Impact of European IVD Regulations in Australia

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At all times, an IVD medical device sponsor must:

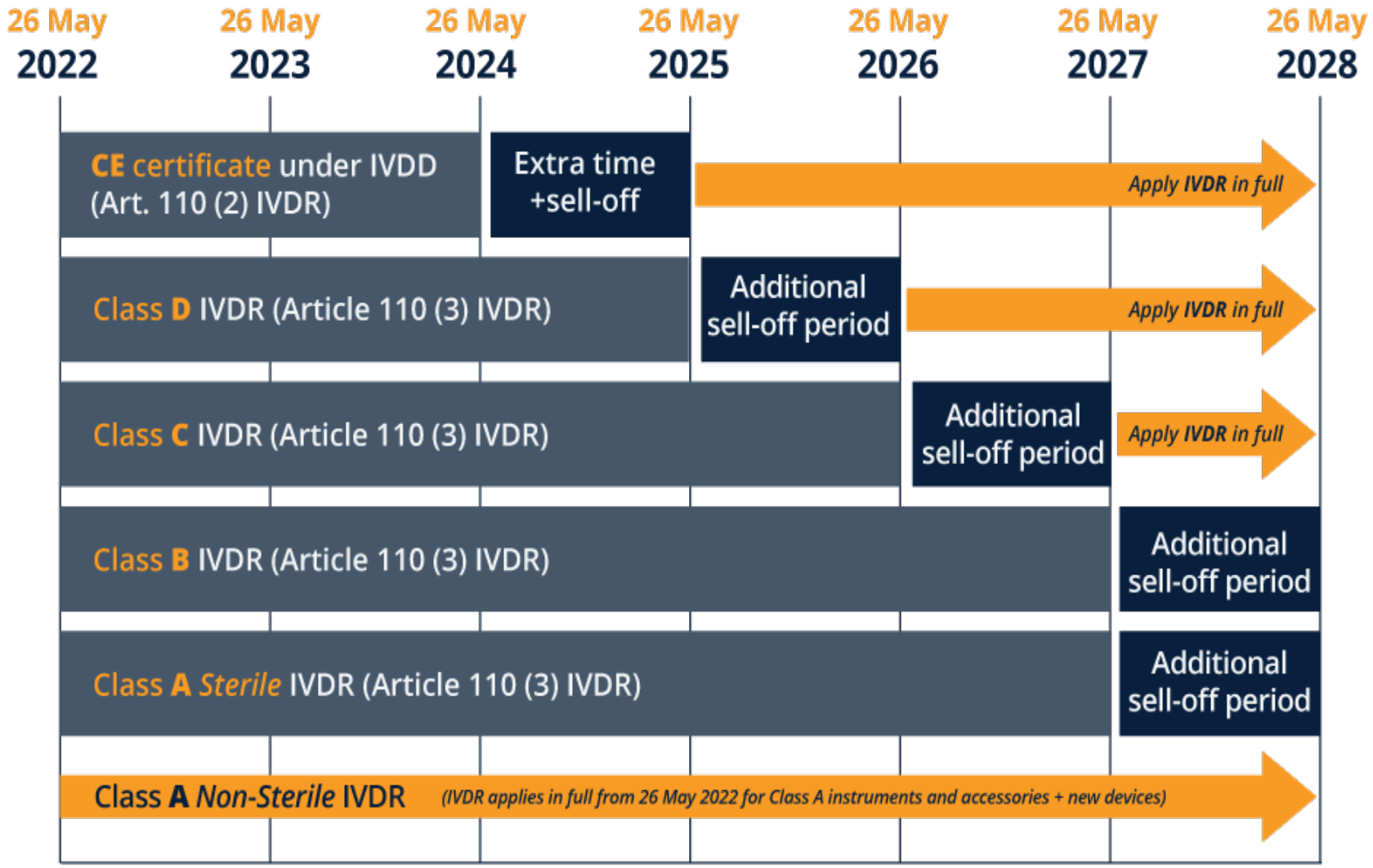
- maintain ARTG entries that cover the IVD medical devices they supply
- maintain conformity assessment evidence that supports their ARTG entries.
- Evidence must cover the IVD medical devices included under the relevant ARTG entry.

Background and Context

- More than 60% ARTG entries supported by ISO 13485 certification.
- ISO 13485 certificates are no longer accepted for new inclusion applications.
- Introduction of new IVDR Regulations that replaces EU IVDD.

IVD ARTG entries based on conformity assessment certification (Jan 2023)

IVDR Implementation timeframes



- IVDR applied from 26 May 2022 - Implementation with staggered transition period
- March 2023 amendments – Sell off period abolished

Diagram taken from [Understanding the IVDR Transition (qservegroup.com)]

Overview of TGA approach

- Transition to new conformity assessment required for continued supply in Australia, if IVD medical device ARTG entry:
  - Is supported by IVDD certification
  - Is supported by ISO 13485 certification, unless supported by EU Declaration of Conformity

You are **NOT** required to **transition to IVDR, if your ARTG entry is supported by valid acceptable conformity assessment evidence**

Acceptable Conformity assessment evidence

Manufacturer evidence **(QMS certification and evidence of product review)**	**TGA cut-off dates**
EU IVDR certificate	Ongoing acceptance
MDSAP certificate	Ongoing acceptance
ISO 13485 certificate with EU Declaration of Conformity (issued before 26 May 2022)	Class 2 IVD until 26 May 2027 Class 3 IVD until 26 May 2026
EU IVDD certificate	Class 2 IVD until 26 May 2027 Class 3 IVD until 26 May 2026 Class 4 IVD until 26 May 2025
US FDA PMA (class II and III IVD) or Singapore HSA approval (class B and C IVD)	Ongoing acceptance
TGA conformity assessment certificate	Ongoing acceptance
MDSAP certificate with product review evidence, such as: • Health Canada medical device licence (class II and III IVD) • US FDA PMA or 510(k) (class II or III IVD) • Singapore HSA-approval (class B and C IVD)	Ongoing acceptance

Impact of IVDR

A medical device manufacturer that has transitioned to the EU IVDR will have new conformity assessment evidence.

This may be associated with changes to their devices and documentation, such as:

- Changes to the scope of indications or intended purpose
- Changes to labelling and instructions for use

Depending on the type of change, actions may be required from sponsors to ensure continued compliance.

Summary of Regulatory actions in Australia

Change	Sponsor action
Updating manufacturer evidence(ME)	Variation to Manufacturer Evidence (ME) New ME application followed by Device Change Request
Changes to ARTG entry information	Device Change Request
Adding a new device of the same kind	Variation
Non-compliance with Essential Principles	Consent to Supply
Lapsing or expiring of manufacturer evidence	TGA Notification

Updating Manufacturer evidence

Change	Sponsor Action
Update the **manufacturer evidence associated with your ARTG entries** to your new certification.	**A variation to manufacturer evidence to link a**ll ARTG entries to a particular conformity assessment certificate. **A new manufacturer evidence application,** followed by a **Device Change Request (DCR)** to link some relevant ARTG entries to the new certification. Use this pathway if you only wish to update some, and not all ARTG entries linked to a manufacturer evidence identifier. Fee reduction applies*

Change to ARTG information

Change – ARTG related changes	Sponsor Action
• Information on ARTG is incomplete/incorrect. • ARTG intended purpose needs changing to reflect the devices under the entry. • Change to GMDN code by the manufacturer to a more relevant, active, or preferred code. • Linking an ARTG entry to a new a ME identifier (e.g. if EU IVDR certification was submitted as new ME and given a new identifier). • Manufacturer details (name or address).	You can update your ARTG entries by submitting a **Device Change Request** (**DCR) application** for your affected ARTG entries.

Adding a new device – IVD Variation

Change	Sponsor Action
Adding a new device of the same kind under a current ARTG entry. This requires notification in limited cases.	For certain devices with non-TGA and non-IVDR certification, automatic conditions of inclusion require new devices of the same kind to be notified to the TGA via an IVD variation application.

Consent to Supply

Change	Sponsor Action
Non-compliance with the Essential Principles (EPs) It is acknowledged that the transition to EU IVDR or other manufacturing certification may require sponsors to request consent to import, supply or export IVD medical devices which do not meet an EP for a limited period (e.g. labelling). *Note: Consent to supply does not apply for stock that has already been supplied to market (i.e. with the distributor or end user).*	If you determine that your IVD medical devices, which are manufactured under a valid ME certificate, no longer comply with the EPs for safety and performance, an application for consent must be submitted before importing, exporting, or supplying the devices. If in doubt, contact mdconsent@health.gov.au

Lapsing or expiring of manufacturer's evidence

Change	Regulatory Action
Lapsing or expiring manufacturer evidence IVD medical devices that are included in the ARTG and were manufactured under valid QMS certification (manufacturer's evidence) can be supplied after the certificate has expired or lapsed.	Sponsors should **notify the TGA within 60 days** of becoming aware of the lapsing, revocation, suspension or cancellation of conformity assessment certification using the Lapses in Conformity Assessment Notification Form or by emailing dvs@health.gov.au. Criminal and civil penalty could apply, if a sponsor fails to notify the TGA within the timelines

Guidance and Resources (in progress)

- Overview of managing transition to new manufacturer evidence
- Changes to acceptance of manufacturer evidence and relevant cut-off dates
- Sponsor actions when transitioning the evidence – examples and scenarios

Moving forward

Experience with IVDR

- TGA continues to build its experience with applications supported by IVDR certification

Application Audit framework

- Increased predictability and transparency on the criteria, the risk factors and the documentation required to inform application audits.
- Applicable for all medical devices including IVDs

Website references

TGA website	www.tga.gov.au
Understanding the IVDR Transition	https://www.qservegroup.com/eu/en/b1127/understanding-the-ivdr-transition---theres-still-a-lot-of-work-to-do
Guidance for completing an application for consent to import, supply, or export a medical device that does not comply with the Essential Principles	https://www.tga.gov.au/resources/resource/guidance/guidance-completing-application-consent-import-supply-or-export-medical-device-does-not-comply-essential-principles#:~:text=This%20document%20provides%20guidance%20on%20how%20to%20successfully,from%20a%20paper%20form%20to%20an%20online%20form
Enquiries	mdconsent@health.gov.au
Lapses in Conformity Assessment Notification Form	https://consultations.tga.gov.au/tga/notification-form-lapses-in-conformity-assessment/

Therapeutic Goods Administration (TGA)

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