Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

EU MDR Transition - Conformity assessment, Essential Principles and consent to supply

Case studies and scenarios

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Introduction

This guidance covers case studies and scenarios about conformity assessment, Essential Principles, and consent to import, export, or supply medical devices that are non-compliant with the Essential Principles (Consent to supply) for manufacturers and sponsors transitioning their ARTG entries to the EU MDR certification.

This guidance is to be read in conjunction with the guidance EU MDR Transition – Overview and management under the Australian regulatory framework - guidance for manufacturers and sponsors available on the TGA website.

You may also find the following related guidance useful:

- EU MDR Transition – Online assessment tool and notification form - user guide
- EU MDR Transition – Manufacturer evidence – case studies and scenarios
- EU MDR Transition – DCRs and variations – case studies and scenarios
- EU MDR Transition – Recalls and market notifications - case studies and scenarios

Supply during transition

Under the Australian regulatory framework, sponsors must ensure that the medical devices remain compliant with the Essential Principles and that the conformity assessment procedures have been applied to the kind of medical device and ensure compliance with all conditions applying automatically, and if applicable, any additional conditions imposed. If you determine that your medical devices, manufactured under a valid conformity assessment certificate, no longer comply with the Essential Principles, you must submit an application for consent to import, export, or supply medical devices that do not comply with the Essential Principles before you import, export, or supply the devices.

Medical devices that are included in the ARTG which were manufactured under a valid conformity assessment certificate can be supplied after the certificate has expired. Sponsors must notify the TGA within 60 days of becoming aware of the lapsing, revocation, suspension or cancellation of conformity assessment certification using the Lapses in Conformity Assessment Notification Form. The TGA may review the information provided to inform on whether the entries can remain included in the Australian Register of Therapeutic Goods (ARTG). Any decision made is on a case-by case basis. There are criminal and civil penalty sanctions if a sponsor fails to notify the TGA within 60 days of becoming aware that a conformity assessment document (other than a conformity assessment certificate issued by the TGA) has been restricted, suspended, revoked or is no longer in effect.

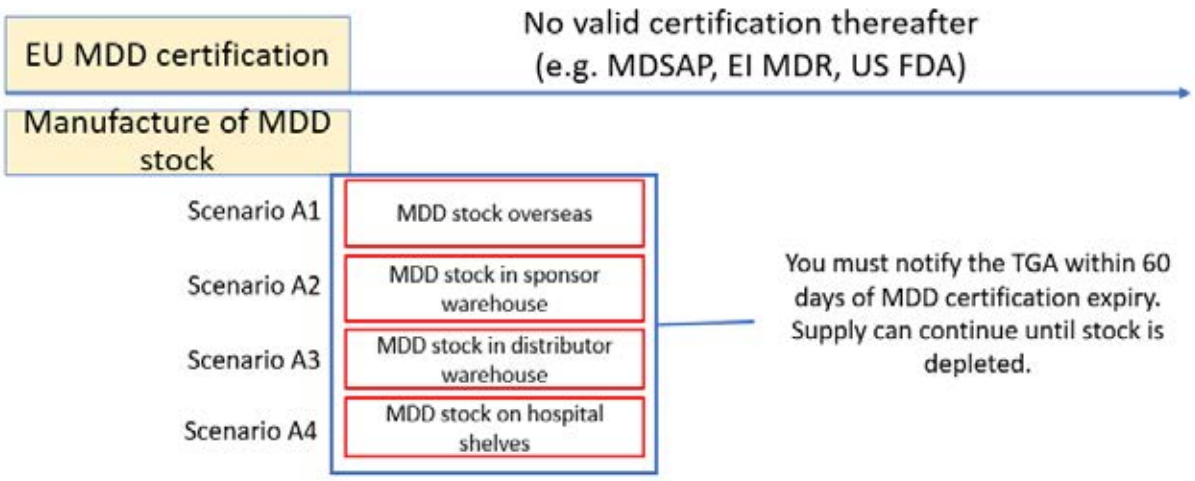
Scenarios

Outlined below are three different scenarios relating to the supply of medical devices transitioning to EU MDR. In each example scenario, the MDD certification covers the use of a hip implant on both adults and children, and the MDR certification covers the use of a hip implant on adults only.

Scenario A: No valid certification after MDD certification expiry

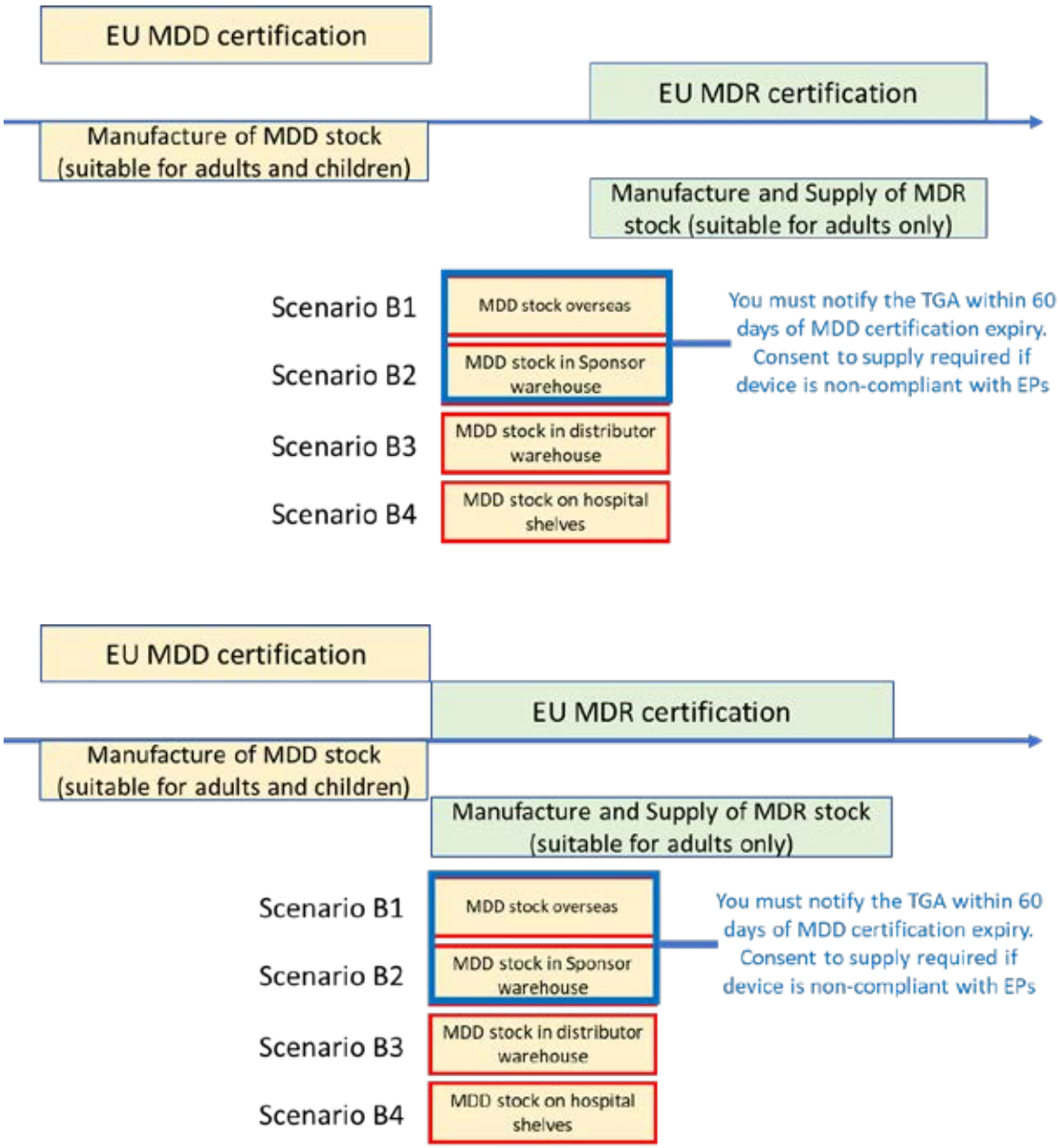
Sponsors must notify the TGA within 60 days of their EU MDD certification expiry using the Lapses in Conformity Assessment Notification Form. The TGA will consider the lapses on a case-by-case basis and may contact sponsors to ascertain the situation. The TGA may cancel or suspend an ARTG entry that no longer has conformity assessment certification. Subsection 41GN(1)(g) of the *Therapeutic Goods Act 1989* (the Act) refers to cancellation of an ARTG entry where the conformity assessment document that applies to the kind of the device expires.

If an EU MDR certificate is issued, then Scenario B should be considered.



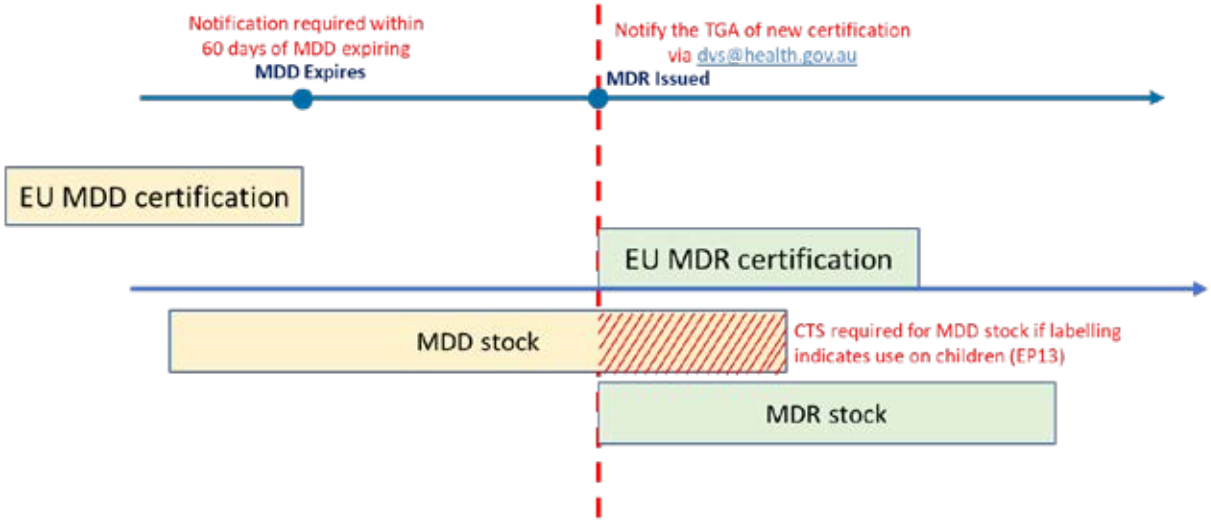
Scenario B: Gap in certification, or contiguous EU MDD and EU MDR certifications

Sponsors must notify the TGA within 60 days of their EU MDD certification expiry using the Lapses in Conformity Assessment Notification Form if there is a gap in certification, or if the EU MDR certification will no longer apply in the same way to all the kinds of medical devices previously supported by the EU MDD certification. Sponsors will also need to notify dvs@health.gov.au of their new MDR certification when it is issued. This could be a copy of the new certification or advice that the MDR Manufacturer Evidence on the eBS portal has been updated. Sponsors will also need to advise of any changes in scope.



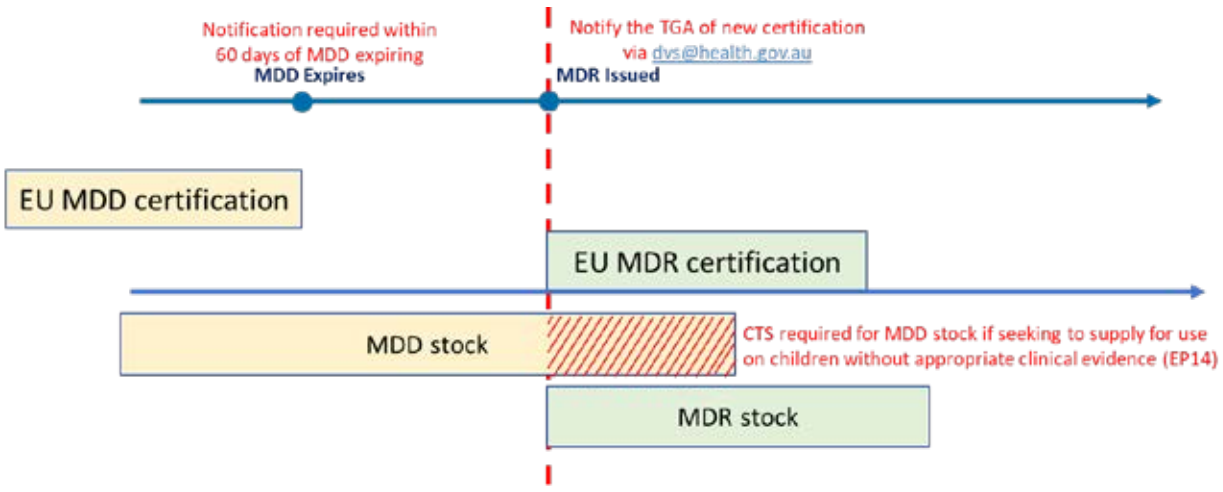
In the event that the sponsor wishes to supply medical devices that were manufactured whilst the EU MDD certification was current (MDD stock) with indications/scope aligned with the MDR certification:

- Consent to Supply **will** be required for MDD stock if the labelling **has not** been updated to remove device use on children (due to non-compliance against EP13)
- Consent to Supply **will not** be required for MDD stock if the labelling **has** been updated to remove device use on children
- MDD stock can then be supplied till stock is exhausted, as long as labelling is updated or if the sponsor has a valid consent to supply approval in place
- Market notifications are required for changes that health care providers and/or end users would need to be made aware of.



In the event that the sponsor wishes to supply MDD stock with indications/scope certified under the EU MDD, which is broader than the indications/scope certified under the EU MDR:

- Consent to Supply will be required for MDD stock if the manufacturer does not hold appropriate evidence for the device against any of the Essential Principles. E.g. if the manufacturer does not hold appropriate clinical evidence for the device to be used in children, then the device is non-compliant against EP14
- If the manufacturer holds appropriate clinical evidence for device to be used in children (i.e. evidence is held that the device is compliant with EP14 and all other EPs), Consent to Supply is not required but the sponsor must notify the TGA within 60 days of their EU MDD certification expiry using the Lapses in Conformity Assessment Notification Form. The TGA may request clinical evidence demonstrating suitability of MDD stock on children and determine on a case-by-case basis whether MDD stock could continue to be supplied for use with children.



In summary, consent to supply MDD stock following the issuance of MDR certification with reduced indications is not required if the MDD stock has been relabelled to match MDR indications (i.e. adult use only), or if clinical evidence is held for use on children (MDD indication).

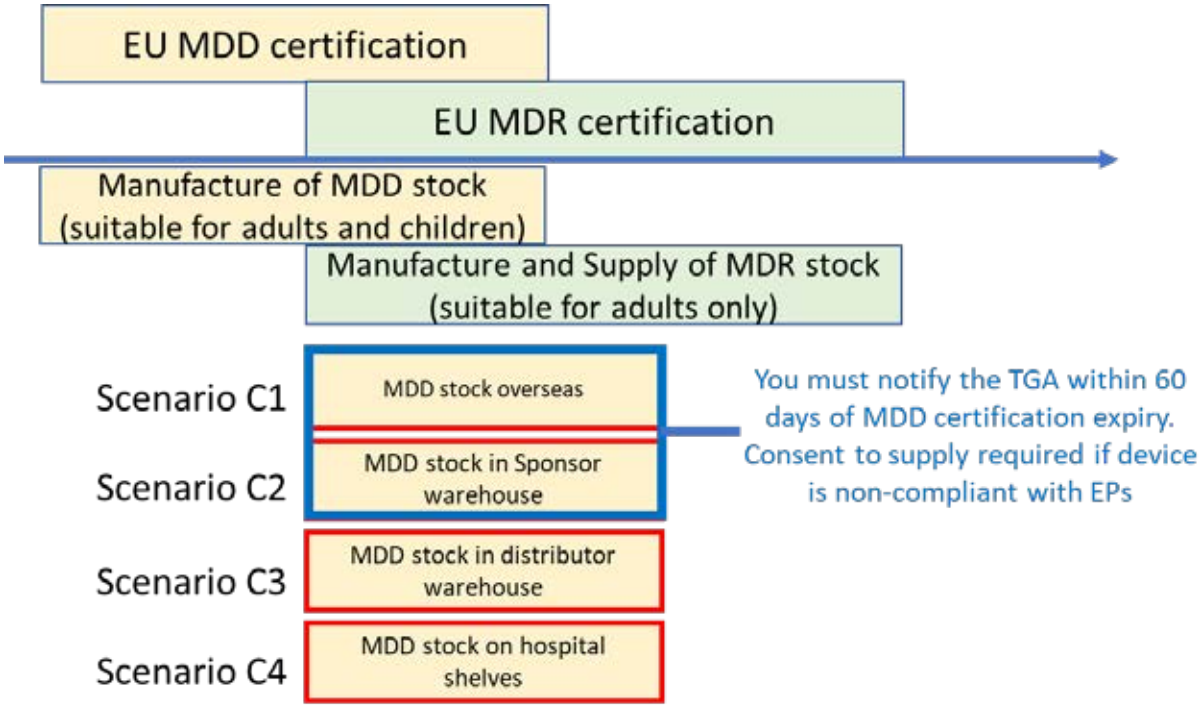
Scenario C: Overlapping EU MDD and EU MDR certifications

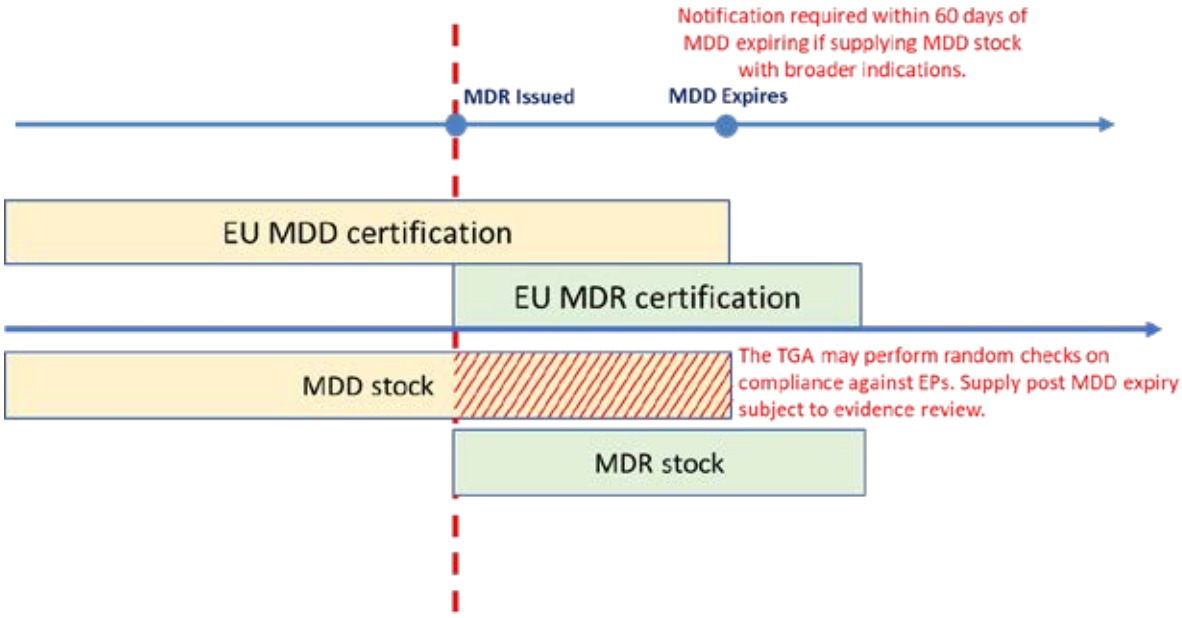
Requirements are identical to those outlined in Scenario B.

Devices can be supplied if they are manufactured under both MDD and MDR certification with different indications if the relevant certification is in force and the manufacturer holds all evidence to demonstrate compliance against all the Essential Principles.

For the supply of MDD stock with indications/scope certified under MDD, which are broader than the indications/scope certified under the EU MDR, the TGA may perform random checks and request for evidence to verify compliance (e.g. request for clinical evidence to verify compliance against EP14).

The sponsor must notify the TGA within 60 days of their EU MDD certification expiry using the Lapses in Conformity Assessment Notification Form if the EU MDR certification will no longer apply in the same way to all the kinds of medical devices previously supported by the EU MDD certification. The TGA may request for clinical evidence demonstrating suitability of MDD stock on children and determine on a case-by-case basis whether MDD stock could continue to be supplied for use on children.





Essential Principles and consent to supply

If you intend to supply medical devices that are transitioning to the EU MDR that no longer comply with the Essential Principles (e.g. reduction in class of persons for whom the device is suitable for under EU MDR certification due to lack of clinical evidence to demonstrate compliance against EP14), you are required to apply for Consent to Supply for your non-compliant devices.

Note: There are criminal and civil penalty sanctions if a sponsor imports, exports, or supplies non-compliant medical devices without consent.

The following are non-exhaustive examples of non-compliance with Essential Principles, whereby Consent to Supply would be required:

- The intended purpose of the medical device is no longer reflected accurately in the instructions for use, labelling, or patient information leaflets (if applicable).
- The manufacturer identifies that clinical evidence to support the intended purpose is not held for all patient cohorts.
- The manufacturer identifies that all the risks or hazards associated with the medical device have not been appropriately identified and mitigated.
- Identification of carcinogenic, mutagenic, toxic to reproduction/endocrine disrupting safety information that is not included in the instructions for use, labelling, or patient information leaflets (if applicable).

Case studies

Case studies – Labelling changes

1

Lime Co is a sponsor which supplies shoulder implants under EU MDD certification. The implant manufacturer transitioned the device to EU MDR certification, during which it was identified that labelling amendments were needed to include a warning about product storage. Lime Co has a surplus of MDD stock with the old MDD labelling not yet supplied to the hospitals. To supply the MDD stock without updating the labelling to include the warning about product storage, Lime Co would need to submit a Consent to Supply application.

2

Maroon Pty Ltd is a sponsor supplying hip implants under EU MDD certification. The labelling includes a symbol indicating that the product is MR safe. However, during the transition of the device to EU MDR certification, it was identified that the labelling required amendments to indicate that the device is MR *unsafe*. To supply the device with the old MDD labelling, Maroon Pty Ltd would need to submit a Consent to Supply application.

3

Magenta Co. is a sponsor supplying forceps under EU MDD certification. After the manufacturer transitioned the device to EU MDR certification, the design of the labelling required font type and font size changes. There are no additional changes. To supply the device with the MDD labelling, Magenta Co. would **not** need to submit a Consent to Supply application.

Case studies – Instructions for use (IFU) changes

1

Ivan is an agent for a sponsor supplying shoulder implants under EU MDD certification. The IFU indicated that the product can be used in both adults and children After the implant manufacturer transitioned the device to EU MDR certification, the IFU required amendments to indicate that the device is only suitable for adults. If the manufacturer does not hold clinical evidence to support the use in children, to supply the device with the MDD IFU, Ivan would need to submit a Consent to Supply application.

2

Lilac Co. is a sponsor supplying pacemakers under EU MDD certification. After the pacemaker manufacturer transitioned the device to EU MDR certification, the IFU required amendments to incorporate harmonised symbols relevant to the EU MDR framework, but these symbols are of no relevance to the Australian medical device regulatory framework. To supply the device with the MDD labelling, Lilac Co would **not** need to submit a Consent to Supply application.

Scenarios

Conformity assessment and supply

My EU MDD certification has expired, how do I notify the TGA? Is there a cost and what information is required to notify of MDD certificate lapse?

Sponsors must notify the TGA within 60 days of becoming aware about the lapsing, revocation, suspension or cancellation of conformity assessment certification using the Lapses in Conformity Assessment Notification Form.

There is no fee associated with notification and a guidance document is available to assist sponsors with completing and submitting the notification form: https://www.tga.gov.au/resources/resource/guidance/guidance-completing-notification-form-lapses-medical-device-conformity-assessment-certification.

I have a large volume of ARTG entries that will have their EU MDD certification expire at the same time; can I notify the TGA of all these entries in the one form?

Sponsors must notify the TGA within 60 days of becoming aware about the lapsing, revocation, suspension or cancellation of conformity assessment certification using the Lapses in Conformity Assessment Notification Form. If you need to notify the TGA of lapsing/lapsed conformity assessment certification for more than 20 ARTG entries, you can either submit multiple notification forms or contact the TGA at dvs@health.gov.au to discuss the best way to submit this information.

My EU MDD certification has expired and I do not intend on obtaining EU MDR certification. Can I continue to supply my outstanding MDD stock?

Refer to Scenario A above. Medical devices supplied in Australia must be manufactured with a valid conformity assessment document in place. Sponsors must notify the TGA within 60 days of becoming aware about the lapsing, revocation, suspension or cancellation of conformity assessment certification using the Lapses in Conformity Assessment Notification Form. There are criminal and civil penalty sanctions if a sponsor fails to notify the TGA within 60 days of becoming aware that a conformity assessment document (other than a conformity assessment certificate issued by the TGA) has been restricted, suspended, revoked or is no longer in effect. The TGA will consider the lapses on a case-by-case basis and may contact sponsors at the 12-month mark to ascertain the situation. The TGA may cancel or suspend an ARTG entry that no longer has conformity assessment certification. Subsection 41GN(1)(g) of the Act refers to cancellation of an ARTG entry where the conformity assessment document that applies to the kind of the device expires. Therefore, the decision to cancel an ARTG entry could be made as soon as the conformity assessment documentation lapses. However, the TGA will make any regulatory decisions, such as suspension or cancellation of an ARTG entry, with consideration to the information provided by the sponsor. The 12 month sell off provision has been removed from the EU MDR. TGA's strategy about the 12-month transition for sponsors to supply devices manufactured before their EU MDD certificate expired, which mirrored the previous EU "sell-off" deadline, also no longer applies. The devices manufactured under a valid MDD certificate can be supplied until stock is depleted.

My EU MDR certification has reduced indications which overlaps with my EU MDD certification. Can I manufacture devices under both the EU MDD and EU MDR certifications, and supply the same device but with different indications?

Refer to Scenario C above. Devices can be supplied that have been manufactured under either MDD or MDR certification with different indications if the relevant certification is in force during manufacture and the manufacturer holds all evidence to demonstrate compliance against all the Essential Principles. The TGA may perform random checks prior to, or following, EU MDD certification expiry and request for evidence to verify compliance (e.g. request for clinical evidence to verify compliance against EP14). The sponsor must notify the TGA within 60 days of their EU MDD certification expiry using the Lapses in Conformity Assessment Notification Form. The TGA may request clinical evidence demonstrating suitability of MDD stock on the broader indications and determine on a case-by-case basis whether MDD stock can continue to be supplied with the broader indications following the expiry of the EU MDD certification.

Do I need separate ARTG inclusions and pay separate annual fees for the MDR certified product if there is an overlap in the MDD and MDR certification?

No, only a single ARTG entry is required if the device is of the same kind and shares the same sponsor, manufacturer, GMDN code and classification (and UPI for Class III devices). Even though only a single manufacturer evidence can be linked to an ARTG entry, sponsors can hold multiple conformity assessment evidence related to the same kind of device and provide the evidence when requested by the TGA.

Can I get a new ARTG inclusion with MDR certification and retain the old entry with MDD certification and continue the manufacture and supply with two types of intended purpose?

No. If the device is of the same kind and shares the same sponsor, manufacturer, GMDN code and classification (and UPI for Class III devices), the ARTG inclusion should remain the same. Refer to Scenario C above for how overlapping certifications are considered.

What if the conformity assessment document issued under the MDD has expired or is due to expire and the manufacturer has not yet obtained a new conformity assessment document?

Refer to Scenarios A and B above. Where a conformity assessment document has expired, that supports a medical device inclusion, this will not result in the automatic cancellation of a device entry from the ARTG.

Sponsors must notify the TGA within 60 days of becoming aware about the lapsing, revocation, suspension or cancellation of conformity assessment certification using the Lapses in Conformity Assessment Notification Form.

The TGA will consider, in deciding whether suspension or cancellation of a device entry is warranted, whether the sponsor has taken reasonable steps to maintain certification (i.e. applied for EU MDR certification prior to the MDD certificate expiring).

It is expected that the manufacturer has applied for conformity assessment certification under the EU MDR, or other appropriate regulatory pathway, for the devices they manufacture prior to, or following, the expiry of their current MDD conformity assessment document.

The sponsor should advise the TGA of the pending expiry of the conformity assessment document and provide the manufacturer's supporting evidence demonstrating actions undertaken to be recertified or the request for conformity assessment document extension.

For further information, please refer to https://www.tga.gov.au/resource/tgas-approach-delays-medical-device-conformity-assessment-recertification

Essential Principles and consent to supply

How do I submit a consent to supply application?

To complete an application for consent to import, supply, or export a medical device that does not comply with the Essential Principles, please complete the online application form available on the TGA Business Services (TBS) portal. Guidance is available to assist you when submitting a consent to supply application on the TGA website.

Why do I need consent to supply my surplus MDD stock with broader indications when I obtain my MDR certification, given that my MDD stock was manufactured under a valid EU MDD certificate?

You only need consent to supply for stock manufactured under the MDD certification with broader indications than the EU MDR certification if the manufacturer does **not** hold clinical evidence to support the broader indications.

If the manufacturer holds evidence to demonstrate compliance with the Essential Principles, then MDD stock with broader indications can continue to be supplied, but the sponsor must notify the TGA within 60 days of their EU MDD certification expiry using the Lapses in Conformity Assessment Notification Form. The TGA may request clinical evidence demonstrating suitability of MDD stock on the broader indications and determine case-by-case whether MDD stock can continue to be supplied with the broader indications.

You can continue supplying the MDD stock, without a consent to supply, till the end of device lifetime if the indications in the labelling and instructions for use are amended to align with the updated indications in the MDR certification. In this case, a device change request application also needs to be submitted to the TGA to update the intended purpose in the ARTG.

What is the likely approval timeline for consent to supply applications?

It is expected that if the consent to supply application has sufficient information, with particular emphasis on the risk mitigation/implementation plan, then once an application has been paid, the TGA will provide a decision within a week.

Version history

Version	Description of change	Author	Effective date
V1.0	Draft publication for feedback	Medical Devices Authorisation Branch	June 2022
V1.1	Publication for beta release	Medical Devices Authorisation Branch	June 2022
V1.2	Publication for stakeholder review	Medical Devices Authorisation Branch	October 2022
V2.0	Publication for final release	Medical Devices Authorisation Branch	December 2022
V2.1	Update due to EU MDR transition extension	Medical Devices Authorisation Branch	February 2024

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Reference/Publication #