Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

EU MDR Transition – Recalls and market notifications

Case studies and scenarios

Version 2.1, February 2024

Contents

Introduction

This guidance covers case studies and scenarios about recalls and market notifications 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 – Conformity assessment, Essential Principles and consent to supply – case studies and scenarios

Scenarios

Market notification

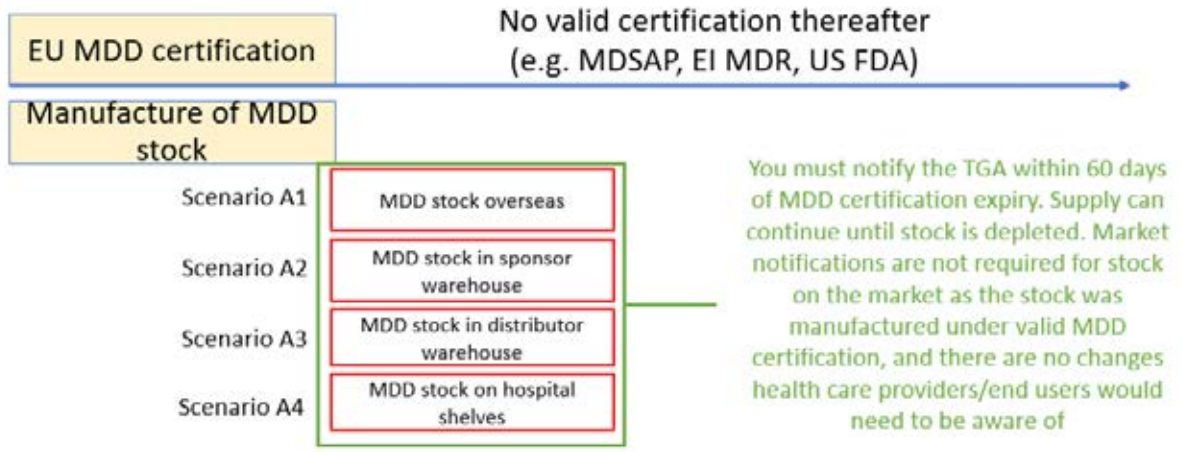
If certain criteria are met, sponsors of medical devices transitioning from EU MDD to EU MDR can undertake market notifications, which may include referring consumers to the TGA website for a full list of changes about the devices without needing to also submit potential changes as separate recall notifications to the TGA Recalls Section. Please refer to the guidance EU MDR Transition – Overview and management under the Australian regulatory framework - guidance for manufacturers and sponsors for the eligibility criteria.

Essential Principles and market notification

Three different scenarios relating to the market notification obligations of medical devices transitioning to EU MDR are outlined below:

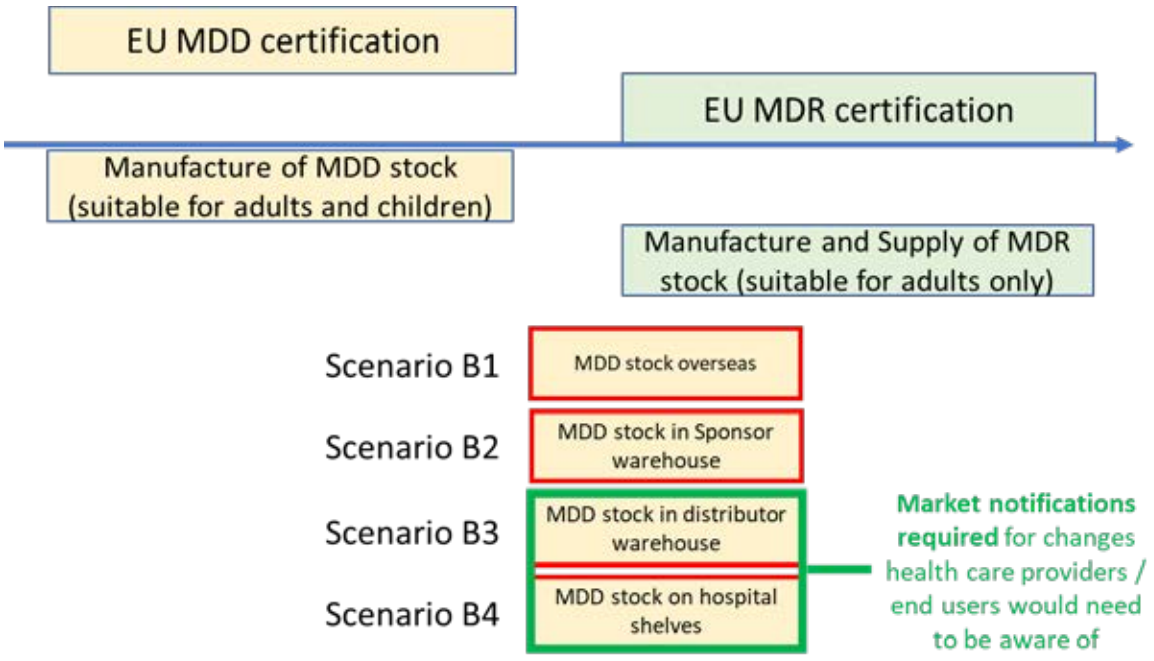
Scenario A: No valid certification afterMDD certification expiry

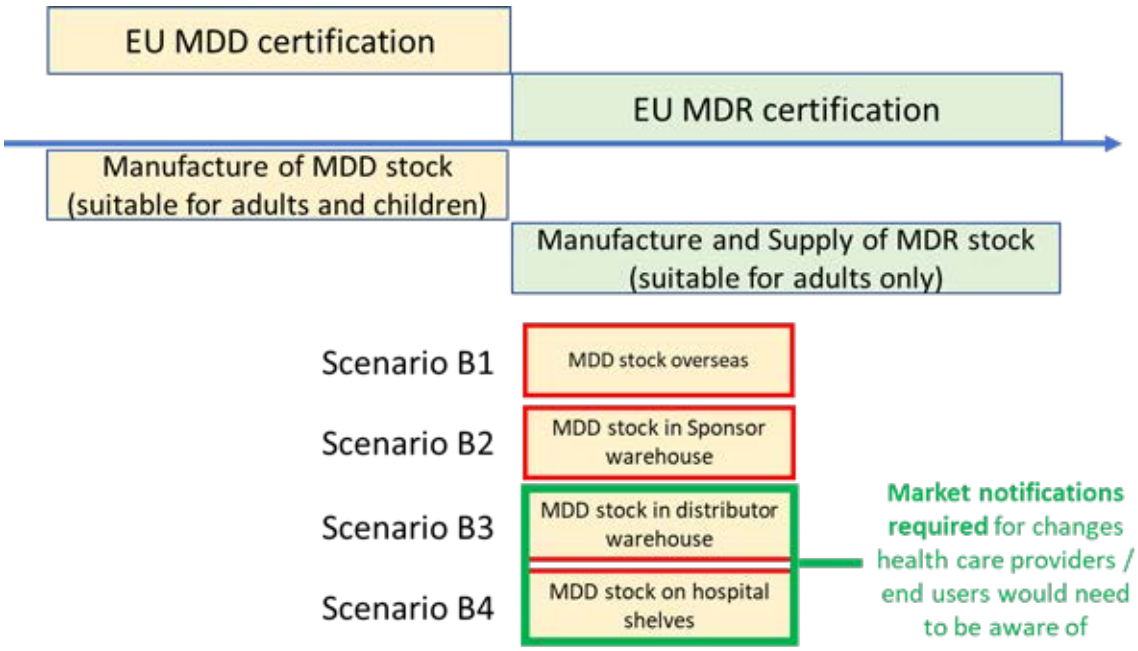
Sponsors must notify the TGA within 60 days of their EU MDD certification expiry using the Lapses in Conformity Assessment Notification Form. Devices manufactured under a valid MDD certificate can be supplied until stock is depleted. If an EU MDR certificate is issued, then Scenario B should be considered.



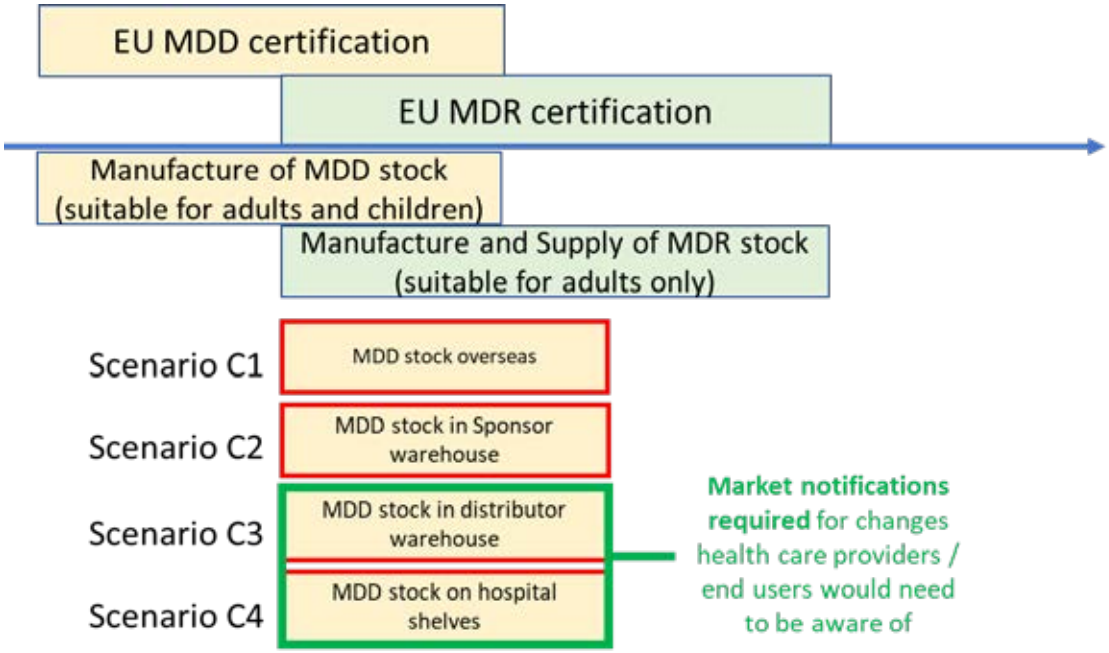
Scenario B: Gap in certification, or contiguous EU MDD and EU MDR certifications

Sponsors must notify the TGA within 60 days of their EU MDD certification expiry using the Lapses in Conformity Assessment Notification Form. 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. Market notifications are required for changes that health care providers and/or end users would need to be made aware of.





Scenario C: Overlapping EU MDD and EU MDR certifications



Sponsors who qualify for streamlined market notifications can either:
a. Submit an Online Notification Form to use the TGA's EU MDR Transition web publication service to provide market notifications to health care providers or end users, OR
b. Notify health care providers or end users about changes to their devices and maintain documentation to confirm that the notifications had occurred and be able to produce them to the TGA upon request.

Recalls

If the device does not meet any of the six eligibility criteria outlined in guidance document **EU MDR Transition – Overview and management under the Australian regulatory framework - guidance for manufacturers and sponsors**, then sponsors must submit new recall notifications via the TGA Business Systems portal. Before submitting recall or non-recall information to the TGA, please refer to the Uniform recall procedure for therapeutic goods (URPTG) which provides a consistent approach for undertaking recall and non-recall actions of therapeutic goods supplied, imported into or exported from Australia.

Case studies are provided in the following examples:

Case studies – Changes to labelling, instructions for use and patient information material

1

Jessica is the sponsor of a hip implant system. As part of the MDR certification the IFU, labelling and patient information material of the system/components were amended to make the following changes:

- Update to storage conditions to distinguish between storage and excursion temperatures and revise humidity values
- Addition of warnings and precautions related to safe disposal of the system
- Update the single-use precaution to include risks associated with re-use
- Additional information on composition or product materials
- Addition of new symbols solely to harmonise the information in the IFU, labels and patient information material

Jessica does not have to initiate a recall or market notification if the changes are not safety related and have been made to meet the new labelling requirements in Europe and if the labels, IFU and patient information material continue to comply with the relevant essential principles.

2

Tobias is the sponsor agent of a transcranial stimulation system. The instruction for use under the MDD certification had transient headache listed as a common side effect. This was undertaken to merge product portfolios and not due to any safety signals. As part of MDR certification the wording in the IFU was amended to the following:

- Neuropathic pain

Tobias do not have to initiate a recall action or market notification since it is not a safety related change.

3

Purple Pty Ltd. is the sponsor of a patient monitor intended to be used for monitoring physiologic parameters in adult, paediatric and neonatal patient groups. The following change was implemented as part of the MDR certification:

- Reduction in target patient group to remove paediatric and neonatal patients.

JO Corp. do not have to initiate a recall action if this is not a safety related change or a change initiated due to an unfavourable adverse event profile or other user / customer complaints. However, they must initiate a market notification.

JO Corp. also needs to submit a Device Change Request to update the target patient group in the intended purpose of the ARTG entry.

4

Ivan is the sponsor agent of a hernia mesh. As part of the MDR certification, patient management recommendations were changed due to signals and information arising from reported adverse events. As a result, the following was added:

- Bowel and hip pain and nausea

Ivan must notify TGA Recalls because it is a safety related change.

5

Teal Pty Ltd is the sponsor of an intraluminal stapler. The following was added as part of the MDR certification as a newly identified safety issue due to reported safety related incidents that have resulted in patient harm:

- Addition of oedema as a contraindication

Teal Pty Ltd must notify TGA Recalls because it is a safety related change.

6

Grey Pty Ltd is the sponsor a PEG tube. As part of the MDR certification the IFU and labelling were amended to make the following changes:

- Update the expiry date from 2 years to 5 years
- Update the MRI safety status from 'MR Conditional' to 'MR Safe'

For extending the expiry date, Grey Pty Ltd do not have to initiate a recall action or market notification since it is not a safety related change.

Grey Pty Ltd must submit a Device Change Request (DCR) application for the MRI safety status update.

7

Matthew is the sponsor agent of a hip implant. The hip implant was suitable for use in adults and children under the MDD certification. When the manufacturer sought MDR certification, a business decision was made to target the product for the adult population only. This change was purely a business decision and was not due to any safety signals, or lack of evidence against any of the Essential Principles.

Matthew does not have to initiate a recall action but will need to provide market notifications to ensure that end users are made aware of the change.

Case study - Changes to intended purpose

Red Pty Ltd is the sponsor of a spinal implant system which was intended to be used as a cervical and lumbar fusion device under the MDD certification. The following changes were implemented as part of the MDR certification due to deficiencies in the performance of the device:

- Reduction of intended purpose to remove lumbar spine

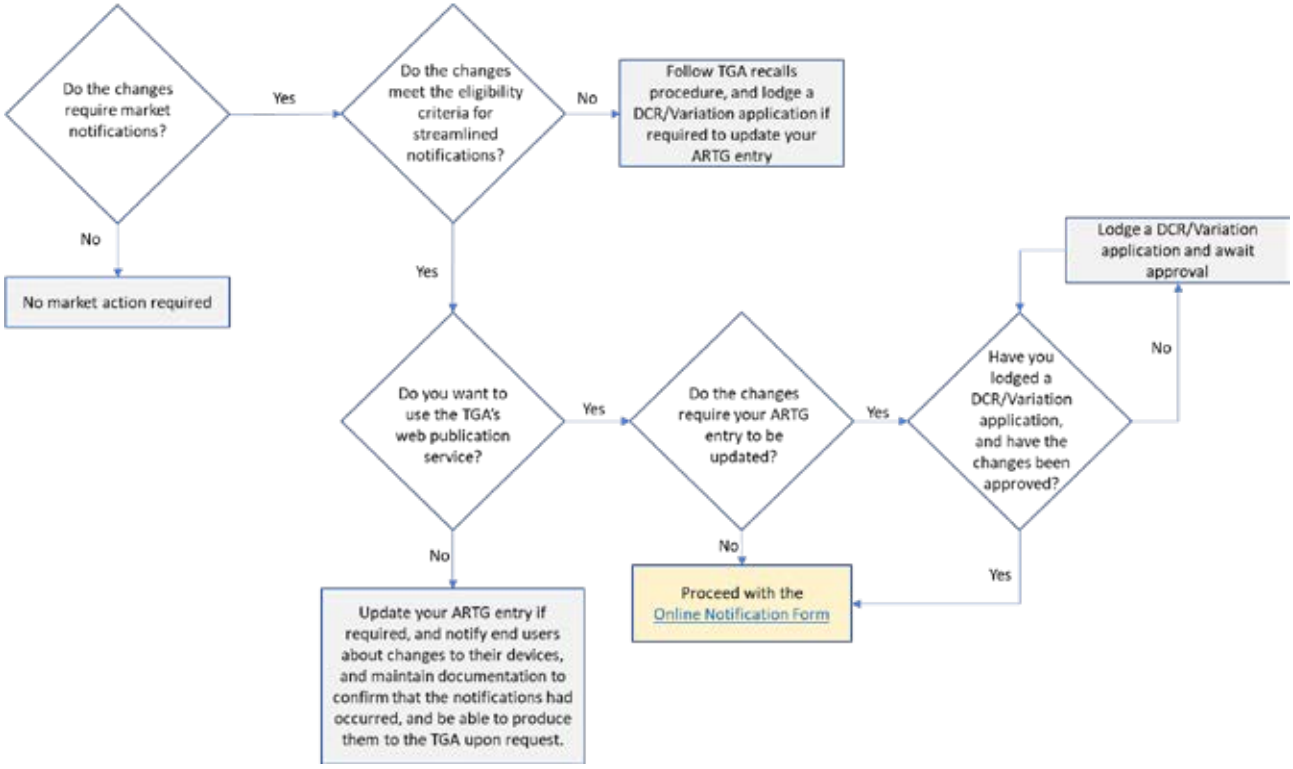
- Reduction of indications to remove spinal tumour

Red Pty Ltd must notify TGA Recalls.

Red Pty Ltd must also submit a Device Change Request to amend the intended purpose of the ARTG entry.

Decision tree for recalls and market notification

The decision tree below can assist in determining what regulatory actions are required based on the changes to the ARTG inclusions following EU MDR transition.



Scenarios

Recalls and market notification

What is meant by the term 'market notification'?

A market notification provides information about a therapeutic good in a situation that is unlikely to involve significant adverse health consequences.

A market notification is intended to notify customers of information relating to MDD certified device stock already supplied in the Australian market.

Do I need to submit a recalls notification for minor updates to wording in the IFU and patient information material to improve clarity?

No. A recall notification is not required for changes that do not impact the quality, safety or performance of the device. Please refer to the guidance document EU MDR Transition –

Overview and management under the Australian regulatory framework - guidance for manufacturers and sponsors for the eligibility criteria to determine if the changes need to be notified to the TGA recalls.

Do I need to submit a recalls notification for changing the design of the existing symbols or addition of symbols or rephrasing existing information related to safety in the labels and IFU?

No. A recall notification is not required for changes that do not impact the quality, safety or performance of the device.

The design and intended purpose of the device remain unchanged. The IFU was amended to add safety information on substances known to be mutagenic, carcinogenic or toxic to reproduction or have endocrine-disrupting properties. Should I initiate a recall action?

Provided no safety claims have changed, and evidence previously assessed by the TGA remains current, a recall notification is not required for the above change.

I have changed from paper IFU to electronic IFU. The content remains unchanged. Do I need to submit a market notification?

No.

What if I am aware of changes to my medical device but I do not wish to use the TGA's EU MDR Transition web publication service for market notifications?

As the sponsor of the medical device, you have certain obligations under the regulatory framework in Australia, including the requirement to advise of changes related to the safety and performance of your product. If you do not wish to submit an Online Notification Form to use the TGA's EU MDR Transition web publication service to provide market notifications to health care providers and/or end users, you will need to notify health care providers and/or end users about changes to their devices and maintain documentation to confirm that the notifications had occurred and be able to produce them to the TGA upon request.

My device has changes which are relevant to the EU MDR but are not relevant under the Australian regulatory framework. Do I need to undertake market notifications or notify the TGA?

Changes that are driven by the new EU MDR requirements which are of no relevance to the Australian medical device regulatory framework do not need to be notified to the TGA.

If I use the market notification system, have I fulfilled all my obligations to notify users about the changes to my medical device.

Yes, if a market notification is identified as the correct pathway for any changes required.

If, however, the device does not meet any of the six eligibility criteria, then sponsors must submit new recall notifications via the TGA Business Systems portal.

If I do not meet the eligibility criteria and must submit a recall action, how do I do this?

Please refer to the Uniform Recall Procedure for Therapeutic Goods located at: **https://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg**

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	Updates due to EU MDR transition extension	Medical Devices Authorisation Branch	February 2024

Therapeutic Goods Administration

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Reference/Publication #