Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

EU MDR Transition – DCRs and variations

Case studies and scenarios

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Contents

Introduction

This guidance covers case studies and scenarios about Device Change Requests (DCRs) and variations for 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 – Recalls and market notifications - case studies and scenarios
- EU MDR Transition - Conformity assessment, Essential Principles and consent to supply - case studies and scenarios

Case studies

Device Change Requests (DCR) and variations

It is important the information included in the ARTG is complete and correct.

When information included in the ARTG has changed as a result of the manufacturer transitioning to EU MDR certification, the sponsor should consider if they need to request the TGA to vary the respective ARTG entry. The Online Assessment Tool will assist you in determining whether a DCR or variation application is required.

Case studies are provided in the following examples:

Case study - Changes to manufacturer's details

1

Jessica is the sponsor of a hip implant system. There has been a change in the manufacturer's name and site address. The new details are reflected in the MDR certificate.

Jessica needs to submit an ME Variation application, followed by a DCR application. As part of the DCR application review Jessica has to provide evidence on how the new manufacturer would be considered the 'same' under s41BE of the Act. This could be in the form of a letter from the notified body or manufacturer stating when and why the name and/or address changed and state that the amendment did not change the QMS and that the legal entity of the manufacturer remains the same.

Case Studies - Changes to intended purpose

1

Red Pty Ltd. is the sponsor of a patient monitor intended to be used for monitoring physiologic parameters in adult patients. The following change was implemented as part of the MDR certification:

- Expansion in the target patient group to add paediatric and neonatal patients.

Red Pty Ltd. needs to submit a DCR application.

2

Purple Ltd is the sponsor of an intraluminal stapler. At the time of inclusion with the MDD certification the IFU stated that the device was not tested for MRI safety. The manufacturer has now done the testing and the MRI safety statement in the IFU, labels and patient information materials were amended to MRI Conditional.

MRI safety status changes such as above should be notified via a DCR application. Even though the device design might remain unchanged, the MRI environment presents safety risks for end users of medical devices and therefore it is crucial that the MRI safety status of medical devices are appropriately labelled based on validation data reviewed and approved by the TGA. Therefore, Purple Ltd needs to submit a DCR application and as part of the DCR review TGA will request the MRI test reports.

3

Sophie 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:

- Reduction of intended purpose to remove lumbar spine
- Reduction of indications to remove spinal tumour.

Sophie needs to submit a DCR application.

4

Ivan is the sponsor of a spinal implant system which was intended to be used as a cervical fusion device under the MDD certification. The following changes were implemented as part of the MDR certification:

- Expansion of intended purpose to add lumbar spine
- Expansion of indications to add spinal tumour
- Expansion of product names to include additional models.

Ivan needs to submit a DCR application.

5

Tobias is the sponsor of a vascular guidewire which was intended to be used in the central circulatory system (CCS) under the MDD certification. As part of the MDR certification the intended purpose was revised to exclude the CCS.

Tobias needs to submit a new application for inclusion and cancel the existing entry as the guidewire is a new 'kind' of device with a different risk classification.

Case study – Changes to the number of devices and variants

1

Jessica is the sponsor of a hip implant system. As part of the MDR certification the total number of devices and variants has increased.

Jessica needs to submit a Variation application.

Case study - Changes to GMDN code

1

Brown Pty Ltd is the sponsor of a wound barrier dressing. The manufacturer has amended the GMDN code to a more relevant code.

Brown Pty Ltd needs to submit a DCR application.

Case study - Addition of safety related information

1

James is the sponsor of an aspiration catheter. The indications in the IFU was amended as part of MDR certification to include the minimum vessel diameter.

No DCR or recall action required. James would need to notify consumers/health professionals via the market notification process.

Scenarios

When should I submit a DCR vs a Variation application?

Changes to any of the following (for all classifications) can be lodged as a DCR application:

- Intended purpose
- GMDN code and term
- Linking the EU MDR document to an existing ARTG inclusion
- Manufacturer details (name and/or address)

Changes to any of the following (for class III devices) should be submitted as a variation application:

- Total number of devices
- Variant list
- UPI (Unique Product Identifier)

- Functional Description

Do I need to submit multiple DCR applications for the same change across multiple ARTG entries?

If the same change (e.g., re-linking the same manufacturer evidence ID) is to be applied to multiple ARTG entries, then you are not required to submit multiple DCRs. You can include up to 10 ARTG entries in one DCR application.

The GMDN term that I used when I submitted my application for inclusion has now been made obsolete by the GMDN agency. Do I need to do anything?

No. Once the GMDN term has been applied to a product, the GMDN term can continue to be used throughout the life of that unchanged product.

You may, however, submit a DCR application to change the GMDN Term applied to an ARTG entry if you wish, provided the proposed GMDN term does not change the 'kind' of device that the ARTG entry relates to.

For example:

Current GMDN term: Scissors general (INACTIVE CODE)

Intended purpose as stated in the ARTG entry: Scissors used in orthopaedic surgery to dissect tissue.

Proposed GMDN term: Scissors, orthopaedic (ACTIVE CODE)

If a GMDN term has been made obsolete by the GDMN agency, it cannot be used for any new applications for inclusion.

For an ARTG entry of a lower classification (e.g. IIa), the intended purpose may be generic as many device families are considered the same kind of device under one entry. If the intended purpose for some products under the ARTG entry is changing in the IFU but not the intended purpose on the ARTG, do I still need to lodge a DCR?

For devices where the intended purpose in the ARTG entry is generic and not changing, there is no need to make any amendment to the ARTG entry (i.e. no need to submit a DCR). For the devices where the intended purpose is changing in the IFU, market notifications to end users may be required to ensure that end users are aware of the changes to the intended purpose.

If the changes result in the devices being of a different kind, then new applications for inclusion will be required for the new kinds of devices.

As part of EU MDR transition, a separate general intended purpose statement has been included in the IFU in addition to the indications. The ARTG inclusion has the indications as the intended purpose. Should I submit a DCR or initiate a recall action?

No. An update to the IFU to include a general intended purpose statement is not a safety related change and therefore a recall action do not have to be initiated. A change request is not required if the indications remain the same and the information captured in the ARTG certificate has not changed as part of the EU MDR transition. Manufacturers can decide whether they want to amend the intended purpose in the ARTG to align with the EU MDR IFU. A device change request needs to be submitted if the manufacturer decides to amend the intended purpose to include the broader intended use in the EU MDR IFU rather than the specific indications currently stated in the ARTG certificate.

Do I need to submit a DCR for minor updates to wording in the intended purpose or functional description in the IFU and patient information material to improve clarity?

No. A device change request or variation is not required if there is no change to the design characteristics or intended purpose of the device and the only update is amending the wording in the intended purpose or functional description to improve clarity.

Do I need to submit the clinical evidence report as an attachment when I lodge my DCR or variation application?

No. An assessor will review your application and if a clinical review is warranted, you will be advised by the assessor to provide the CER and any other relevant documents.

I have large files which cannot be uploaded to eBS or sent via email. How can I submit them?

For sponsors seeking to submit large files in relation to their applications, GovTEAMS (https://www.govteams.gov.au/) has been identified as an appropriate temporary solution to submit large dossiers to the TGA electronically. Please send an email to devices@tga.gov.au to request access.

Note that Sponsors can have multiple users on the GovTEAMS platform. As their access is setup individually per user, they will need to email devices@tga.gov.au for access to their already setup company folder.

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	Updated links and review due to EU MDR transition extension	Medical Devices Authorisation Branch	February 2024

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