EU MDR Transition – Webinar 3

Consent to Supply, Market Notifications and Recalls

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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

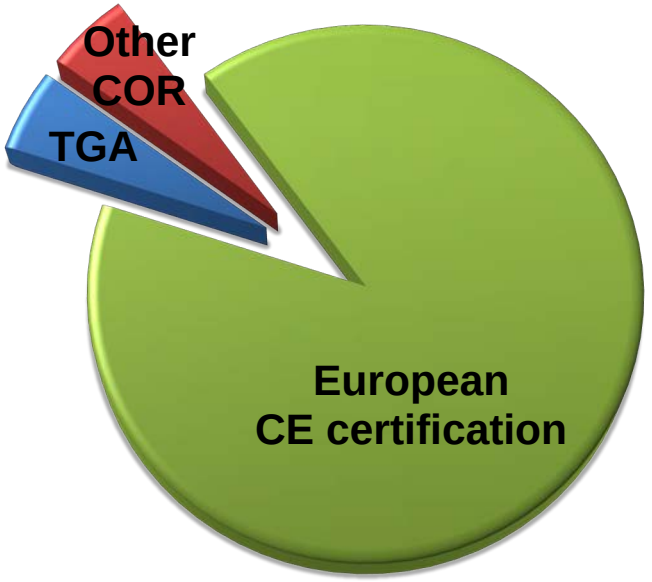
- Background
- Consent to supply, conformity assessment lapses
- Recalls and market notifications
- Fees and charges
- Resources on a page
- Q&A

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).

- To continue supply, these devices will need to transition by 26 May 2024 to the new certification under the European Union Medical Device Regulation (EU MDR).



Implications for medical devices ARTG inclusions

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

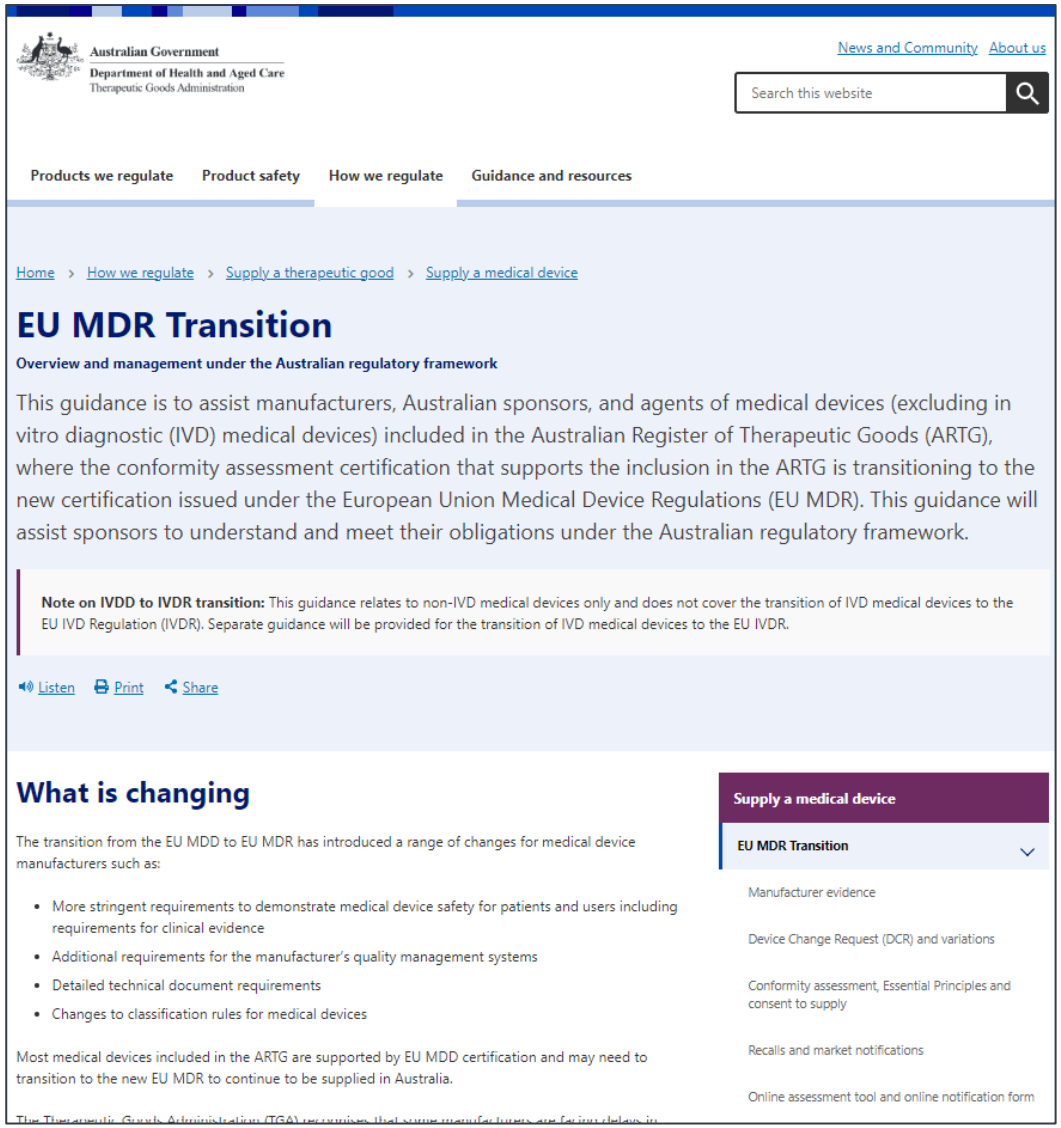
Recalls /
Market notifications

Consent to supply
(Essential Principles)

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

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Consent to Supply, Market Notifications and Recalls

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Consent to supply vs Notifying lapsed certification

Application for consent to import, export, or supply non-compliant medical devices

- **Approval required** prior to importing, exporting, or supplying medical devices that are non-compliant with the Essential Principles
- Medical device was manufactured when conformity assessment certification was valid
- Medical device may be non-compliant with one or more of the Essential Principles
- Manufacturer is working to bring device back into compliance with Essential Principles
- Risk mitigation plan
- Civil and criminal penalties for importing, exporting, or supplying non-compliant devices without approval

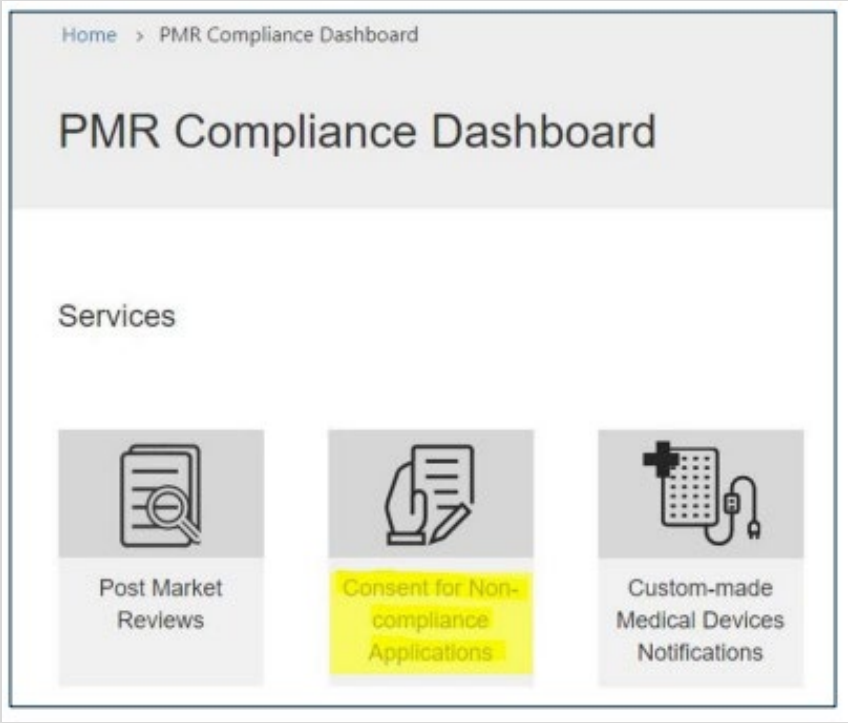
Lapse in conformity assessment notification

- **Notification needed** within 60 days of certification no longer being current
- Conformity assessment certificate has lapsed, been revoked, amended, or suspended
- Medical device can be supplied if it was manufactured when conformity assessment certification was valid
- The ARTG entry may be cancelled or suspended when conformity assessment is no longer current

Consent to supply vs Notifying lapsed certification

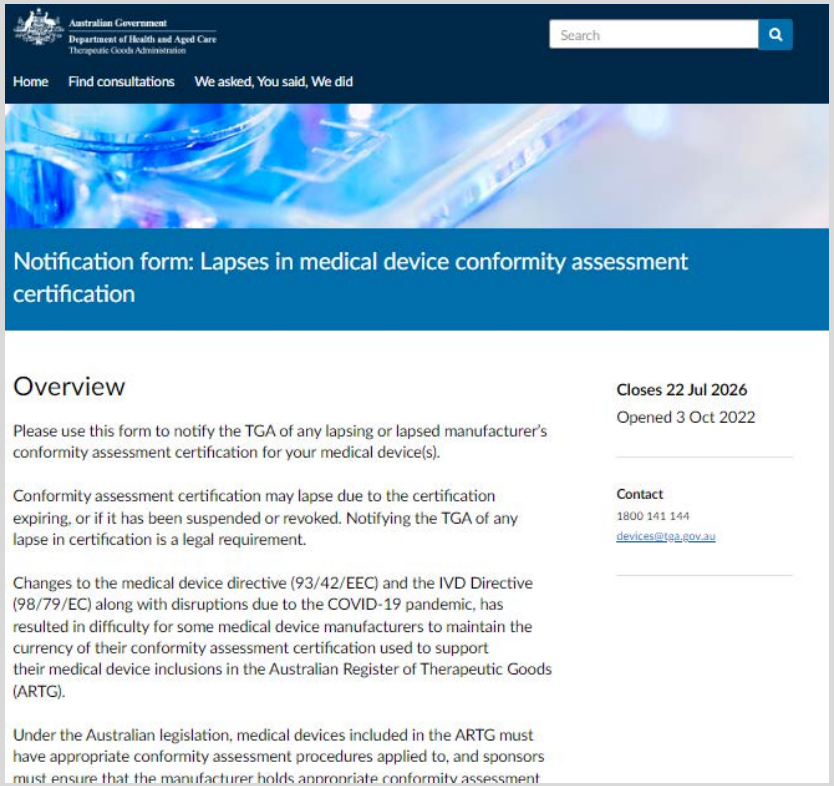
Application for consent to import, export, or supply non-compliant medical devices

Application for consent to import, export, or supply medical devices that do not comply with the Essential Principles



Lapse in conformity assessment notification

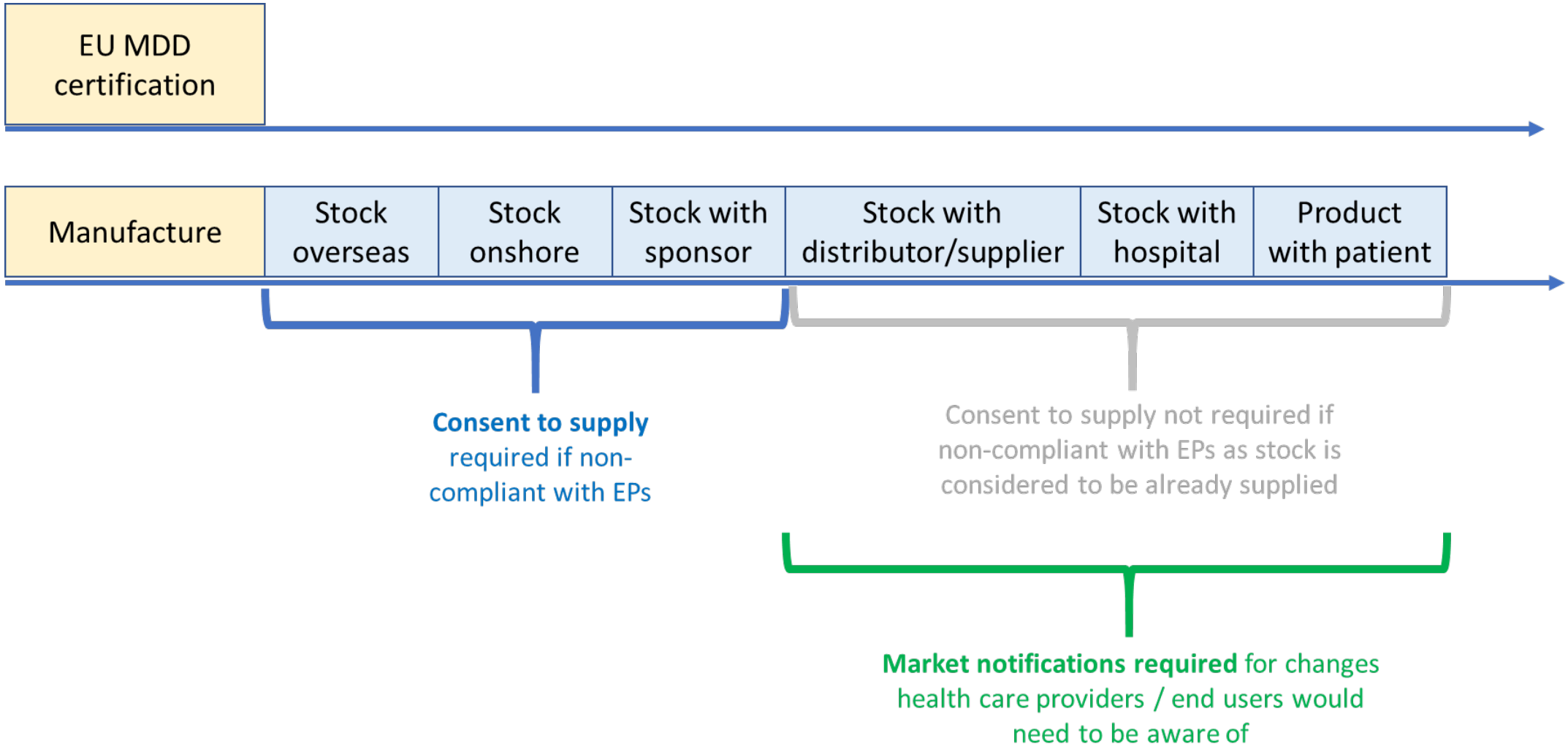
Lapses in Conformity Assessment Notification Form



Examples of non-compliance with Essential Principles

- 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 critical safety information that is not included in the instructions for use, labelling, or patient information leaflets (if applicable).

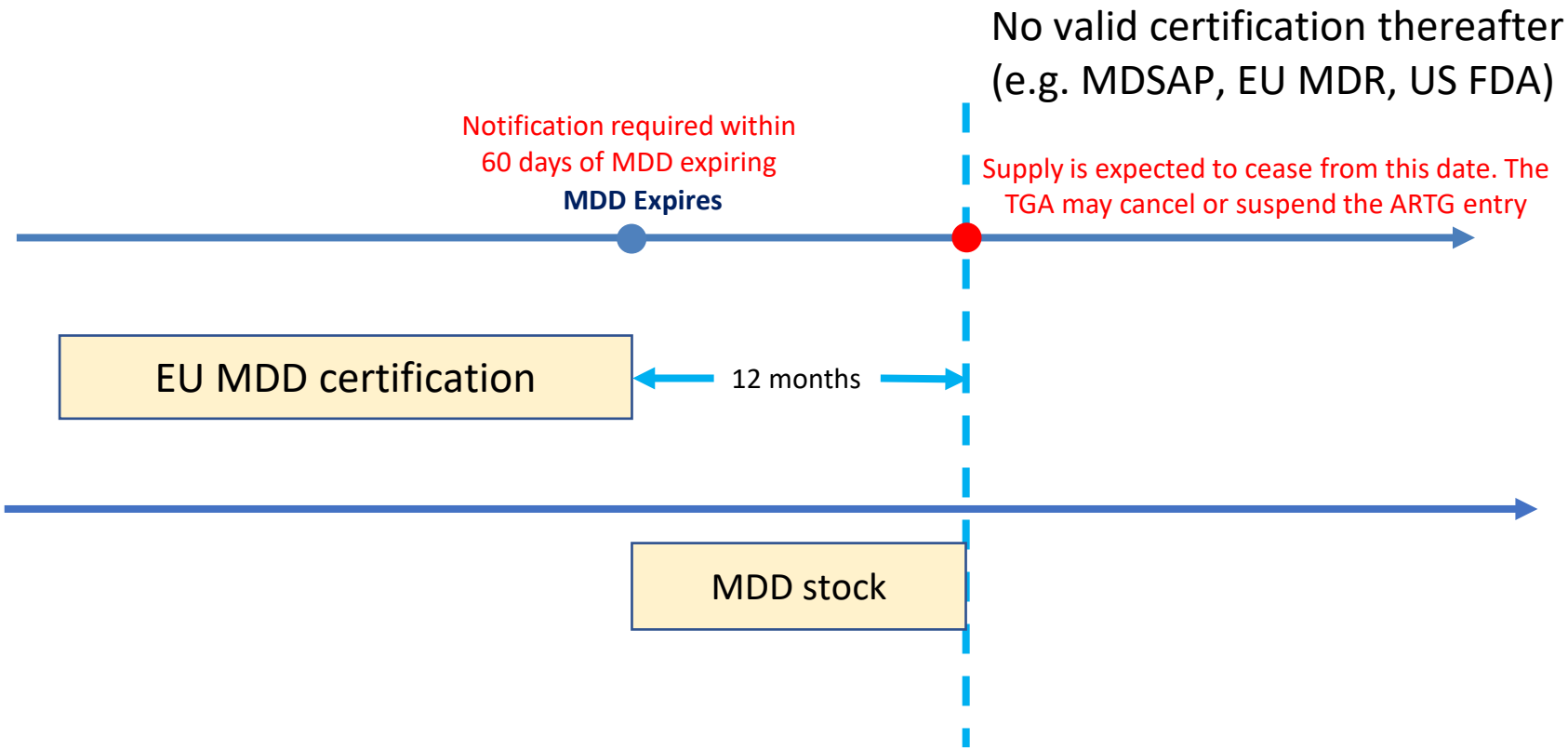
Regulatory obligations - manufacture and supply chain



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

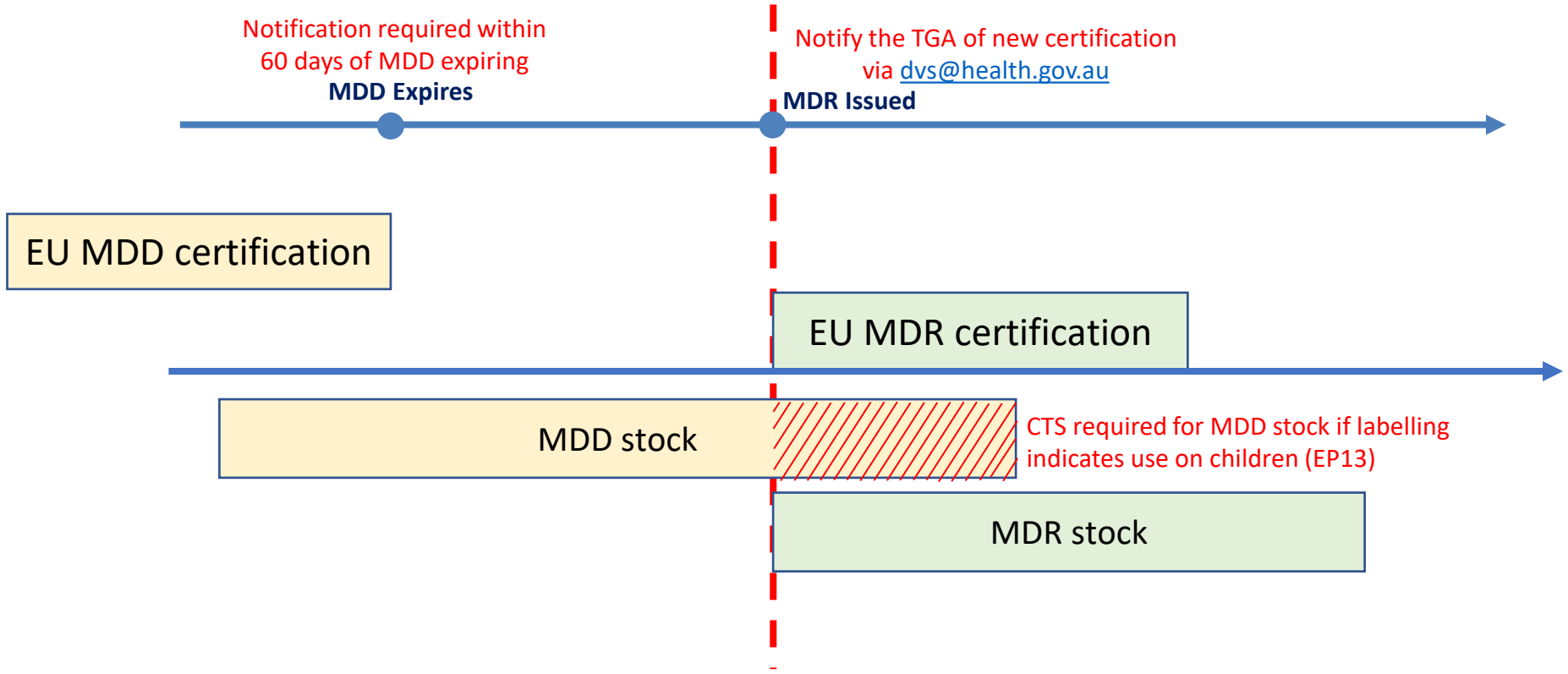


EU MDR “sell-off’ provision

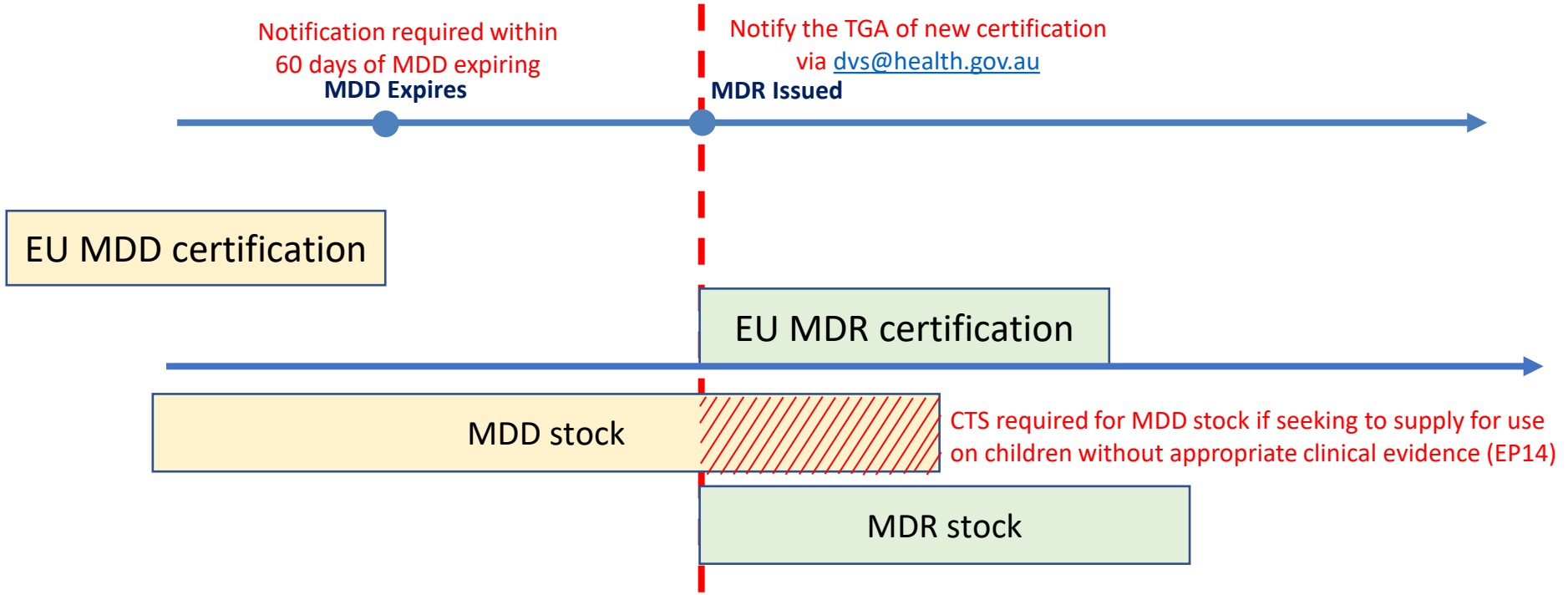
Art. 120 par. 4 MDR

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.

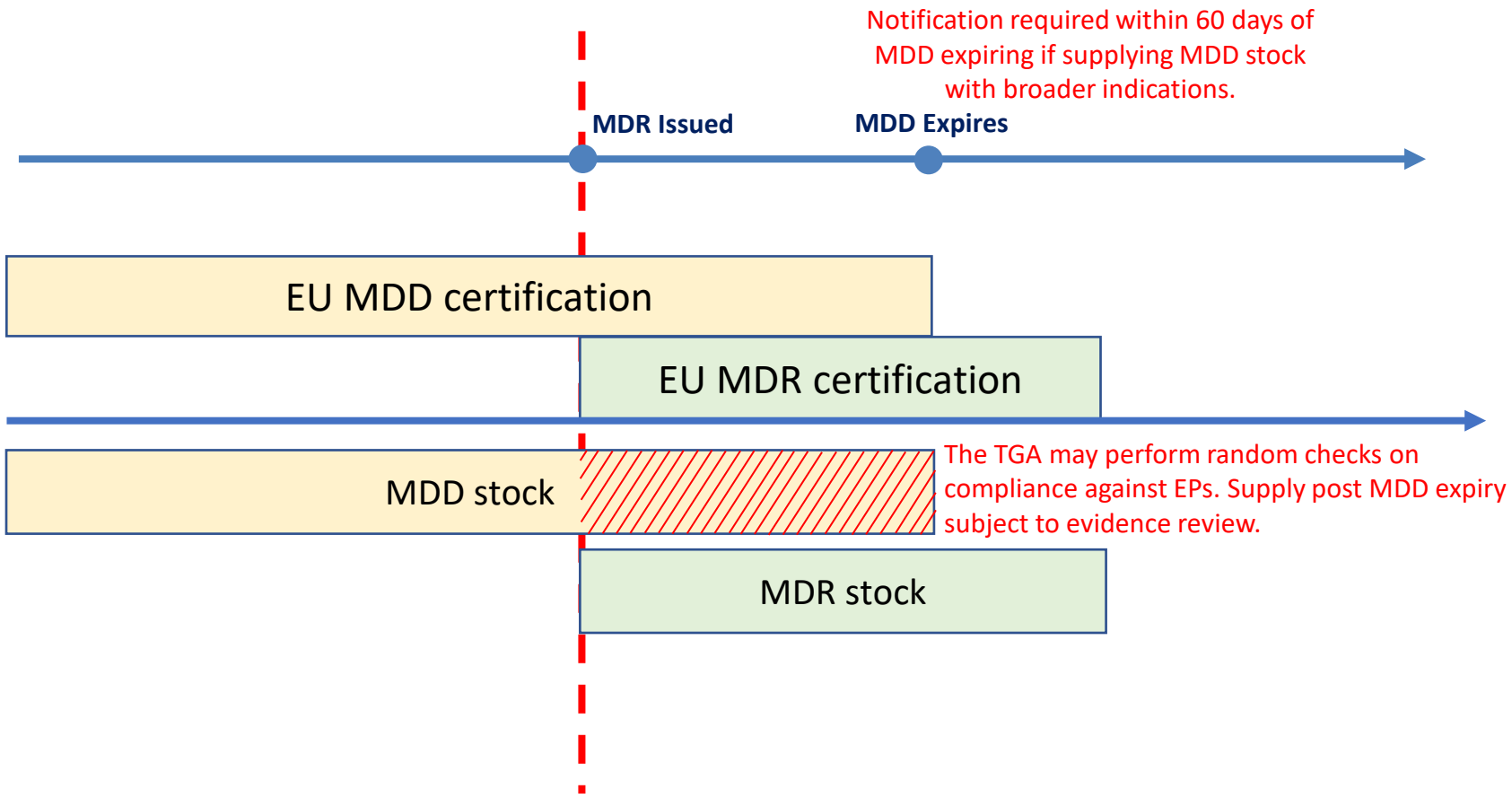
Example 2a:
Gap in certification - Supply MDD stock with MDR indications



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



Example 3:
Overlapping certifications



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Consent to Supply, Market Notifications and Recalls

Craig Davies
Director
Recalls

Recalls

- A **recall action** is a set of market actions that are undertaken, typically via the *Uniform Recall Procedure for Therapeutic Goods (URPTG)*, to resolve a problem with a therapeutic good already supplied in the Australian market for which there are issues, deficiencies or defects in relation to the safety, quality, efficacy (performance) or presentation of the therapeutic good.

- There are four distinct recall actions available to sponsors - recall, product defect correction, hazard alert, and product defect alert. Further information on the standard procedures is outlined on the TGA website.

https://www.tga.gov.au/resources/resource/guidance/uniform-recall-procedure-therapeutic-goods-urptg

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.

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

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/

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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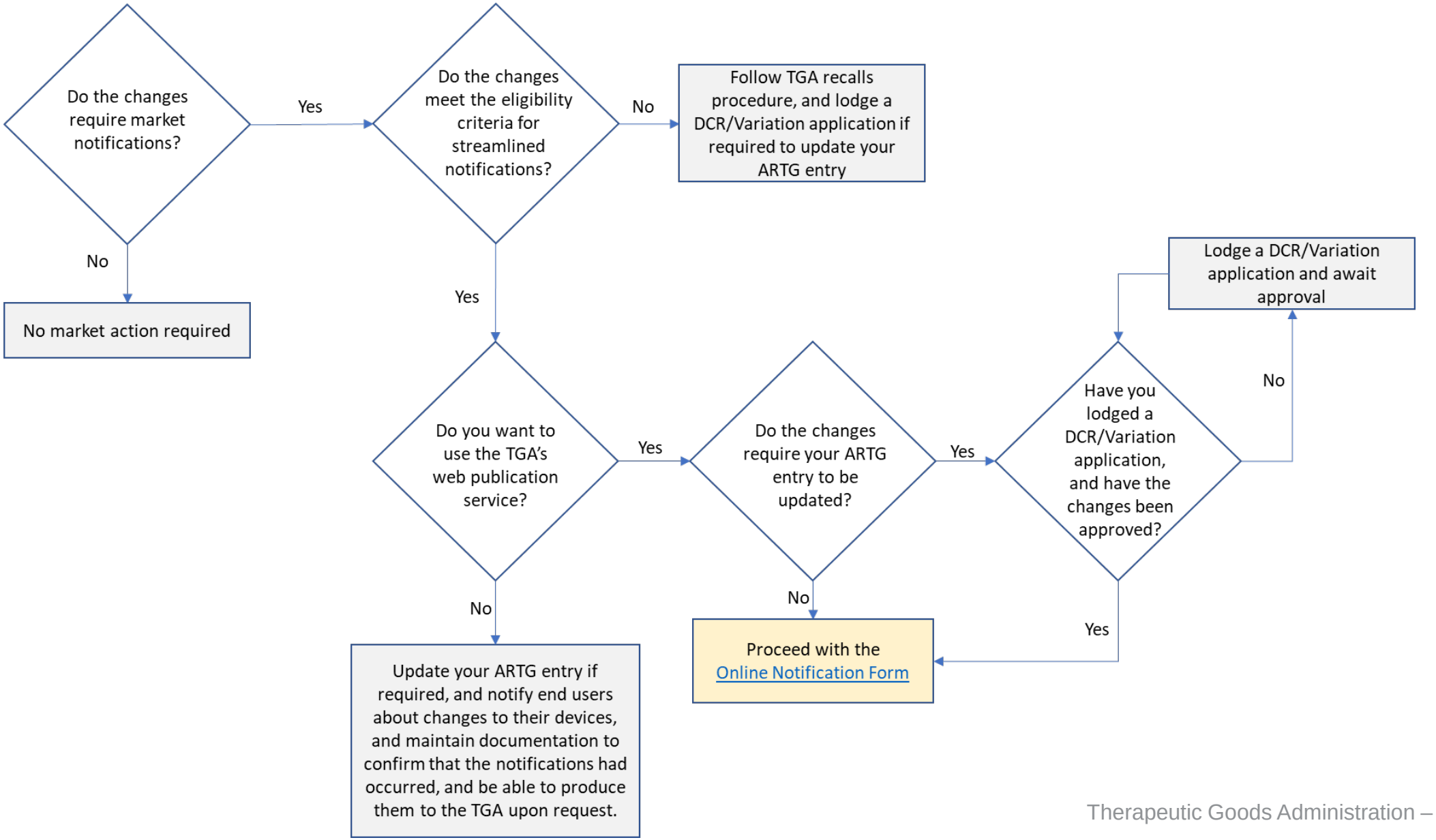
It is the **sponsor's responsibility** to refer health care providers and end users to the web publication service for changes about their devices.

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

Recalls and Market Notifications Flowchart



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

- Web publication service for streamlined market notifications
  - No charge

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	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

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Questions

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Therapeutic Goods Administration