

# In vitro diagnostic (IVD) medical device - reforms and processes

**Shraddha Swami**

Director, Devices In Vitro Diagnostics Section  
Department of Health, Disability and Ageing, TGA



Australian Government

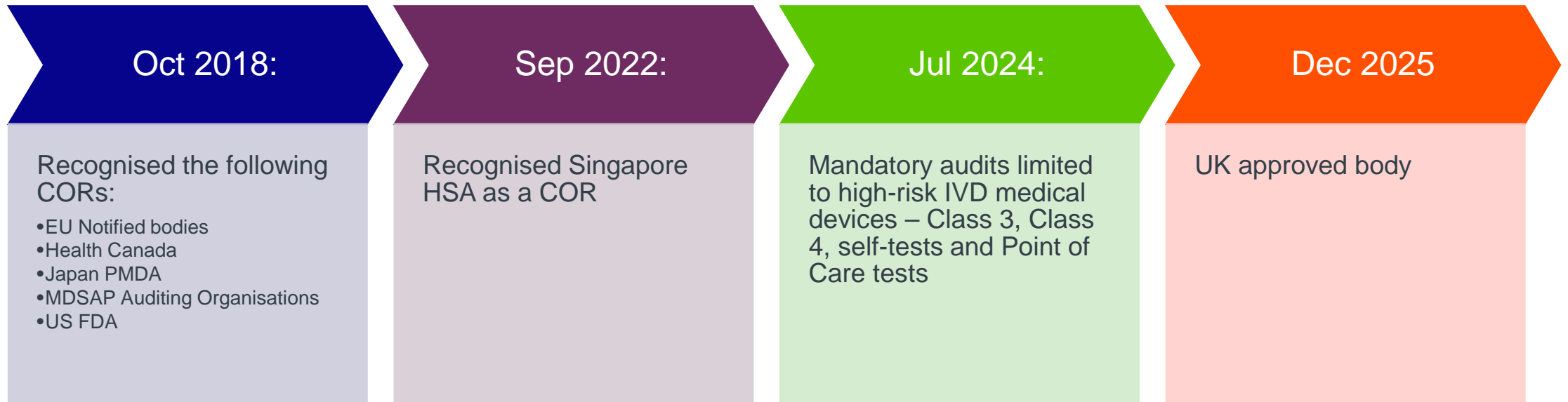
Department of Health, Disability and Ageing  
Therapeutic Goods Administration

## Session overview

- Overview of IVD medical device reliance framework
- Roadmap for IVD inclusion – the process improvements and challenges
- Progress update: IVD medical device reforms



# Comparable Overseas Regulator Framework – Reliance pathways



# Australian manufacturers

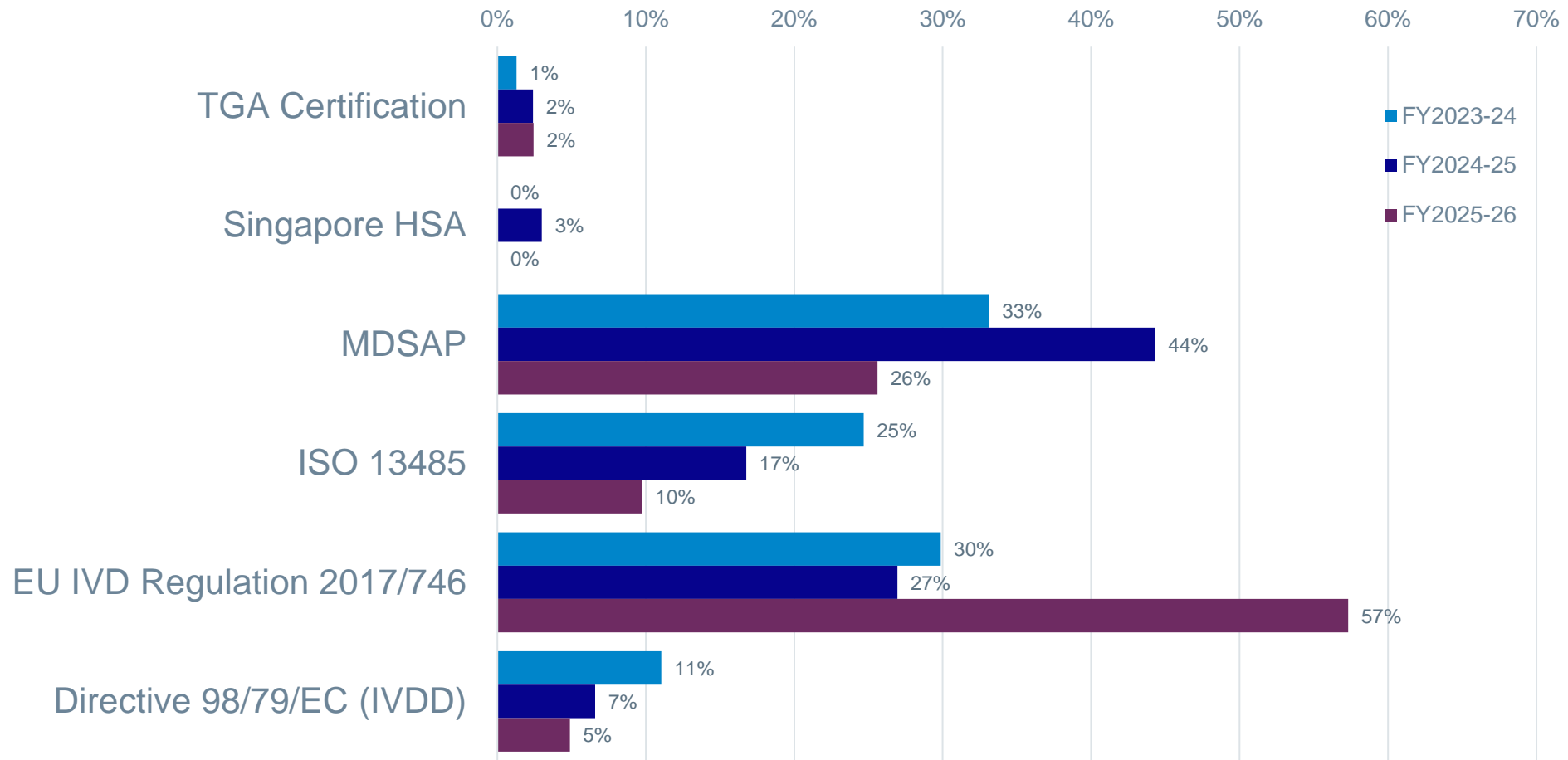
## We still need the TGA conformity assessment pathway

- TGA conformity assessment certification
- Based on quality management system audit and product technical file review
- This is less used than the reliance pathways but important for some manufacturers
- We can abridge assessment based on MDSAP audits



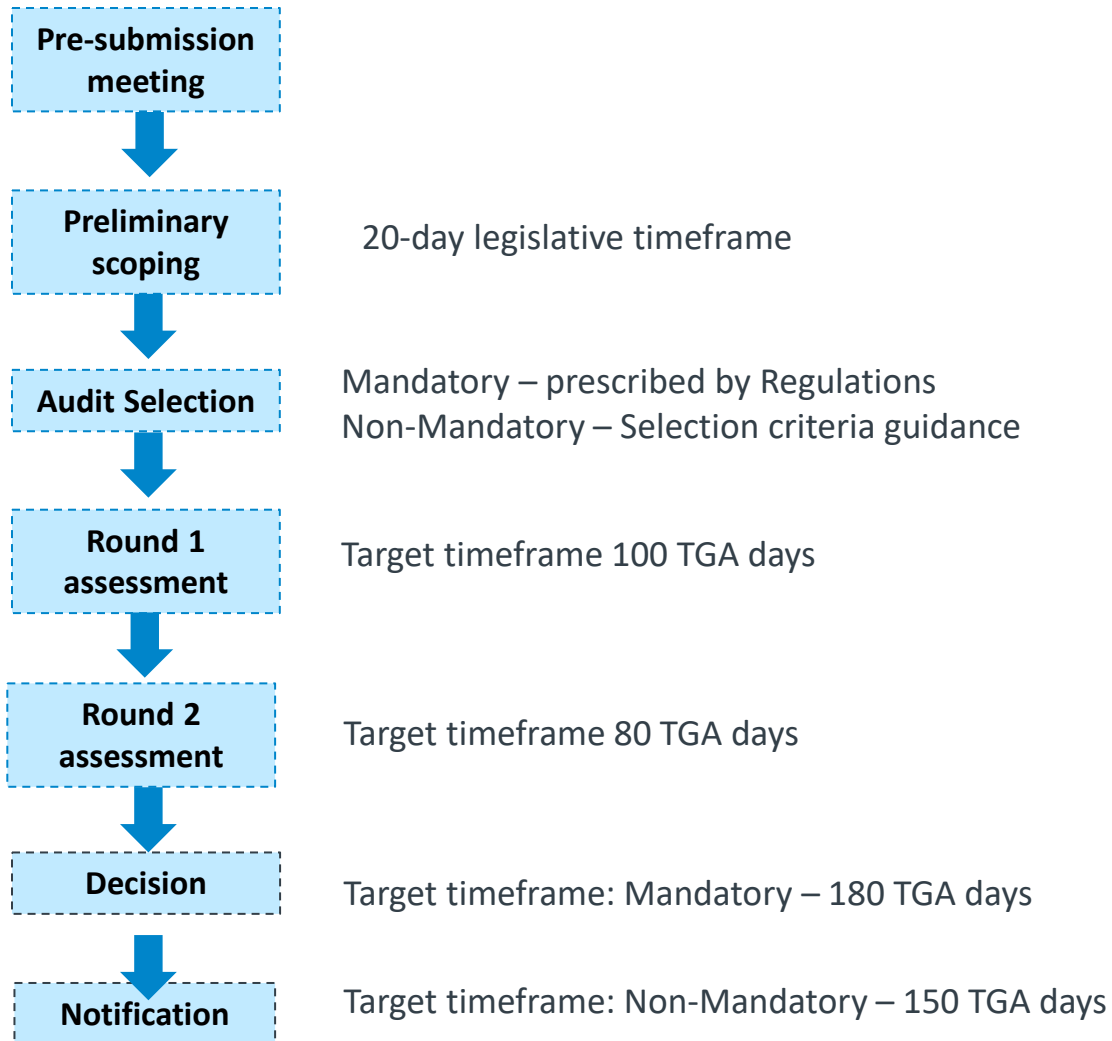
# Applications for inclusion – IVD landscape (slightly different)

## Application pathways



\*July 2025 – Jan 2026

# ARTG Inclusion application audit flow



## New Process Improvements



Provide early feedback to applicants.



Increased pre-submission engagement and education.



Improved and more transparent timeframes to provide better predictability.



Improved transparency regarding applications selected for audit.



The TGA will discuss major concerns about your application with you via phone or video conference (not just via email).



The TGA will limit to two rounds of assessment before deciding on the application.



You will have a dedicated case manager for your application.

# Regulatory Engagement meetings

Come and talk to us:

- Common understanding of the IVD
- Understand what is needed to achieve the outcome you are after
- Plan for submission and application.

Please note:

- We discuss regulatory requirements and processes;
- We provide advice to prepare a submission
- We **do not co-design** applications for inclusion or clinical trials

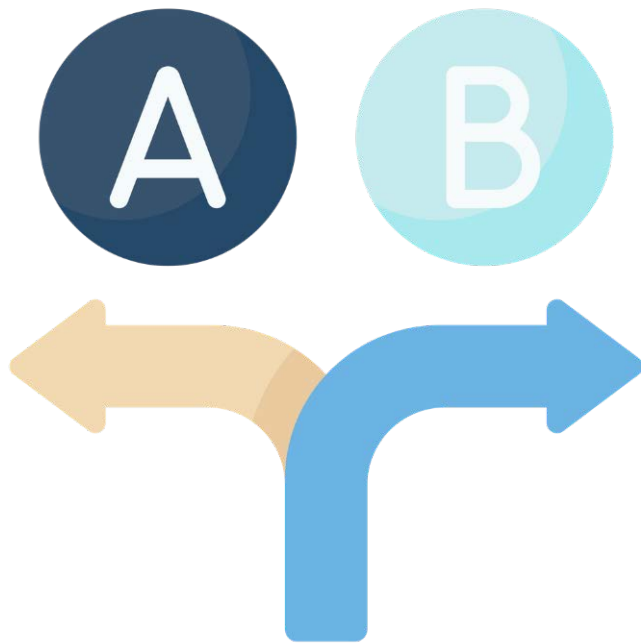
Typical meeting requests

- IVD Software
- Point of Care tests

## Key takeaway messages:

1. ENGAGE early!!
2. Reference your meeting identifier when you make a submission

Which do you think is a better application?



## Preliminary scoping: Case study 1:

Device: Class 3 point of care IVD

- Inclusion form: Completed
- Cover letter provided
- Assessment report provided for the device under EU IVDR
- IFU for the device provided

## Preliminary scoping: Case study 2:

Device: Class 2 IVD software

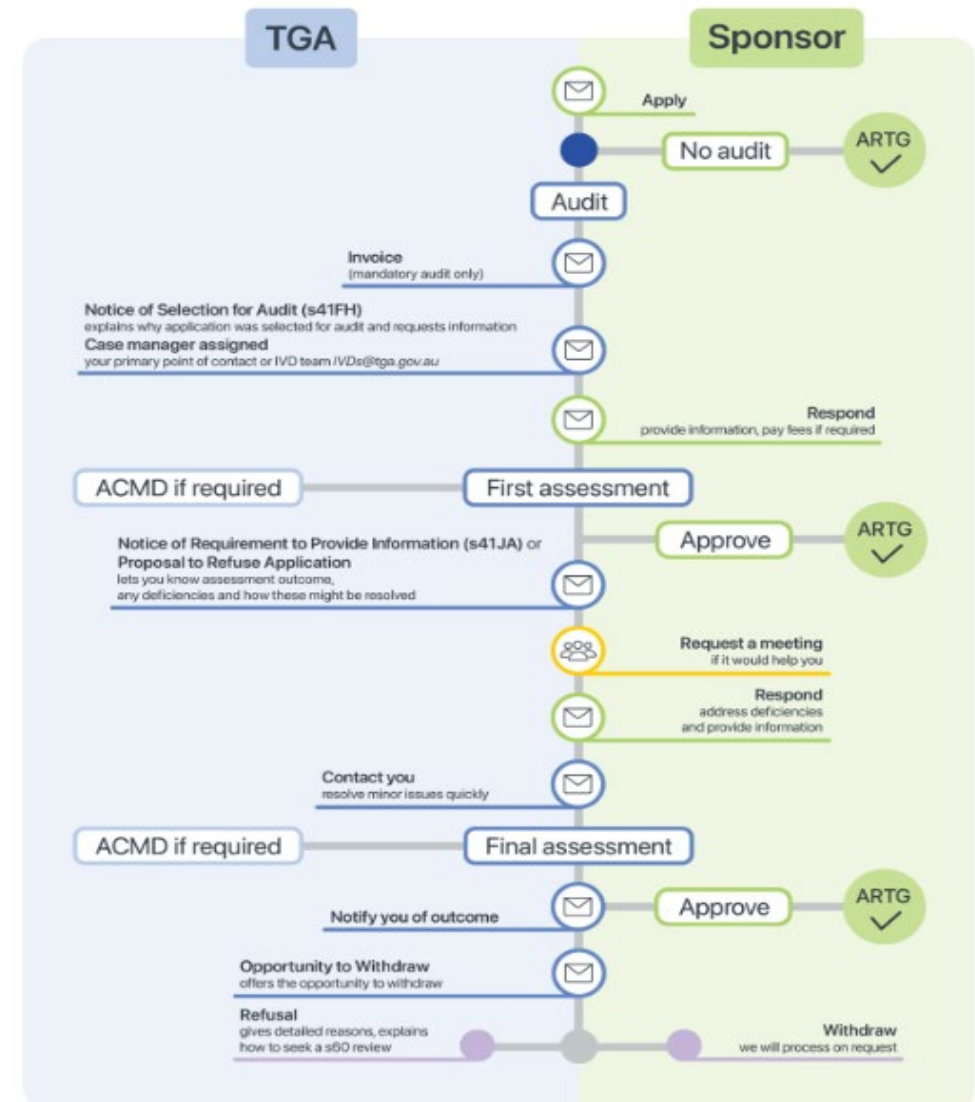
- No cover letter
- Assessment report for the representative device selected under EU IVDR provided
- No IFU provided.

# IVD case management model for application audits

Same as current medical device case management model but with slight tweaks

- Dedicated case managers --- but --- IVD inbox will remain the primary point of contact for sponsors.
- Proactively notify sponsors – assessment round assigned and expected assessment round completion time

## Medical device case management process



# Challenges with submissions ...

Poor quality data + submission

Lack of clarity around regulatory requirements

Lack of clarity around regulatory processes



# So... what are we doing about this?

- ✓ Continued stakeholder education
  - Updated the guidance on 'Technical review for IVD application audits'.
  - Proactively contact sponsors to clarify issues rather than lengthy email exchanges
  - Sending de-identified clinical assessment reports for improved clarity
- ✓ Everything that comes from TGA, medical devices is in the same format - Introduced consistent templates
- ✓ We recognise sponsors communicate to manufacturers - Detailed s41JA requests.

## Preparing for technical file review (application audit) for in-vitro diagnostic medical devices

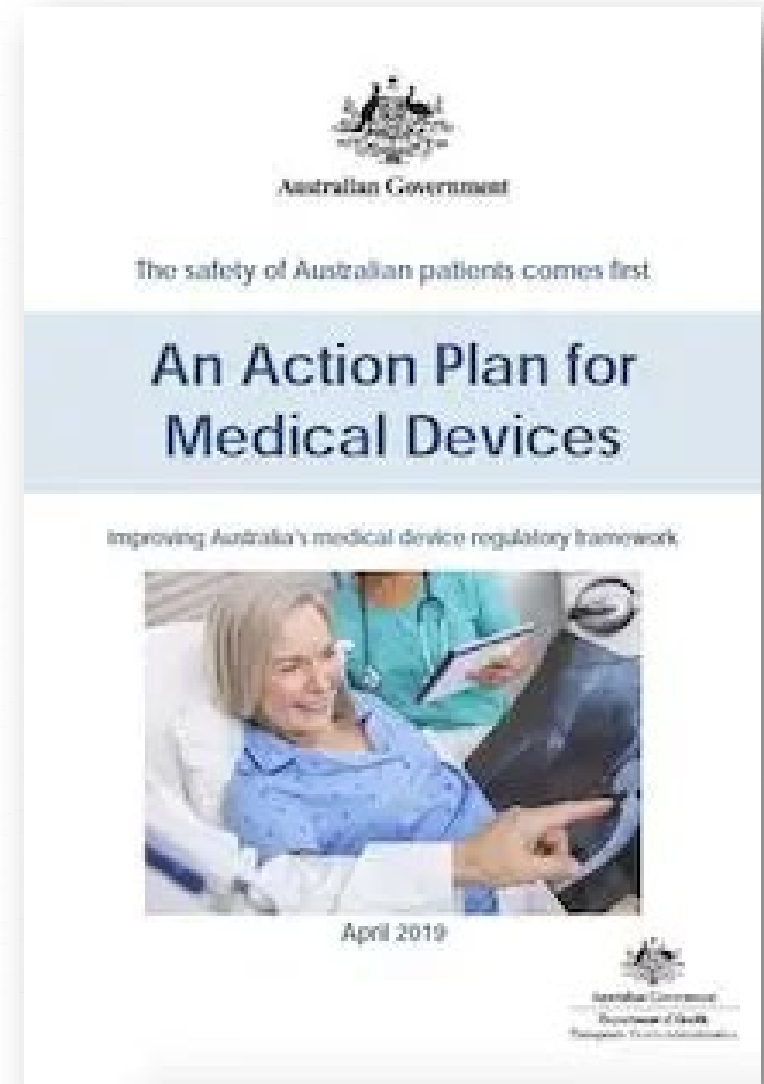
Guidance for preparing a technical file review, as part of your application to include an in-vitro medical device (IVD) in the Australian Register of Therapeutic Goods.

The image displays two screenshots of official communication templates from the Therapeutic Goods Administration (TGA). Both templates are marked as 'OFFICIAL' and include a 'Respond by' box with the instruction 'Click or tap to enter a date.' The top screenshot is titled 'Notice of Selection for Audit<sup>1</sup> and Requirement to Provide Further Information (s41FH)' and is for an 'Application for ARTG inclusion of an in vitro diagnostic medical device'. It features a progress bar with 'Apply', 'Prelim-Select', and 'Info' (highlighted) stages, and a 'wait for assessment' indicator. The bottom screenshot is titled 'Notice of Requirement to Provide Information (s41JA)' and is for an 'Application for ARTG inclusion of an in-vitro medical device'. It features a progress bar with 'Apply', 'Prelim-Select', 'Info' (highlighted), 'Assess', 'Info', and 'Decide' stages, and a 'wait for assessment' indicator. Both templates include contact information for the IVD Inbox (IVDs@tga.gov.au) and a phone number (1800 141 144). The bottom template also includes a 'Date of this notice' field and a 'Choose an item' field for the application ID.

# Medical Device Reforms

The Action Plan is a three-part strategy to:

- improve how new devices get on the market in Australia
- strengthen monitoring and follow up of devices in use
- provide more information to patients about the devices they use



# Reforms: IVD classification

## Stakeholder Participation

25 submissions were received from industry, laboratories, pathology providers, and community health organisations.

## Outcomes:

- Supported - Proposed changes to classification rules and principles
- Supported - Proposed changes to definitions
- Transitional arrangements – 6 months not supported.
- Emphasised need for clearer guidance specifically with IVD software.

[Home](#) > [Resources and guidance](#)

## Consultation for proposed changes to the IVD medical device classifications and definitions

We are seeking stakeholders' feedback on proposed changes to the IVD medical device classifications and definitions.

**Consultation period:** 12 March 2025 - 23 May 2025

[Listen](#) [Print](#) [Share](#)

While the consultation is open you can make a submission at our [TGA consultation hub](#). We then review the submissions.

After that the submissions and our decision will be available on the same page at the [TGA consultation hub](#).

### About this consultation

We are seeking stakeholders' feedback on proposed changes to the IVD medical device classifications and definitions.

This consultation aims to confirm views on aligning classification rules, principles, and definitions with the European Regulation 2017/746 for in vitro diagnostic medical devices (IVDR) where appropriate.

## Next Steps:

- Seek Government approval
- Targeted consultation on transitional arrangements

# Reforms: Companion Diagnostics & software

## Companion Diagnostics (CDx)

- May 2025: Guidance on Companion Diagnostics and introduction of the Cdx list.
- Input into CDx requirements for in-house IVDs as part of consultation for update on in-house IVD standard.
- Consistency in requirements for commercial and in-house IVD tests.

## IVD Software

- August 2025 - TGA commenced a review of software-based medical devices and those utilising artificial intelligence (AI).
- Feb 2026 - published and updated guidance on software and AI

The screenshot displays two pages from the Therapeutic Goods Administration (TGA) website. The top page is titled "Understanding regulatory requirements for in vitro diagnostic (IVD) companion diagnostics (CDx)" and provides guidance on the regulatory framework for IVD companion diagnostics. Below the text is a table with columns for "IVD companion diagnostic -name", "IVD - ARTG", "Biomarker", "Corresponding medicine name (generic name)", and "Indication (refer to medicine PI)". The bottom page is titled "Understanding how we regulate software-based medical devices" and provides guidance on the regulation of such devices. It includes a "Published:" date of 24 February 2026 and a "On this page" section with links to various sub-topics like Purpose, Legislation, Introduction, and Who we regulate.

IVD companion diagnostic -name	IVD - ARTG	Biomarker	Corresponding medicine name (generic name) Click on link to PI (if available)	Indication (refer to medicine PI)
			ZELBORAF (vemurafenib) in combination with COTELLIC (cobimetinib)	Melanoma
			ALHEMO (concizumab)	Haemophili B congenital factor IX (FIX) deficiency with FIX inhibitors
			IRESSA (gefitinib)	Non-small cell lung cancer
			TAGRISO (osimertinib)	
			XOSPATA (gilteritinib fumarate)	myeloid leukaemia (AML) with a FLT3 mutation
			XALKORI (crizotinib)	Non-small cell lung cancer
			ALUNBRIG (brigatinib)	Non-small cell lung cancer
			TAFINLAR (dabrafenib) in	Non-small cell lung cancer

# Review of ARTG variations

- Aligned with principles of Application Audit Framework
- Establishment of working group with industry
- High Level outcomes to inform public consultation:
  - What are reportable variations.
  - Two-tier process model for variations
  - Target timeframes
  - Simplified terminology and
  - Single form

## Electronic Instructions for Use

- Planned for June 2026



# Key takeaways

## Tips for well-prepared submission:

- Supported by Comparable overseas regulator (CoR) approvals – Cover letter (with rationale for classification and GMDN), Overseas approval assessment reports and Instructions for Use for the device.
- NOT supported by CoR approvals - Technical file prepared as per the published guidance. Encourage Regulatory Engagement meeting.

## Expectations from TGA:

- Improved transparency around application status and any time delays and clear communication on assessments

## Reach out and stay connected:

- Requests for Regulatory engagement meetings and questions around IVD premarket applications: [ivds@tga.gov.au](mailto:ivds@tga.gov.au)
- Stay connected and up to date: [Email subscriptions | Therapeutic Goods Administration \(TGA\)](#)



# Questions?

[www.tga.gov.au](http://www.tga.gov.au)



**Australian Government**

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**Department of Health, Disability and Ageing**  
Therapeutic Goods Administration