. This is the same certification options available for manufacturers of Class IIa medical devices using the European comparable overseas regulator pathway in Australia. By up-classifying to Class IIa, the pathways available for other comparable overseas regulator approvals, such as those involving the MDSAP, also apply. Up-classifying reusable surgical instruments to Class IIa also makes the established TGA conformity assessment certification options also available.

Although the use of current comparable overseas regulator arrangements would not see a cost incurred for manufacturers with certification from European notified bodies, those manufacturers of reusable Class I and Class Is devices manufactured in other jurisdictions would need to seek alternative certification, such as comparable overseas regulator approval or TGA conformity assessment certification. Further to this, there would also be additional costs to include the devices on the ARTG at the higher Class IIa and higher on-going annual charges that are payable for some ARTG entries due to the up-classification.

Proposal 6

11. Do you agree with up-classifying reusable surgical instruments:
    a. to Class IIa medical devices? Yes/No

OR

    b. to a new subclassification of Class I similar to the EU? Yes/No
    c. Please provide reasons for your position (optional).

12. Do you agree a 3-year period would be sufficient time to allow this transition to occur? Yes/No
    a. Please provide a reason for your position (optional).

Proposal 7 – Clinical and post-market planning and reporting

This proposal seeks to align our processes with the intent of *An Action Plan for Medical Devices*, to strengthen the monitoring and follow-up of devices already in use. The aim of this proposal is to more promptly identify and address threats to patient safety and to take quicker action. This proposal also aligns with the European Regulations, as well as the post-market surveillance requirements that have been recently updated in Great Britain[3].

As the Australian post-market requirements are part of the conformity assessment procedures and other parts of the legislation, this proposal will impact all medical devices supplied in Australia.

Clinical evidence and post-market surveillance

Australia has a conformity assessment procedure (Part 8) relating to clinical evaluation requirements and post-market requirements that are included in most of the other procedures. However, these Australian requirements are not as detailed as the new European requirements (see Appendix 3 and Appendix 4). To align, we are proposing the Australian requirements be amended to expand the clinical investigation data and literature review requirements to include more detail. Namely planning, evaluating, reporting of the clinical, performance and post-market experience with medical devices, including real-world evidence. This would include a requirement for the development and documentation of a clinical evaluation plan, post-market clinical follow up plan (for non-IVD medical devices), performance evaluation plan, post-market performance follow up plan (for IVD medical devices) and post-market surveillance report or periodic safety update report.

These requirements are generally in line with the IMDRF guidance on Clinical Evaluation and Post-market Clinical Follow-up Studies[4], which highlight the importance of a systematic approach to the ongoing processes conducted throughout the life cycle of a medical device to verify the safety, performance and effectiveness of the medical device. However, the new European requirements go beyond the guidance by prescribing specific data that must be provided to the notified body.

Similarly, when compared to other jurisdictions, such as the US, the new European post-market requirements are more stringent (for example, in the US, there is a requirement for periodic post-market reports, whereas in Europe the requirement is on-going). However, there are also other jurisdictions that have similar reporting requirements to those in Europe. Since 2021, medical device manufacturers are required to provide summary reports, every year for Class III and IV devices and every two years for Class II devices, as well as create issue-related analysis reports within 30 days of request from Health Canada[5].

It is anticipated that the standardisation of documentation being provided across multiple jurisdictions and provision of greater detail on the requirements would bring clarity for manufacturers and improve our post-market surveillance activities. Efficiencies in identifying safety, quality and performance signals are envisaged by having comparable information from multiple manufacturers available in the same format, leading to faster identification of new or emerging concerns and improved patient outcomes.

Safety and clinical performance summaries

Further to these reports, the European Regulations include that manufacturers make available to the public a summary of the safety and clinical performance of implantable and Class III medical devices through a regulatory database (Article 32 of EU MDR). These summaries are intended to be a concise

[3] The Medical Devices (Post-market Surveillance Requirements)(Amendment)(Great Britain) Regulations 2024 https://www.legislation.gov.uk/uksi/2024/1368/contents/made

[4] https://www.imdrf.org/documents/clinical-evaluation and https://www.imdrf.org/documents/post-market-clinical-follow-studies

[5] Health Canada - Guidance on summary reports and issue-related analyses for medical devices https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/reports-publications/medeffect-canada/medical-device-reports-analyses-guidance/medical-device-reports-analyses-guidance-en.pdf

overview of a medical device's safety and clinical performance, including relevant clinical data, for public access. They do not replace instructions for use or patient information material but rather provide an additional tool to assist healthcare professionals and patients make informed decisions. We are seeking your views on aligning with this requirement.

Annual reporting

In Australia, the current requirements for annual reports is limited to higher risk medical devices for the first three years of inclusion in the ARTG, with content that is similar to that of the European periodic safety update reports. The European annual reporting requirements extend upon our current reporting requirements for both the longevity of reporting and the classification of medical devices that are required to provide reports. The European Regulations require that post-market reports be provided for the lifetime of the medical device, either annually for high risk medical devices or every two years for medium risk medical devices. Lower risk medical devices are only required to provide the reports upon request.

While we propose to align with the EU for annual reporting requirements, if this was to proceed there will be an increase in the number of annual reports impacting the TGA's resourcing and analysis capability to process this data.

Adverse event reporting

Currently, sponsors are legally required to provide us with details of adverse events and field safety corrective actions that relate to medical devices supplied in Australia, within specified timeframes and to report adverse event trends. There is no requirement for manufacturers to report the same events in a similar timely manner to the Australian sponsors. This can result in significant delays in appropriate action being taken to support patient safety. We propose to amend the Australian requirements for manufacturers to report adverse events and field safety corrective actions to sponsors, for onward reporting to us, and to be more specific in the information required.

The current timeframes for sponsors to report to us are:

- within 48 hours for an incident that represents a serious threat to public health
- 10 days for an incident that led to the death or serious deterioration of the health of a patient, user, or another person
- 30 days for an incident that might have led to the death or serious deterioration of the health of a patient, user, or another person
- 60 days for other information, including field safety corrective actions.

For each adverse event report submitted by the sponsor, a final report with updates and actions taken is also required to be provided within 120 days of lodging the initial report. The absence of clear requirements for manufacturers has led to some sponsors not being able to provide us with information in a timely manner or to provide a final report within the legislated period.

The European Regulations also require the manufacturer to provide information on adverse event reports and field safety corrective actions to a country where that medical device is being supplied, even in cases where the country is different to that of where the event occurred. This allows greater transparency on the safety, quality and performance of the medical device being supplied in each country. In several cases, there have been reports of patient harm that may have been avoided had the international information been provided locally. We are proposing to introduce the same requirement for manufacturers to provide sponsors with this additional information for medical devices they supply in Australia. We also propose that sponsors will only need to provide the overseas adverse event information to us upon request and the field safety corrective actions are to be provided in accordance with the Procedure for recalls, product alerts and product corrections (PRAC).

Providing evidence of compliance

Currently, it is a legislated requirement in Australia that documents and information be provided to demonstrate evidence of compliance with the Essential Principles and conformity assessment

procedures when requested by the TGA. During post-market surveillance activities, however, some manufacturers and sponsors have voiced concerns as they did not understand that this was applicable to all medical devices, in particular those that were complying with Part 6 or Part 7 of the conformity assessment procedures with the provision of a declaration of conformity. The provision of the documents and information to support compliance of the conformity assessment procedures, as opposed to just the declaration, is important during investigations and safety-related reviews. We propose to amend the wording in the legislation and guidance to provide further clarity on these requirements.

Proposal 7

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? Yes/No
    b. Post-market clinical/performance follow-up plan? Yes/No
    c. Post-market surveillance/periodic safety update report? Yes/No
    d. Please provide reasons for your position (optional).
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? Yes/No
    b. Other classifications to be updated every two years? Yes/No
    c. Please provide reasons for your position (optional).
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? Yes/No
    b. All other classes of devices, submitted upon request? Yes/No
    c. Please provide reasons for your position (optional).
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. Yes/No
    b. Please provide a reason for your position (optional).
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/No
    b. Manufacturers be required to report international adverse events to sponsors, where the sponsor supplies the same medical device in Australia? Yes/No
    c. Manufacturers are required to report trends in adverse events to sponsors? Yes/No
    d. The timeframes for manufacturers to report to sponsors be the same for sponsors to report to the TGA? Yes/No
    e. Adverse events are required to be reported to the TGA, by sponsors, even after an ARTG entry has been cancelled? Yes/No

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

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/No

    b. Actions that have been raised internationally and the medical devices are supplied in Australia? Yes/No

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

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? Yes/No

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

Proposal 8 – General alignment & transition arrangements

We are seeking your views on amending the Regulations to incorporate relevant additional conformity assessment requirements specified in the European Regulations (refer to Appendix 1). Some of the requirements for manufacturers, in the European Regulations, are included in the Australian Regulations rather than solely in the conformity assessment procedures, which will mean that this proposal will impact those medical devices that have been included in the ARTG with comparable overseas regulator certification or TGA conformity assessment certification.

In Australia, the requirements, in this proposal, are specific to sponsors and have not been reflected similarly in the manufacturer's responsibilities. These responsibilities include documentation of the manufacturer-sponsor relationship. The absence of this requirement for manufacturers results in a discrepancy between the requirements for sponsors and manufacturers, may impact sponsors receiving timely support and input from manufacturers, and can also result in a disparity between the audits being undertaken by us and those undertaken by a European notified body.

An additional requirement for manufacturers is to have a designated, qualified, person within the manufacturer's organisation, or for small companies at their disposal, who is responsible for regulatory compliance[6]. This requirement would potentially ensure a robust quality management system is in place and maintained appropriately and improve the readiness of a manufacturer to respond to any relevant enquiries.

The European Regulations require manufacturers of Class 4 IVD, Class III and implantable Class IIb medical devices to retain documentation for 15 years and 10 years for all other classes of medical devices, after the last device has been placed on the market. This documentation includes the manufacturer's quality management system and post-market surveillance system, substantial changes to those systems, and audit reports and decisions.

The US Food and Drug Administration (US FDA) has taken an approach to more closely align with the requirements specified in ISO 13485. These requirements are to retain records for at least the lifetime of the medical device, as defined by the manufacturer.

Currently, Australian legislation requires manufacturing documentation to be retained for 5 years, and distribution records for Class 4 IVD, Class III and implantable Class IIb medical devices to be kept for 10 years and 5 years for other classes of medical devices, except for implantable medical devices used for special purposes, where the documentation is to be retained for 15 years.

[6] Article 15 of EU MDR and EU IVDR

This proposal seeks to align the document retention timeframes, as well as the types of documents to be retained, with the European Regulations, the US FDA, and ISO 13485. With recent incidents involving medical devices, such as metal-on-metal hips, transvaginal mesh, and breast implants, the need to access more complete long-term information on design, performance, supply, and adverse events has been made evident.

The relevant definitions in the European Regulations, which relate to conformity assessment, were reviewed and compared to the definitions in the Australian Act and Regulations. Where the term is mentioned in the Act or Regulations, and the general meaning is well understood in the Australian context, and therefore there does not appear to be a necessity to explicitly define the terms, they have not been included as part of the consultation. Where there are mismatches or an absence of a comparable definition these have been considered and a proposal, with a justification, is provided in Appendix 5. Terms that relate to other areas of the legislation have been or will be included in other consultations.

Your views on the proposals are welcomed, as well as providing feedback on other terms that you consider would benefit from defining.

We are also seeking your feedback on the timeline to implement any alignments. Currently the European Regulations have a transition period for medical device conformity assessment ending on 31 December 2027 for high risk medical devices, 31 December 2028 for moderate risk medical devices, and 31 December 2028 for lower risk medical devices. The transition period for IVD medical device conformity assessment ends on 31 December 2027 for high risk IVD medical devices, 31 December 2028 for moderate risk IVD medical devices, and 31 December 2029 for lower risk IVD medical devices.

Proposal 8

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/No

    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/No

    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/No

    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/No

    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/No

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/No

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

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

    a. Adverse event? Yes/No

    b. Post-market surveillance? Yes/No

    c. Information society service? Yes/No

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

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

    a. Yes/No

    b. If yes, please provide a list of the other terms you would like defined.

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? Yes/No

    b. When their current manufacturer's evidence expires or six months later than the European Regulations, whichever is earliest? Yes/No

    c. Immediately for new manufacturers? Yes/No

    d. A different timeframe (please provide the suggested date and reason below)? Yes/No

    e. Please provide reasons for your position (optional)

What we invite you to do

In your submission, we ask you to consider and respond to the questions outlined above, and to provide comments on the issues outlined in this consultation paper.

How to submit your feedback

Your views and feedback will help inform any changes to our practices, the Act, or the Regulations relevant to medical devices. In addition to the scope of this consultation, we welcome feedback on our 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@tga.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 the TGA website. This is expected to occur in 2026.

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

This consultation closes at 23:59pm on 14 April 2026

Appendices

Appendix 1: Comparing Australia and Europe

Part 1: Full quality assurance procedure

The conformity assessment procedures set out in this part provide for the manufacturer of a kind of device to implement a quality management system (QMS) for the design, production, packaging, labelling and final inspection of the kind of device.

The equivalent European conformity assessment procedures are in Annex IX of the European Regulations.

Key Differences[7]

The key differences in the European Regulations in comparison with the Australian Regulations are:

1. Emphasis on implementation of the QMS systematically throughout the life cycle of the device.
2. Increase in retention period of documents from 10 to 15 years for Class 4, Class III, and implantable Class IIb medical devices, and an increase from five to 10 years for all other medical devices, after the last device has been placed on the market. This relates to documents such as: Declaration of conformity, QMS documentation, information on QMS/devices changes, technical documentation and notified body decisions and reports.
3. Emphasis on requirement of documentation on a post market surveillance system, including post market clinical follow-up plan or post-market performance follow-up plan (where applicable), clinical evaluation plan or performance evaluation plan, and the relevant procedures to ensure compliance with the obligations resulting from provisions on vigilance[8] detailed below.
    a. In case of serious incident, the reporting timelines specified for a manufacturer and related procedures.
    b. Requirements for manufacturers to report any statistical significant increase in severity of non-serious incidents that could have a significant impact on the benefit risk analysis and the methods used for such determinations.
    c. Procedures around performing investigations of serious incidents and undertaking field safety corrective actions, taking into account the protection of public health.
    d. Requirement for manufacturers to ensure information around field safety corrective action is bought to the attention of the users in the form of field safety notice.
    e. Establishment of the vigilance systems that contains periodic summary reports, report on serious incidents and field safety corrective actions, reports by manufacturers on trends, periodic safety update reports and field safety notices.

[7] Annex IX, Chapter 1 The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
[8] Article 87 – 92 of EU MDR

4. Requirement for Class I medical devices that are sterile, with a measuring function, or are reusable surgical instruments to have assessment of technical documentation relating to the specialised procedures.

Part 1.6: Design examination

The equivalent European conformity assessment procedures, for the European Regulations are in Chapter II of Annex IX.

Key differences[9]

The key differences in the European Regulations in comparison with the Australian Regulations are:

1. Assessment of technical documentation is applicable to:
    a. Class IIb medical devices (except those devices with a special purpose, being a medical device to which Regulation 3.10 applies).
        i. Class IIb non-implantable medical devices are to include an assessment of design dossier of **at least one representative device per generic device group.**
        ii. Class IIb implantable medical devices (except for sutures, staples, dental filings, dental braces, tooth crowns screws, wedges, plates, wires, pins, clips and connectors), include an assessment of design dossier **for every device**.
    b. Class 2, 3, and 4 IVD medical devices.
        i. Class 2 IVD medical devices will have reviews of technical documentation on a representative basis, with reviews based on ‘product categories’.
        ii. Class 3 IVD medical devices will be assessed as kinds of medical devices.
        iii. Class 4 IVD medical devices will have their technical documentation reviewed (no sampling approach).
2. All medical devices are to have technical documentation as per:
    a. Annex II – Technical Documentation.
    b. Annex III – Post market surveillance documentation[10].
3. Detailed procedures for assessment of technical documentation for the devices such as:
    a. Class III and Class IIb active devices that are intended to administer and/or remove medicinal product.
    b. Devices containing a medicinal substance.
    c. Devices containing tissues or cells of animal origin or their derivatives.
    d. Devices containing tissues or cells of human origin or their derivatives.
    e. Devices containing substances or combination of substances that are absorbed by or locally dispersed in the human body.
    f. Self-testing IVD medical devices.
    g. IVD medical devices to be used at point of care.

[9] Chapter II, Annex IX, The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
[10] Refer Appendix B and C for detailed technical and post market documentation requirements.

h. IVD companion diagnostics.

4. Increase in retention period of documents from 10 to 15 years for Class 4, Class III, and implantable Class IIb medical devices, and an increase from five to 10 years for all other medical devices, after the last device has been placed on the market. This relates to documents such as: Declaration of conformity, QMS documentation, information on QMS/devices changes, technical documentation and notified body decisions and reports.

Part 2: Type examination

This conformity assessment procedure sets out requirements for manufacturer to arrange for examination of a **representative sample** of a kind of medical device.

The equivalent European conformity assessment procedures are in **Annex X** of the European Regulations.

Key Differences

The key differences in the European Regulations in comparison with the Australian Regulations are:

1. Application to include technical documentations outlined in Annexes II (technical documentation) and Annex III (post-market surveillance documentation)[11].
2. Increase in retention period of documents from 10 to 15 years for Class 4, Class III, and implantable Class IIb medical devices, and an increase from 5 to 10 years for all other medical devices, after the last device has been placed on the market. This relates to documents such as: Declaration of conformity, QMS documentation, information on QMS/devices changes, technical documentation and notified body decisions and reports.

Part 3: Product verification

This procedure sets out requirements for manufacturers to arrange for examination and testing of each device of that kind of representative sample from a batch of medical device of that kind.

The equivalent to this conformity assessment procedure in the European Regulations is Annex XI.

Key Differences:

The key differences in the European Regulations in comparison with the Australian Regulations are:

1. Emphasis on requirement of documentation on a post market surveillance system, including post market clinical follow-up plan or post-market performance follow-up plan (where applicable), clinical evaluation plan or performance evaluation plan, and the relevant procedures to ensure compliance with the obligations resulting from provisions on vigilance detailed below.
    a. In case of serious incident, the reporting timelines specified for a manufacturer and related procedures.
    b. Regulatory body to take appropriate measures such as organising targeted information campaigns to health professionals, users, and patients.
    c. Requirements for manufacturers to report any statistically significant increase in severity of non-serious incidents that could have a significant impact on the benefit risk analysis and the methods used for such determinations.
    d. Procedures around performing investigations of serious incidents and undertaking field safety corrective actions, accounting for the protection of public health.
    e. In case of serious incidents related to substances such as medicinal substance, derivatives of tissues or cells of human origin incorporated in the devices, the relevant competent

[11] Refer Appendix 3 and 4 for detailed technical documentation requirements and Appendix 6 for post market documentation requirements.

authority of the substance to be informed of the of the incident and the relevant corrective action.

f. Requirement for manufacturers to ensure information around field safety corrective action to be bought to the attention of the users in the form of field safety notice.

g. Establishment of the vigilance systems that contains periodic summary reports, report on serious incidents and field safety corrective actions, reports by manufacturers on trends, periodic safety update reports and field safety notices.

2. Increase in retention period of documents from 10 to 15 years for Class 4, Class III, and implantable Class IIb medical devices, and an increase from five to 10 years for all other medical devices, after the last device has been placed on the market. This relates to documents such as: Declaration of conformity, QMS documentation, information on QMS/devices changes, technical documentation and notified body decisions and reports.
3. Requirement that the Class IIa medical devices conform to the technical documentation referred to in Annex II and III.
4. Verification of Class 4 IVD medical devices on each manufactured batch of devices, with conclusions of the tests provided to the notified body without delay.

Part 4: Production quality assurance procedure

This conformity assessment procedure sets out requirements to implement a QMS for the production and final inspection of the kind of medical device.

The equivalent to this conformity assessment procedure is provided in Annex XI of the European Regulations.

Key Differences:

The key differences in the European Regulations in comparison with the Australian Regulations are:

1. Emphasis on requirement of documentation on a post market surveillance system, including post market clinical follow-up plan or post-market performance follow-up plan (where applicable), clinical evaluation plan or performance evaluation plan, and the relevant procedures to ensure compliance with the obligations resulting from provisions on vigilance, including:
    a. In case of serious incident, the reporting timelines and related procedures.
    b. Requirements for manufacturers to report any statistically significant increase in severity of non-serious incidents that could have a significant impact on the benefit risk analysis and the methods used for such determinations.
    c. Procedures around performing investigations of serious incidents and undertaking field safety corrective actions, taking into account the protection of public health.
    d. Requirement for manufacturers to ensure information around field safety corrective action to be bought to the attention of the users in the form of field safety notice.
    e. Establishment of the vigilance systems that contains periodic summary reports, report on serious incidents and field safety corrective actions, reports by manufacturers on trends, periodic safety update reports and field safety notices.
2. Requirement for technical documentation referred to in Annex II and III.
3. Increase in retention period of documents from 10 to 15 years for Class 4, Class III, and implantable Class IIb medical devices, and an increase from five to 10 years for all other medical devices, after the last device has been placed on the market. This relates to documents such as:

Declaration of conformity, QMS documentation, information on QMS/devices changes, technical documentation and notified body decisions and reports.

Part 5: Product quality assurance procedure

The European Commission has removed the equivalent Part 5 - Product Quality Assurance Procedure detailed in previous European Medical Device Directives.

Part 6: Declaration of conformity

The equivalent to this conformity assessment procedure is found in Annex IV in the European Regulations.

Our requirements and the European requirements are similar.

Part 7: Procedures for medical devices used for special purpose

This conformity assessment procedure requires manufacturers of a medical device used for a special purpose, such as custom made medical devices and system or procedure packs, to prepare a statement containing information related to the device and prepare and keep up to date particular documentation in relation to the device.

The European equivalent to this conformity assessment procedure is in Annex XIII of the EU MDR; there is no equivalent in the EU IVDR.

Key Differences:

The key differences in the European Regulations in comparison to the Australian Regulations are:

1. All Class III implantable custom devices[12], in addition to Annex XIII procedure will be required to undergo procedure under Annex IX (i.e. Full Quality Assurance Procedure) or Annex XI – Part A (i.e. Production quality assurance procedure).
2. Explicit mention of requirement for indication, if the device contains medicinal substance, or tissues or cells of human origin, or of animal origin.
3. Emphasis on manufacturer to review and document experience gained in post-production phase, including the post-market clinical follow-up plan.
4. Increase in retention period of documents from 10 to 15 years for implantable medical devices, and an increase from five to 10 years for all other medical devices, after the last device has been placed on the market.

Part 8: Clinical evaluation procedures

This conformity assessment procedure requires manufacturers of a medical device to obtain and evaluate clinical data in relation to the device. The equivalent European conformity assessment procedures are Annex XIV Clinical evaluation and post-market follow-up in the EU MDR Regulation and Annex XIII Performance evaluation and post-market follow-up in the EU IVDR Regulation.

We have recently updated guidance to explain our interpretation of our existing Australian Regulations for clinical evidence for medical devices, including IVD medical devices:

- Clinical evidence guidelines: Medical devices
- Clinical evidence guidelines supplement: In vitro diagnostic (IVD) medical devices

[12] **Article 52**(8), The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The EU MDR Regulation Annexes XIV (p164) has reinforced requirements for medical devices (non-IVDs) on clinical evidence, including:

- clinical follow-up
- clinical evaluation and investigation
- specified requirements on the content of:
  - clinical evaluation reports
  - clinical evaluation plan
  - post-market clinical follow-up plan
  - post-market clinical follow-up evaluation report.

The EU MDR provides further information in Chapter VI – Clinical evaluation and clinical investigations (Article 61-81).

Similarly, the EU IVDR Regulation, Annex XIII has reinforced requirements for IVD medical devices on performance evaluation, including specified requirements on the content for:

- performance evaluation:
  - performance evaluation plan
  - demonstrating the scientific validity and analytical and clinical performance
  - clinical evidence and performance evaluation report
- clinical performance studies:
  - methods for studies
  - study reports

The EU IVDR provides further information in Chapter VI – Clinical evidence, performance evaluation and performance studies (Articles 56-77).

Key Differences from EU MDR:

The key differences in the EU MDR Regulation in comparison to the Regulations are:

1. Emphasis on requirement of clinical documentation such as clinical evaluation plan, clinical evaluation report and post market clinical follow up plan.
2. Clear details on contents of the clinical evaluation plan, clinical evaluation report and post market clinical follow up plan. Refer to Appendix 5 for more details.
3. For Class III and Class IIb medical devices, consideration for the manufacturer to consult with an external panel regarding the manufacturer's intended clinical development strategy and incorporate the panel's recommendation in the clinical evaluation report.
4. Details the procedure for clinical evaluation to be based on scientific literature, evaluation of clinical investigations and consideration of alternative treatment options.
5. Emphasises that clinical investigations must be conducted on implantable devices and Class III devices, except if:
   a. the device has been designed by modification of an already marketed device by the same manufacturer and there is a sound rationale that this modification will not adversely affect clinical safety and performance.
   b. the modified device has been demonstrated by the manufacturer to be equivalent to a marketed device that has been approved by the notified body, along with the two manufacturers having a contract in place that explicitly allows the manufacturer of the

modified device full access to technical documentation of the equivalent device and original clinical evaluation has been performed on the equivalent device in compliance with requirements of this regulation.

c. the clinical evaluation of the marketed device claimed equivalent is sufficient to demonstrate conformity of the modified device with relevant safety and performance requirements.

d. the device has already been placed on the market on basis of sufficient clinical data and is in compliance with product specific common specifications where available, or

e. devices are sutures, staples, dental filings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which clinical evaluation is based on sufficient clinical data, or

f. Justification in view of well-established technologies similar to those used in exempted Class IIb implantable devices (such as sutures, staples…) or to protect health and safety of patients or other aspects of public health.

6. Clinical evaluation and its documentation shall be updated throughout the lifecycle of the device concerned and for Class III and Class IIb implantable devices, post market clinical follow-up evaluation report shall be updated at least annually.
7. Detailed requirements for:
   a. conduct of clinical investigations to demonstrate conformity of devices that includes considerations for designing and conduct of investigations.
   b. informed consent by the subject for clinical investigation.
   c. considerations when clinical investigations are conducted on minors.
   d. considerations when clinical investigations are conducted on pregnant or breastfeeding women.
   e. considerations when clinical investigations are conducted on incapacitated subjects.
   f. considerations when clinical investigations are conducted in emergency situations and damage compensation that covers any damage suffered by the subject.
   g. considerations for clinical investigations on devices already approved.
8. Detailed requirements around the clinical investigation application and assessment requirements by the member states which include assessment of compliance of investigational device with applicable general safety and performance requirements and risk minimisation to ensure health and safety of the subjects.
9. Details requirements for conduct of clinical investigation, electronic system on clinical investigation, substantial modifications to clinical investigations.
10. Details requirements for recording and reporting of adverse events that occur during clinical investigations.
11. Requirements around information from the sponsor at the end of clinical investigation or in the event of temporary halt or early termination.

Key differences from EU IVDR:

The EU IVDR Annex XIII has specific requirements for IVD medical devices which are modified, or additional, to the Part 8 conformity assessment procedure requirements, including:

1. To plan, continuously conduct and document a performance evaluation by which data are assessed and analysed to demonstrate the scientific validity, analytical performance and clinical performance of that device for its intended purpose, as stated by the manufacturer.
2. Specific requirements for information to be included in a performance evaluation plan, including:
    a. demonstrating scientific validity.
    b. demonstrating analytical performance.
    c. demonstration of the clinical performance, includes:
        i. an additional option for using “published experience gained by routine diagnostic testing”.
        ii. that clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.
        iii. that clinical performance shall be demonstrated and documented in a clinical performance report.
3. Clinical evidence and its assessment is to be **updated throughout the life cycle of the device** with data obtained from the implementation of the manufacturer's post-market performance follow-up plan (referenced in Part B of Annex III, as part of the performance evaluation and the post-market surveillance system, referred to in Article 10(9)).
4. Specific requirements for the clinical performance studies to include
    a. the purpose of the study, which cannot be determined by analytical performance studies, literature or previous experience gained by routine testing
    b. Ethical principles to be applied to all aspects of the clinical study
5. Specific detailed requirements for methods used in clinical performance studies, including:
    a. Clinical performance study design type.
    b. Detailed requirements for the clinical performance study plan.
    c. Clinical performance study report.
6. Provision that where “other performance studies” are conducted, that the same requirements apply as those for clinical performance studies.

Appendix 2: Proposed amendments summarised

The current and proposed changes to the minimal applicable conformity assessment procedure pathways in the Therapeutic Goods (Medical Devices) Regulations 2002 are.

Device class	Current options for conformity assessment	Proposed options for conformity assessment
Class I	• Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary)	Part 6 (Declaration of Conformity Procedures)
Class I with measuring function and/or sterile	• Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 3 (Verification Procedures other than clause 3.5) OR • Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures other than clause 4.7) • Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 (Examination of Design) with limited assessment • Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 5 (Product Quality Procedures other than clause 5.7)	• Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 (Examination of Design) with limited assessment, OR • Proposed MDSAP procedure
Class IIa,	• Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 (Examination of Design) OR • Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 3 (Verification Procedures other than clause 3.5) OR • Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures other than clause 4.7) OR • Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 5 (Product Quality Procedures other than clause 5.7)	**Include reusable surgical instruments** • Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 (Examination of Design), OR • Proposed MDSAP procedure
Class IIb implantable	• Part 1 (Full Quality Assurance Procedures) OR	• Part 1 (Full Quality Assurance Procedures) +

	• Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures) OR • Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures) • Part 2 (Type Examination Procedures) + Part 5 (Product Quality Procedures)	Clause 1.6 (Examination of Design), OR • Proposed MDSAP procedure + Examination of Design
Class IIb non-implantable	• Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 OR • Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures) OR • Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures) • Part 2 (Type Examination Procedures) + Part 5 (Product Quality Procedures)	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design) for representative device, OR • Proposed MDSAP procedure + Examination of Design for representative device
Class III	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design) OR • Part 2 (Type Examination Procedures) + Part 3 (Verification Procedures) OR • Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design), OR • Proposed MDSAP procedure + Examination of Design
System or Procedure Packs or custom made medical device	• Part 7 (Procedures for Medical Devices Used for a Special Purpose)	To note: Part 1 would be the only option for sterile devices if Part 4 is removed
Class 1 IVD	• Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary)	• Part 6 (Declaration of Conformity Procedures)
Class 2 IVD	• Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 (Examination of Design) for representative device OR • Part 4 (Production Quality Assurance Procedures other than clause 4.7) + Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary)	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design) for representative device, OR • Proposed MDSAP procedure + Examination of Design for representative device
Class 3 IVD	• Part 1 (Full Quality Assurance Procedures) excluding Clause 1.6 OR	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of

	• Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)	Design) for representative device, OR • Proposed MDSAP procedure + Examination of Design for representative device
Class 4 IVD	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design) OR • Part 2 (Type Examination Procedures) + Part 4 (Production Quality Assurance Procedures)	• Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design), OR • Proposed MDSAP procedure + Examination of Design

Appendix 3: Clinical evaluation and post-market follow-up

The table below provides a snapshot of the detailed requirements for the clinical evaluation and post market follow-up documentation in Annex XIV of the EU MDR and the performance evaluation, performance studies, and post-market performance follow-up in Annex XIII of the EU IVDR.

For the **complete list** of European requirements, refer to:

- Annex XIV of EU MDR – Clinical evaluation and post-market clinical follow-up
- Annex XIII of EU IVDR – Performance evaluation and post-market follow-up

Clinical evaluation – EU MDR
To plan, continuously conduct and document a clinical evaluation, manufacturers shall:

- establish and update a clinical evaluation plan, which shall include at least:
  - an identification of the general safety and performance requirements that require support from relevant clinical data;
  - a specification of the intended purpose of the device;
  - a clear specification of intended target groups with clear indications and contra-indications;
  - a detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters;
  - a specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects;
  - an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device;
  - an indication how benefit-risk issues relating to specific components such as use of pharmaceutical, nonviable animal or human tissues, are to be addressed; and
  - a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a post-market clinical follow-up with an indication of milestones and a description of potential acceptance criteria;
- identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic scientific literature review;
- appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device;
- generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues; and
- analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits.

The results of the clinical evaluation and the clinical evidence on which it is based shall be documented in a clinical evaluation report which shall support the assessment of the conformity of the device.

A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:

- - Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;
- - Biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;
- - Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.
- The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

The results of the clinical evaluation and the clinical evidence on which it is based shall be documented in a clinical evaluation report which shall support the assessment of the conformity of the device. The clinical evidence together with non-clinical data generated from non-clinical testing methods and other relevant documentation shall allow the manufacturer to demonstrate conformity with the general safety and performance requirements and shall be part of the technical documentation for the device in question. Both favourable and unfavourable data considered in the clinical evaluation shall be included in the technical documentation.

Post Market Clinical Follow-up – EU MDR
A post market clinical follow-up (PMCF) is a continuous process that updates the clinical evaluation (above) and shall be addressed in the manufacturer's post-market surveillance plan. The manufacturer shall proactively collect and evaluate clinical data from the use of the device when it has been supplied in the market, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and detecting emerging risks on the basis of factual evidence.

The PMCF plan shall specify the methods and procedures for proactively collecting and evaluating clinical data with the aim of:

- Confirm the safety and performance of the device throughout its expected lifetime
- identifying previously unknown side-effects and monitoring the identified side-effects and contraindications,
- identifying and analysing emergent risks on the basis of factual evidence,
- ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex I, and
- identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

The PMCF plan shall include at least:

- the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;
- the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;
- a rationale for the appropriateness of the methods and procedures;
- a reference to the relevant parts of the clinical evaluation report and to the risk management;
- the specific objectives to be addressed by the PMCF;
- an evaluation of the clinical data relating to equivalent or similar devices;
- reference to any relevant common specification (CS), harmonised standards when used by the manufacturer, and relevant guidance on PMCF; and
- a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer.

The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the clinical evaluation report and the technical documentation.

The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation and in the risk management. If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

Performance evaluation and performance studies – EU IVDR

Performance evaluation of a device is a continuous process by which data are assessed and analysed to demonstrate the scientific validity, analytical performance and clinical performance of that device for its intended purpose as stated by the manufacturer. To plan, continuously conduct and document a performance evaluation, the manufacturer shall establish and update a performance evaluation plan. The performance evaluation plan shall specify the characteristics and the performance of the device and the process and criteria applied to generate the necessary clinical evidence.

The performance evaluation shall be thorough and objective, considering both favourable and unfavourable data.

Its depth and extent shall be proportionate and appropriate to the characteristics of the device including the risks, risk class, performance and its intended purpose.

1. Performance evaluation

1.1 Performance evaluation plan

As a general rule, the performance evaluation plan shall include at least the intended purpose of the device, specification of the characteristics of the device and the analyte or marker to be determined by the device, identification of certified reference materials or reference measurement procedures, clear identification of specified target patient groups with clear indications, limitations and contra-indications, the general safety and performance requirements that require support from relevant scientific validity and analytical and clinical performance data, specification of methods, including the appropriate statistical tools, used for the examination of the analytical and clinical performance of the device and of the limitations of the device and information provided by it, a description of the state of the art, including an identification of existing relevant standards, CS, guidance or best practices documents, an indication and specification of parameters to be used to determine the acceptability of the benefit-risk ratio for the intended purpose or purposes and for the analytical and clinical performance of the device, for software qualified as a device, an identification and specification of reference databases and other sources of data used as the basis for its decision making, an outline of the different development phases including the sequence and means of

determination of the scientific validity, the analytical and clinical performance, including an indication of milestones and a description of potential acceptance criteria, and a post-market performance follow-up plan.

1.2 Demonstration of the scientific validity and the analytical and clinical performance
As a general methodological principle the manufacturer shall identify through a systematic scientific literature review the available data relevant to the device and its intended purpose and identify any remaining unaddressed issues or gaps in the data; appraise all relevant data by evaluating their suitability for establishing the safety and performance of the device; and generate any new or additional data necessary to address outstanding issues.

1.3 Clinical evidence and performance evaluation report
The manufacturer shall assess all relevant scientific validity, analytical and clinical performance data to verify the conformity of its device with the general safety and performance requirements. The amount and quality of that data shall allow the manufacturer to make a qualified assessment whether the device will achieve the intended clinical benefit or benefits and safety, when used as intended by the manufacturer. The data and conclusions drawn from this assessment shall constitute the clinical evidence for the device. The clinical evidence shall scientifically demonstrate that the intended clinical benefit or benefits and safety will be achieved according to the state of the art in medicine.

2. Clinical performance studies
The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and/or previous experience gained by routine diagnostic testing. This information is used to demonstrate compliance with the relevant general safety and performance requirements with respect to clinical performance. When clinical performance studies are conducted, the data obtained shall be used in the performance evaluation process and be part of the clinical evidence for the device. Clinical performance studies shall be performed on the basis of a clinical performance study plan (CPSP).

3. **Other performance studies**
The performance study plan and the performance study report shall be documented for other performance studies than clinical performance studies.

Post-market performance follow-up – EU IVDR
The post-market performance follow-up (PMPF) shall be a continuous process that updates the performance evaluation and shall be specifically addressed in the manufacturer's post-market surveillance plan. When conducting PMPF, the manufacturer shall proactively collect and evaluate performance and relevant scientific data from the use of a device with the aim of confirming the safety, performance and scientific validity throughout the expected lifetime of the device, of ensuring the continued acceptability of the benefit-risk ratio and of detecting emerging risks on the basis of factual evidence.

The PMPF shall be performed pursuant to a documented method laid down in a PMPF plan.

The PMPF plan shall specify the methods and procedures for proactively collecting and evaluating safety, performance and scientific data with the aim of: (a) confirming the safety and performance of the device throughout its expected lifetime, (b) identifying previously unknown risks or limits to performance and contra-indications, (c) identifying and analysing emergent risks on the basis of factual evidence, (d) ensuring the continued acceptability of the clinical evidence and of the benefit-risk ratio, and (e) identifying possible systematic misuse.

The PMPF plan shall include at least: (a) the general methods and procedures of the PMPF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of performance or scientific data; (b) the specific methods and procedures of PMPF to be applied, such as ring trials and other quality assurance activities, epidemiological studies, evaluation of suitable patient or disease registers, genetic databanks or post-market clinical performance studies; (c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b); (d) a reference to the relevant parts of the performance

evaluation report; (e) the specific objectives to be addressed by the PMPF; an evaluation of the performance data relating to equivalent or similar devices, and the current state of the art; (g) reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMPF, and; (h) a detailed and adequately justified time schedule for PMPF activities, such as analysis of PMPF data and reporting, to be undertaken by the manufacturer.

The manufacturer shall analyse the findings of the PMPF and document the results in a PMPF evaluation report that shall update the performance evaluation report and be part of the technical documentation.

The conclusions of the PMPF evaluation report shall be taken into account for the performance evaluation. If, through the PMPF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

If PMPF is not deemed appropriate for a specific device then a justification shall be provided and documented within the performance evaluation report.

Appendix 4: Post-market surveillance

The information below provides a snapshot of the detailed requirements for post-market surveillance documentation in Annex III of the European Regulations.

For the **complete list** of European requirements, refer to Annex III:

EU MDR Annex III Technical documentation on post-market surveillance, and Chapter VII, Articles 83-86.

EU IVDR Annex III Technical documentation on post-market surveillance, and Chapter VII, Articles 78-81.

Annex III in the European Regulations states the purpose and requirements of the post-market surveillance plan. In summary:

a. It shall address the collection and utilization of available information:

– Information concerning serious incidents, including information from periodic safety update reports (PSURs), and field safety corrective actions;

– Records referring to non-serious incidents and data on any undesirable side-effects;

– Information from trend reporting;

– Relevant specialist or technical literature, database and/or register;

– Information, including feedbacks and complaints, provided by users, distributors and importers; and

– Publicly available information about similar medical devices.

b. It shall cover at least:

– A proactive and systemic process to collection information;

– Effective and appropriate methods and processes to assess the collected data;

– Suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and risk management;

– Effective and appropriate methods and tools to investigate complaints and analyse market-related experience;

– Methods and protocols to manage the events subject to trend report;

– Methods and protocols to communicate effectively with competent authorities;

– Reference to procedures to fulfil the manufacturers obligations;

– Systematic procedures to identify and initiate appropriate measures;

– Effective tools to trace and identify devices that require corrective actions; and

– A PMCF plan or a justification as to why it is not applicable.

Annex III in the European Regulations also requires both a PSUR and a post-market surveillance report (PMSR), in accordance with:

- EU MDR Article 86 of (PSUR) and Article 85 (PMSR)
- EU IVDR Article 81 (PSUR) and Article 80 (PMSR)

Post Market Surveillance Report (PMSR)

Article 85 (EU MDR) and Article 80 (EU IVDR) state:

Manufacturers of class I non-IVD and Class A and B IVD devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 (EU MDR) and Article 79 (EU IVDR) together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request.

Periodic Safety Update report (PSUR)

Article 86 (EU MDR) and Article 81 (EU IVDR) state:

Manufacturers of class IIa, class IIb and class III devices and Class 3 and 4 IVD devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 (EU MDR) and Article 79 (EU IVDR) together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

a. the conclusions of the benefit-risk determination;

b. the main findings of the PMCF; and

c. the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of Class IIb and Class III medical devices and Class 3 and 4 IVD medical devices shall update the PSUR at least annually.

That PSUR shall, except in the case of custom-made devices, be part of the technical documentation.

Manufacturers of Class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

For custom-made devices, the PSUR shall be part of the documentation.

Appendix 5: Definitions related to conformity assessment

The relevant definitions in the European Regulations, which relate to conformity assessment, were reviewed and compared to the definitions in the Australian Regulations. Where there are mismatches or an absence of a comparable definition, a proposal, with a justification, is provided below. Where the term is mentioned in the Australian Regulations, and the general meaning is well understood in the Australian context, and therefore there does not appear to be a necessity to explicitly define the terms, they have not been included as part of the consultation. Additional definitions that relate to other parts of the Australian Regulations will be included in upcoming consultations.

EU Regulation	Australian definition	Proposal for amendments
'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, **in the context of a clinical investigation, whether or not related to the investigational device.**	No equivalent definition. However, the term is mentioned in the Regulations.	**Propose to adopt the intent of this definition with modification.** Justification: Whilst the term 'adverse event' in its general meaning is understood in the Australian context, there is sometimes confusion about when an incident relating to a medical device is considered an 'adverse event'. We propose that the latter part of the EU definition (in bold) not be included as those terms are not used in the Australian context.
'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.	No equivalent definition. The term 'post-market surveillance' is referred to in the Regulations in the Requirements for Australian conformity assessment bodies. Here the term is equated to the post-marketing requirements in Schedule 3 of the Regulations.	**Propose to adopt the intent of this definition with modification.** Justification: Whilst the term 'post-market surveillance' in its general meaning may be understood in the Australian context, defining it will aid in providing further clarity on the post-market requirements of manufacturers. Modifications will be needed to remove reference to 'other economic operators' as this is not a term used in the Australian Regulations.
'Information society service' means any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services	No equivalent definition.	**Propose to adopt the intent of this definition.** Justification: This is a new feature in the European Regulations which clarifies the regulation of direct to consumer testing over the internet and other services provided by electronic means which are more difficult to categorise under the Australian Regulations.

Version history

Version	Description of change	Author	Effective date
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V1.1	Consultation closure date amended	Therapeutic Goods Administration	12 February 2026
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