

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.

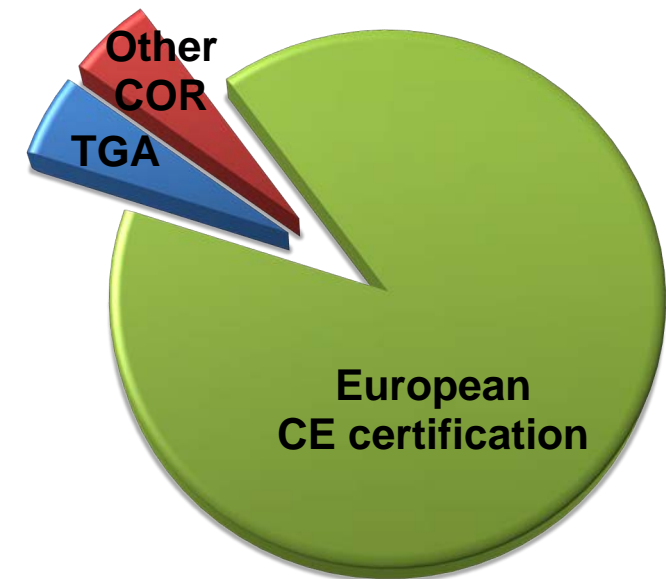
I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

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

The screenshot shows the Australian Government website page for EU MDR Transition guidance. The page header includes the Australian Government logo, the Department of Health and Aged Care, and the Therapeutic Goods Administration. A search bar is located 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 is 'Home > How we regulate > Supply a therapeutic good > Supply a medical device'. The page title is 'EU MDR Transition' with the subtitle 'Overview and management under the Australian regulatory framework'. The main content area contains a paragraph explaining the guidance's purpose and a 'Note on IVDD to IVDR transition'. Below the main content are 'Listen', 'Print', and 'Share' icons. A 'What is changing' section lists several changes for manufacturers. On the right side, there is a sidebar menu with a dropdown for 'EU MDR Transition' containing links to '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'.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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Products we regulate Product safety How we regulate Guidance and resources

Home > How we regulate > Supply a therapeutic good > Supply a medical device

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

EU MDR Transition – Webinar 3

Consent to Supply, Market Notifications and Recalls



Merryn Steer
Assistant Director
Post Market Reviews and Reforms



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

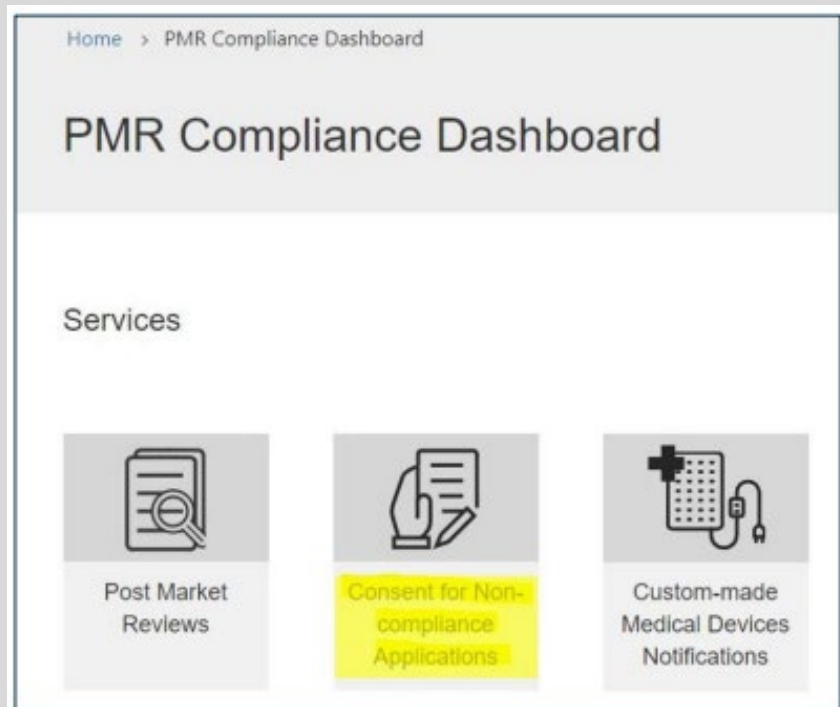
Lapse in conformity assessment notification

- **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](#)



Home > PMR Compliance Dashboard

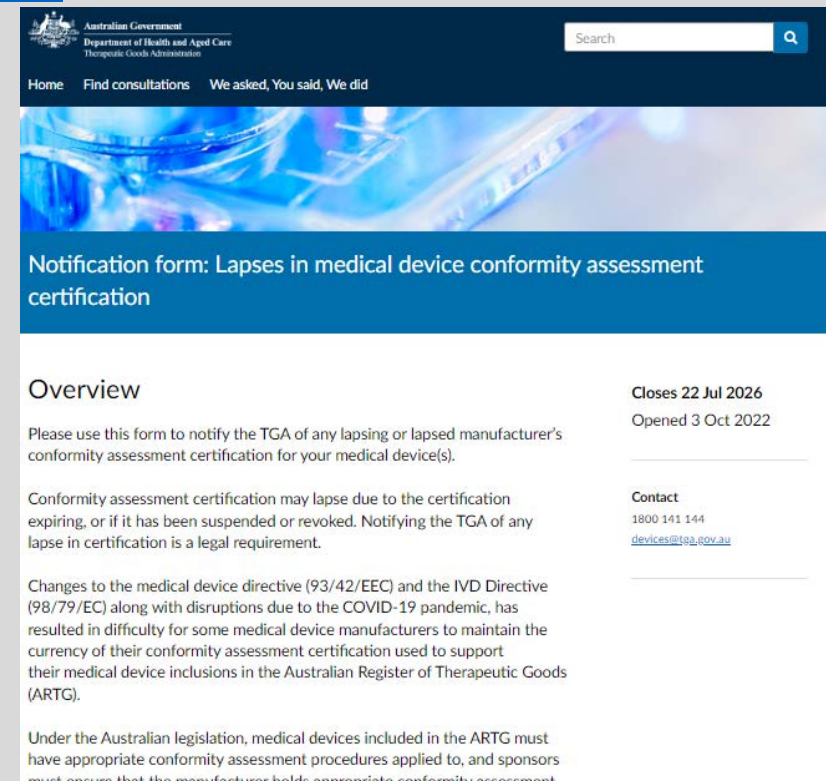
PMR Compliance Dashboard

Services

- Post Market Reviews
- Consent for Non-compliance Applications**
- Custom-made Medical Devices Notifications

Lapse in conformity assessment notification

[Lapses in Conformity Assessment Notification Form](#)



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Home Find consultations We asked, You said, We did

Notification form: Lapses in medical device conformity assessment certification

Overview

Please use this form to notify the TGA of any lapsing or lapsed manufacturer's conformity assessment certification for your medical device(s).

Conformity assessment certification may lapse due to the certification expiring, or if it has been suspended or revoked. Notifying the TGA of any lapse in certification is a legal requirement.

Changes to the medical device directive (93/42/EEC) and the IVD Directive (98/79/EC) along with disruptions due to the COVID-19 pandemic, has resulted in difficulty for some medical device manufacturers to maintain the currency of their conformity assessment certification used to support their medical device inclusions in the Australian Register of Therapeutic Goods (ARTG).

Under the Australian legislation, medical devices included in the ARTG must have appropriate conformity assessment procedures applied to, and sponsors must ensure that the manufacturer holds appropriate conformity assessment

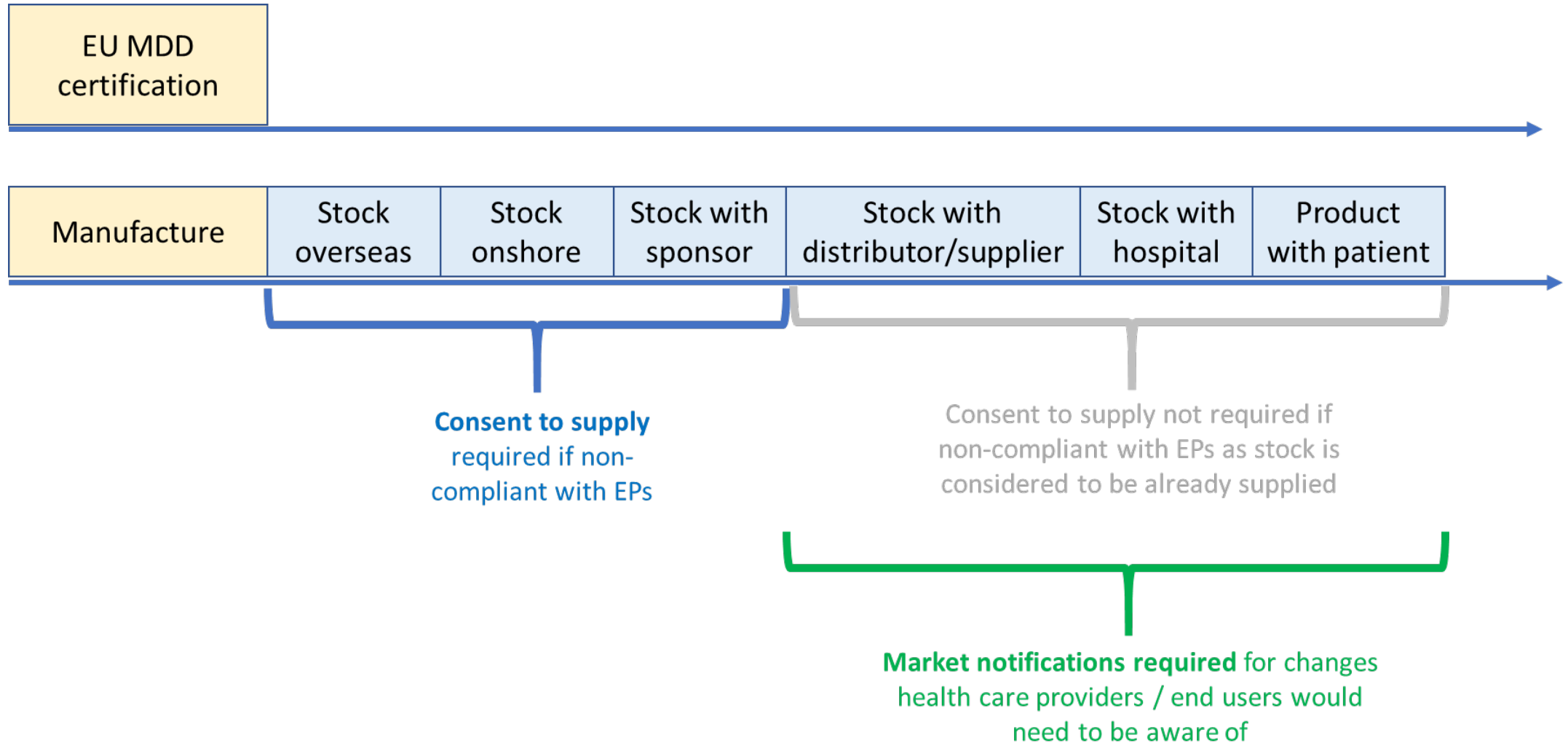
Closes 22 Jul 2026
Opened 3 Oct 2022

Contact
1800 141 144
devices@tga.gov.au

Examples of non-compliance with Essential Principles

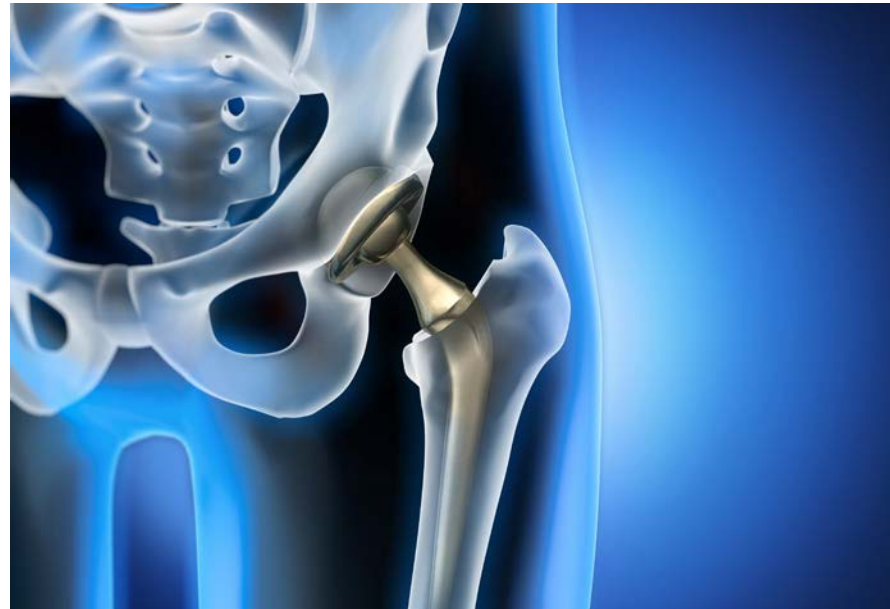
- The intended purpose of the medical device is no longer reflected accurately in the instructions for use, labelling, or patient information leaflets (if applicable).
- The manufacturer identifies that clinical evidence to support the intended purpose is not held for all patient cohorts.
- The manufacturer 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



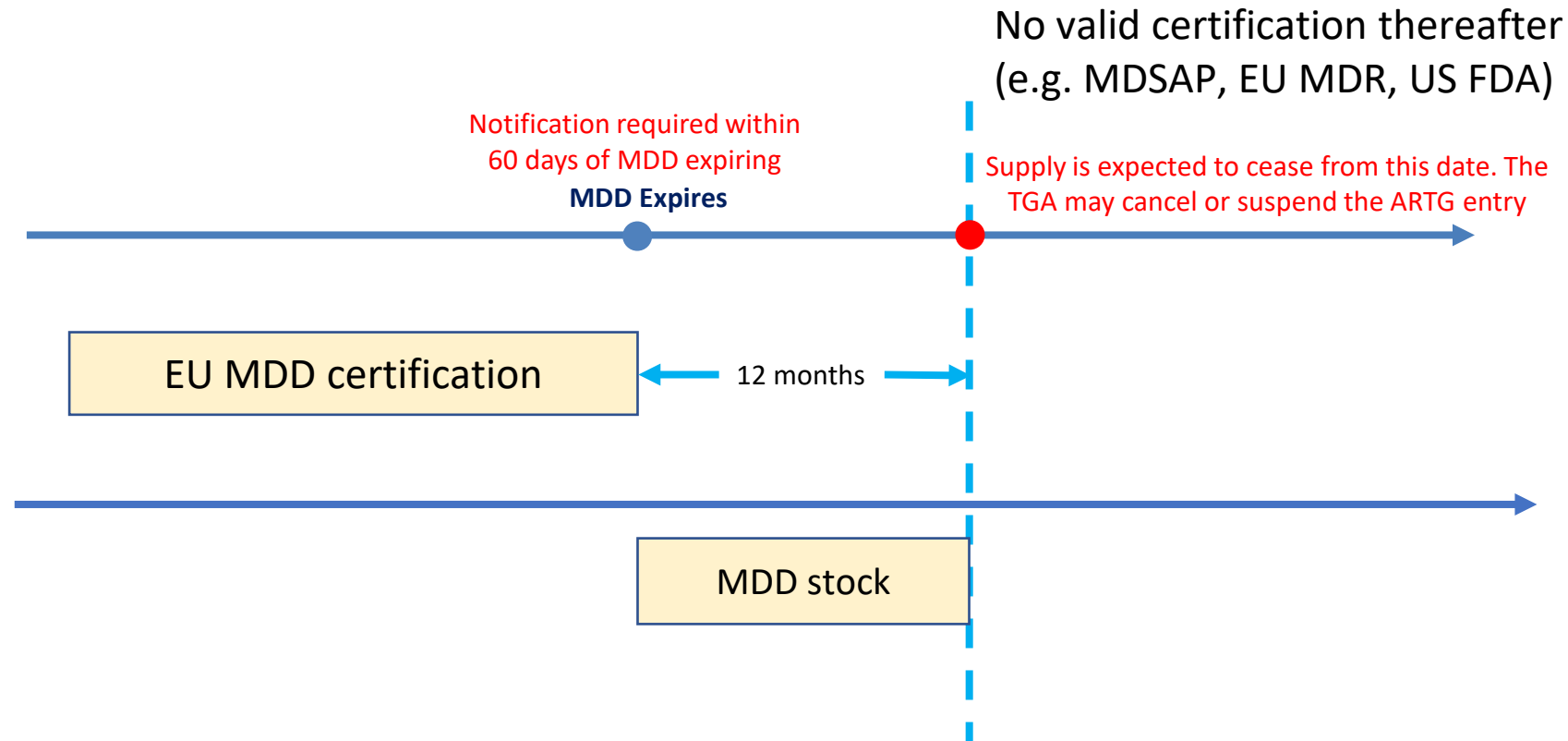
Context for example scenarios in the following slides

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



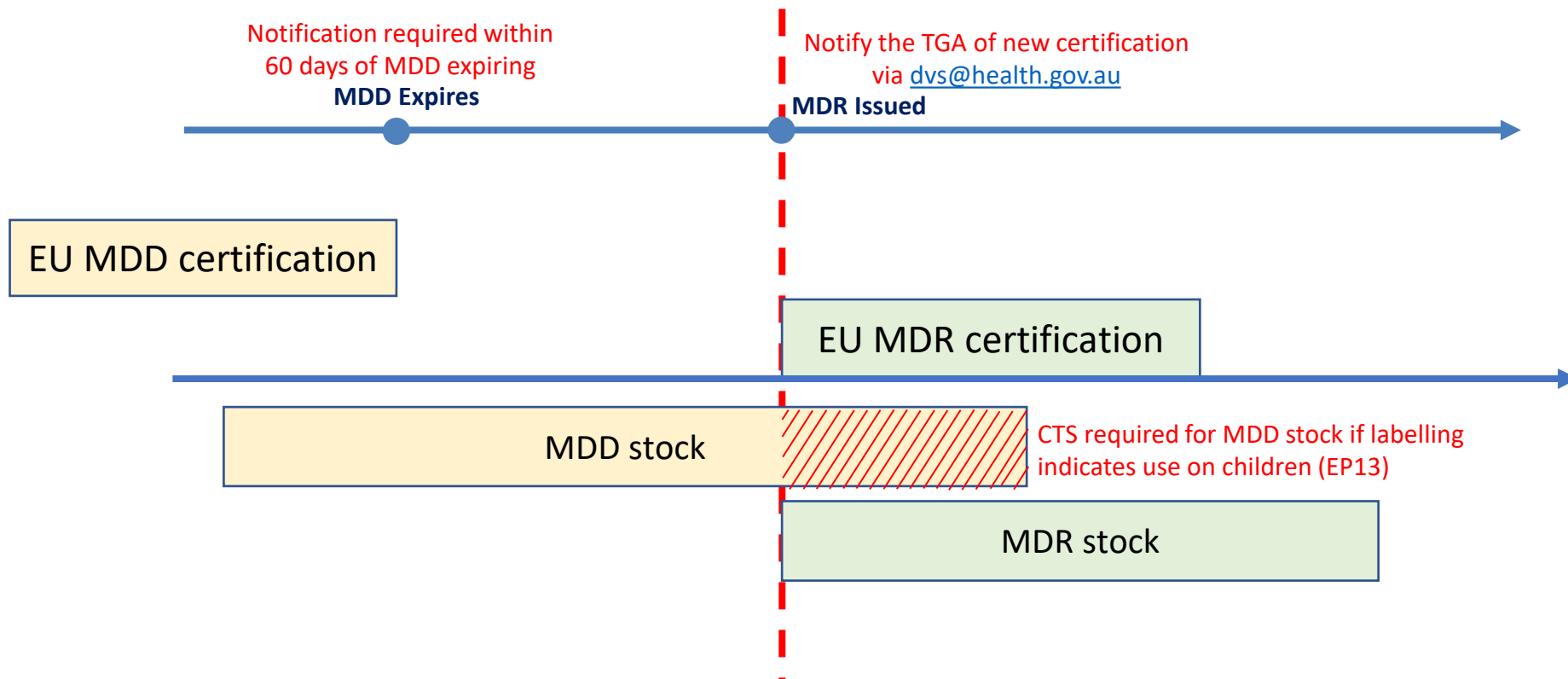
EU MDR “sell-off” provision

Art. 120 par. 4 MDR

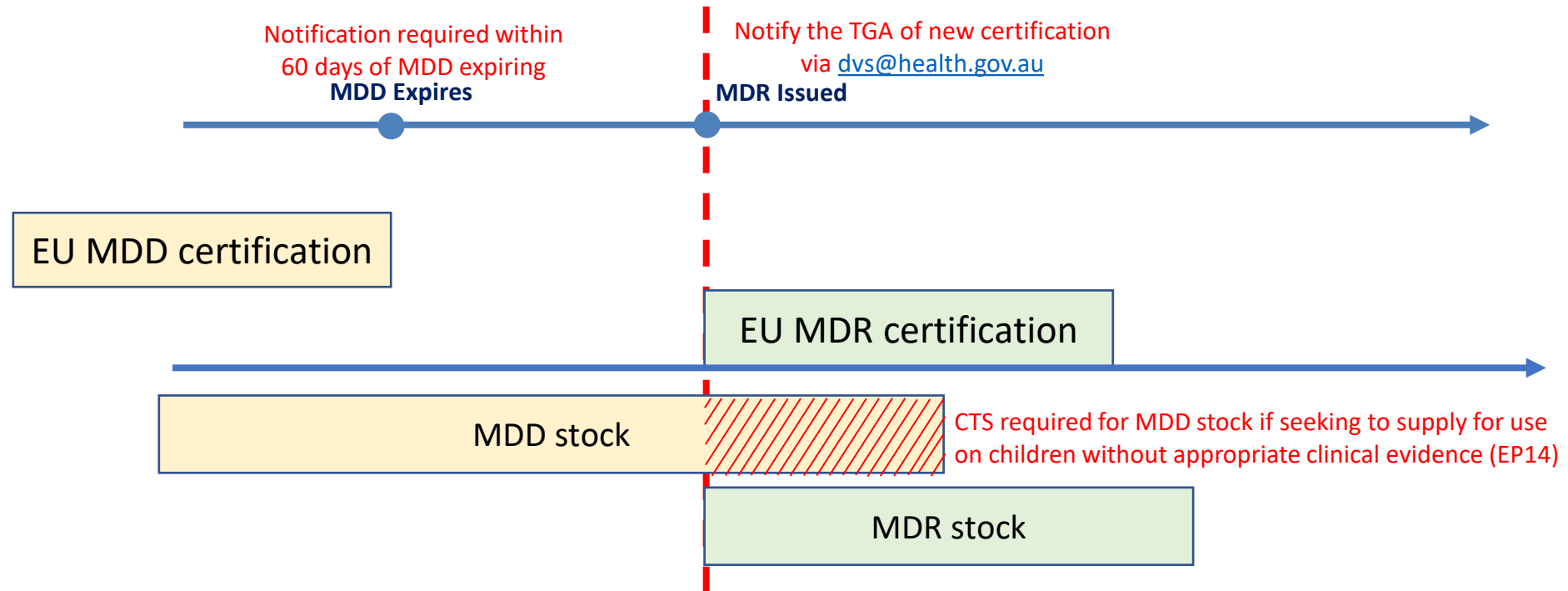
AIMDD/MDD compliant devices **placed on the market before 26 May 2021** or devices with certificates issued in accordance with AIMDD/MDD **placed on the market after the Date of Application** [of the MDR] with no significant change in design and intended purpose can be **made available until 27 May 2025**. 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:

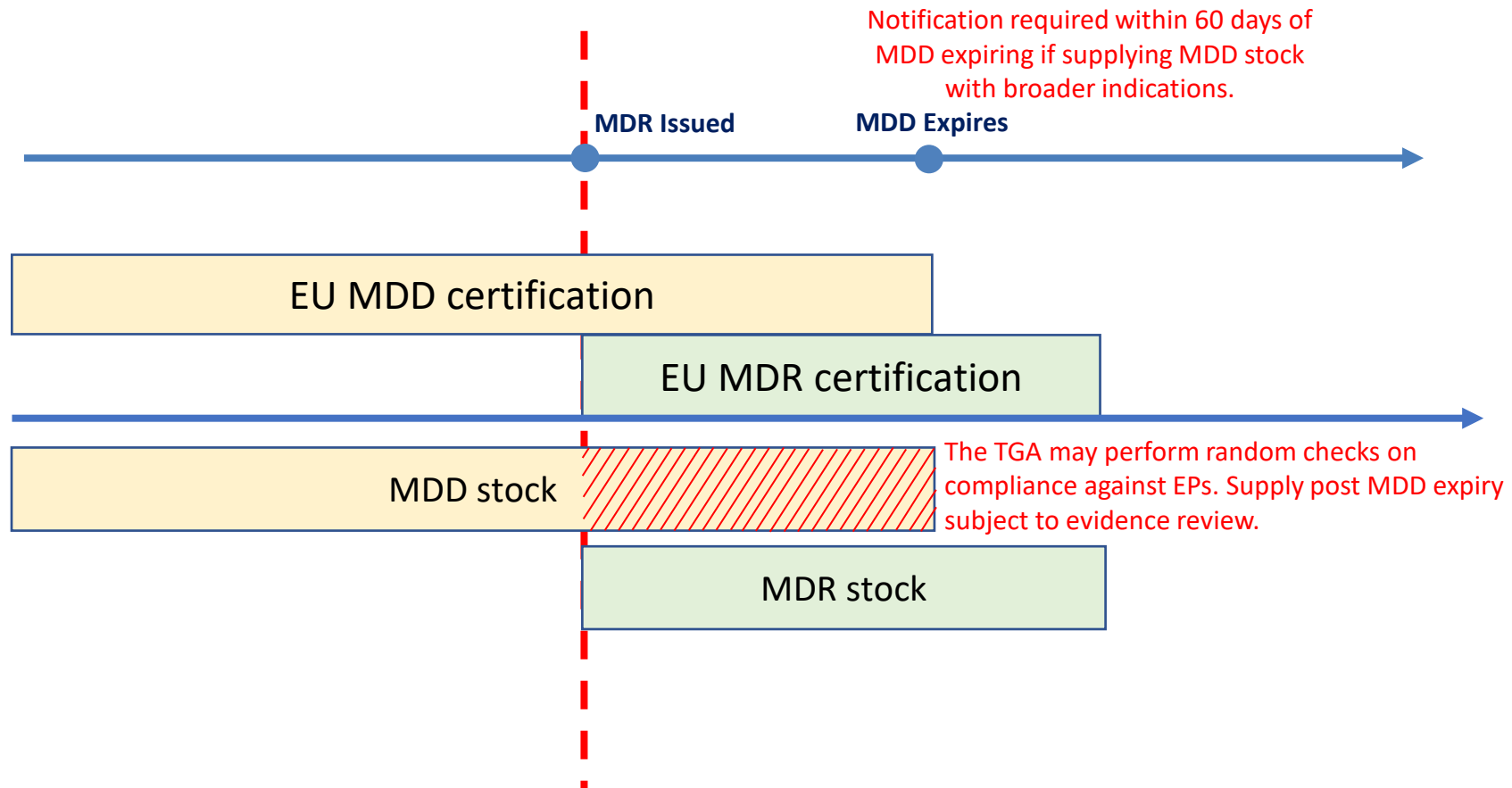
Gap in certification - Supply MDD stock with MDR indications



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



Example 3: Overlapping certifications



EU MDR Transition – Webinar 3

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.

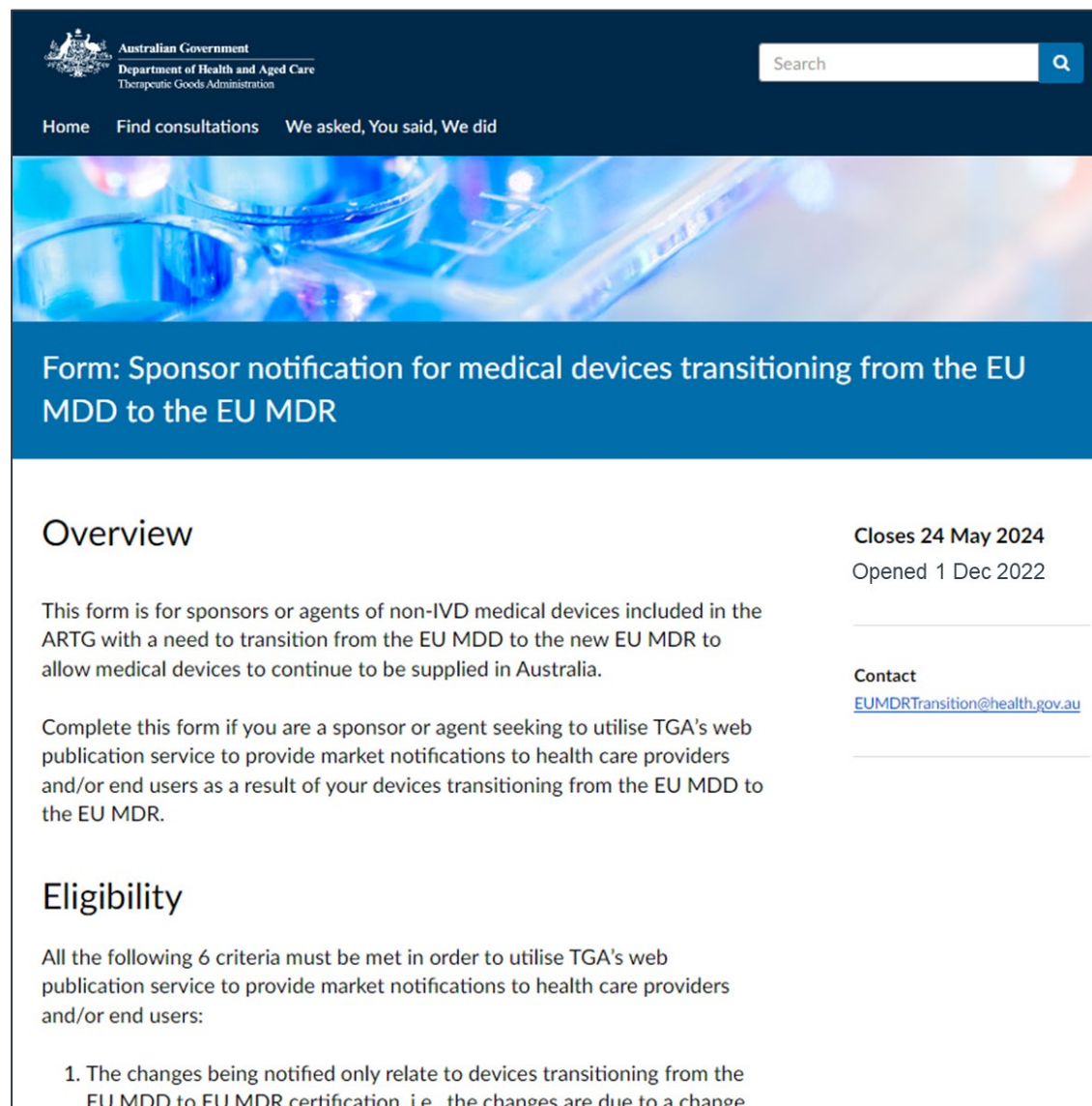
<https://consultations.tga.gov.au/tga/form-sponsor-notification-for-medical-devices-tra/>

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



The screenshot shows the top of the TGA website with the Australian Government logo, Department of Health and Aged Care, and Therapeutic Goods Administration. A search bar is visible in the top right. Below the header is a navigation menu with 'Home', 'Find consultations', and 'We asked, You said, We did'. A large blue banner features a laboratory image and the text 'Form: Sponsor notification for medical devices transitioning from the EU MDD to the EU MDR'. The main content area is divided into two columns. The left column has an 'Overview' section with a paragraph about the form's purpose and a 'Complete this form' section. The right column has a 'Closes 24 May 2024' and 'Opened 1 Dec 2022' section, and a 'Contact' section with the email EUMDRTransition@health.gov.au. Below the overview is an 'Eligibility' section with a list of criteria, starting with '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'.

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.

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

Closes 24 May 2024
Opened 1 Dec 2022

Contact
EUMDRTransition@health.gov.au

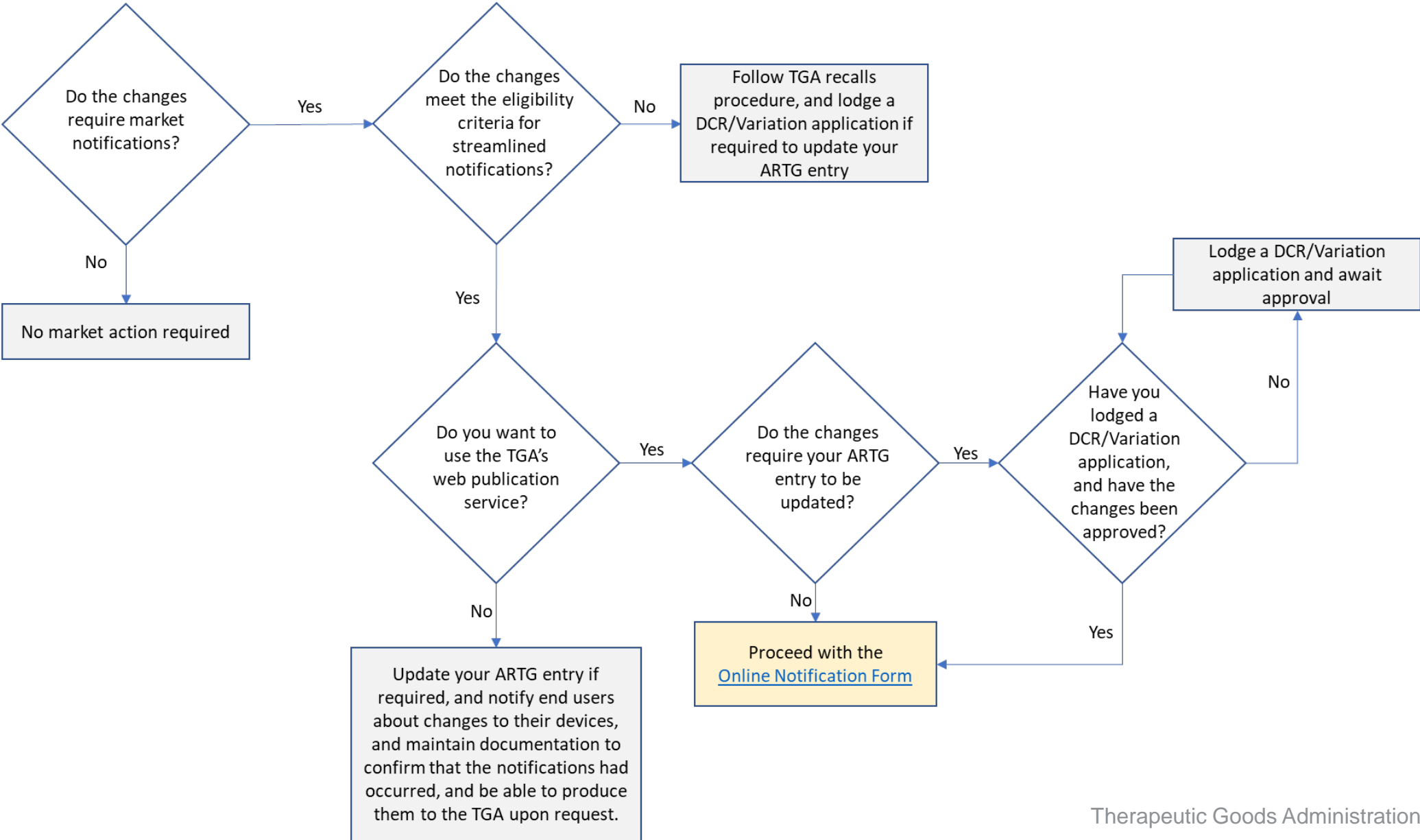
Web Publication Service

- 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
	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.

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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