

# EU MDR Transition – Webinar 1

Overview and management under the Australian regulatory framework



Medical Devices and Product Quality Division  
Therapeutic Goods Administration (TGA)

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# Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

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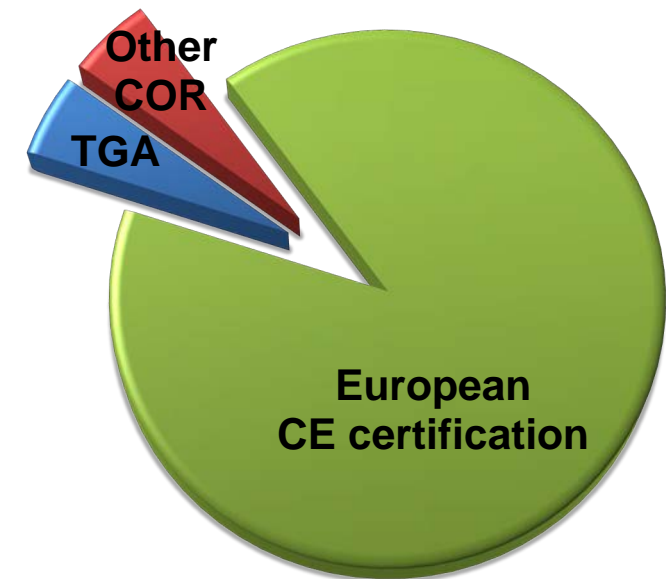
# Agenda

- Background
- Overview of the TGA's approach
- Handling approaches using examples
- Resources on a page
- Q&A



# Background

- Majority of medical device ARTG inclusions are supported by European certification.
- Medical device regulation in Europe is undergoing transition to replace the existing Medical Device Directive (MDD) (93/42/EEC) and the Active Implantable Medical Device Directive (90/385/EEC) (AIMDD) with the new Medical Device Regulation (MDR) (2017/745/ EU).
- Devices supported by EU MDD certification will need to transition by 26 May 2024 to the new EU MDR certification to continue supply.



# Implications for medical device ARTG inclusions

- Regulatory actions may include
  - Updates to manufacturer evidence (conformity assessment documents)
  - New applications for inclusion due to changes in device classification
  - Variations to the ARTG entry
  - Recall action
  - Market notifications
  - Consent to supply

Manufacturer Evidence  
(Conformity Assessment)

Variations to the ARTG  
(DCR/Variations)

Recalls /  
Market notifications

Consent to supply  
(Essential Principles)



# Overview of the TGA's approach

- We seek to minimise regulatory burden, cost and impact on supply without compromising the safety, quality, or performance of medical devices supplied in Australia.
- We developed a risk-based approach to streamline the type of actions sponsors must take to meet their regulatory obligations

## Our approach

A range of regulatory actions in relation to the transition:

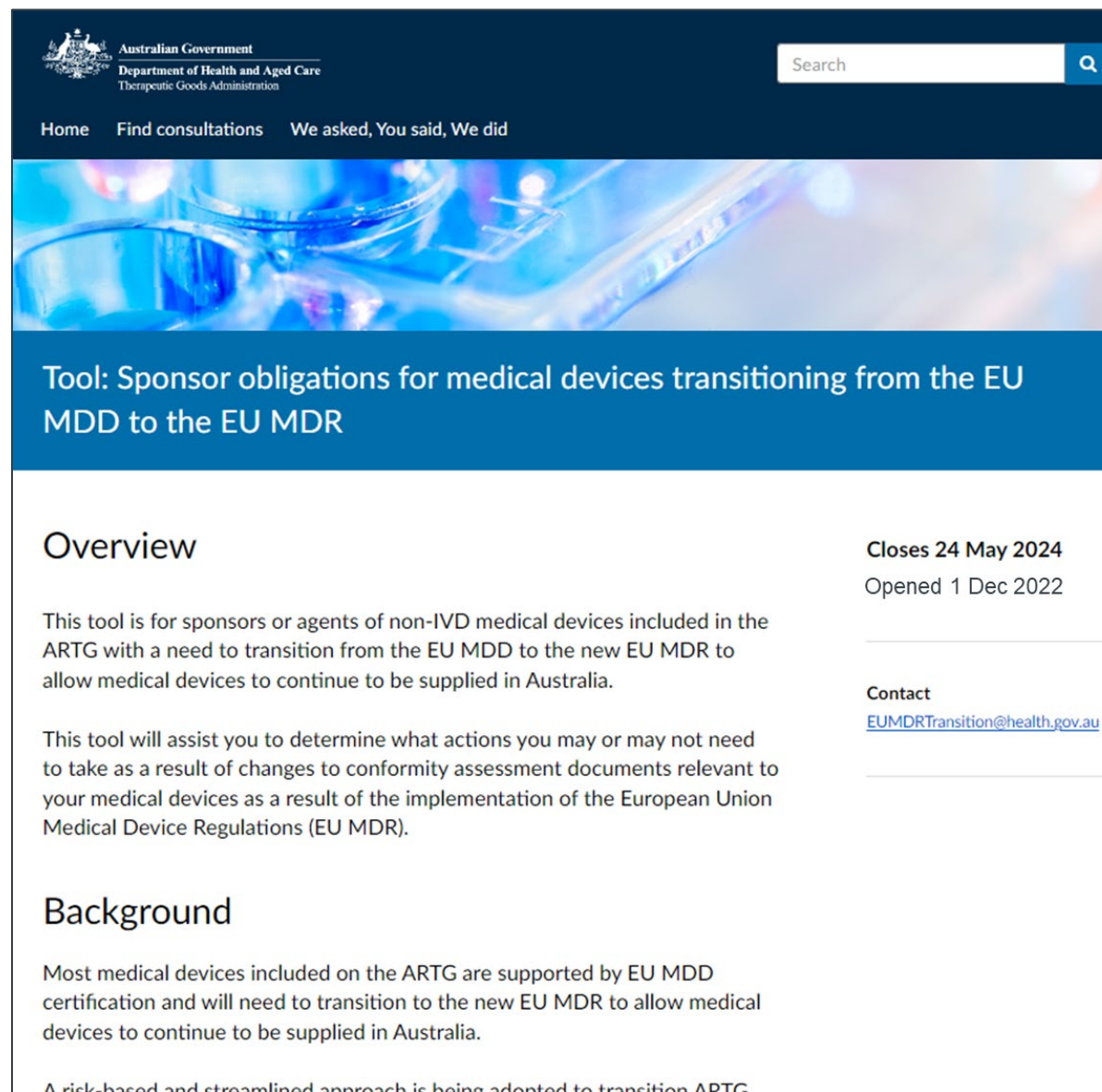
- Streamlined process to notify the market of low-risk changes
- Web publication service for market notifications
- Handling approach for devices not transitioning
- Handling approach for devices transitioning, with gap in certification
- Handling approach for devices transitioning, with overlaps in certification
- Fee reduction measures

# Summary of regulatory actions in Australia

	<b>Change</b>	<b>Regulatory action</b>
1	New MDR certification	ME variation or new ME
2	Changes to device classification	New application
3	Changes to any of the following (for all classifications): <ul style="list-style-type: none"> <li>•Intended purpose</li> <li>•GMDN code and term</li> <li>•Linking the EU MDR document to an existing ARTG inclusion</li> <li>•Manufacturer details (name or address)</li> </ul>	Device Change Request
4	Changes to any of the following (for class III/AIMD): <ul style="list-style-type: none"> <li>•Total number of devices</li> <li>•Variant list</li> <li>•UPI (Unique Product Identifier)</li> <li>•Functional Description</li> </ul>	Variation
5	Changes to any of the following: <ul style="list-style-type: none"> <li>•Indications in IFU</li> <li>•Class of persons for which the device is suitable for</li> <li>•Reduction in scope of intended purpose</li> <li>•Functional description</li> <li>•Addition of a warning for a newly identified safety issue or contraindication</li> <li>•Addition of adverse event information which would change patient management recommendations</li> </ul>	Recalls or Market notifications
6	Non-compliant with the Essential Principles	Application for consent to Supply
7	Lapse in conformity assessment certification	Notification of lapse in CA



# Online Assessment Tool



The screenshot shows the Australian Government Department of Health and Aged Care Therapeutic Goods Administration website. The header includes the Australian Government logo, the department name, and a search bar. The main navigation menu contains 'Home', 'Find consultations', and 'We asked, You said, We did'. The main content area features a blue banner with the title 'Tool: Sponsor obligations for medical devices transitioning from the EU MDD to the EU MDR'. Below the banner, the 'Overview' section provides details about the tool's purpose and the regulatory transition. The 'Background' section explains the need for the tool. On the right side, there is a 'Contact' section with an email address and a 'Closes 24 May 2024' notice.

**Australian Government**  
Department of Health and Aged Care  
Therapeutic Goods Administration

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## Tool: Sponsor obligations for medical devices transitioning from the EU MDD to the EU MDR

### Overview

This tool is for sponsors or agents of non-IVD medical devices included in the ARTG with a need to transition from the EU MDD to the new EU MDR to allow medical devices to continue to be supplied in Australia.

This tool will assist you to determine what actions you may or may not need to take as a result of changes to conformity assessment documents relevant to your medical devices as a result of the implementation of the European Union Medical Device Regulations (EU MDR).

### Background

Most medical devices included on the ARTG are supported by EU MDD certification and will need to transition to the new EU MDR to allow medical devices to continue to be supplied in Australia.

**Closes 24 May 2024**  
Opened 1 Dec 2022

**Contact**  
[EUMDRTransition@health.gov.au](mailto:EUMDRTransition@health.gov.au)



# Streamlined Market Notifications

What is a market notification?

- provides information about a therapeutic good in a situation that is unlikely to involve significant adverse health consequences
- intended to notify customers of information relating to MDD certified device stock already supplied in the Australian market

If certain criteria are met, sponsors of medical devices transitioning to the EU MDR can

- undertake streamlined market notifications
- do not need to submit these as separate recall notifications to the TGA Recalls Section.

Sponsors who **qualify** for streamlined market notifications can either:

- a) Submit an [Online Notification Form](#) to provide market notifications to health care providers or end users, using TGA's web publication service, OR
- b) Notify health care providers or end users about changes to their devices, maintain documentation to confirm that the notifications occurred, and be able to produce them to the TGA upon request.

# Streamlined Market Notifications – Eligibility Criteria

**All 6** of the following criteria need to be met to qualify for streamlined market notifications:

1. The changes being notified only relate to devices transitioning from the EU MDD to EU MDR certification. i.e. the changes are due to a change in regulatory requirements and not because devices currently supplied to the market are unsafe or defective, AND
2. The devices comply with all Australian regulatory requirements when supplied to the market, AND
3. There are no deficiencies in safety, quality, performance, or presentation of the devices as currently supplied to the market, AND
4. The changes being notified are not because of any reported safety related incidents that have resulted in patient or user harm, AND
5. The changes being notified are not because of any signals arising from adverse event reporting and investigation, AND
6. The devices were manufactured whilst a conformity assessment certificate was valid.

# Online Notification Form



The screenshot shows the Australian Government Department of Health and Aged Care Therapeutic Goods Administration website. The header includes the logo, navigation links (Home, Find consultations, We asked, You said, We did), and a search bar. The main content area features a blue banner with the title "Form: Sponsor notification for medical devices transitioning from the EU MDD to the EU MDR". Below the banner, the "Overview" section explains the purpose of the form and provides a contact email. The "Eligibility" section lists criteria for using the form, with the first item being: "1. The changes being notified only relate to devices transitioning from the EU MDD to EU MDR certification. i.e., the changes are due to a change".

**Australian Government**  
Department of Health and Aged Care  
Therapeutic Goods Administration

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## Form: Sponsor notification for medical devices transitioning from the EU MDD to the EU MDR

### Overview

This form is for sponsors or agents of non-IVD medical devices included in the ARTG with a need to transition from the EU MDD to the new EU MDR to allow medical devices to continue to be supplied in Australia.

Complete this form if you are a sponsor or agent seeking to utilise TGA's web publication service to provide market notifications to health care providers and/or end users as a result of your devices transitioning from the EU MDD to the EU MDR.

**Closes 24 May 2024**  
Opened 1 Dec 2022

**Contact**  
[EUMDRTransition@health.gov.au](mailto:EUMDRTransition@health.gov.au)

### Eligibility

All the following 6 criteria must be met in order to utilise TGA's web publication service to provide market notifications to health care providers and/or end users:

1. The changes being notified only relate to devices transitioning from the EU MDD to EU MDR certification. i.e., the changes are due to a change

# EU MDR Web Publication Service

- Downloadable spreadsheet
- Updated weekly on Tuesdays

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
	Date Published	Manufacturer name	Sponsor name	ARTG number	GMDN code	GTIN code (if available)	ARTG intended purpose	Names of devices that are affected by EU MDR changes	Date of effect of EU MDR	Indications in IFU	Class of persons for which the device is suitable for	Intended Purpose reduced	Functional Description	Addition of a warning for a novel or newly identified safety issue or contraindication	Addition of adverse event information which would change patient management	Contact details for enquiries
1	DDMMYYYY								DDMMYYYY	Previous EU MDD certification: Current EU MDR certification: Products affected:	Previous EU MDD certification: Current EU MDR certification: Products affected:	Previous EU MDD certification: Current EU MDR certification: Products affected:	Previous EU MDD certification: Current EU MDR certification: Products affected:	Previous EU MDD certification: Current EU MDR certification: Products affected:	Previous EU MDD certification: Current EU MDR certification: Products affected:	Contact Name: Contact email: Contact number:
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The screenshot shows the official website for the EU MDR Transition web publication service. At the top, it identifies the Australian Government, Department of Health and Aged Care, and Therapeutic Goods Administration. A search bar is present in the top right corner. The main navigation menu includes 'Products we regulate', 'Product safety', 'How we regulate', and 'Guidance and resources'. The breadcrumb trail indicates the path: Home > How we regulate > Supply a therapeutic good > Supply a medical device > EU MDR Transition. The page title is 'EU MDR Transition web publication service', with options to listen, print, or share. It states the published and last updated date as 01/12/2022. A sidebar on the right lists categories: 'EU MDR Transition', 'Manufacturer evidence', 'Device Change Request (DCR) and variations', 'Conformity assessment, Essential Principles and consent to supply', 'Recalls and market notifications', and 'Online assessment tool and online notification form'. The main content area explains that the service is a platform for sponsors to provide market notifications to health care providers and consumers for devices going through low-risk changes. It includes an 'Important information' section stating that market notifications relate to low-risk changes only and that the service is updated weekly on Tuesdays, with a cut-off for market notification submissions at 11:59pm the preceding Sunday. A footer note mentions that more information about the Australian regulatory framework is available on the EU MDR Transition page.

It is the **sponsor's responsibility** to advise health care providers and end users of the web publication service

# EU MDR Transition – Guidance

## Guidance on our website:

- Overview and management under the Australian regulatory framework
- Online assessment tool and notification form – User guide for sponsors and agents
- Manufacturer Evidence – Example scenarios and FAQs
- DCRs and variations – Example scenarios and FAQs
- Recalls and market notifications - Example scenarios and FAQs
- Conformity Assessment, Essential Principles and Consent to Supply - Example scenarios and FAQs

The screenshot shows the Australian Government Therapeutic Goods Administration website. The page title is "EU MDR Transition" and the sub-heading is "Overview and management under the Australian regulatory framework". The main text explains that this guidance is for manufacturers, Australian sponsors, and agents of medical devices (excluding IVD) included in the ARTG, who are transitioning from MDD to MDR certification. A note states that the guidance is for non-IVD devices and that separate guidance will be provided for IVD devices. The page includes navigation links for "Listen", "Print", and "Share". A sidebar on the right contains a menu with "Supply a medical device" and "EU MDR Transition" selected. The sidebar also lists "Manufacturer evidence", "Device Change Request (DCR) and variations", "Conformity assessment, Essential Principles and consent to supply", "Recalls and market notifications", and "Online assessment tool and online notification form".

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## EU MDR Transition

Overview and management under the Australian regulatory framework

This guidance is to assist manufacturers, Australian sponsors, and agents of medical devices (excluding in vitro diagnostic (IVD) medical devices) included in the Australian Register of Therapeutic Goods (ARTG), where the conformity assessment certification that supports the inclusion in the ARTG is transitioning to the new certification issued under the European Union Medical Device Regulations (EU MDR). This guidance will assist sponsors to understand and meet their obligations under the Australian regulatory framework.

**Note on IVDD to IVDR transition:** This guidance relates to non-IVD medical devices only and does not cover the transition of IVD medical devices to the EU IVD Regulation (IVDR). Separate guidance will be provided for the transition of IVD medical devices to the EU IVDR.

Listen Print Share

### What is changing

The transition from the EU MDD to EU MDR has introduced a range of changes for medical device manufacturers such as:

- More stringent requirements to demonstrate medical device safety for patients and users including requirements for clinical evidence
- Additional requirements for the manufacturer's quality management systems
- Detailed technical document requirements
- Changes to classification rules for medical devices

Most medical devices included in the ARTG are supported by EU MDD certification and may need to transition to the new EU MDR to continue to be supplied in Australia.

The Therapeutic Goods Administration (TGA) recognises that some manufacturers are facing delays in

Supply a medical device

EU MDR Transition

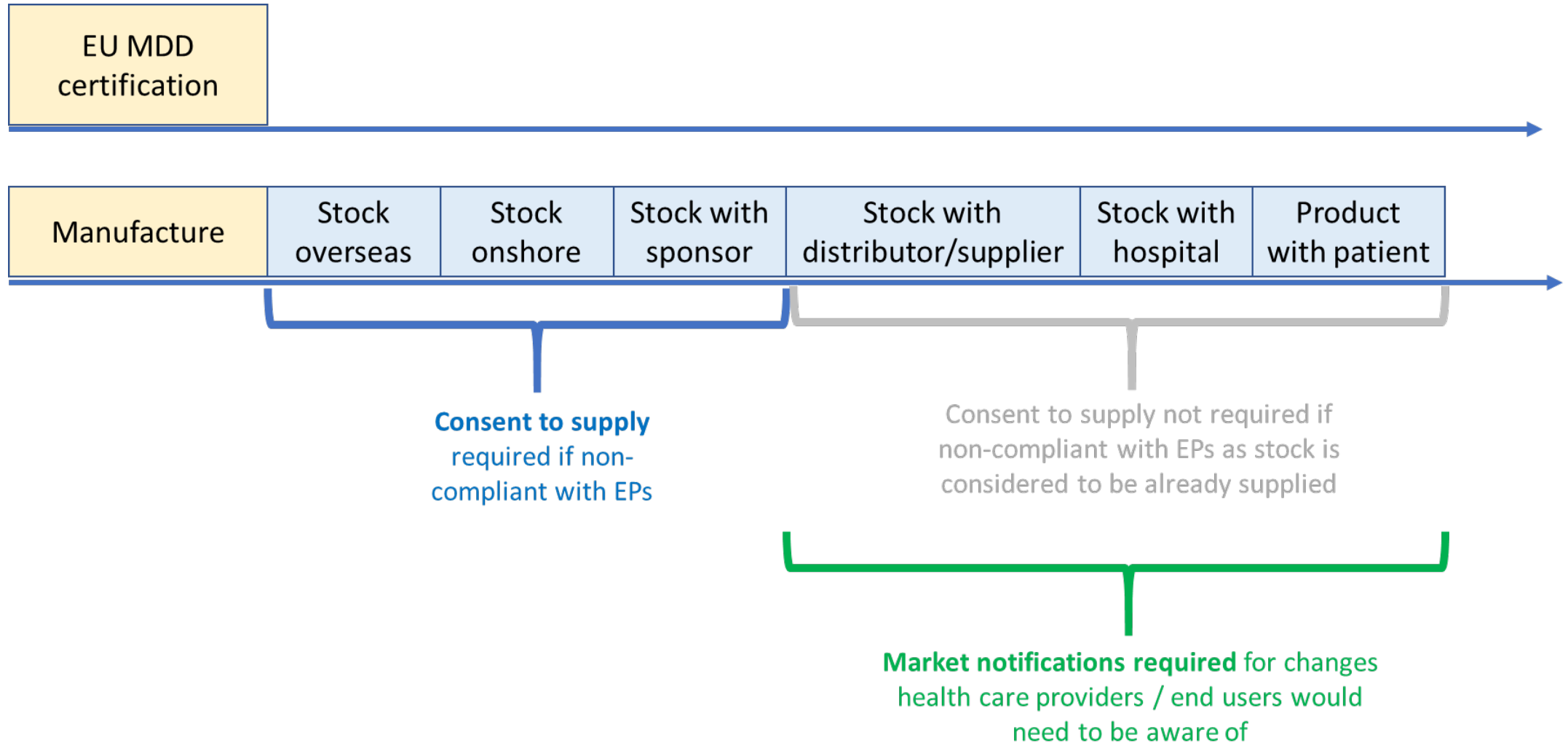
- Manufacturer evidence
- Device Change Request (DCR) and variations
- Conformity assessment, Essential Principles and consent to supply
- Recalls and market notifications
- Online assessment tool and online notification form

# Recap

- a suite of **guidance material** to help manufacturers and sponsors understand their regulatory obligations in the EU MDR transition.
- an **Online Assessment Tool** to help sponsors determine what actions are needed in Australia because of their transition to the EU MDR.
- an **Online Notification Form** for sponsors who qualify for streamlined market notifications to use the **EU MDR Web Publication Service** to advise health care providers and end users of low-risk changes because of the transition.



# Regulatory obligations - manufacture and supply chain



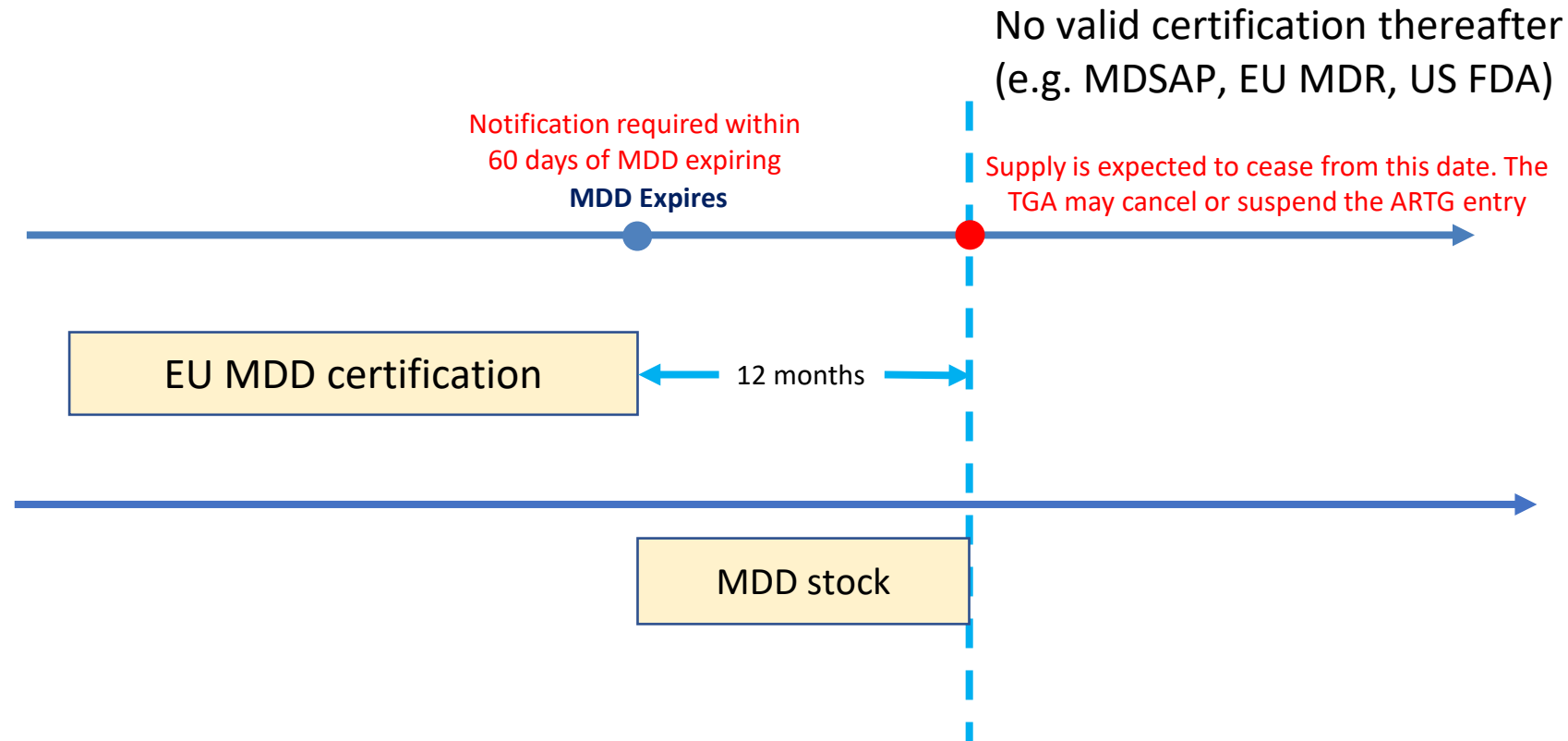


# Context for example scenarios in the following slides

A hip implant was suitable for both the **paediatric and adult population** under **EU MDD** certification, but is only suitable for the **adult population** under the **EU MDR** certification.



# Example 1: No valid certification within 12 months of MDD certification expiry



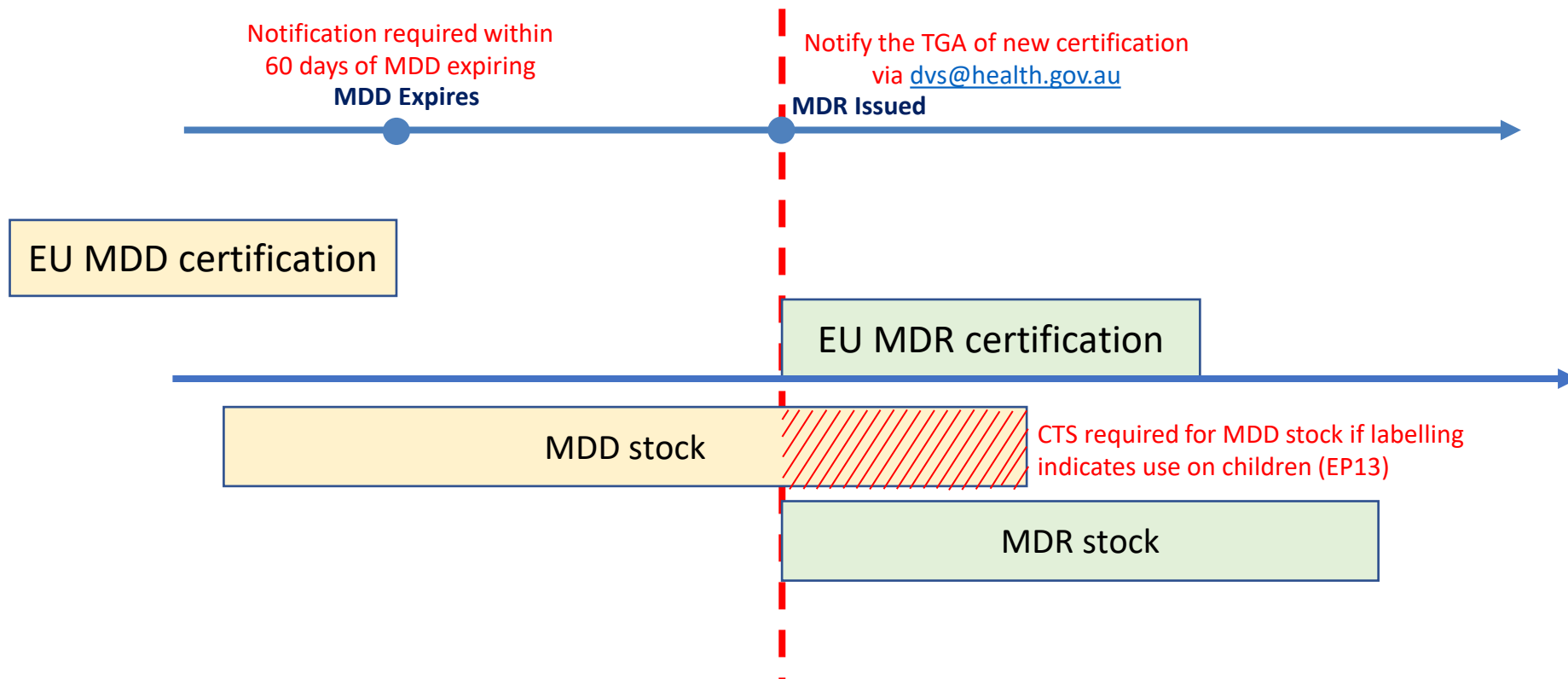
# EU MDR “sell-off” provision

## Art. 120 par. 4 MDR

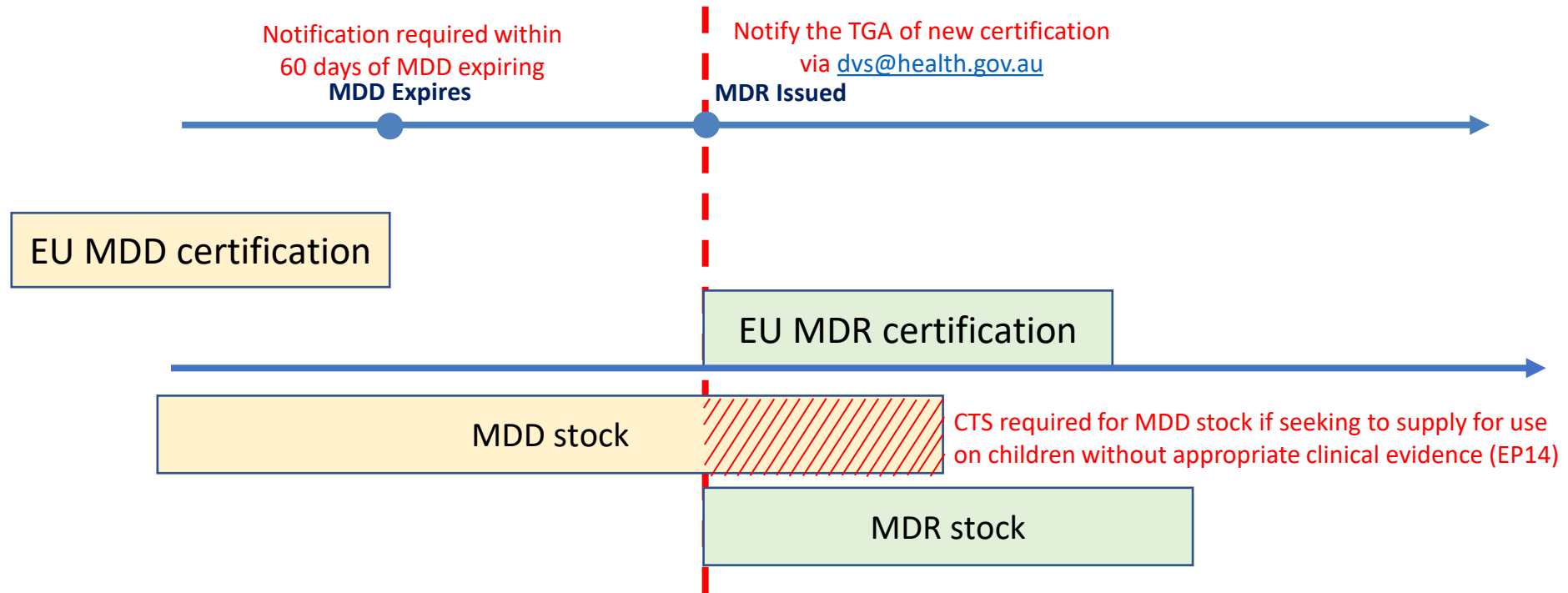
AIMDD/MDD compliant devices **placed on the market before 26 May 2021** or devices with certificates issued in accordance with AIMDD/MDD **placed on the market after the Date of Application** [of the MDR] with no significant change in design and intended purpose can be **made available until 27 May 2025**. After the aforementioned date, these devices will not be *marketable* anymore, even if they are already in the supply chain but have not yet reached the final user.

# Example 2a:

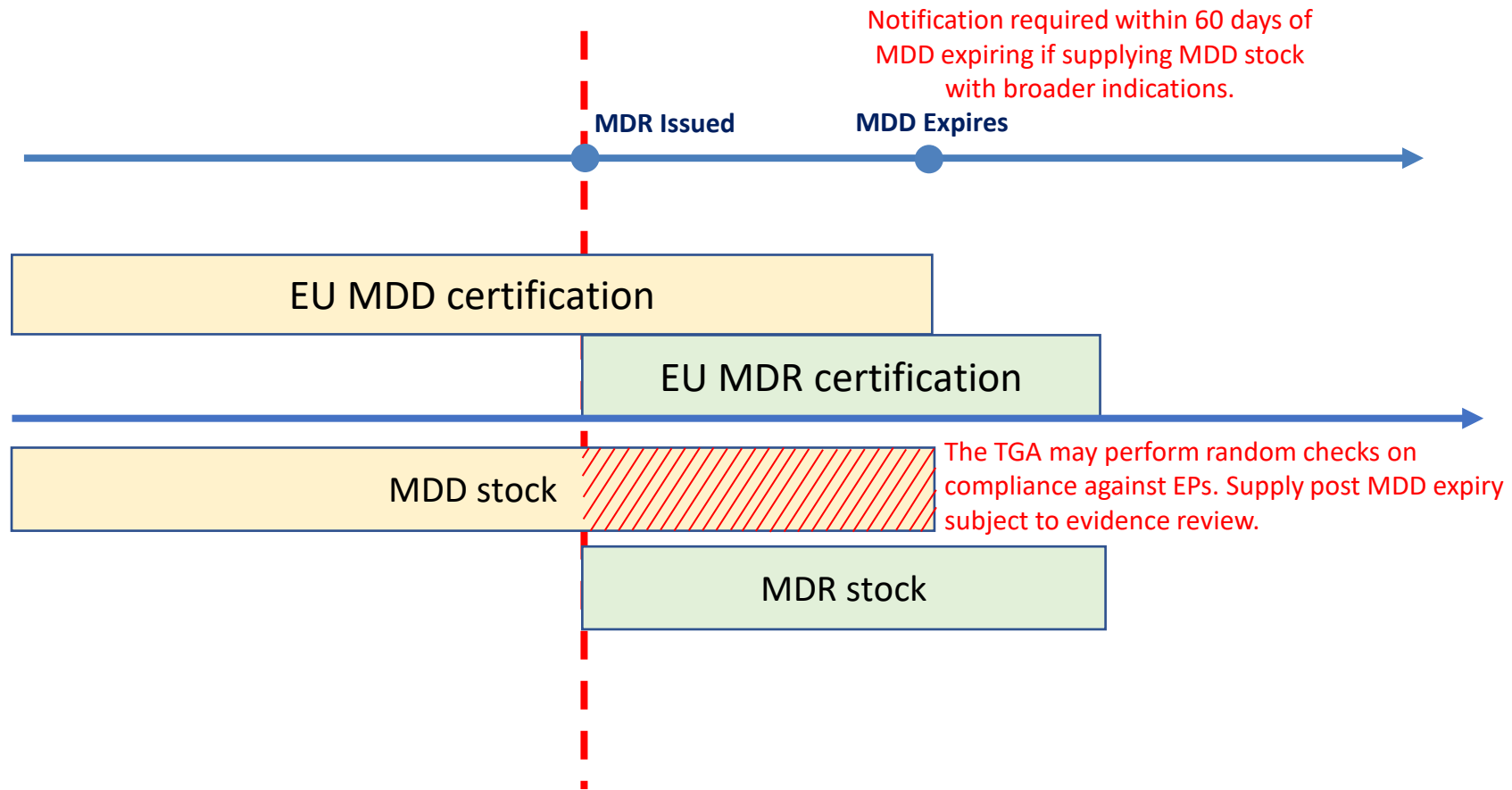
## Gap in certification - Supply MDD stock with MDR indications



# Example 2b: Gap in certification - Supply MDD stock with MDD indications



# Example 3: Overlapping certifications



# Fees and charges

- Consent to Supply
  - Essential Principle 13 only – **reduced fee (\$30 per ARTG entry)**
  - Any other Essential Principles – full fee (\$500 for first ARTG entry, \$100 for subsequent)
  - Implementation plan required
- DCR/Variations
  - Relink manufacturer evidence identifier only – **PROPOSED** reduced fee (\$190 to relink up to 10 ARTG entries to the **same** manufacturer evidence identifier )
  - Any other change – full fee (\$482)
- EU MDR Web publication service
  - No charge



# Upcoming Webinars

<https://www.tga.gov.au/resources/event>

Webinar Topic	Date	Time (GMT+11)
No.2 EU MDR Transition - Manufacturer Evidence and Variations to the ARTG	Wednesday 7 December 2022	2-3pm
No.3 EU MDR Transition - Consent to Supply, market notifications	Tuesday 13 December	1-2pm

# Website and link references

EU MDR guidance material	<a href="http://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-medical-device/eu-mdr-transition">www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-medical-device/eu-mdr-transition</a>
Online Assessment Tool	<a href="https://consultations.tga.gov.au/tga/tool-sponsor-obligations-for-medical-devices-tran/">https://consultations.tga.gov.au/tga/tool-sponsor-obligations-for-medical-devices-tran/</a>
Online Notification Form	<a href="https://consultations.tga.gov.au/tga/form-sponsor-notification-for-medical-devices-tra/">https://consultations.tga.gov.au/tga/form-sponsor-notification-for-medical-devices-tra/</a>
EU MDR web publication service	<a href="http://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-medical-device/eu-mdr-transition/eu-mdr-transition-web-publication-service">www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-medical-device/eu-mdr-transition/eu-mdr-transition-web-publication-service</a>
Consent to supply	<a href="http://www.tga.gov.au/resources/resource/forms/essential-principles-consent-non-compliance">www.tga.gov.au/resources/resource/forms/essential-principles-consent-non-compliance</a>
Lapses in Conformity Assessment Notification Form	<a href="https://consultations.tga.gov.au/tga/notification-form-lapses-in-conformity-assessment/">https://consultations.tga.gov.au/tga/notification-form-lapses-in-conformity-assessment/</a>
Recalls	<a href="http://www.tga.gov.au/safety/product-recalls">www.tga.gov.au/safety/product-recalls</a>
Schedule of fees and charges	<a href="https://www.tga.gov.au/schedule-fees-and-charges">https://www.tga.gov.au/schedule-fees-and-charges</a>
TGA business services	<a href="https://www.tga.gov.au/tga-business-services">https://www.tga.gov.au/tga-business-services</a>

# Contact us

EU MDR Transition Team

[EUMDRTransition@health.gov.au](mailto:EUMDRTransition@health.gov.au)

# Questions



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Post Market Reviews and Reforms



Q&A

# More information



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TGA topics blog <https://www.tga.gov.au/blogs/tga-topics>



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