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.

Agenda

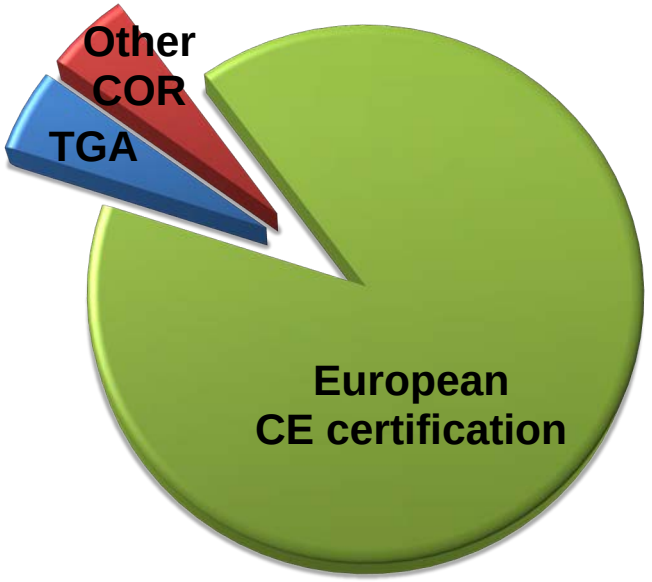
- Background
- Overview of the TGA’s approach
- Handling approaches using examples
- Resources on a page
- Q&A

Background

- Majority of medical device ARTG inclusions are supported by European certification.

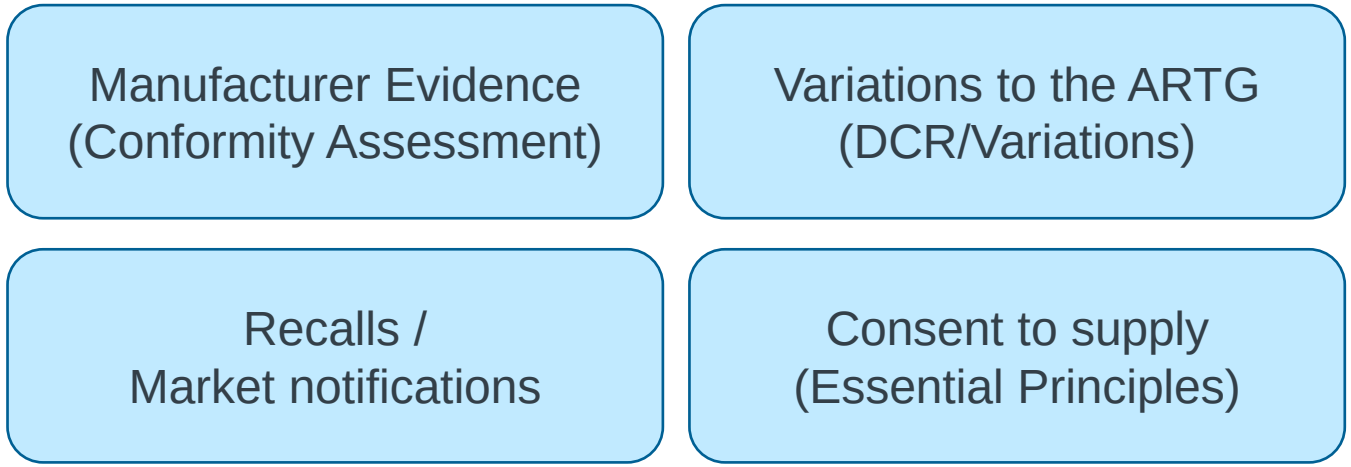
- Medical device regulation in Europe is undergoing transition to replace the existing Medical Device Directive (MDD) (93/42/EEC) and the Active Implantable Medical Device Directive (90/385/EEC) (AIMDD) with the new Medical Device Regulation (MDR) (2017/745/ EU).

- 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



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

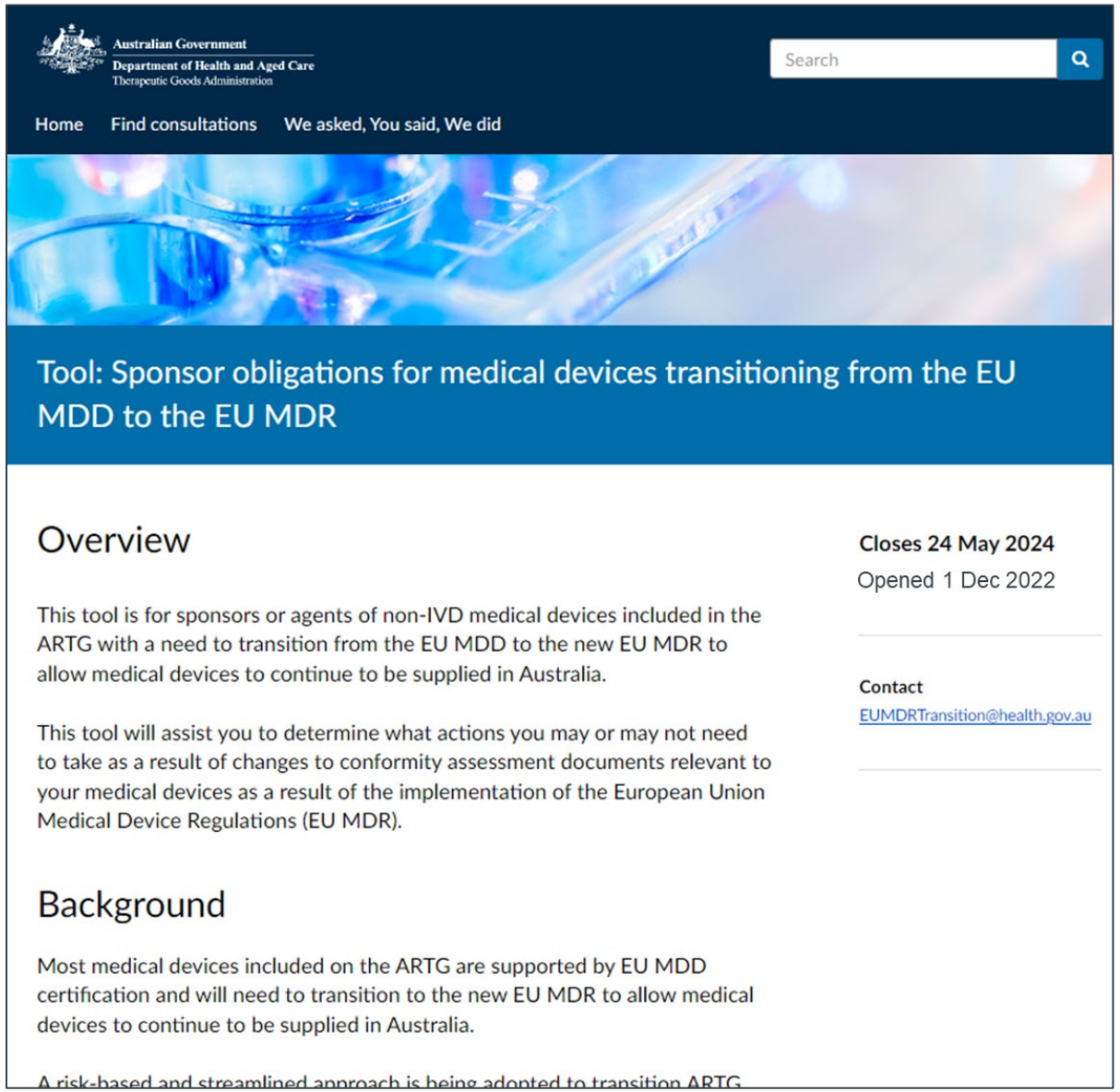
A range of regulatory actions in relation to the transition:

- 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

	Change	Regulatory action
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): •Intended purpose •GMDN code and term •Linking the EU MDR document to an existing ARTG inclusion •Manufacturer details (name or address)	Device Change Request
4	Changes to any of the following (for class III/AIMD): •Total number of devices •Variant list •UPI (Unique Product Identifier) •Functional Description	Variation
5	Changes to any of the following: •Indications in IFU •Class of persons for which the device is suitable for •Reduction in scope of intended purpose •Functional description •Addition of a warning for a newly identified safety issue or contraindication •Addition of adverse event information which would change patient management recommendations	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



https://consultations.tga.gov.au/tga/tool-sponsor-obligations-for-medical-devices-tran/

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:

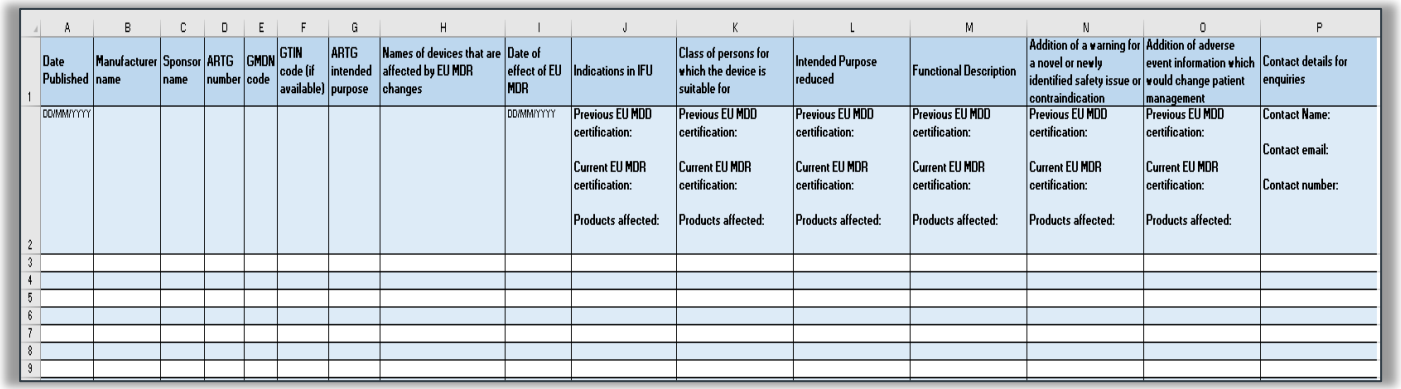
1. The changes being notified only relate to devices transitioning from the EU MDD to EU MDR certification. i.e. the changes are due to a change in regulatory requirements and not because devices currently supplied to the market are unsafe or defective, AND
2. The devices comply with all Australian regulatory 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

https://consultations.tga.gov.au/tga/form-sponsor-notification-for-medical-devices-tra/

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
1	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
2	DD/MM/YYYY								DD/MM/YYYY	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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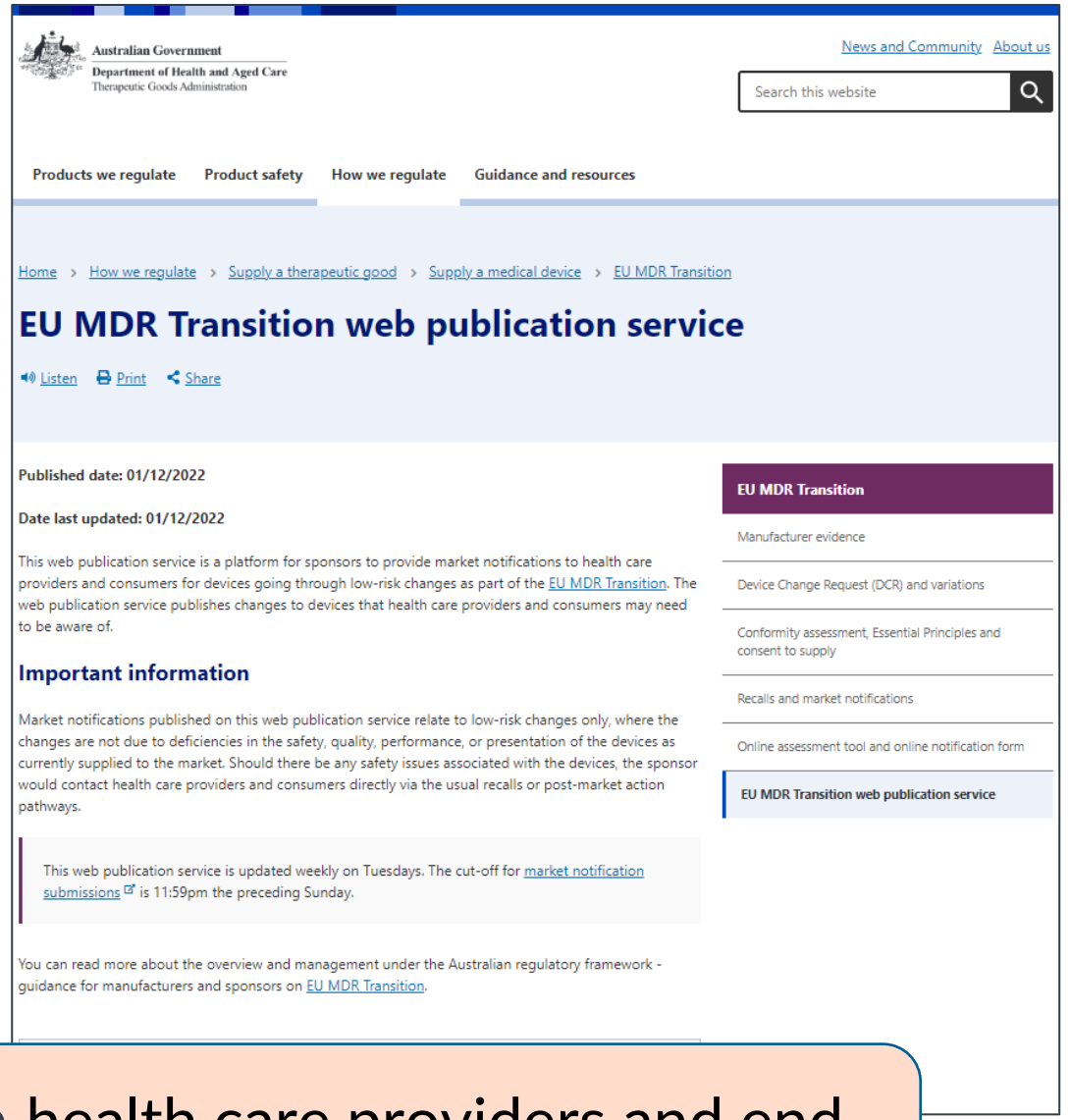

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EU MDR Transition web publication service

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Published date: 01/12/2022

Date last updated: 01/12/2022

This web publication service is a platform for sponsors to provide market notifications to health care providers and consumers for devices going through low-risk changes as part of the EU MDR Transition. The web publication service publishes changes to devices that health care providers and consumers may need to be aware of.

Important information

Market notifications published on this web publication service relate to low-risk changes only, where the changes are not due to deficiencies in the safety, quality, performance, or presentation of the devices as currently supplied to the market. Should there be any safety issues associated with the devices, the sponsor would contact health care providers and consumers directly via the usual recalls or post-market action pathways.

This web publication service is updated weekly on Tuesdays. The cut-off for market notification submissions is 11:59pm the preceding Sunday.

You can read more about the overview and management under the Australian regulatory framework - guidance for manufacturers and sponsors on EU MDR Transition.

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
- EU MDR Transition web publication service

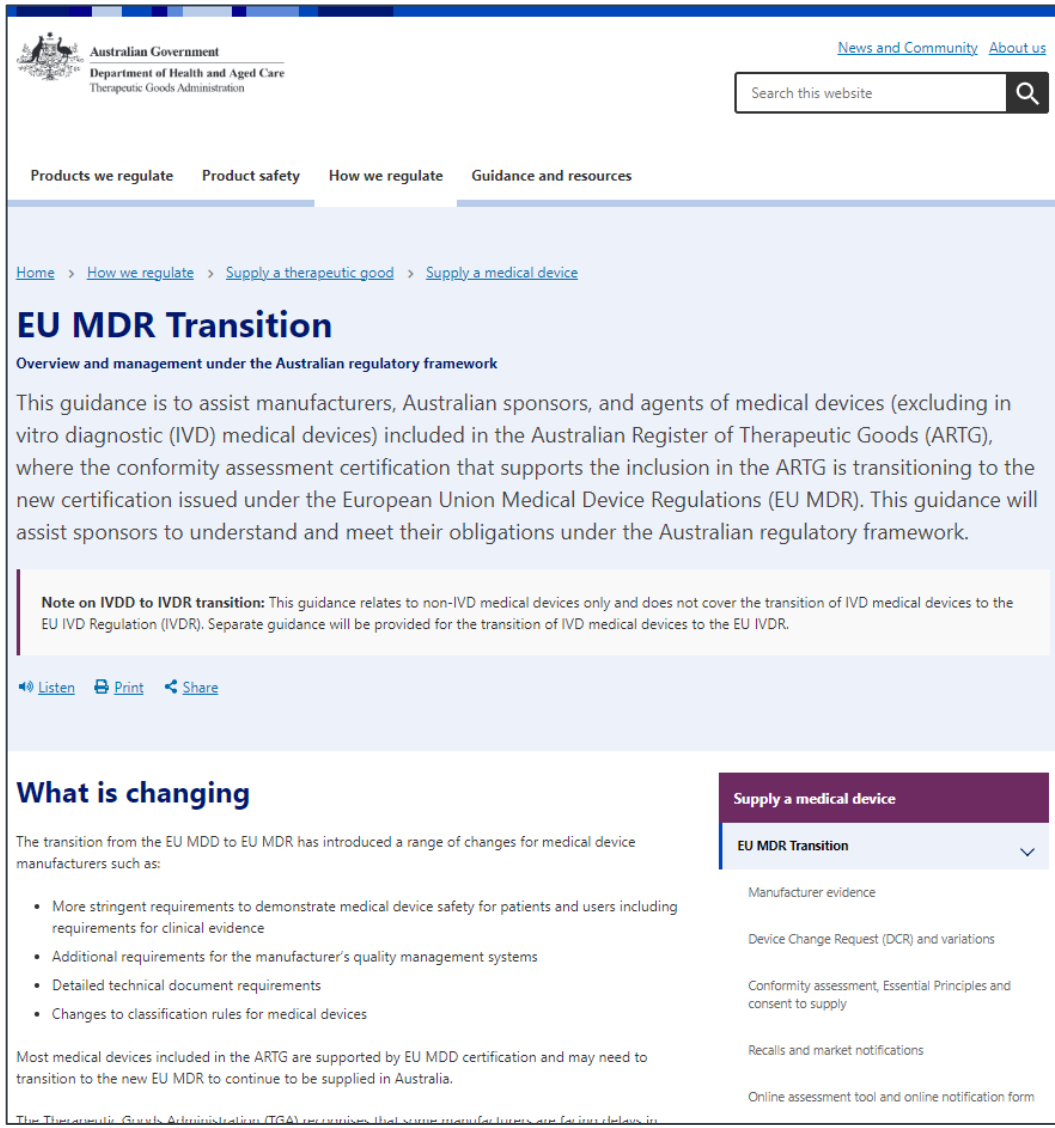
It is the **sponsor's responsibility** to advise health care providers and end users of the web publication service

https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-medical-device/eu-mdr-transition/eu-mdr-transition-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



https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-medical-device/eu-mdr-transition

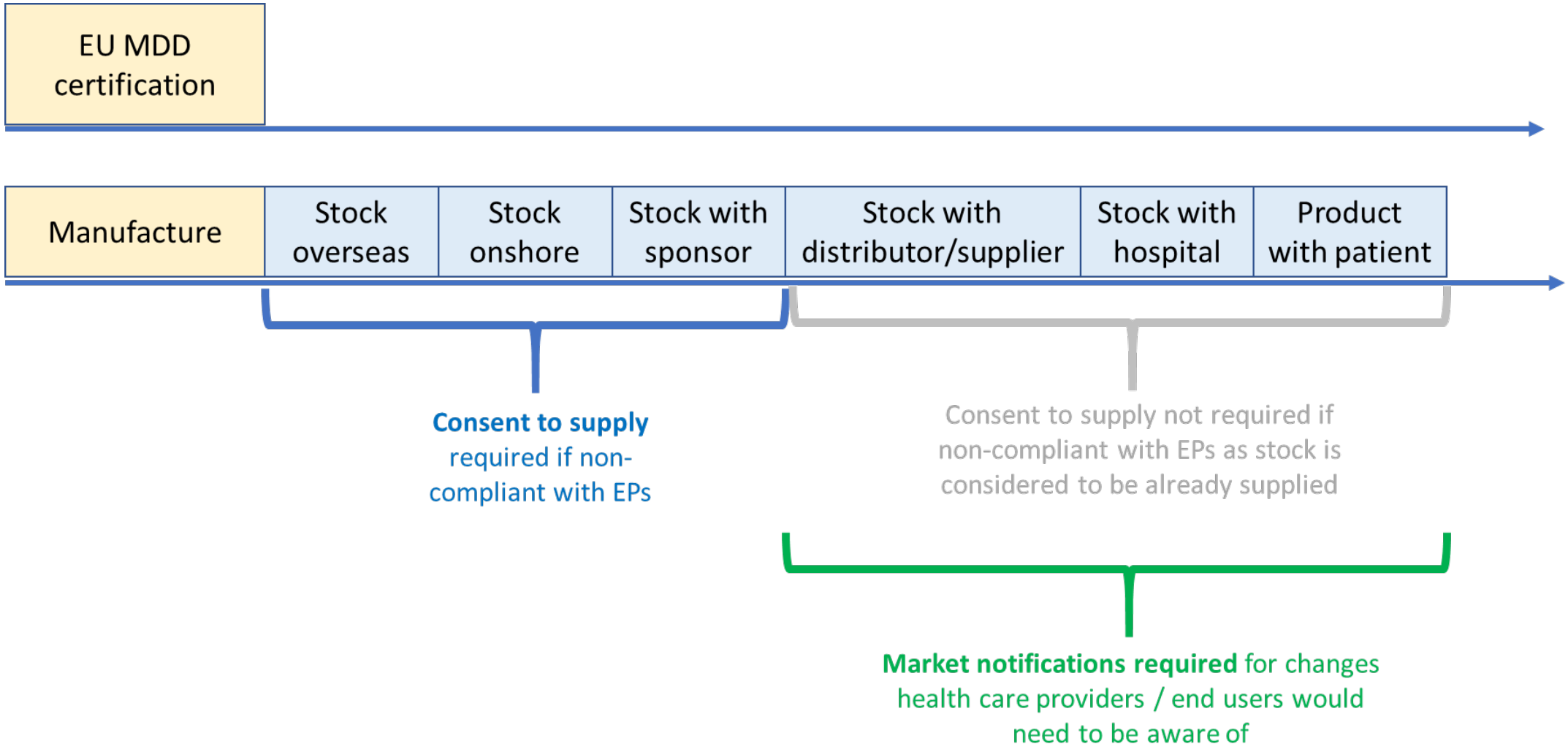
Recap

- 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.

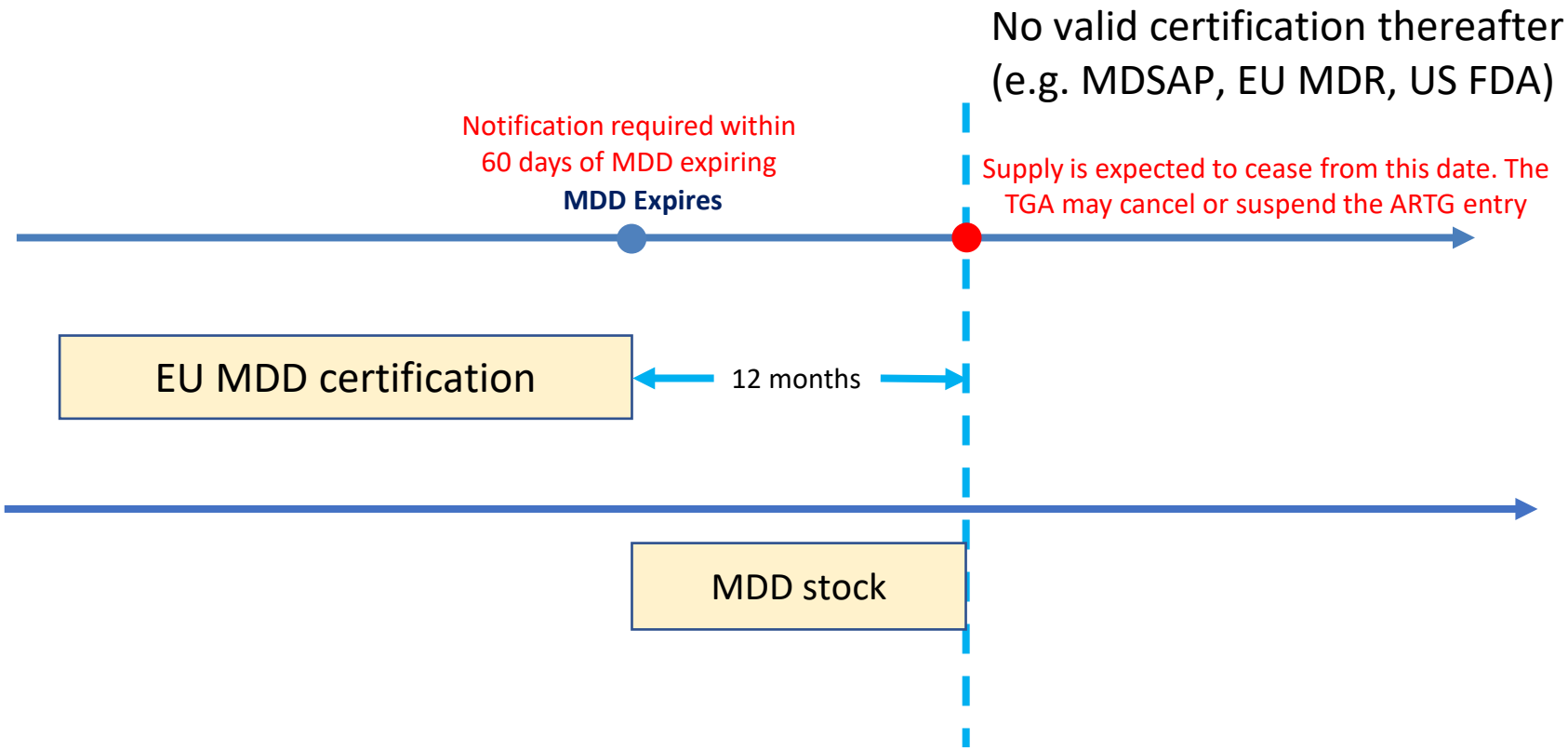
Regulatory obligations - manufacture and supply chain



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

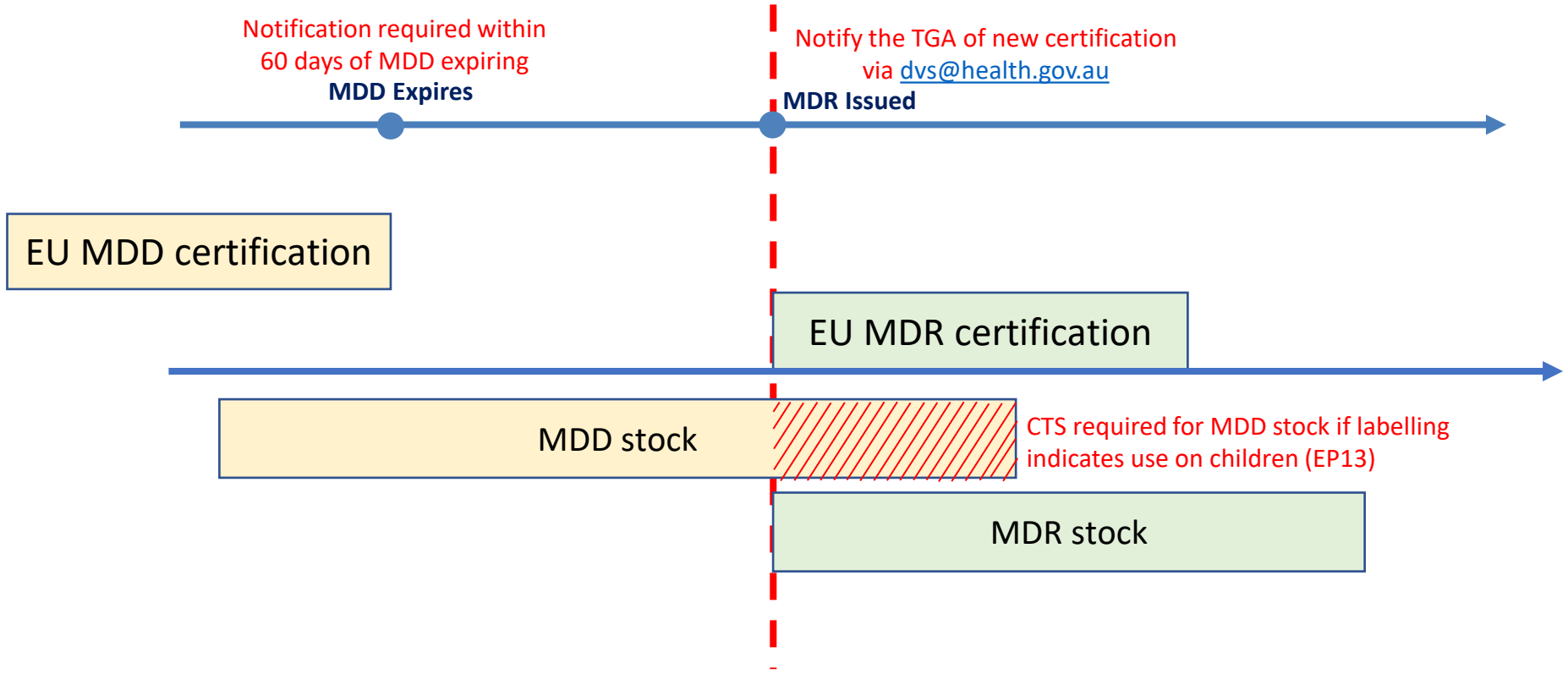


EU MDR “sell-off’ provision

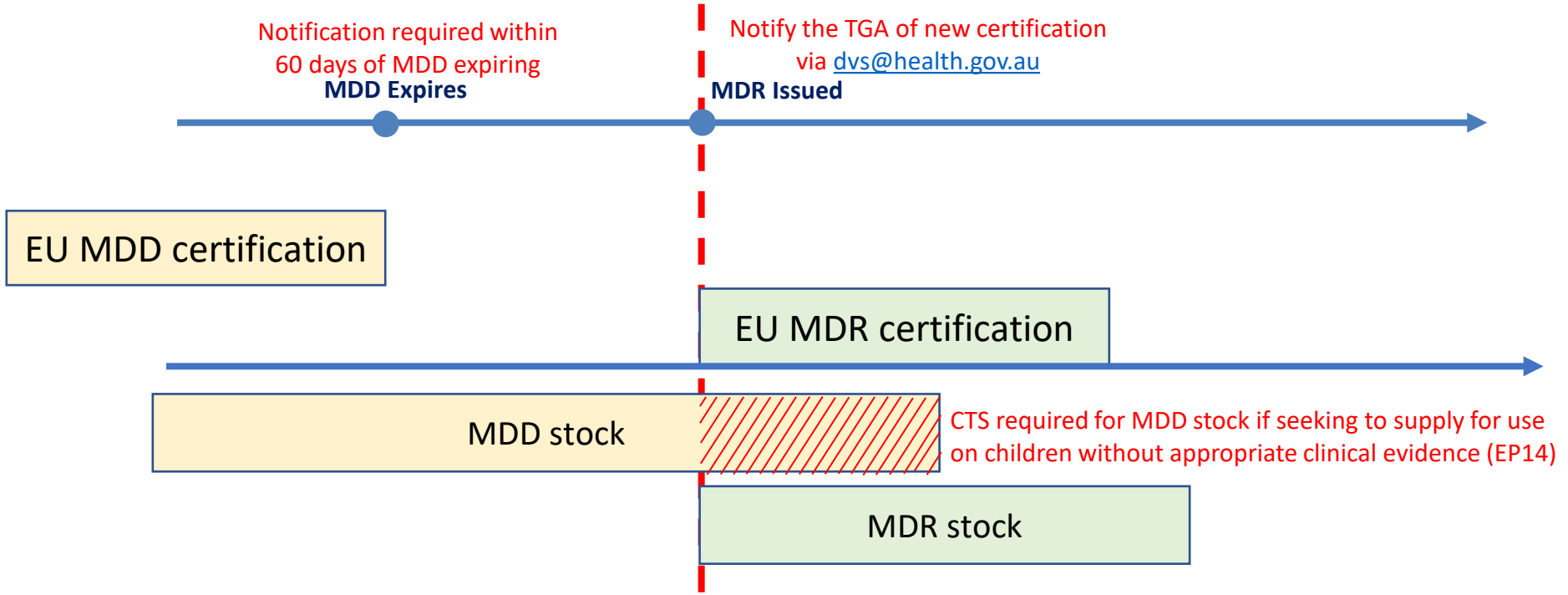
Art. 120 par. 4 MDR

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.

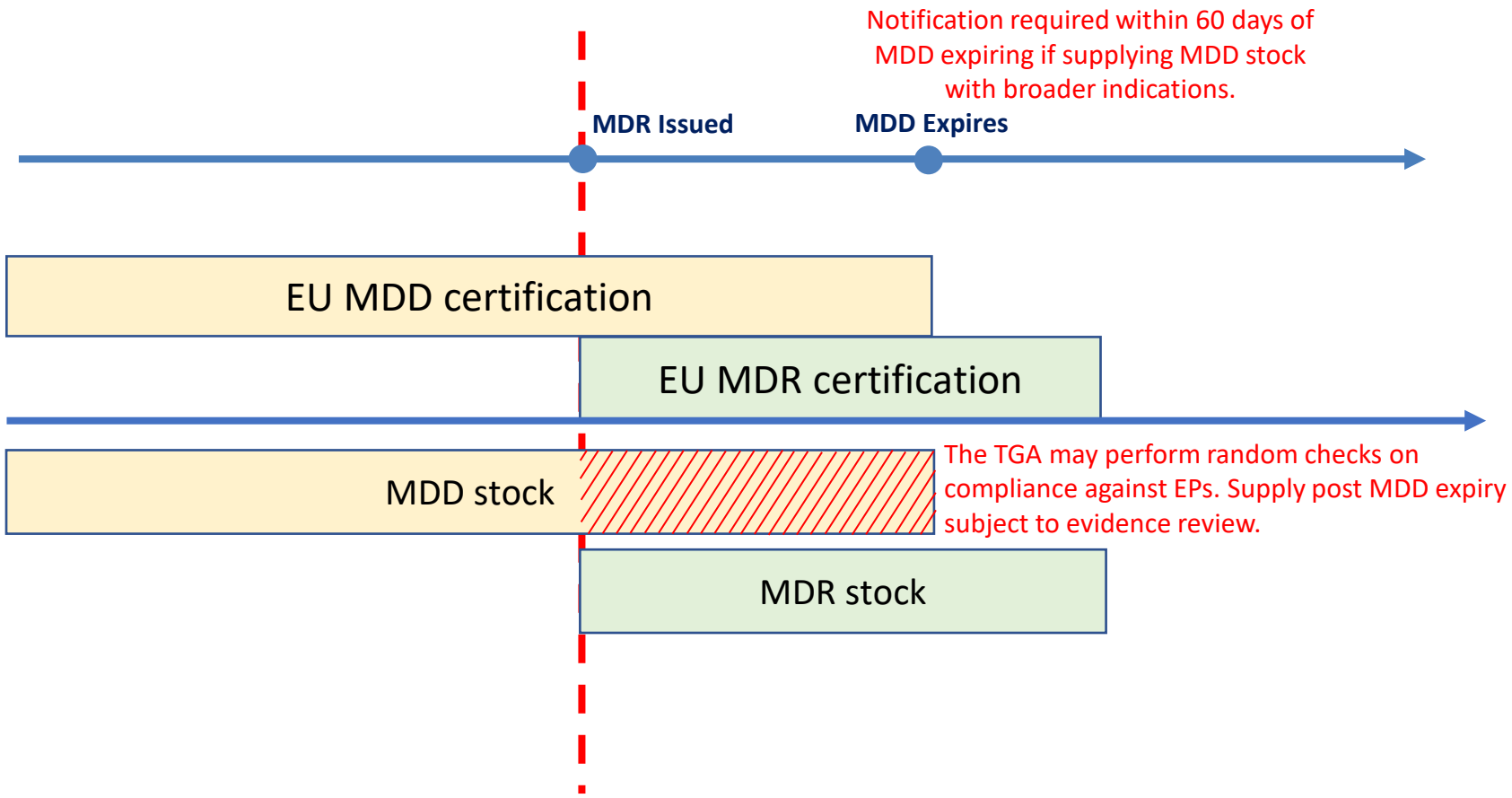
Example 2a:
Gap in certification - Supply MDD stock with MDR indications



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

Contact us

EU MDR Transition Team

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Questions

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Q&A

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