Impact of the EU MDD to EU MDR transition on the Australian regulatory landscape

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Outline

- EU MDR transition and extension
- Impacts of EU MDR transition in Australia
  - Observations
  - Manufacturers and Supply chains
  - Challenges
- Australia’s implementation strategy
  - Guidance
  - Market notifications
  - Managing supply disruptions
- Impacts of EU MDR on device reforms in Australia
- Support and further resources

EU Medical Devices Regulation (EU MDR) Transition

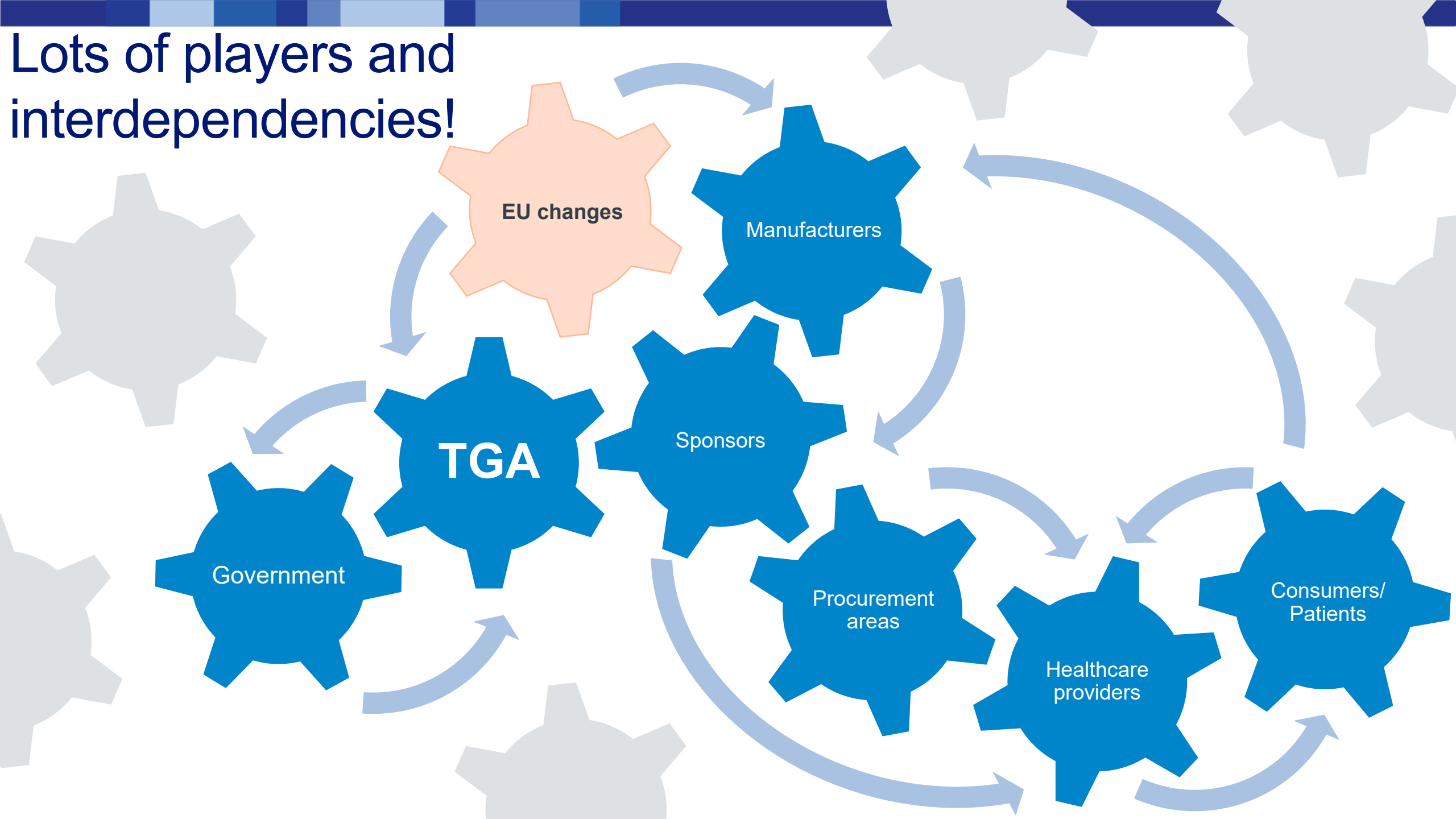
- Medical device regulation in Europe is undergoing transition to replace the previous Medical Devices Directive (MDD) (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC) (AIMDD) with the Medical Devices Regulation (MDR) (2017/745/ EU).
- The transition from EU MDD to EU MDR 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 some medical devices.

The EU MDR transition specifically affects medium to high-risk devices

EU MDR transition extension

- On 15 March 2023, the European Union **extended** the EU MDR transition for devices transitioning to the EU MDR from 26 May 2024 to:
  - 26 May 2026 for class III implantable custom-made devices
  - 31 December 2027 for class III and implantable class IIb devices
  - 31 December 2028 for non-implantable class IIb and lower risk devices
  - 31 December 2028, for class I devices that are a higher class under the MDR.

Lots of players and interdependencies!



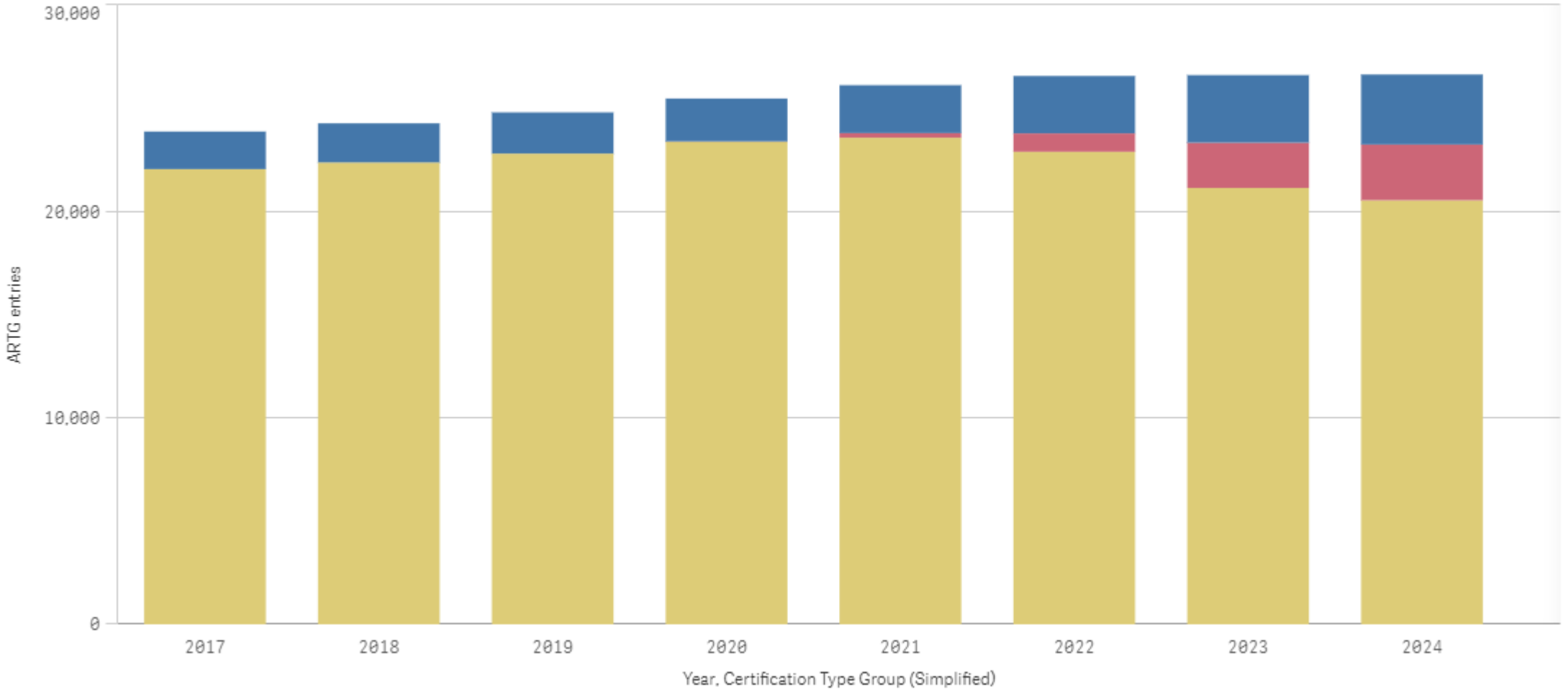
Impacts of EU MDR Transition in Australia

Significant flow on impacts as more than 85% of marketing approvals in Australia are based on EU certification

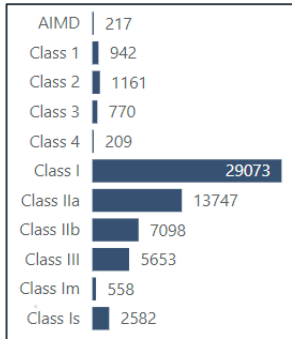
- Reclassifications
- Definitions and scope
- Recertifications
- Conformity assessment and essential principles
- Transition extension
- Unique Device Identifier (UDI)
- In Vitro Diagnostic Regulations (IVDR)

Some observations…

Breakdown of conformity assessment certification types
on an annual basis for all active ARTG entries
(excluding IVDs and class I non-sterile non-measuring devices)

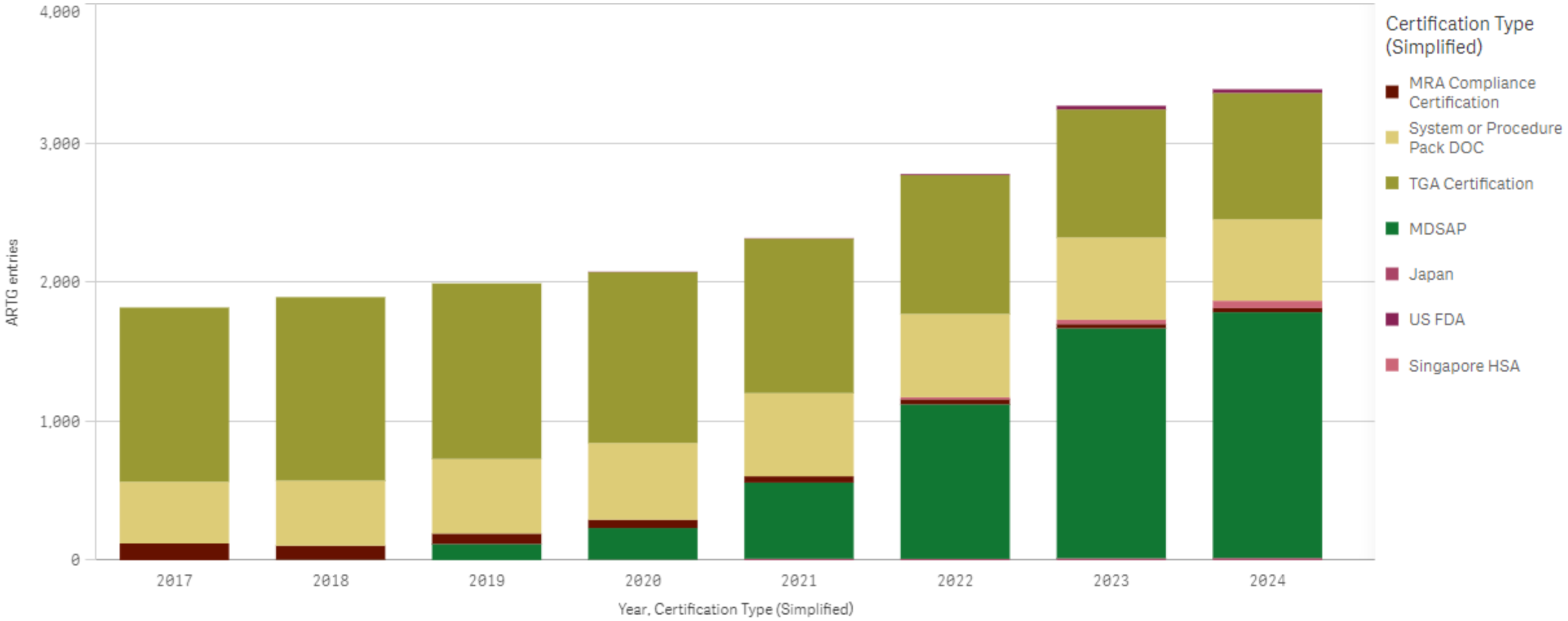


ARTG entries
(30 May 2024)



Some observations…

Breakdown of ‘Other’ conformity assessment certification types on an annual basis for all active ARTG entries (excluding IVDs and class I non-sterile non-measuring devices)



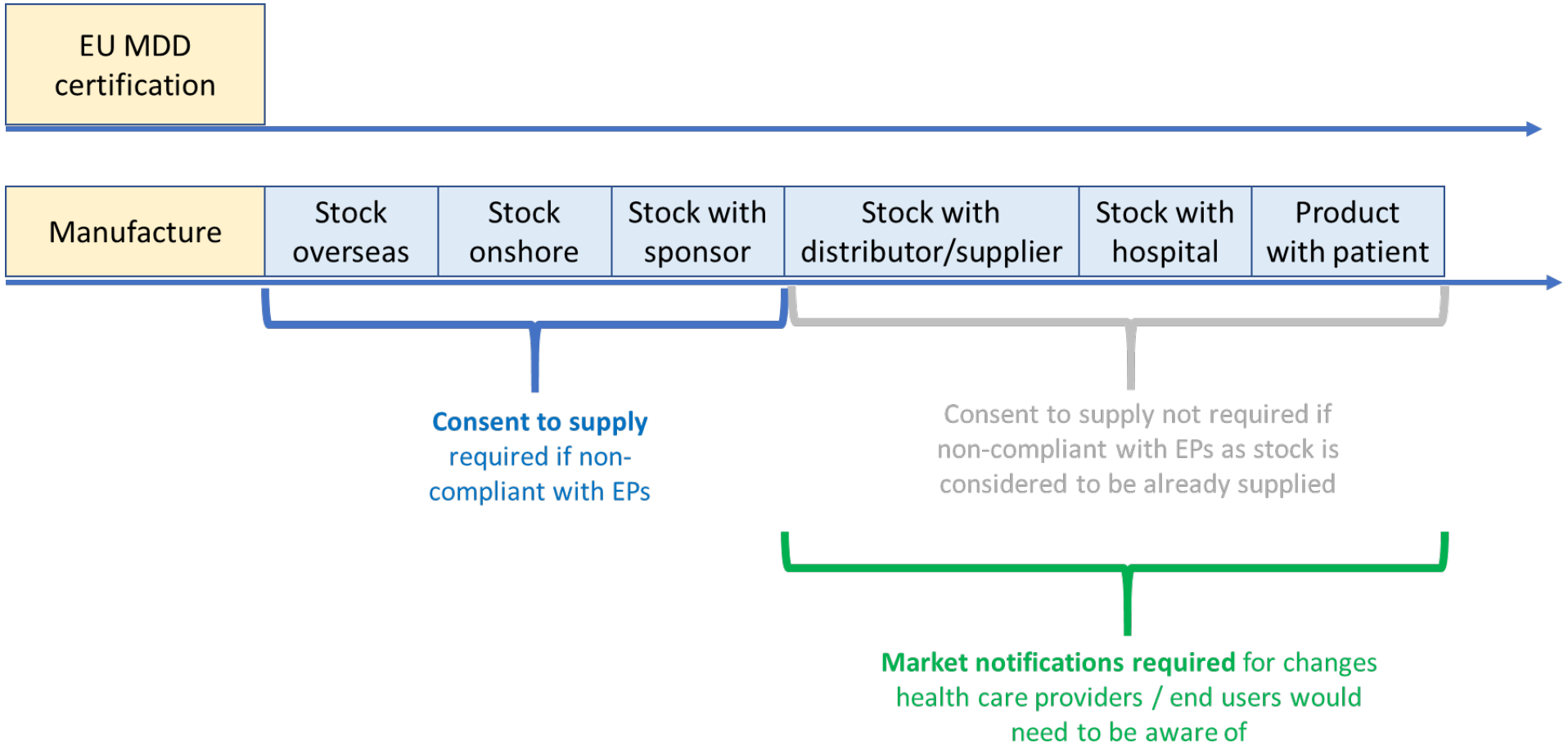
Impacts for manufacturers and sponsors

- Manufacturers that have transitioned to the EU MDR will have new conformity assessment certification.

- However, there may be changes to their devices and associated documentation, such as:
  - device classification
  - scope of indications or intended purpose
  - functional description
  - labelling and instructions for use.

- Depending on the type of change, sponsors may need to act to ensure the devices they already supply in Australia continue to comply with the Australian regulatory framework.

Example – supply chain considerations



Impacts on supply chains

- Potential supply disruptions due to
  - shortage of a raw material, or a component needed to manufacture the device
  - surges in demand of a particular material or product
  - manufacturers or sponsors discontinuing a device
  - delays in certification

- Serious supply disruptions may affect hospitals' ability to provide treatment or surgery to patients.

What we are hearing…

We are seeing roughly 15% discontinuation rate across all our legal manufacturers. In general, it is because the ***expense to recertify the devices under MDR cannot be justified in light of the sales volumes****. It does mean some unique devices are to be removed from the market because they won't be moved to MDR. The MDR transition is also being used as an opportunity by some manufacturers to* ***discontinue older product lines*** *to redeploy resources into new product development.*

From an Australian supply perspective, where there is an opportunity to ***move to an alternative conformity assessment to retain devices****, we are doing but are also considering sales volumes and costs. Overall, I am estimating we will have a* ***discontinuation rate of 8-10% locally.***

7 products have been impacted so far (and more are coming)—our global partners ***decided not to seek recertification under MDR****. We'll be ceasing supply in Australia after we finish supplying products made under valid MDD certificates*

Original EU MDR application submitted in 2022 with expected Q2 2024 approval - this is now ***delayed to Q1 2025 due to NB review time period*** *- gap in supply in stock due to closure of manufacturing plant and transfer to new manufacturing plant in preparation for EUMDR approval.* ***Predict 9-month gap in supply*** *for EU.*

EU MDR – Challenges

- Differing interpretation of classification rules by Notified Bodies

- Regulatory frameworks are not completely aligned. Examples include:
  - Boundary products which may be regulated as a medical device in the EU but as a medicine in Australia (and vice versa)
  - Differing definitions and scope of custom-made medical devices, which are not eligible for CE marking, but some are regulated as personalised medical devices in Australia and require conformity assessment

- Timing of regulatory changes are not always aligned. E.g., PIC/PILs, up-classification of software medical devices.

EU MDR transition – Australia's implementation strategy

How

- Consulted with industry to co-design a risk-based and streamlined approach

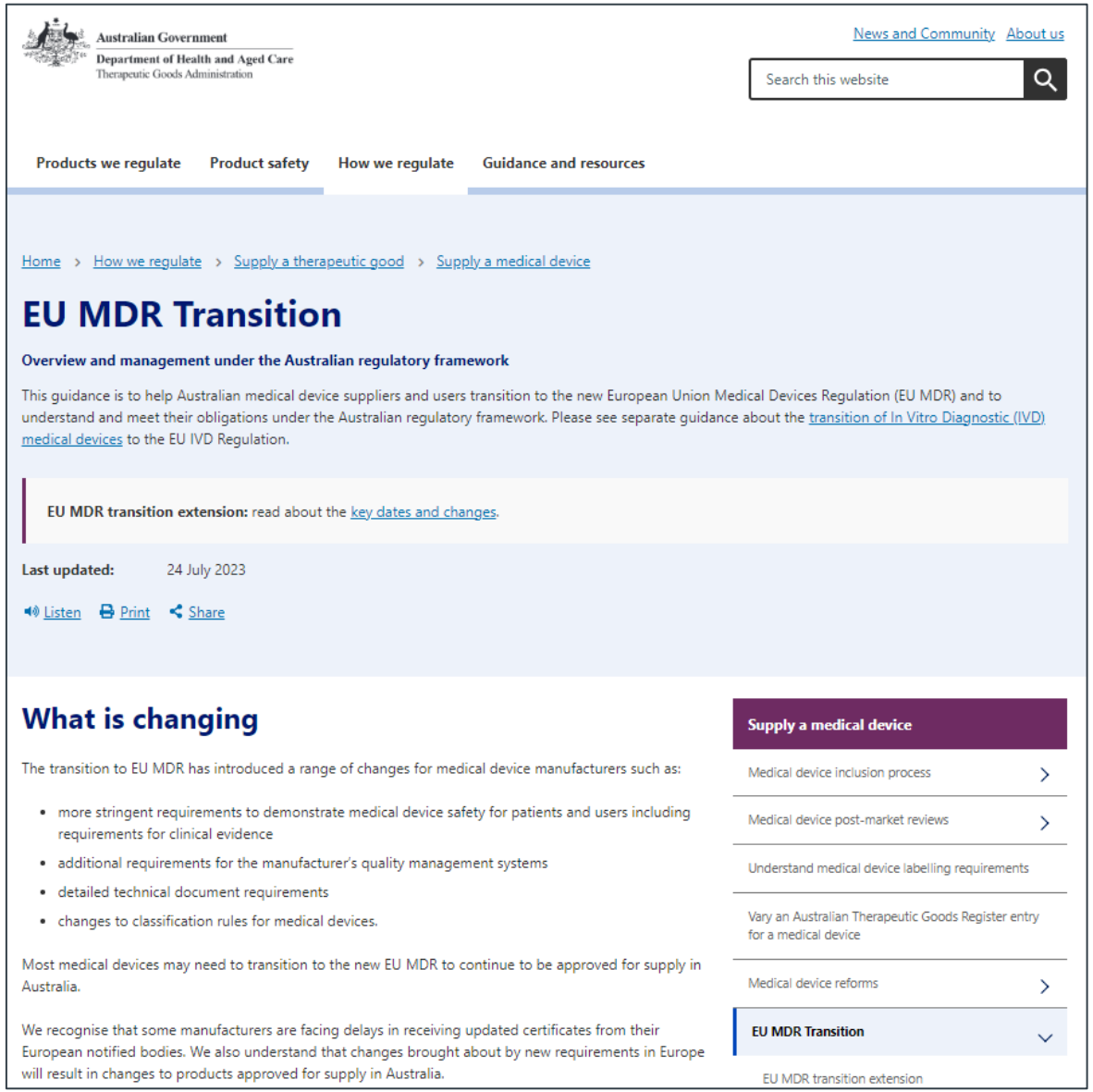
What

- The TGA will accept MDD certificates that have been extended in the EU
- Reduced certain application fees
- Streamlined market notifications process and web publication service
- Allowing "legacy devices" if the MDD certificate has been extended in the EU.
- Guidance outlining approach and sponsors obligations

Guidance Hub

We have published a suite of guidance, including topics such as:

- EU MDR transition extension
- How we are managing medical device supply disruptions resulting from changes in Europe
- Recalls and market notifications
- EU MDR Transition web publication service



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EU MDR Transition

Overview and management under the Australian regulatory framework

This guidance is to help Australian medical device suppliers and users transition to the new European Union Medical Devices Regulation (EU MDR) and to understand and meet their obligations under the Australian regulatory framework. Please see separate guidance about the transition of In Vitro Diagnostic (IVD) medical devices to the EU IVD Regulation.

EU MDR transition extension: read about the key dates and changes.

Last updated: 24 July 2023

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What is changing

The transition 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 may need to transition to the new EU MDR to continue to be approved for supply in Australia.

We recognise that some manufacturers are facing delays in receiving updated certificates from their European notified bodies. We also understand that changes brought about by new requirements in Europe will result in changes to products approved for supply in Australia.

Supply a medical device

- Medical device inclusion process
- Medical device post-market reviews
- Understand medical device labelling requirements
- Vary an Australian Therapeutic Goods Register entry for a medical device
- Medical device reforms
- **EU MDR Transition**
  - EU MDR transition extension

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

Market notifications

The TGA's **web publication service** is a platform for sponsors to provide market notifications to health care providers and consumers to advise of

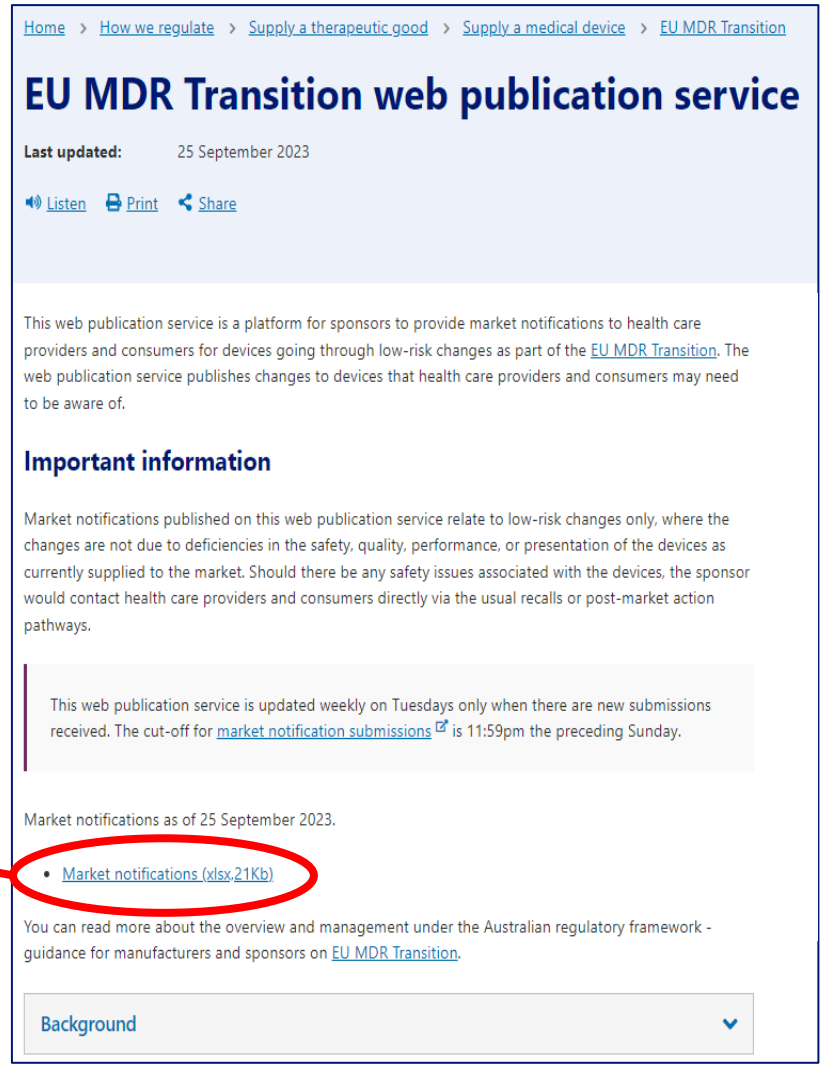
- devices going through low-risk changes as part of the EU MDR transition
- non-transitioning devices

Published information:

- Manufacturer and Sponsor name
- ARTG number, GMDN code
- GTIN code (if available)
- ARTG intended purpose
- Names of affected devices
- Date of effect of EU MDR
- Contact details for enquiries
- Information about the relevant changes

For non-transitioning devices:

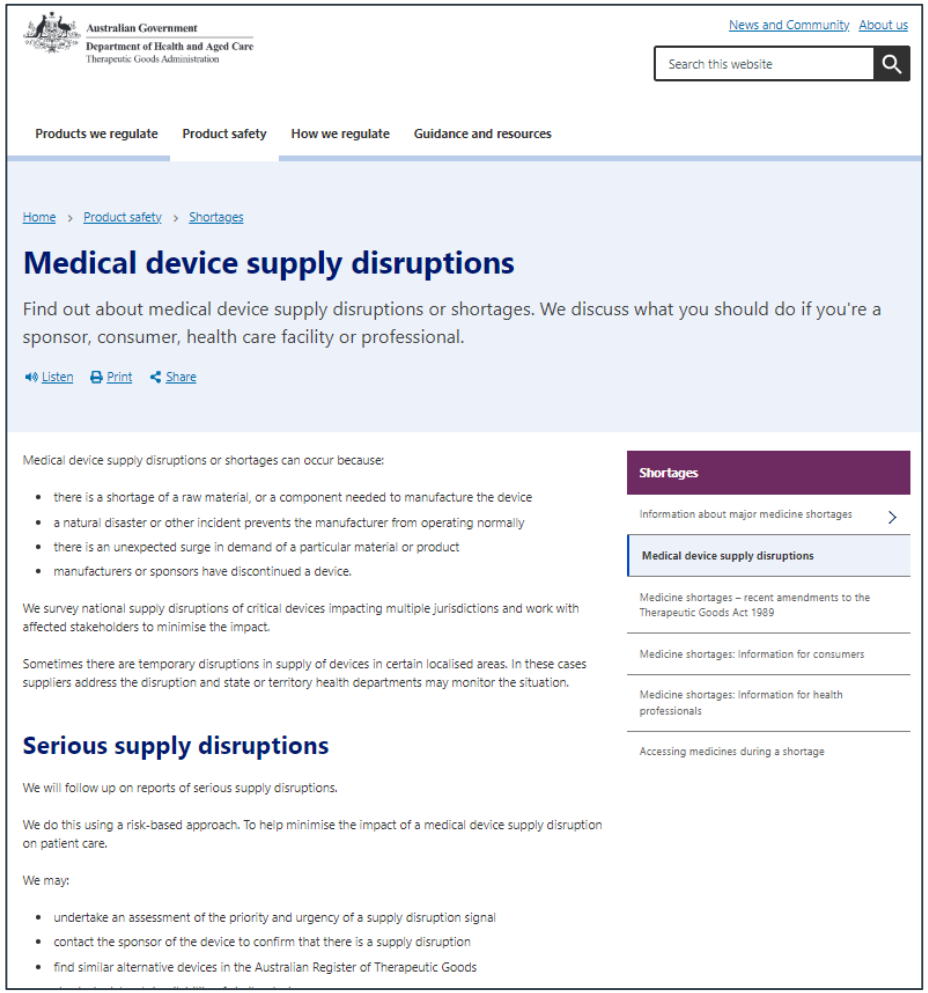
- ARTG and device details
- Date of supply cessation



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

TGA's approach to managing supply disruptions

- Web page to support sponsors, consumers and health facilities
- Fortnightly meetings with States and Territories health representatives to discuss emerging or ongoing signals
- Refining internal processes for signal and assessment
- Establishing channels for collaboration and communication with stakeholders
- For serious supply disruptions, we may
  - Investigate similar alternative devices in the ARTG
  - Seek alternate products for supply into Australia



https://www.tga.gov.au/safety/shortages/medical-device-supply-disruptions

Changes to the Australian regulatory framework

- **23 July 2021** - Medical devices that contain medicines or materials of animal, microbial, recombinant or human origin; and Class 4 in vitro diagnostic (IVD) medical devices no longer require mandatory TGA conformity assessment certification. **Reliance mechanisms through EU pathways**.
- **1 July 2024 (work in progress):**
  - **New reliance pathway for class III devices** – Amendments are underway to the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* to introduce a new **MDSAP + FDA 510k** reliance pathway for class III devices.
  - **Expand reliance pathways for devices containing medicines or substances of animal origin** – Amendments are underway to the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* to expand reliance mechanisms to non-EU pathways for these product categories (i.e., MDSAP, US FDA, Japan, Health Canada, HSA) .
  - **Remove mandatory audit requirements for certain class III devices -** The Government has approved amendments to be made to the *Therapeutic Goods (Medical Devices) Regulations 2002* to remove mandatory audit requirements for class III devices supported by evidence from certain relevant overseas regulators such as US FDA (PMA), Japan, Health Canada, HSA, or in accordance with established mutual recognition agreements.

Impacts on reform activities in AU

- **Devices subjected to reclassification** – transition deadline extended for some transitional devices from 1 November 2024 to 1 July 2029.
- **Patient matched medical devices** - transition arrangements extended to 1 July 2029, and notification period extended to 1 November 2024.
- **Software based medical devices** **-** transition ends on 1 November 2024. The Government has agreed to provide an alternate pathway for transitional arrangements.
- **IVD Classification and Definitions** **–** Policy work is underway to review and align with European requirements.

Summary of transitional deadlines for AU reclassification reforms

Reclassification Reform	Transition deadline for existing ARTG entries
Active medical devices for therapy with diagnostic function	1 July 2029
Spinal implantable medical devices (motion preserving)	1 July 2029
Devices used in direct contact with the heart, central circulatory system, or central nervous system	1 July 2029
Devices that administer medicines or biologicals by inhalation	1 July 2029
Devices that are substances introduced into the body via body orifice or applied to the skin	1 July 2029
Patient-matched medical devices	1 July 2029
Software based medical devices	1 November 2024

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