GMTA/DITTA Workshop on Reliance

- **Scene Setting:** What is reliance and why is it important?
- **Session 1**: Reliance in a premarket setting
- **Session 2:** Reliance in a post market setting
- **Next Steps**

DITTA
GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

GMTA
Global Medical Technology Alliance
Innovating for a Healthier World

Session 1: Reliance in a premarket setting
Case studies in premarket reliance implementation

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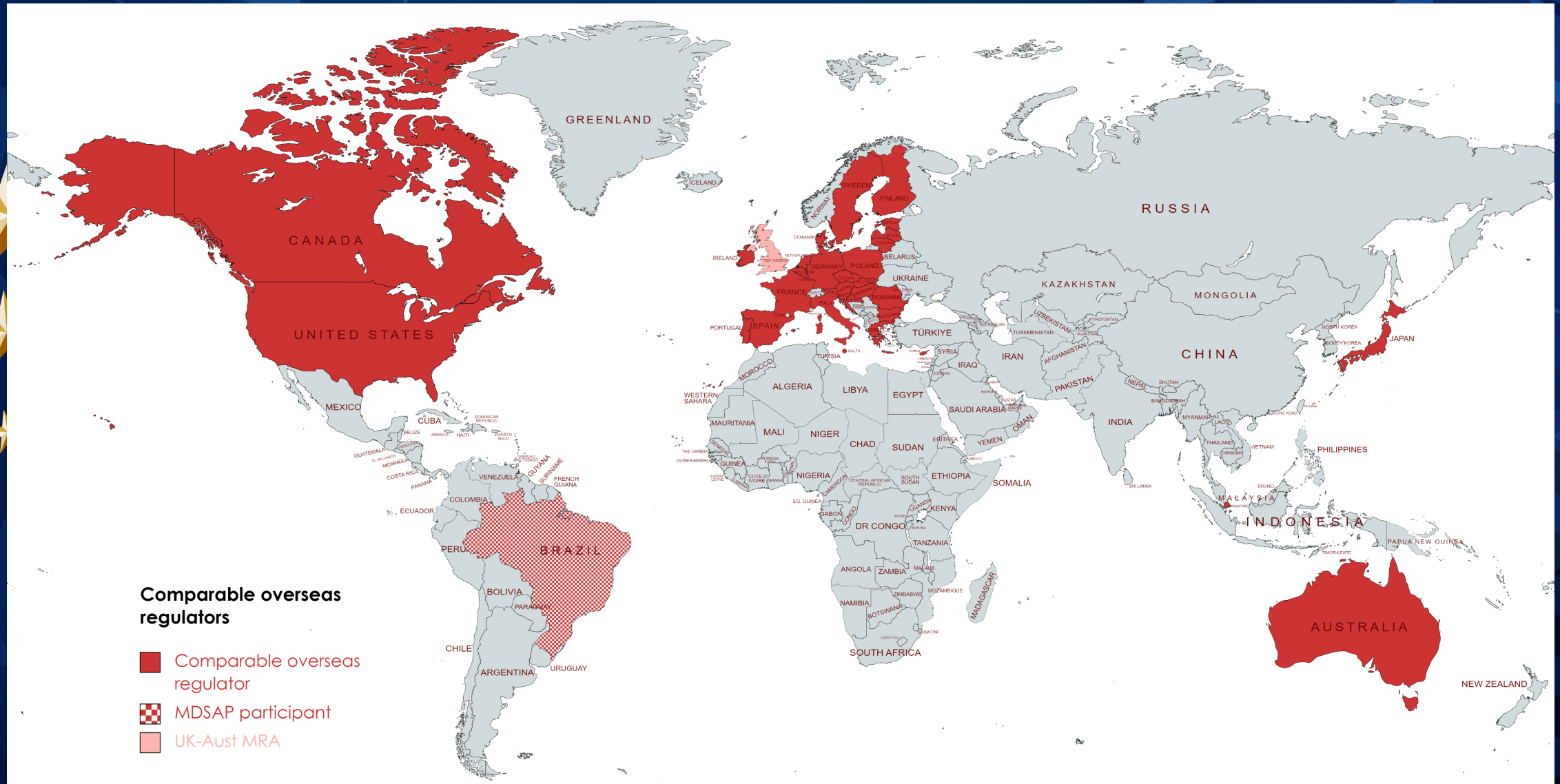
IMDRF International Medical Device Regulators Forum

Outline

- Reliance vs recognition?
- How do we use reliance in the Australian context (maintaining sovereign decision making)
  - Comparable overseas regulators framework
  - Observations on IVDs vs non-IVD devices
- Benefits, Lessons and Challenges
- Case Studies and the Future

Australian context - Comparable overseas regulators framework



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

Note: Decision is made by the Australian Government

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).

Legislation to support reliance

- ***Therapeutic Goods (Overseas Regulators) Determination 2018***

  This instrument lists entities determined to be overseas regulators under the Therapeutic Goods Act

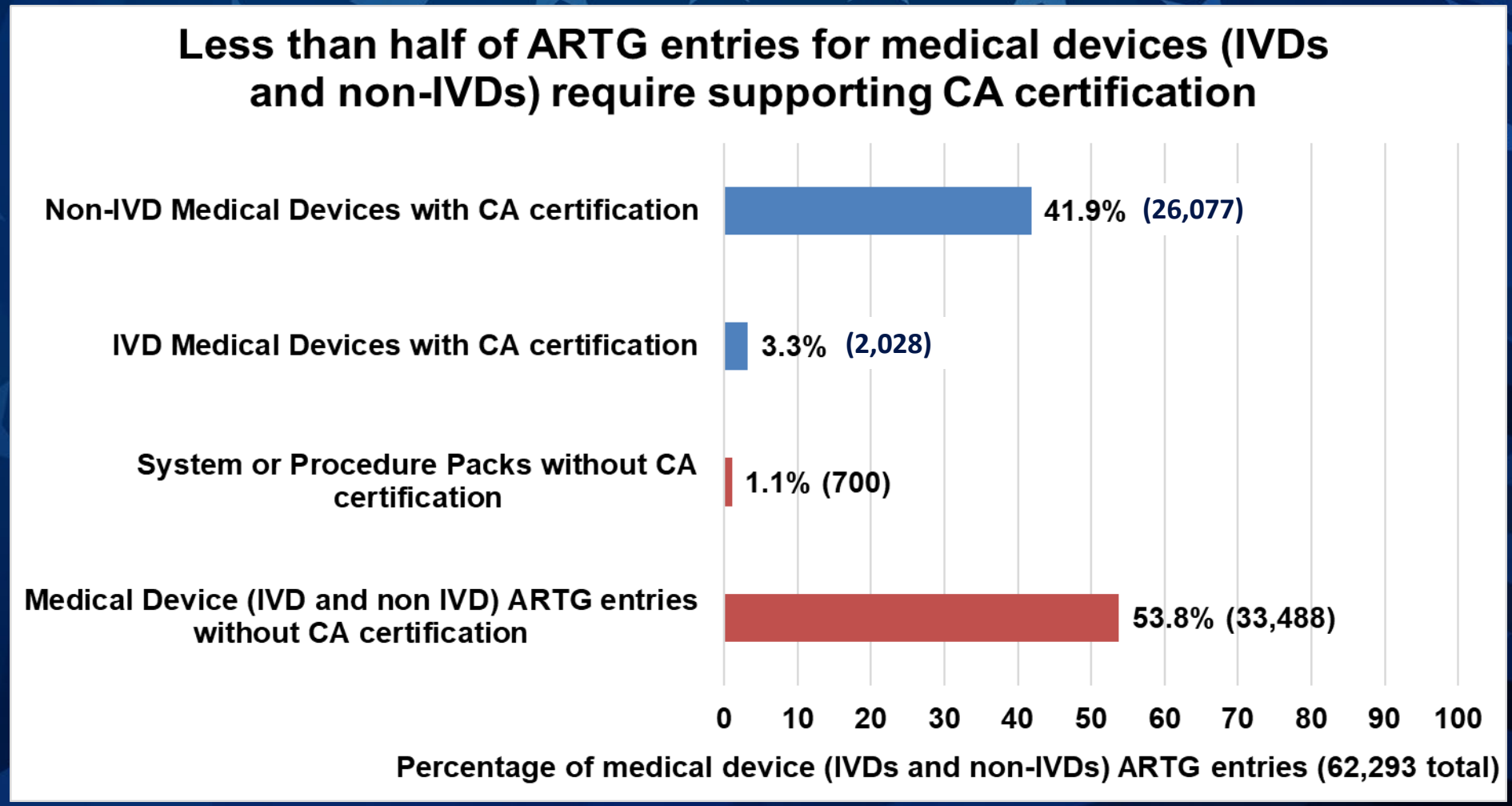
- ***Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018***

  This instrument lists the kind of information that must accompany an application for inclusion in the Australian Register of Therapeutic Goods (ARTG)

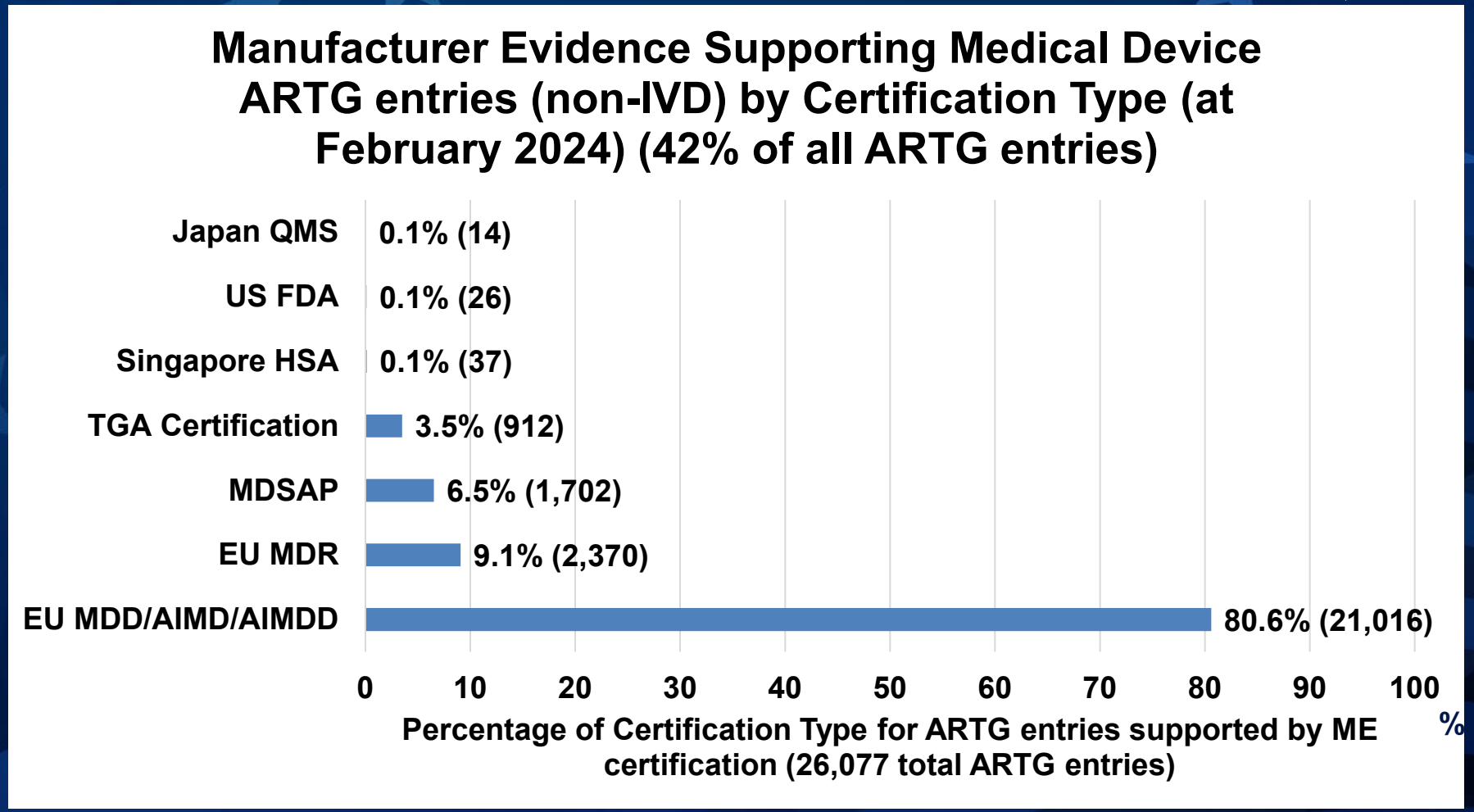
COR evidence accepted for Device Classifications – Class III Example

Comparable Overseas Regulator	Documents required by TGA to support a Class III Medical Device application
Health Canada	MDSAP + Medical device licence Class IV
Japan – Ministry of Health, Labour and Welfare	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 – Health Sciences Authority	Form supporting entry in Singapore Register of Health Products as a Class D medical device

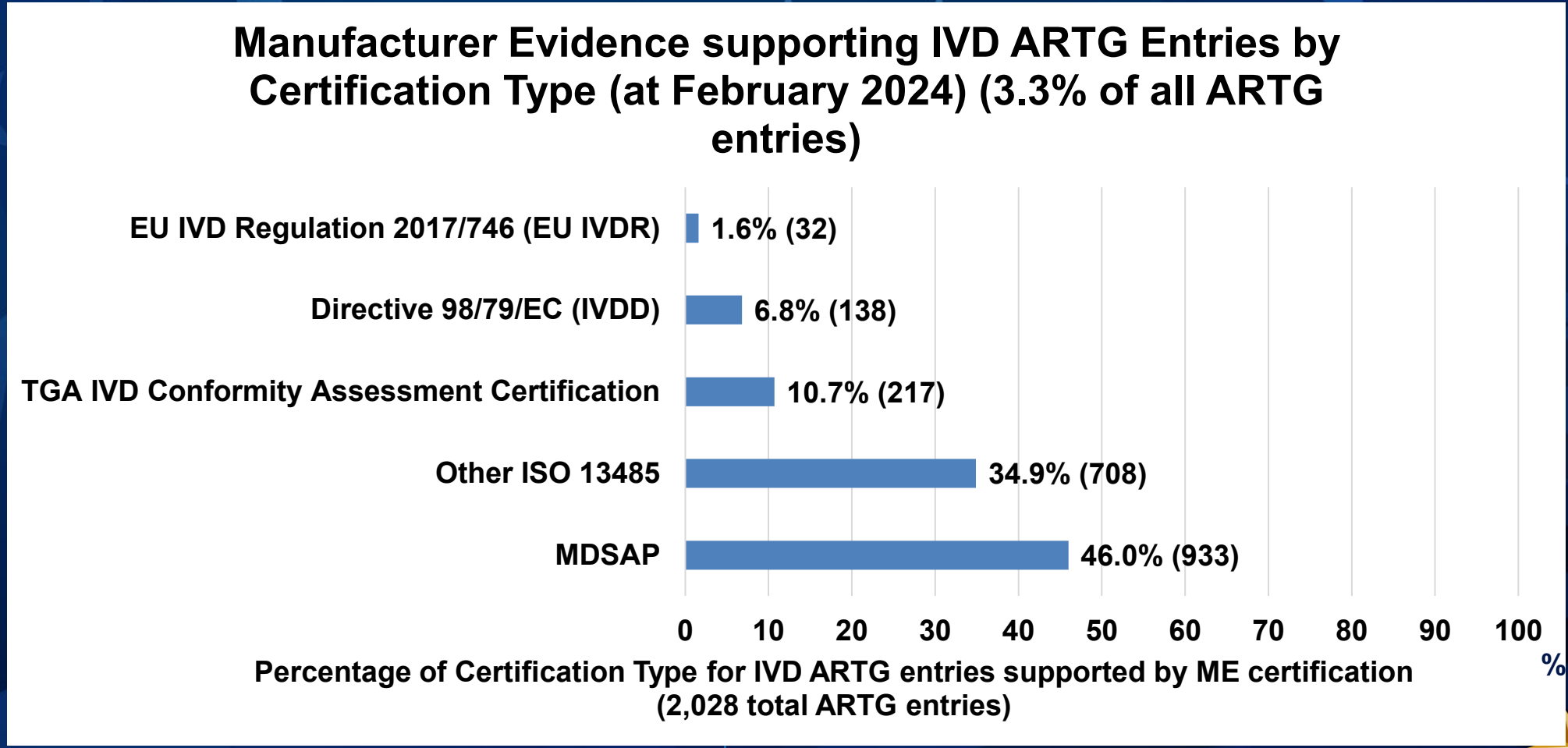
ARTG entries for Medical Devices



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



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



Benefits

- Faster access to technology to improve the health of Australians
- Reduced duplication of regulatory effort and costs to companies
- The TGA is better able to channel its resources to areas of need
- Better export access for Australian companies
- **Introduction to the latest emerging devices**
- We are part of the global regulatory infrastructure
  - Shared regulatory science - knowledge and relationships

Lessons and challenges

- Need Government support
- Positive ongoing relationships with other national regulators are crucial to success
- Late night meetings and travel – it is hard work being distant from regulatory partners!
- Domestic stakeholders may see reliance as a threat to sovereignty
- Need broad support from domestic industry and health care to resist bespoke requirements
- Often challenging to meet expectations of the stakeholders
- Differing interpretation of legislation and/or guidance across jurisdictions
- Other mechanisms such as information sharing agreements, Mutual Recognition Agreements and Memorandum of Understanding

Case Study 1

Class IIb application – cardiac system generator supported by EU MDR

- **TGA checking of application showed:**
  - Details in application and certificates were complete and correct
  - No further information was required
- **Outcome:**
  - Application was approved within the legislated 20 working days

Case Study 2

Class IIb application – skin contouring radio-frequency system supported by MDSAP and US FDA 510k

- **TGA checking of application showed:**
  - IFU did not comply with EP 13.4 (information that must be provided with the device)
  - Intended Purpose stated in the original application was inconsistent with the IFU and 510(k).
  - The entity the 510(k) was issued to did not match the manufacturer name as stated on the MDSAP certificate.
- **Outcome:**
  - The 510(k) Establishment Registration & Device Listing entry showed the registered establishment was the MDSAP certificate holder.
  - An updated Intended Purpose was provided for the application.
  - The IFU was amended to comply with EP 13.
  - Application was approved within 33 working days

Case Study 3

Class III applications (Mitral Valve Clips) supported by EU MDR - with inadequate supporting documents (group of 3 applications)

- **TGA checking of application showed:**
  - Clinical evaluation report, IFU and labels of the devices were not provided.
  - These documents are needed for preliminary clinical assessment to determine the risk/benefit ratio of the devices.
- **Outcome:**
  - Information requested was provided promptly to the TGA.
  - New information received was adequate to proceed to delegate's decision.
  - The applications were approved within 20 working days.

Case Study 4

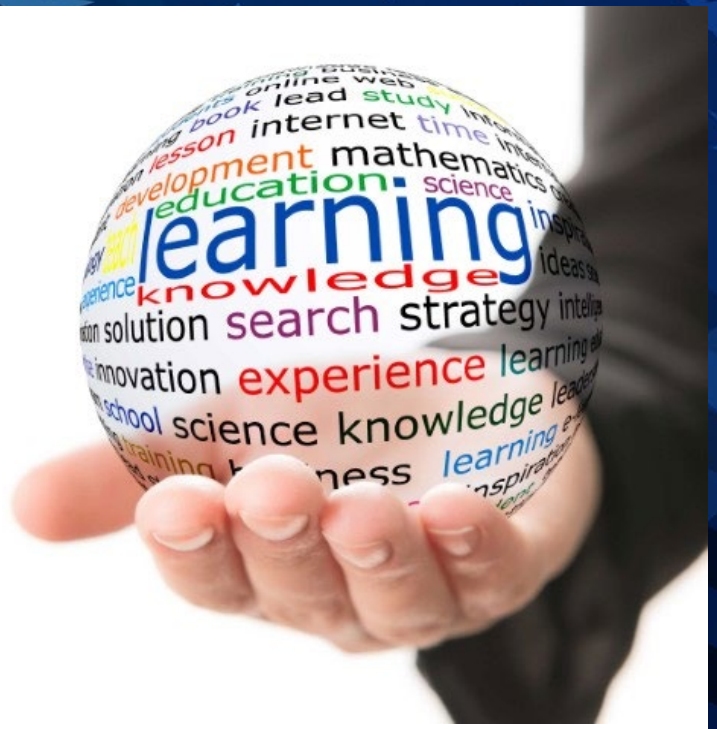
Class III applications (Breast implant support materials)- supported by EU MDR (group of 3 applications)

- **TGA checking of application showed:**
  - Insufficient clinical evidence to establish the safety and performance of the devices for use in breast reconstructive surgery.
  - Lack of robust, long-term comparative safety data for use.
  - Adverse events poorly reported by surgeons outside of clinical trial.

- **Outcome:**
  - Since November 2021, one application has been withdrawn
  - Full Clinical review required by the TGA:
    - Narrow intended purpose to use in reconstructive breast surgery only.
    - IFU/PILs updated with comprehensive list of adverse events.
    - Ongoing PMCF plan with registry data for the next 7-years.

Future

- The TGA continues to build experience with comparable overseas regulator approvals (including EU MDR & IVDR)
- UK MHRA – reliance & recognition discussions underway
- Reviewing potential expansion of reliance mechanisms w existing regulators (eg: USFDA, Health Canada, Japan)



KEY MESSAGES

1. Trust and Confidence takes time and collaboration
2. Significant benefits can be realised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