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

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

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

Oct 2018:

Recognised the following CORs:

- EU Notified bodies
- Health Canada
- Japan PMDA
- MDSAP Auditing Organisations
- US FDA

Sep 2022:

Recognised Singapore HSA as a COR

Jul 2024:

Mandatory audits limited to high-risk IVD medical devices – Class 3, Class 4, self-tests and Point of Care tests

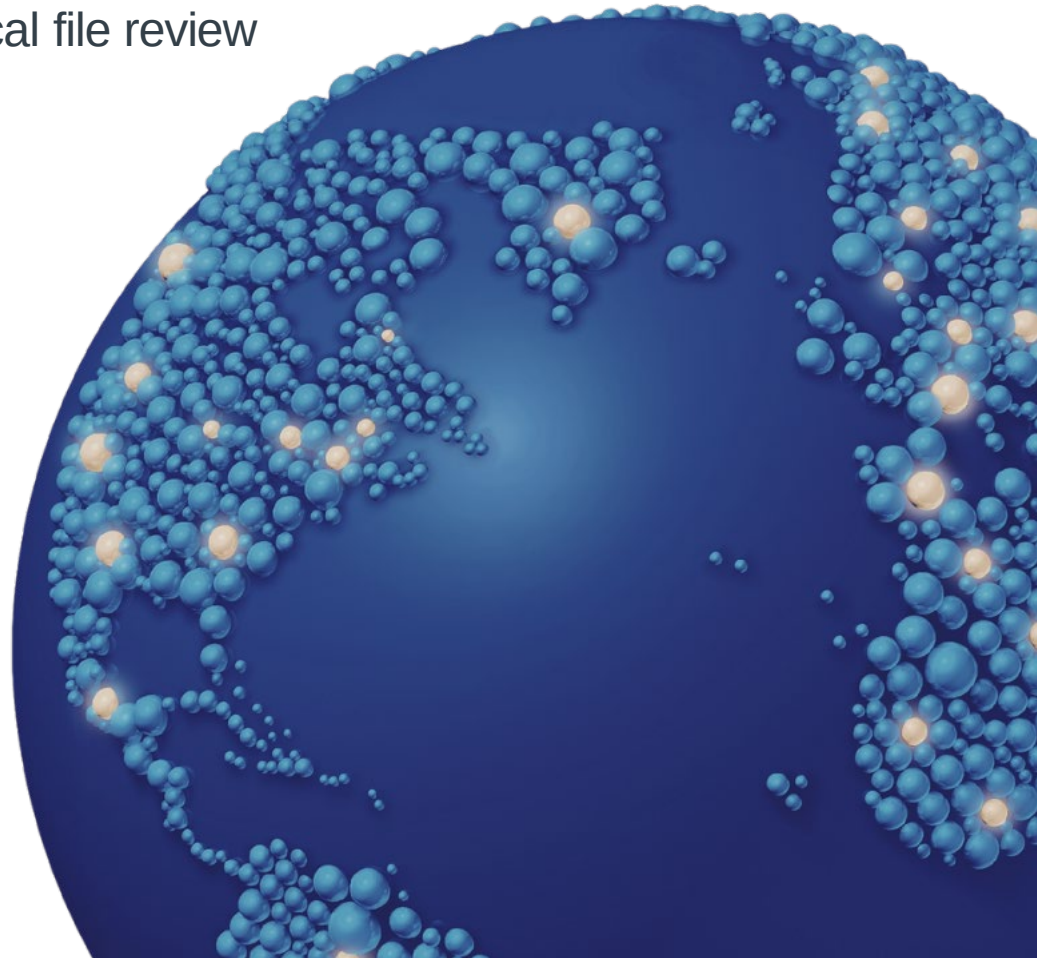
Dec 2025

UK approved body

Australian manufacturers

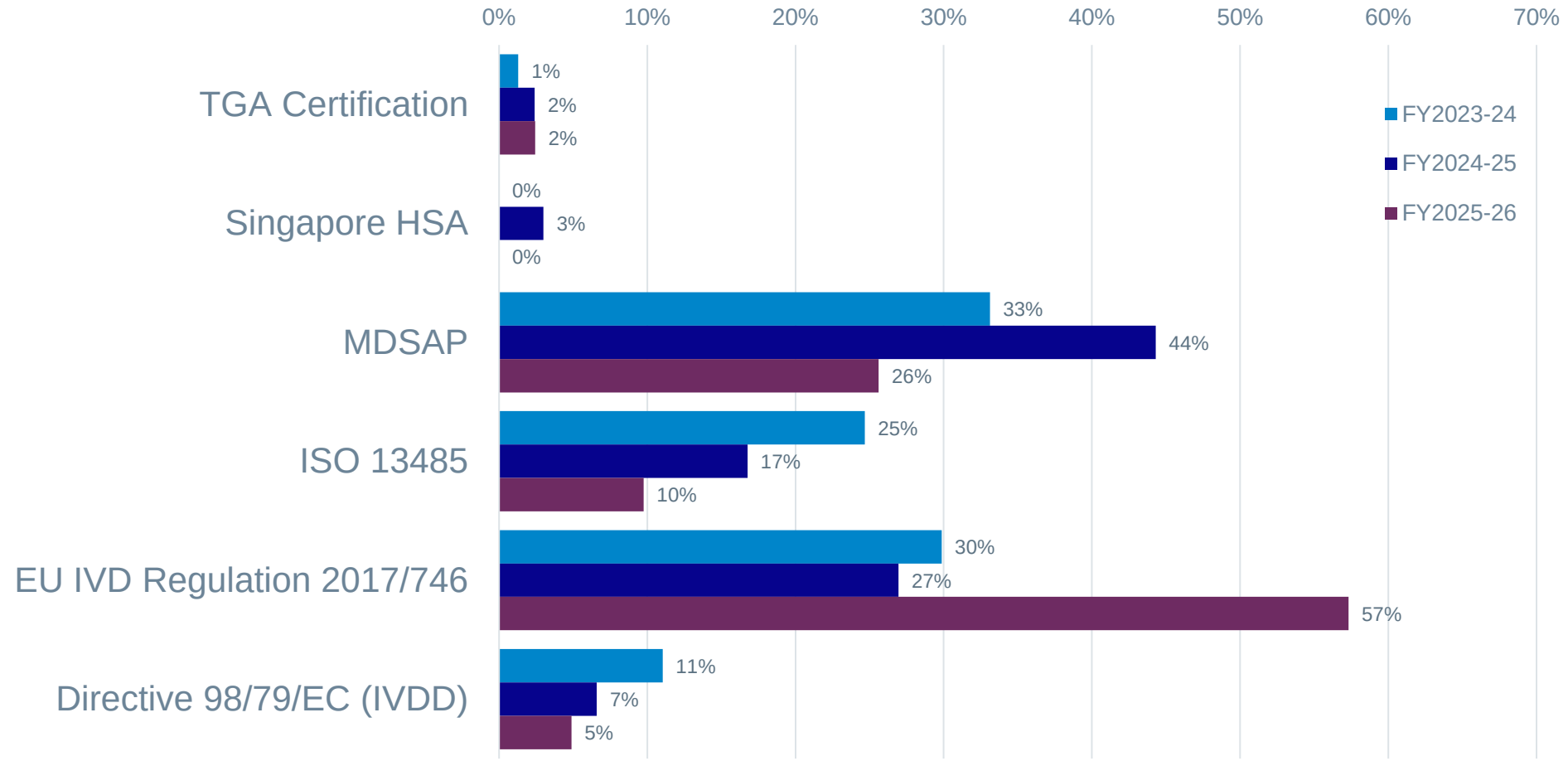
We still need the TGA conformity assessment pathway

- 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



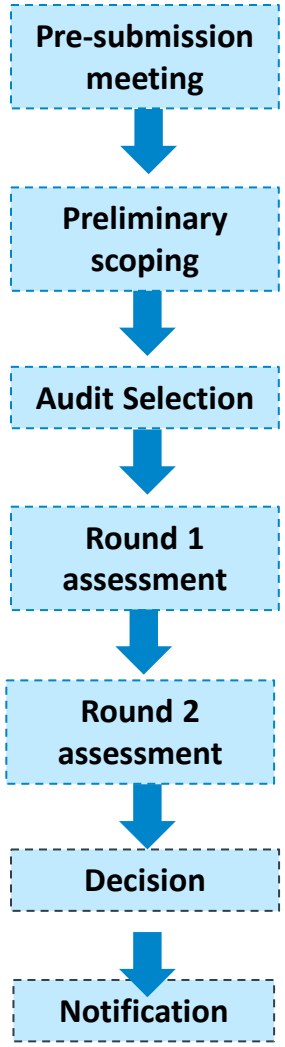
Applications for inclusion – IVD landscape (slightly different)

Application pathways



*July 2025 – Jan 2026

ARTG Inclusion application audit flow



20-day legislative timeframe

Mandatory – prescribed by Regulations
Non-Mandatory – Selection criteria guidance

Target timeframe 100 TGA days

Target timeframe 80 TGA days

Target timeframe: Mandatory – 180 TGA days

Target timeframe: Non-Mandatory – 150 TGA days

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

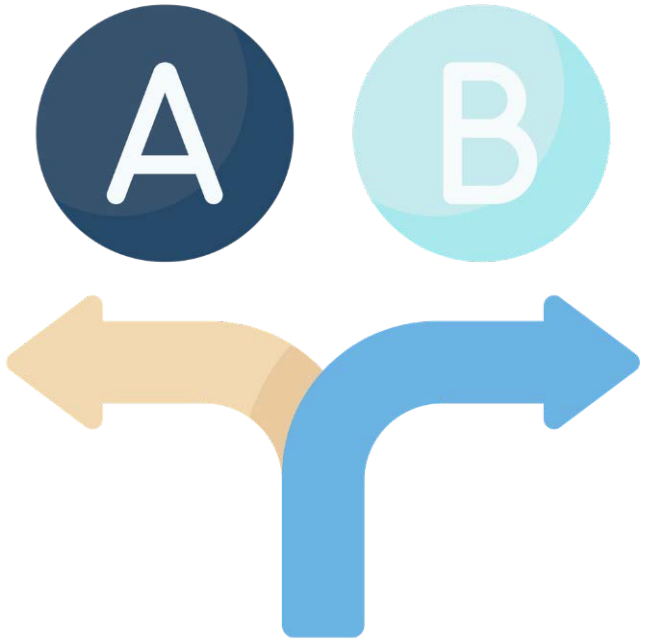
- IVD Software
- Point of Care tests

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

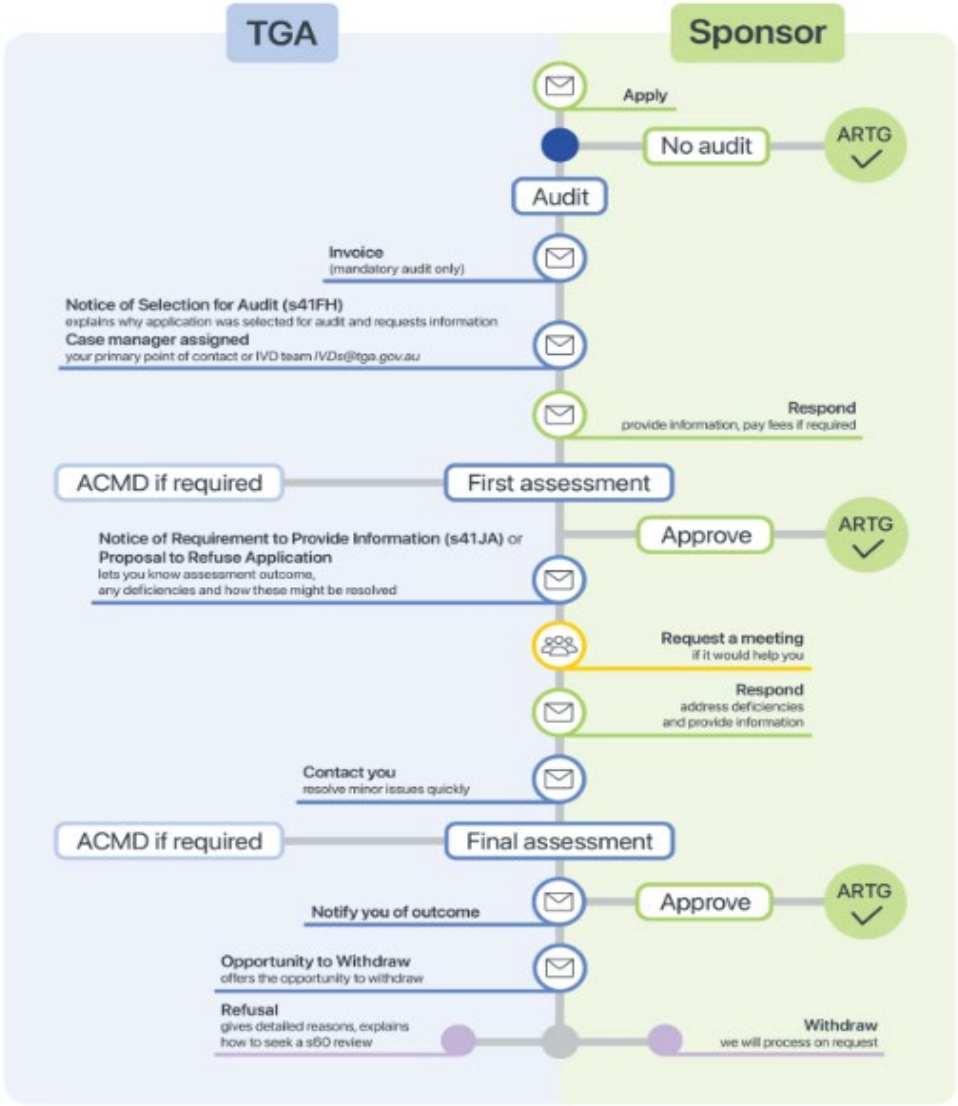
- No cover letter
- Assessment report for the representative device selected under EU IVDR provided
- No IFU provided.

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

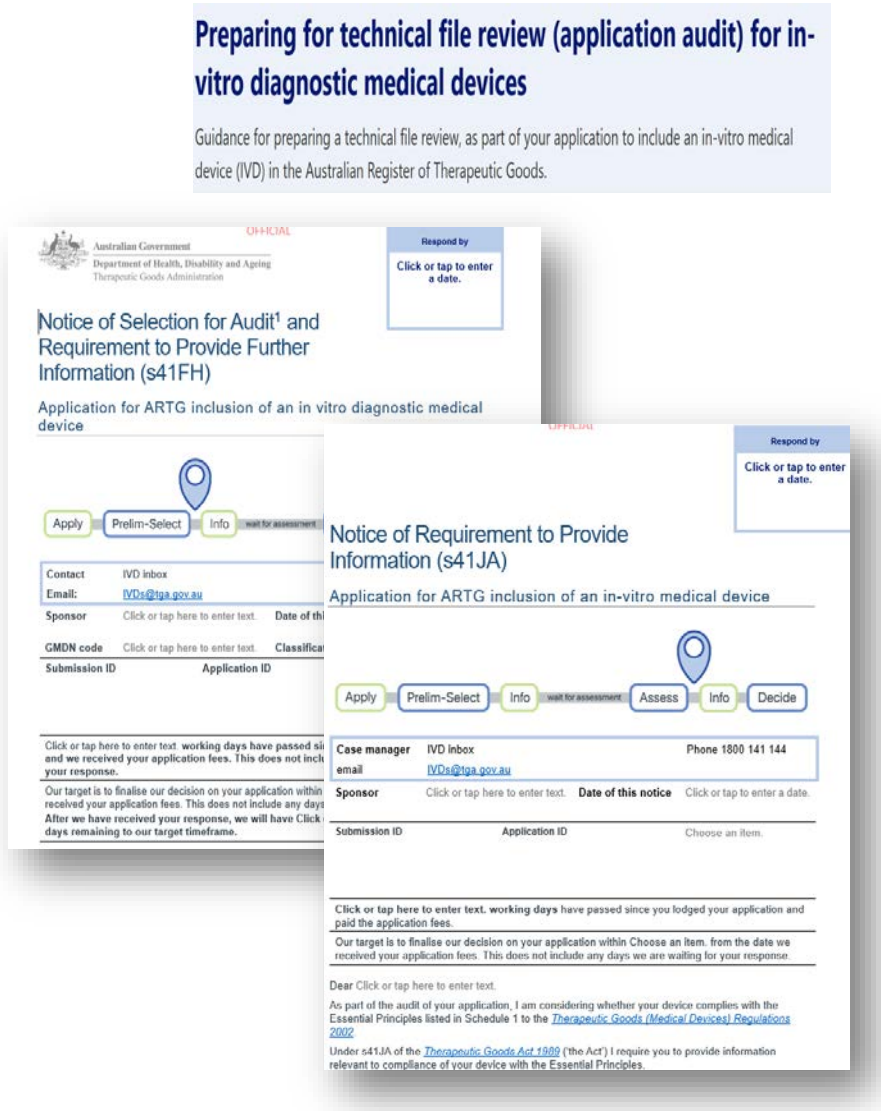


Challenges with submissions …

- Poor quality data + submission
- Lack of clarity around regulatory requirements
- Lack of clarity around regulatory processes

So… what are we doing about this?

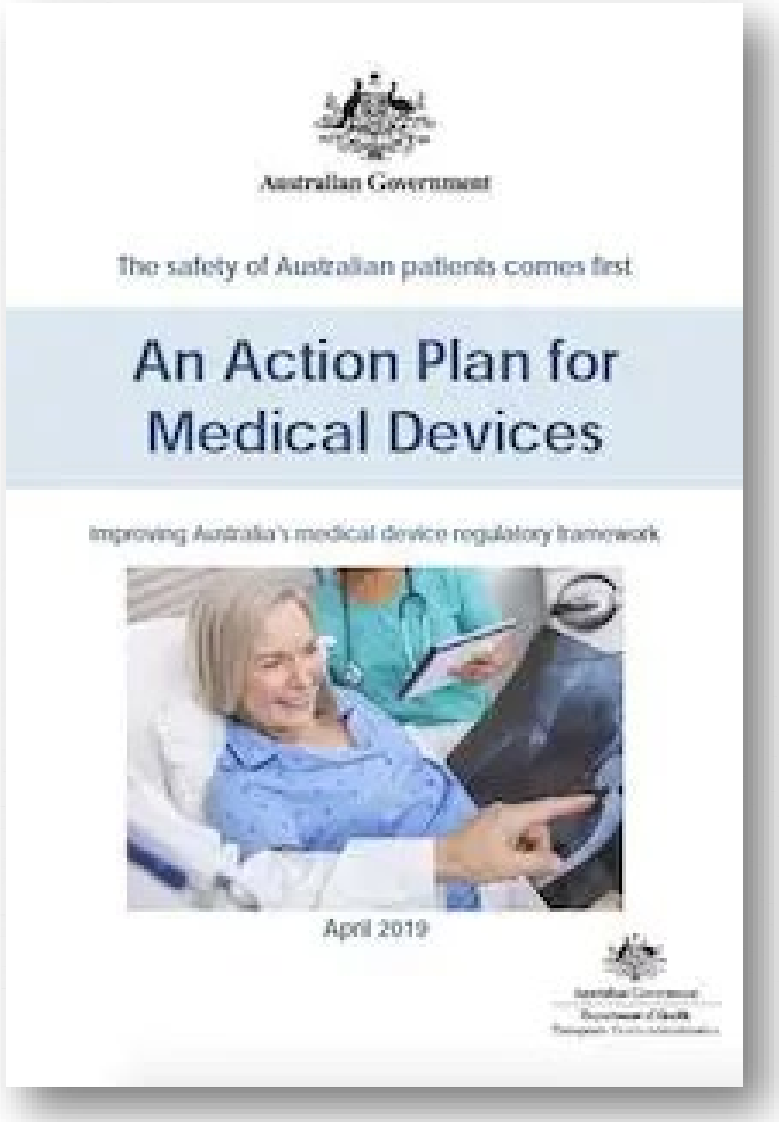
- ✓ Continued stakeholder education
  - Updated the guidance on ‘Technical review for IVD application audits’.
  - Proactively contact sponsors to clarify issues rather than lengthy email exchanges
  - Sending de-identified clinical assessment reports for improved clarity
- ✓ Everything that comes from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



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



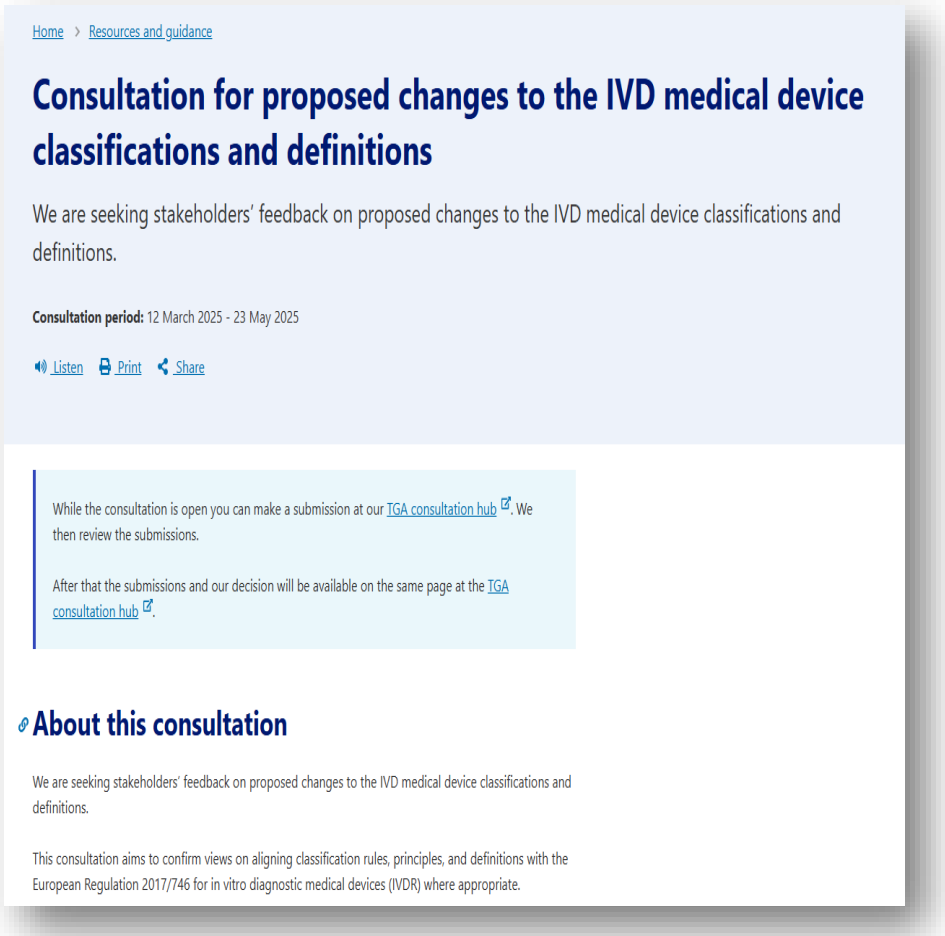
Reforms: IVD classification

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.



Next Steps:

- Seek Government approval
- Targeted consultation on transitional arrangements

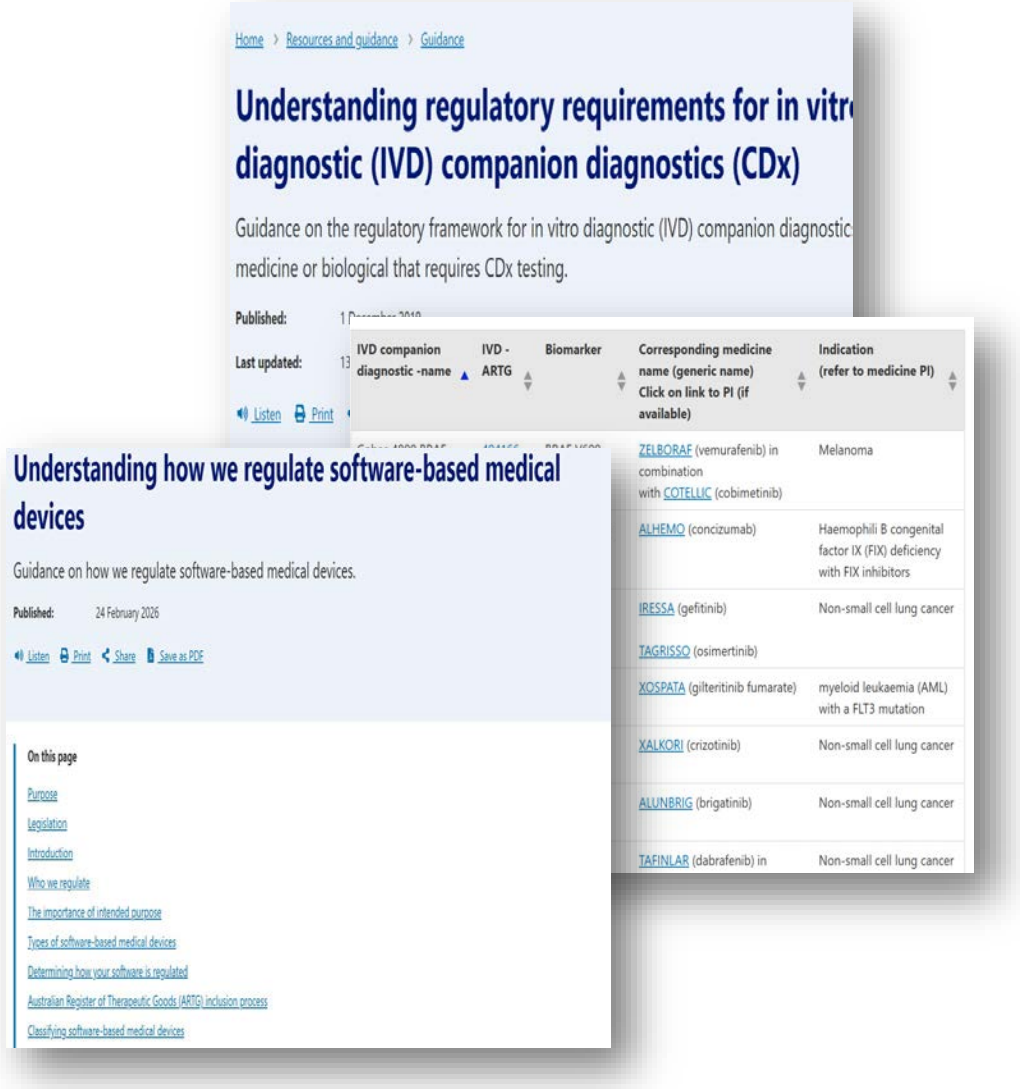
Reforms: Companion Diagnostics & software

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



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
- Stay connected and up to date: Email subscriptions | Therapeutic Goods Administration (TGA)

Questions?

www.tga.gov.au

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration