Good Reliance Practices at Work – Australian experience

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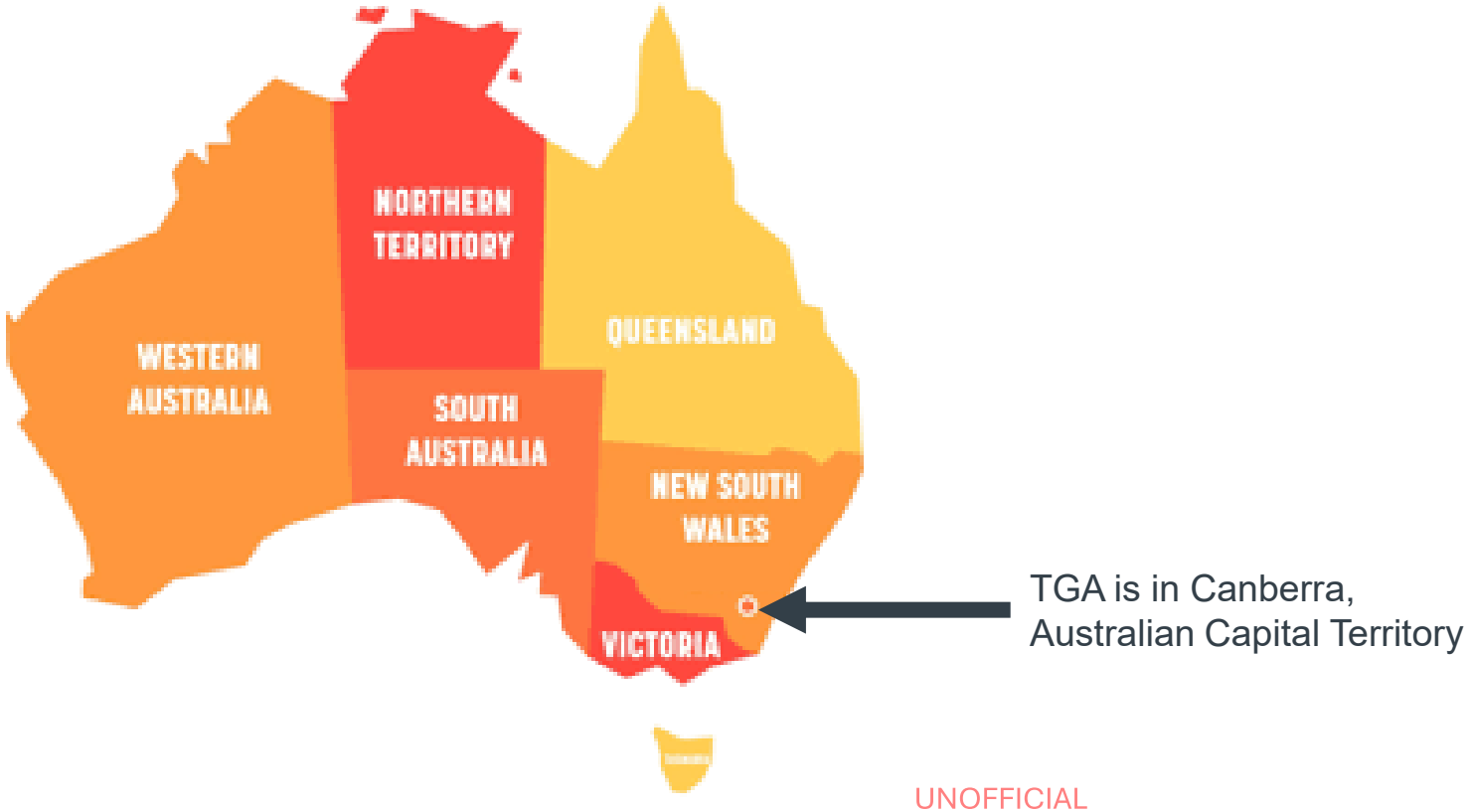
Therapeutic Goods Administration

The role of the TGA

The TGA is Australia's regulatory authority for therapeutic goods.

We **regulate** and **monitor** therapeutic goods in Australia to ensure that they are safe and fit for their intended purpose.



TGA is in Canberra, Australian Capital Territory

The legal framework

The *Therapeutic Goods Act 1989* (the Act) sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia.

The Act is supported by the Regulations, and various Orders and Determinations which provide further details of matters covered in the Act. **Reliance is a feature in the law.**

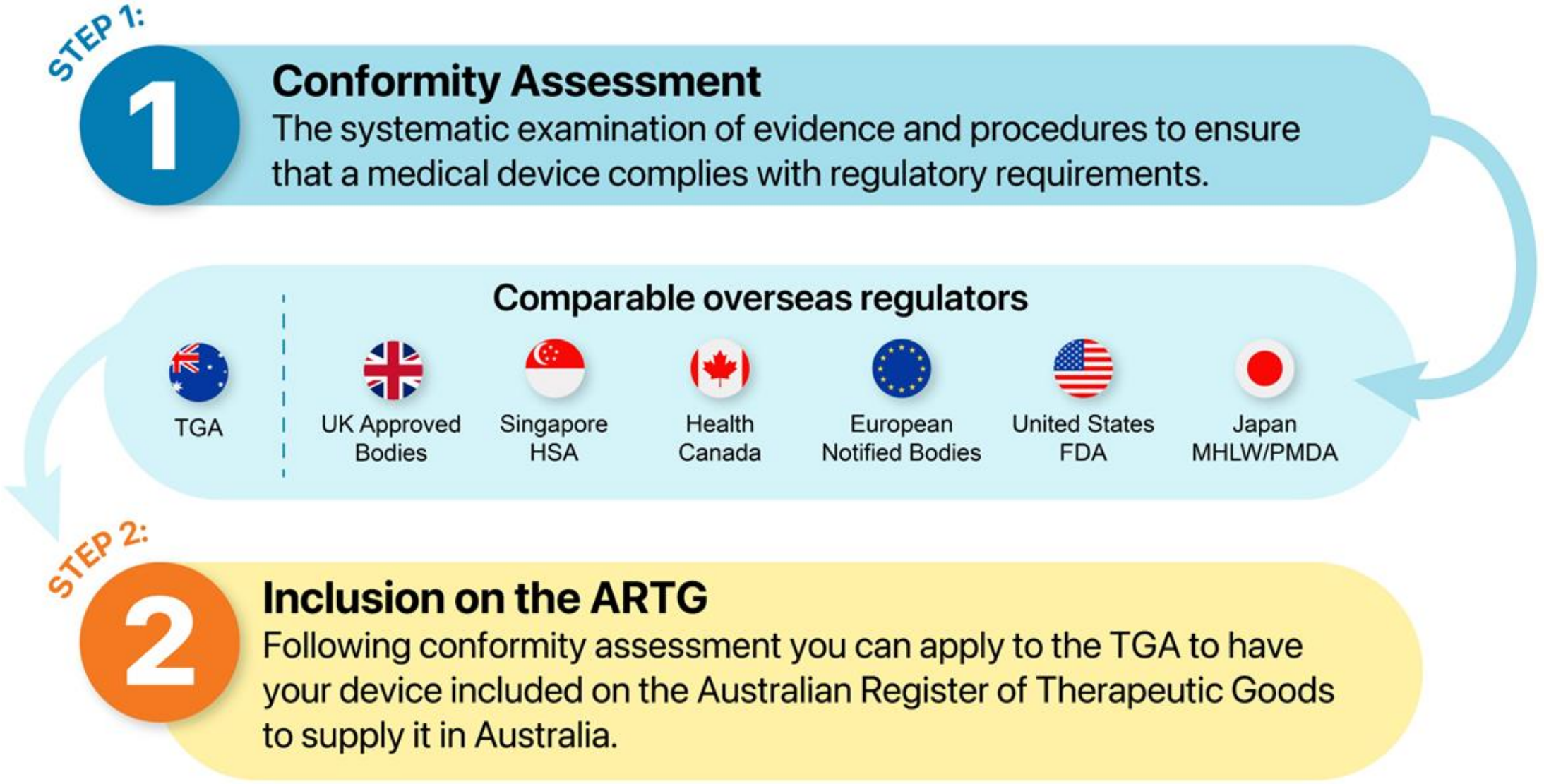
See our Legislation and legislative instruments page on our website for a list of Acts, regulations and legislative instruments.

Australian Register of Therapeutic Goods (ARTG)

All therapeutic goods must be entered in the ARTG before they can be supplied in, imported to, or exported from Australia (noting there are some exemptions and exclusions)

Medicines	Medical Devices	Biologicals	Other Therapeutic Goods

Achieving market authorisation in Australia



Comparable Overseas Regulators (Reliance) Framework

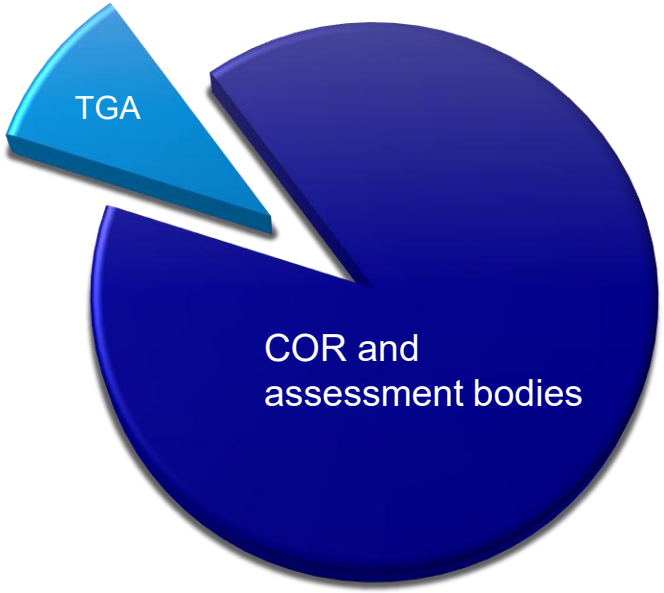
Oct 2018:	Jul 2021:	Sep 2022:	Jul 2024:	Oct 2024:	Discussions underway
Recognised the following CORs: •EU Notified bodies •Health Canada •Japan PMDA, MHLW •MDSAP Auditing Organisations •US FDA	Expanded reliance for previously 'specified' medical devices	Recognised Singapore HSA as a COR	Mandatory audits limited to high-risk devices	Expanded reliance pathways: •Class III devices: MDSAP Certification + USFDA 510(K) clearance •Class IIa devices exempt from USFDA regulation: MDSAP Certification + evidence of exemption from USFDA 510(K) regulation	UK MHRA Brazil ANVISA

Together with an Application Audit Framework – allows TGA to Review COR evidence

Supply of medical devices in Australia

Majority of devices are supplied in Australia using certification from comparable overseas regulators and assessment bodies:

- EU Notified Bodies
- U.S. FDA
- Health Canada
- Medical Device Single Audit Program (MDSAP) Auditing Organisation
- the Ministry of Health, Labour and Welfare and Pharmaceutical and Medical Devices Agency of Japan
- Health Sciences Authority Singapore
- UK MHRA (via MRA)

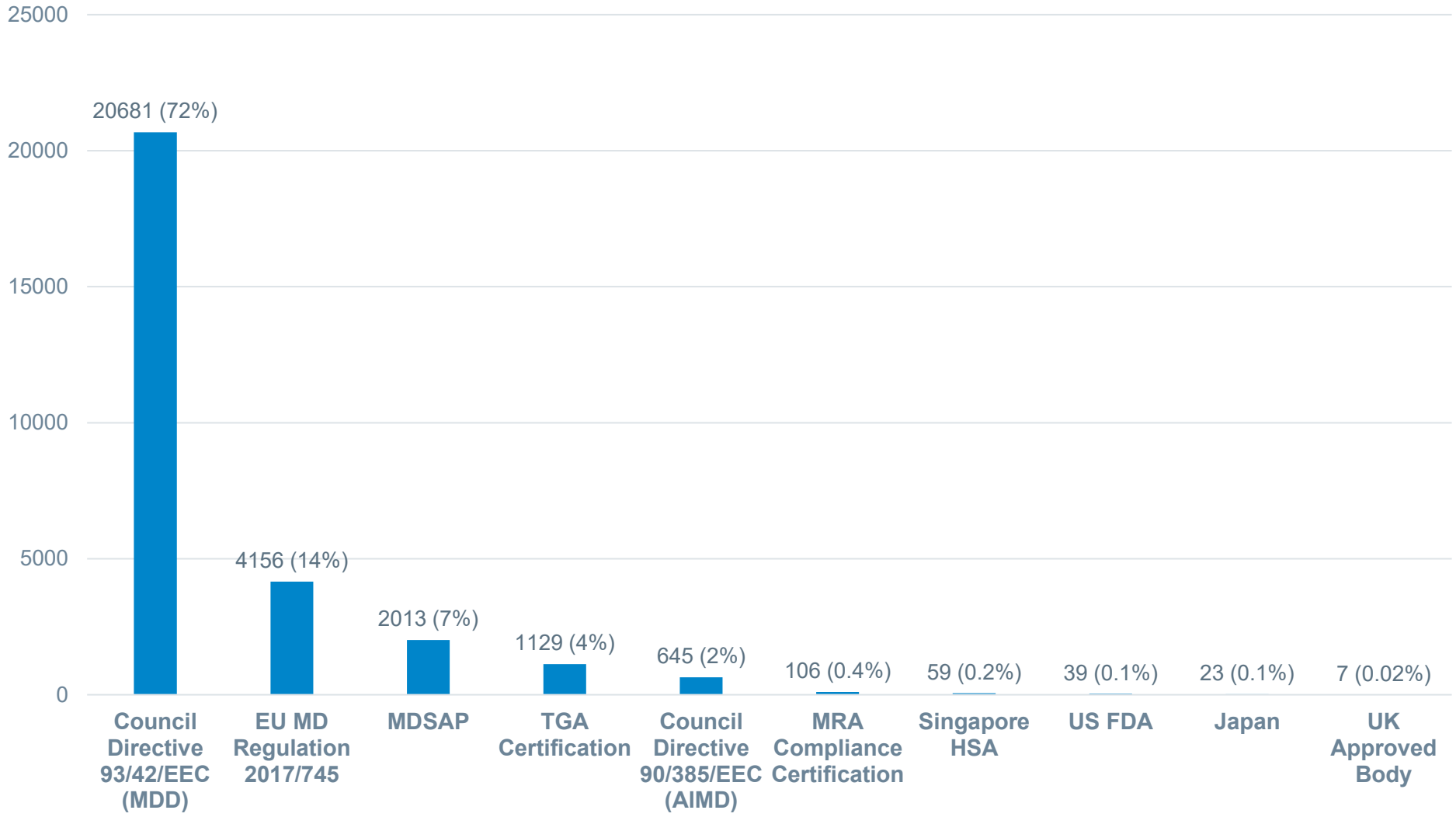


Pre-market reliance example – Types of acceptable COR evidence* for Class III medical devices – set out on website

Comparable Overseas Regulator	Documents accepted by TGA to support a Class III Medical Device application
Health Canada	MDSAP + Medical device licence Class IV
Japan MHLW/PMDA	MDSAP + Pre-market approval certificate
EU MDR	Annex IX(QMS) + Annex IX (Technical documentation)
EU MDD	Annex II.3 + II.4 (design exam)
US FDA	MDSAP + PMA
Singapore HSA	Form supporting entry in Singapore Register of Health Products as a Class D medical device

*The TGA remains independent in reaching its own decision, even when relying on decisions, assessments and information from other regulatory authorities

ARTG entries supported by overseas certifications for medical devices (non-IVDs)



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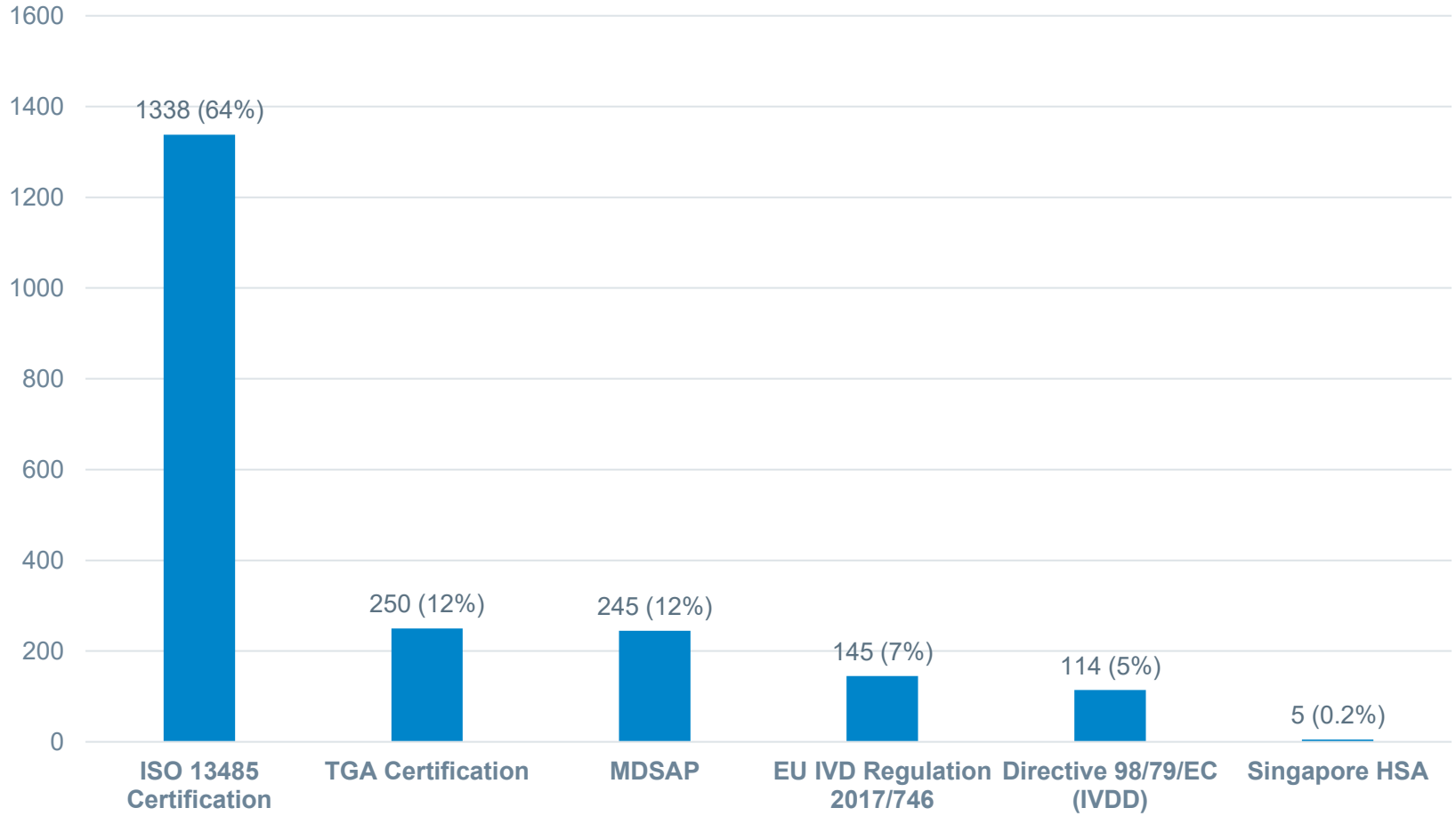


Comparable Overseas Regulator Pathway Application Review: either Mandatory or Non-Mandatory (Review by TGA)

- Application audits (reviews of COR evidence) are conducted to verify that devices submitted for inclusion in the ARTG meet the relevant legislative requirements. Around 30% of applications are selected for review.

- For some applications, an audit is mandatory under the legislation. Others may be selected for auditing at the discretion of the delegate. This may be due to a range of factors including:
  - Inaccuracies in the application or issues with the application that have not been resolved
  - Risk of the device relating to post-market signals
  - Known issues with the type of devices

Application Review (Audit) Framework

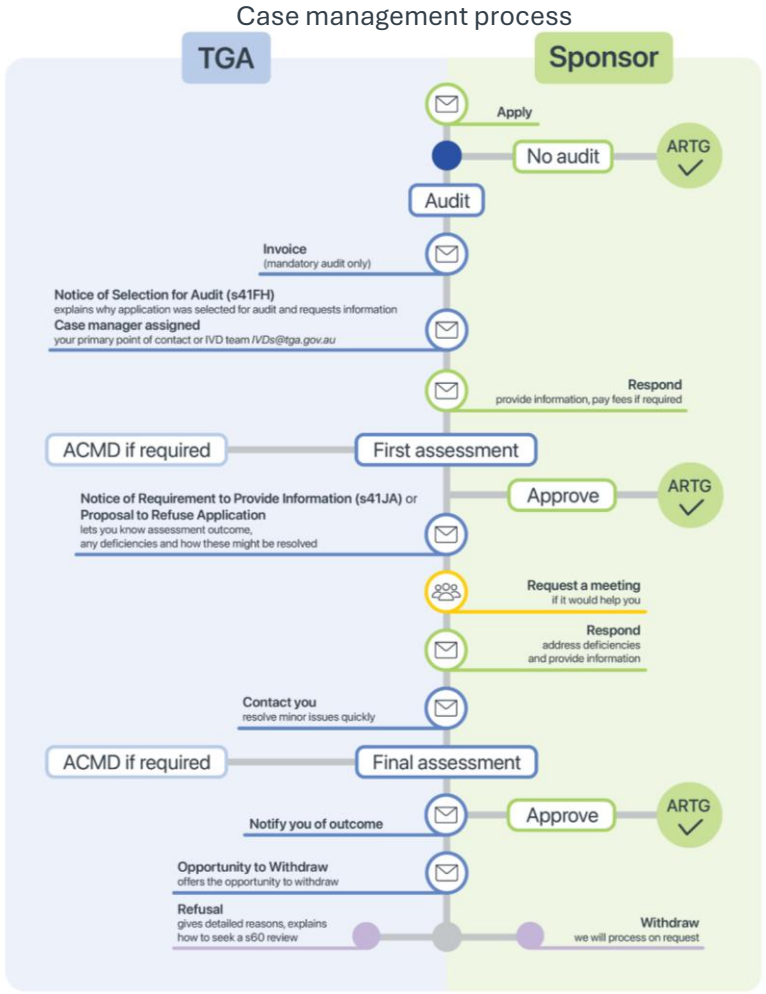
Sets out what we select to review and why?

- Dynamic risk-based selection criteria for application audits
  - Criterion 1: Aspects related to the application and the device
  - Criterion 2: Kinds of devices subject to regulatory reforms
  - Criterion 3: Post market signals
  - Criterion 4: Factors related to the sponsor or manufacturer

- Improvements to clinical assessment processes and timelines
  - Shortened timelines for clinical assessments
  - More targeted, risk-based clinical assessments
  - Enhanced regulatory engagement meetings including pre-submission advice to support application compliance
  - Clinical assessment reports provided directly to sponsors

Reasons for application reviews (audits)

- Clarification of information in the application (79%)
- Medical device software and artificial intelligence (AI) (13%)



Medical Device Single Audit Program (MDSAP) - Benefits

- Faster access to technology and latest emerging devices
- Reduced duplication of regulatory effort and costs to companies
- International resources channelled to areas of need
- Better export access
- Flexible - Pre-market, post-market and ongoing use
- We are part of the global regulatory infrastructure
  - **Shared regulatory science - knowledge and relationships**

MDSAP use in Australia

MDSAP and product approval combinations for medical device applications (including IVDs)

13 % of applications to the TGA use MDSAP certificates (about 740 per year)

QMS evidence	Product evidence
MDSAP	Health Canada licence
MDSAP	US FDA 510(k)
MDSAP	Japan PMDA
MDSAP	No product evidence required for class 2 IVDs

We also review MDSAP audit reports to support our postmarket surveillance

Criteria for comparable overseas regulators – TRUST and CONFIDENCE

1. Comparability of the regulatory framework
2. IMDRF membership
3. Life cycle approach and post-market vigilance
4. Communication and cooperation with overseas regulators
5. Expertise of the overseas regulator

- ***Decision for reliance is made by the Australian Government and documented in law***
- ***The TGA advises the Government based on the above criteria after significant liaising with the other regulator and the outcome is expressed in a Determination (legal instrument).***
- ***Irrespective of the COR evidence, the TGA maintains sovereign decision making approval to include devices in the ARTG (and supply in Australia)***

Considerations for reliance

- Need Government support
- Positive ongoing relationships with other national regulators are crucial to success
- Domestic stakeholders may see reliance as a threat to sovereignty
- Need broad support from domestic industry and health care to resist bespoke requirements
- Differing interpretation of legislation and/or guidance across jurisdictions
- Requires other mechanisms such as information sharing agreements, Mutual Recognition Agreements and Memorandum of Understanding

Challenges for reliance

- Changes in Government views or other stakeholder support
- Changes in other national regulators regulations - are we still aligned or do we need to review and make changes? Eg: EU MDR
- Medical device safety issues that impact confidence levels and questions reliance Eg: mesh
- Differences in regulations makes it difficult to align Eg: in Australia, SaMD classification is higher for direct to consumer devices

Thank you!

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Australia

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