Good Reliance Practices

Medical Device Regulatory Convergence Project
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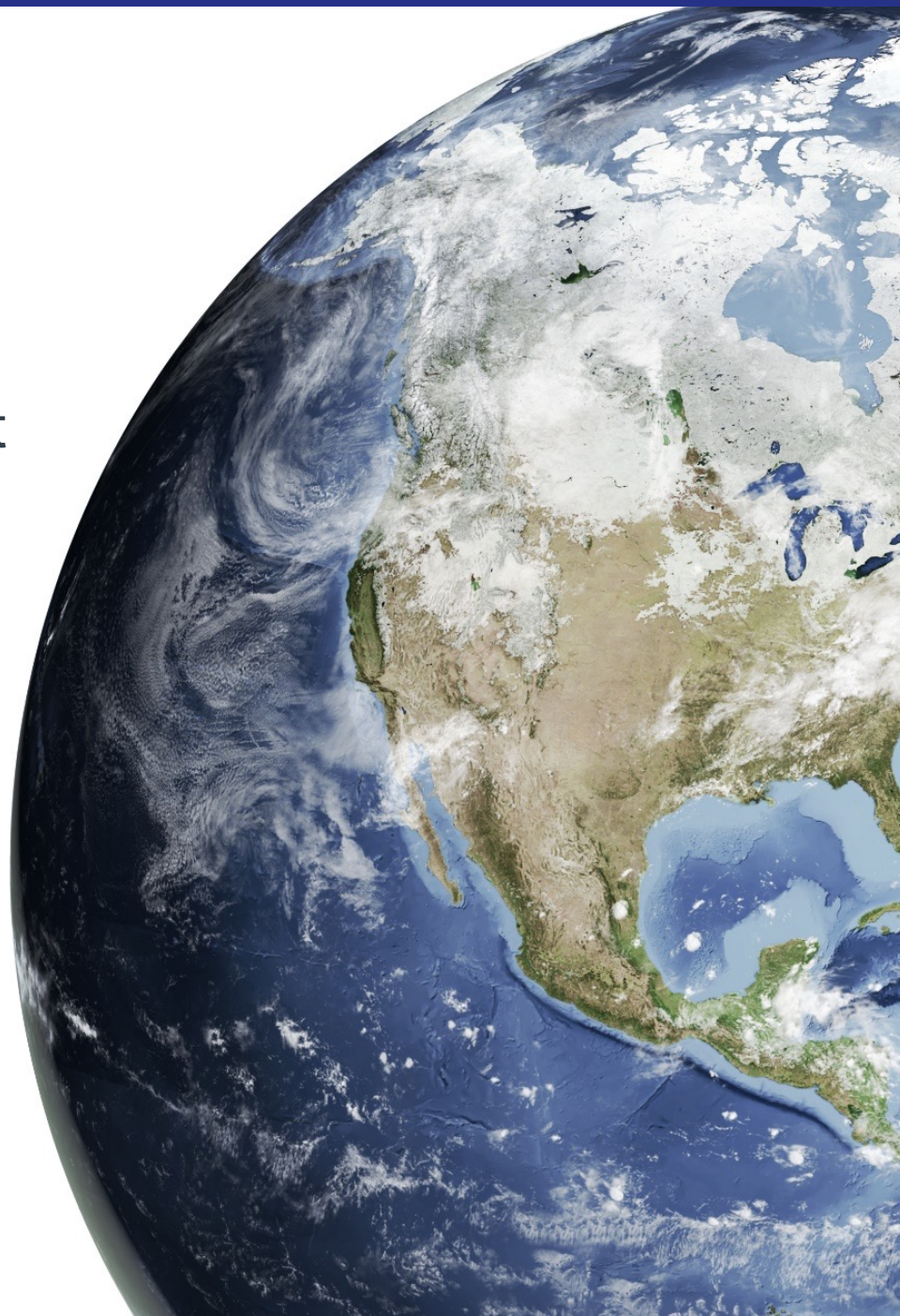
Outline

- What is regulatory reliance
- How do we use reliance in the Australian context
  - Comparable overseas regulators framework
  - Observations on IVDs vs non-IVD devices
- Australia's involvement in IMDRF and MDSAP
- Benefits
- Lessons and challenges
- Future



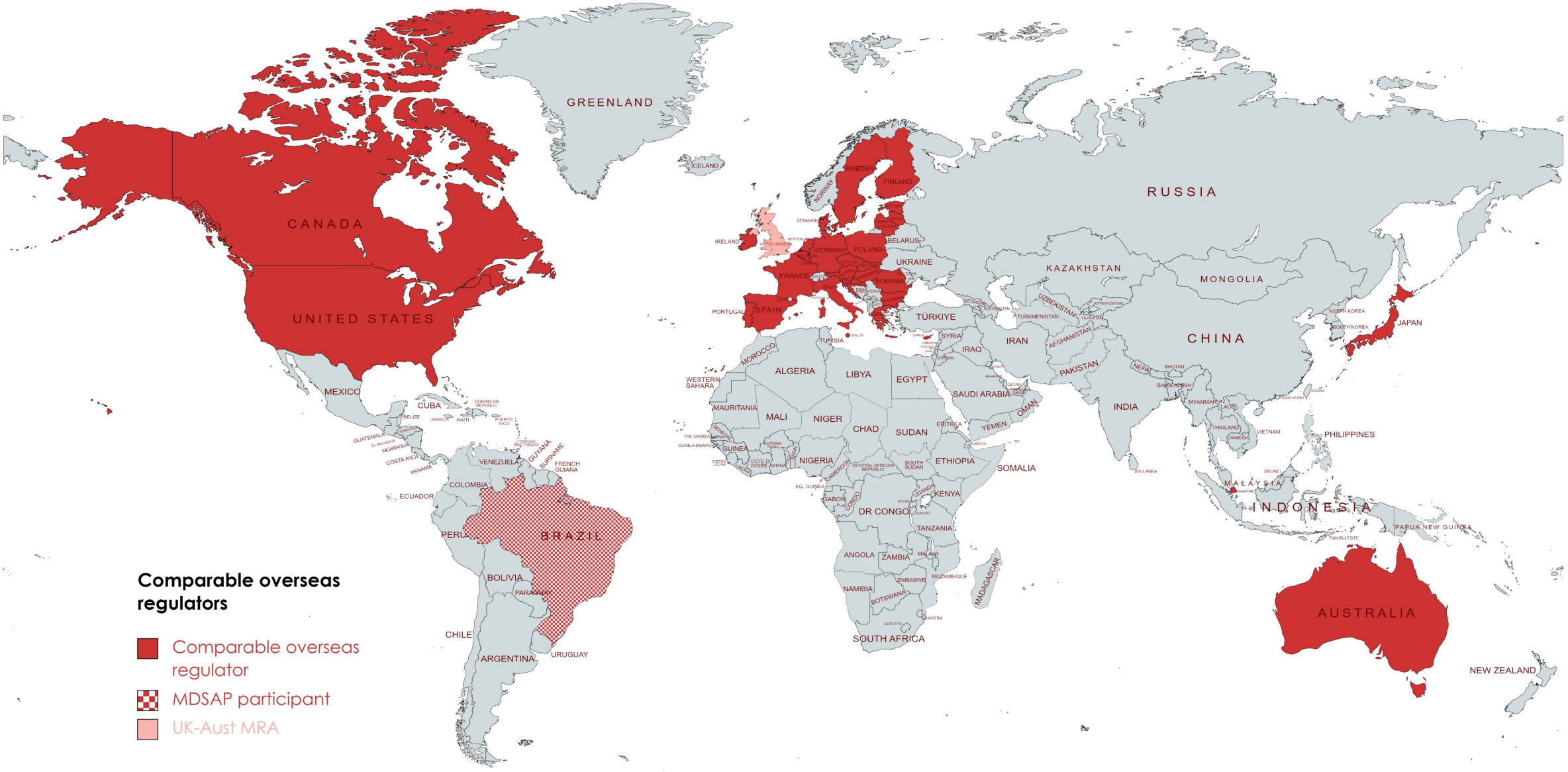
What is regulatory reliance?

Reliance. The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

Mutual recognition agreement. According to a definition issued by the Organisation for Economic Co-operation and Development (OECD), a mutual recognition agreement is: a principle of international law whereby states party to mutual recognition agreements recognize and uphold legal decisions taken by competent authorities in another member state. Mutual recognition is a process which allows conformity assessments (of qualifications, product…) carried out in one country to be recognized in another country.

Recognition. Acceptance of the regulatory decision of another regulator or trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.

Australian context - Comparable overseas regulators framework

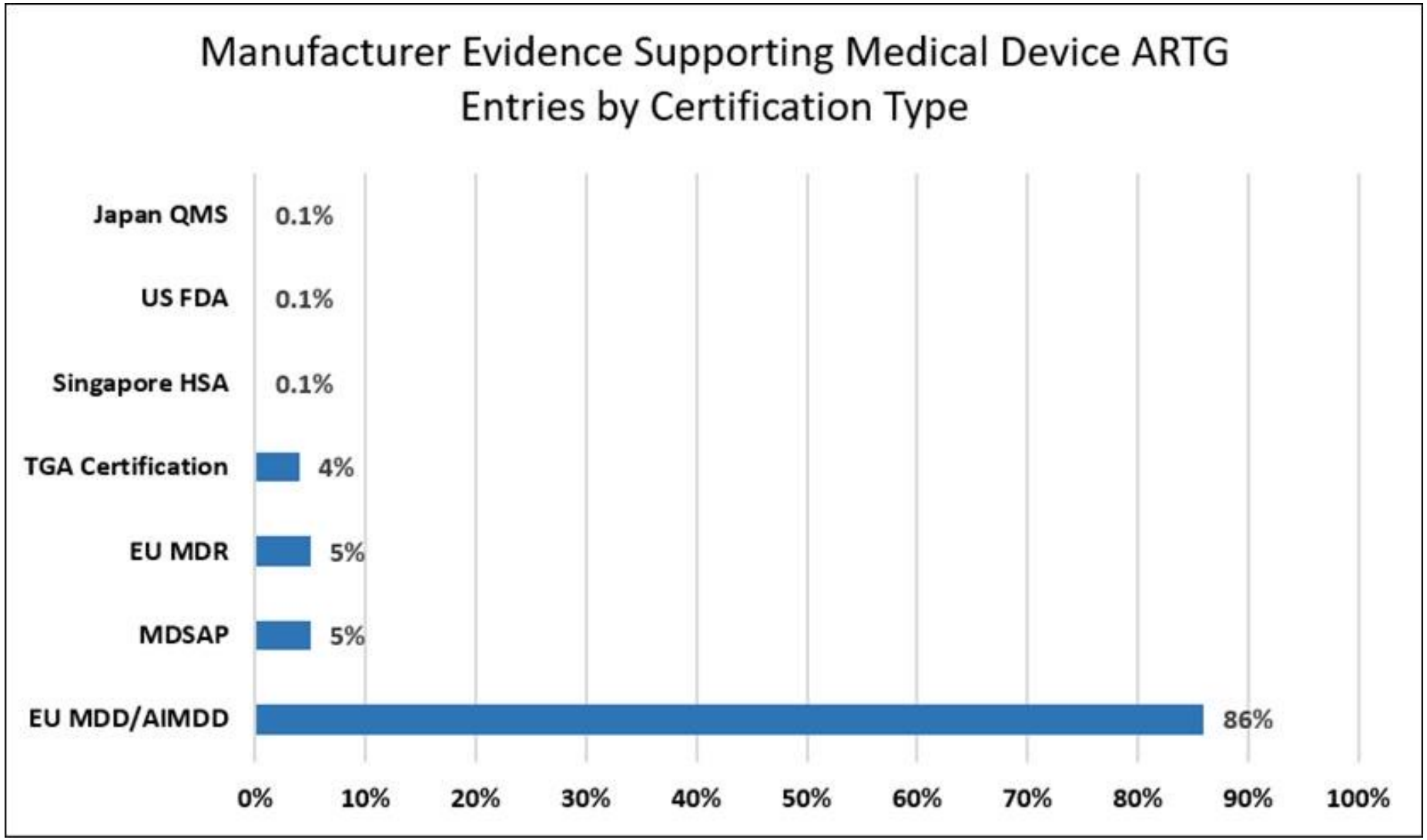


Criteria for comparable overseas regulators - TRUST

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**

- This is an Australian Government decision.
- The TGA advises Government based on these criteria after liaising with the other regulator.
- The outcome is expressed in a Determination – a legal instrument.

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



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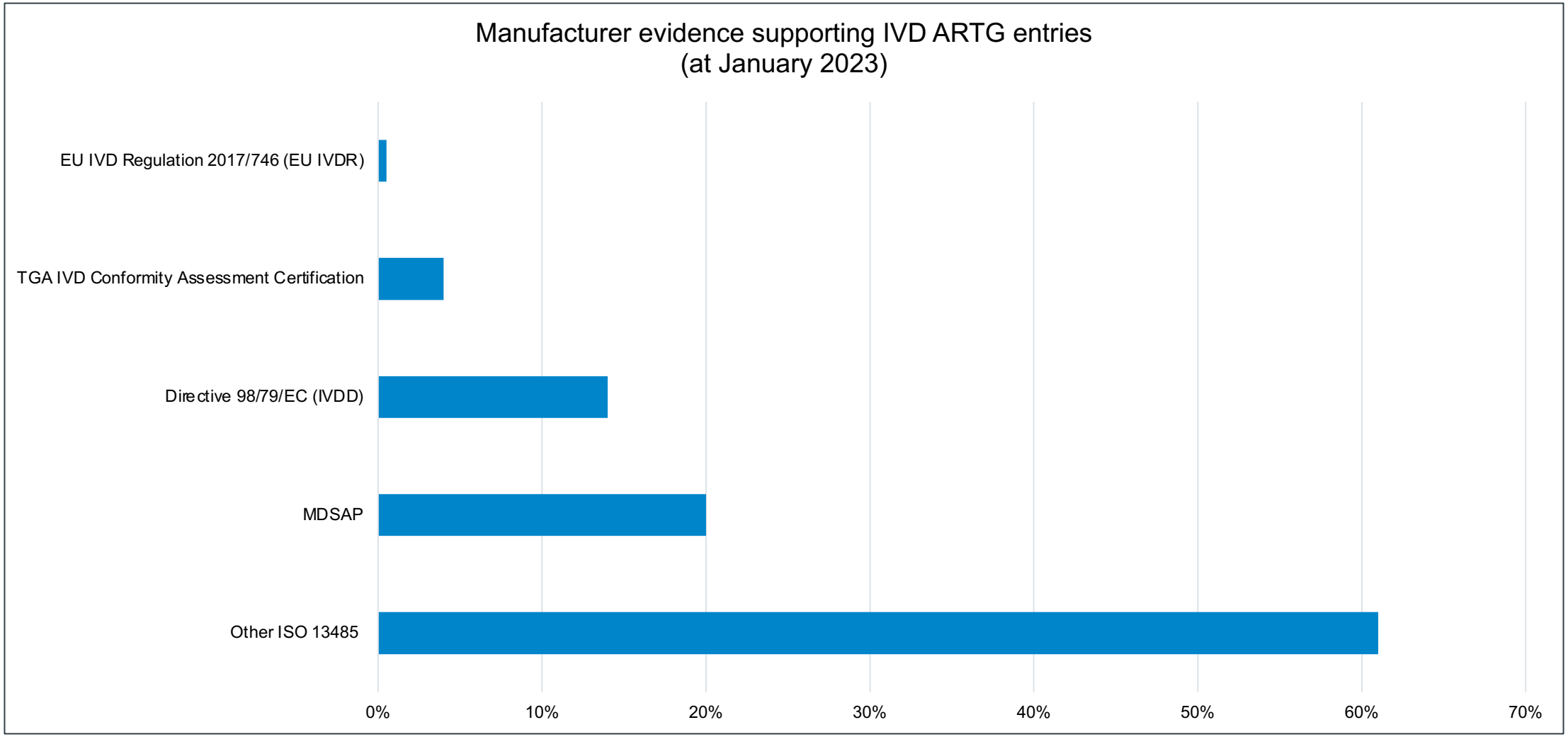

International Medical Device Regulators Forum

Regulatory convergence - Implementation of IMDRF technical documents where appropriate for Australian regulatory framework – future publishing of implementation table

IMDRF Working Groups – supports convergence and reliance

- Adverse Event Terminology
- Artificial Intelligence Medical Devices
- Good Regulatory Review Practices
- Medical Device Cybersecurity Guide
- Personalized Medical Devices (WG Chair)

Challenges - “same but different” divergence (e.g., UDI, SaMD) during adoption processes

Medical Device Single Audit Program (MDSAP)

One inspection report used by 5 regulators – Australia, Canada, Japan, Brazil, USA. Observers are the UK and EU.

Benefits – reduced effort, combined expertise, reduced regulatory burden and cost for manufacturers and regulators

Challenges – consistency between Auditing Organisations, country specific requirements, centralised access to documents

Enhancements

- Increasing capacity of Auditing Organisations (assessors, more efficient audits through remote/virtual options)
- Monitoring performance of AOs, timelines and quality of AO reports
- Quicker identification, escalation and resolution of issues

Benefits

- Faster access to technology to improve the health of citizens
- Reduced duplication of regulatory effort
- Regulation costs less and lets the TGA do more with what we have
- Better export access for Australian industry
- We are part of the global regulatory infrastructure
- Shared regulatory science - knowledge and relationships

Lessons and challenges

- Relationships with other national regulators are crucial to success
- IMDRF requires investment
- Late night meetings and travel – it is hard work being distant from regulatory colleagues
- Domestic stakeholders may see reliance as a threat to sovereignty
- Need broad support from domestic industry, healthcare and Government to resist bespoke requirements

Future

- The TGA continues to build experience with comparable overseas regulator approvals (including EU MDR & IVDR)
- UK MHRA – reliance & recognition discussions underway
- Phasing out acceptance of International Accreditation Forum (IAF) Multilateral Arrangement (MLA) ISO 13485 certificates for IVDs

Assistance and further resources

- TGA Website
  - https://www.tga.gov.au

- TGA comparable overseas regulators
  - www.tga.gov.au/resources/resource/guidance/comparable-overseas-regulators-medical-device-applications

- Medical devices information unit
  - Email devices@tga.gov.au
  - Phone 1800 141 144
  - Inclusion process www.tga.gov.au/publication/medical-device-inclusion-process

Questions?

www.tga.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration