Medical Device Regulatory Convergence Project (MDRC) Good Regulatory Practices & Technical Competencies

Reliance applied to Medical Devices & IVDs International References and Experiences of National Regulatory Authorities

John Jamieson

Medical Devices Authorisation Branch

Therapeutic Goods Administration

Australia

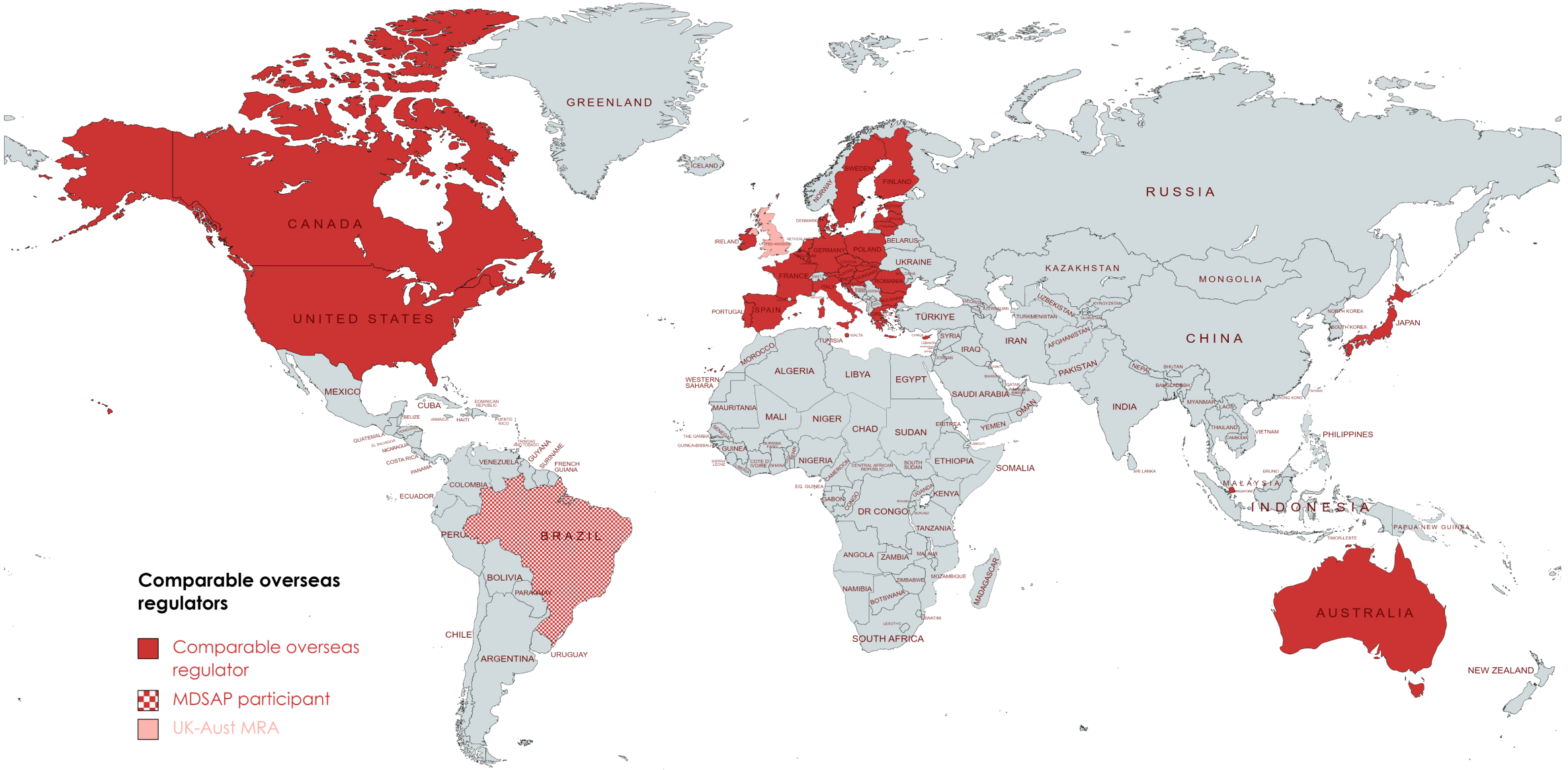
Outline

Reliance in Australia

- Comparable overseas regulator framework
- Medical devices (it is mostly the EU)
- IVDs are different (it is mostly not the EU)
- Future

Why reliance?

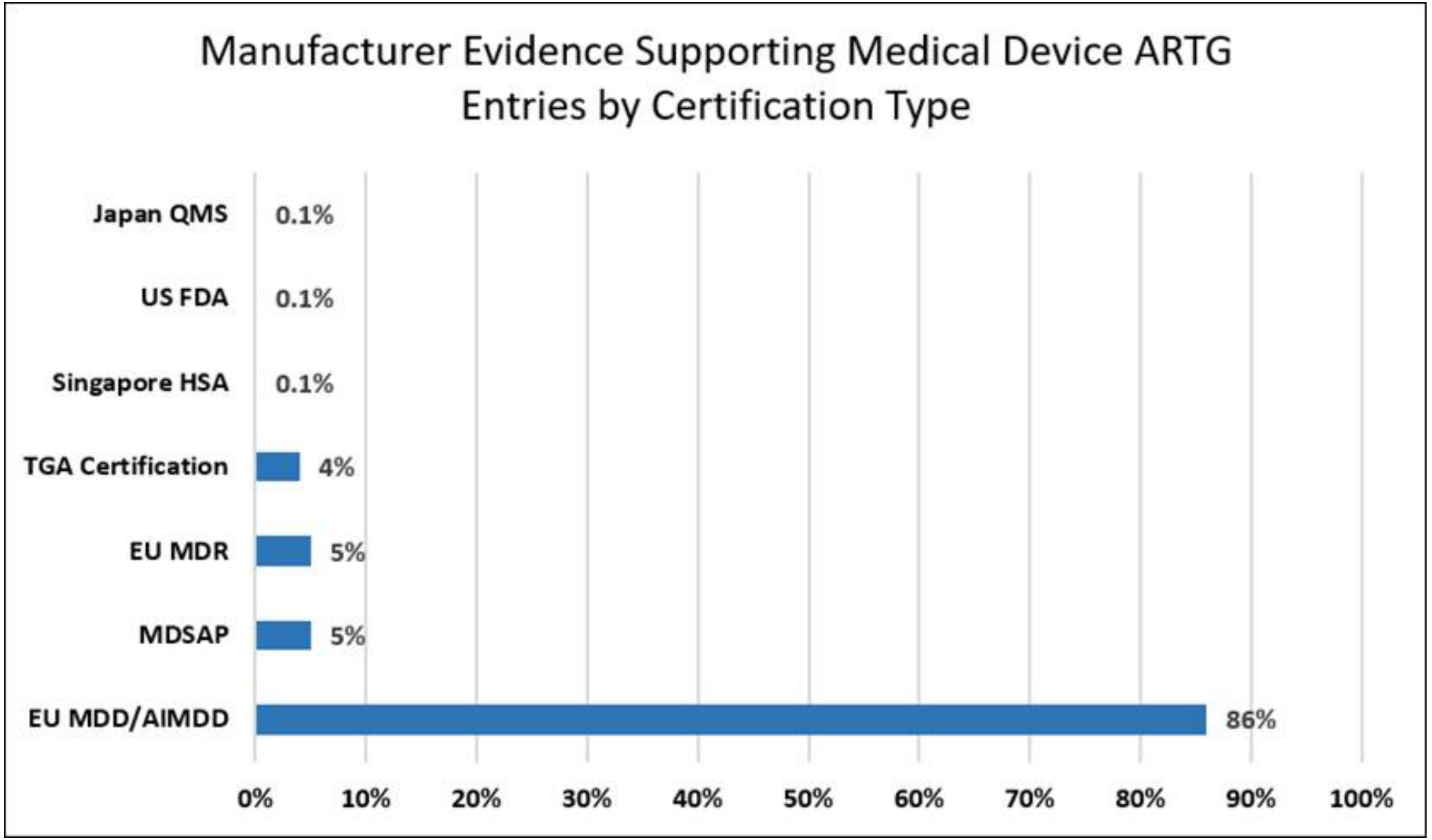
Lessons and challenges

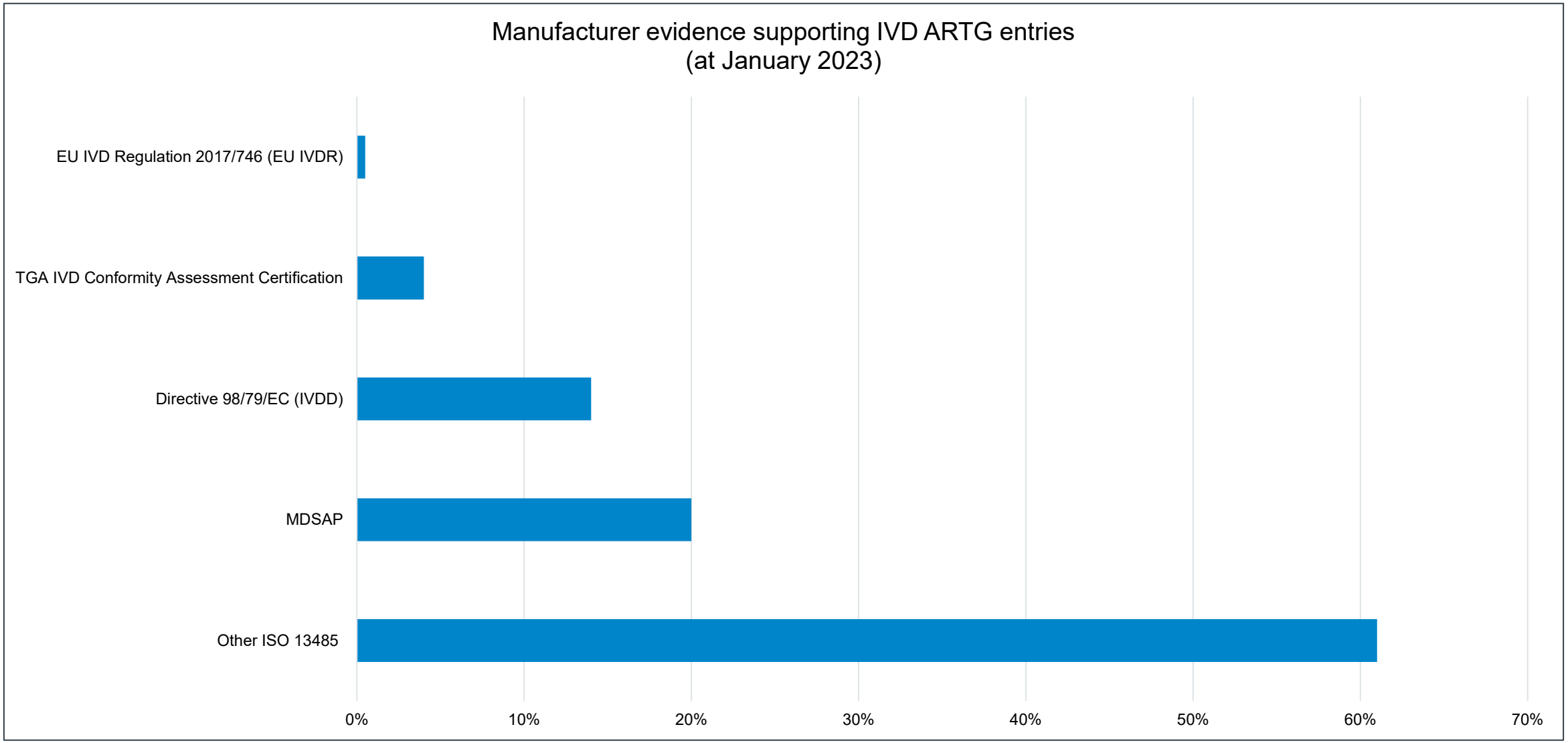

Comparable overseas regulators
Comparable overseas regulator
MDSAP participant
UK-Aust MRA
CANADA
UNITED STATES
GREENLAND
ICELAND
RUSSIA
MEXICO
CUBA
BRAZIL
CHINA
INDIA
AUSTRALIA
INDONESIA
JAPAN
NEW ZEALAND
SOUTH AFRICA
Created with mapchart.net

Criteria for comparable overseas regulators

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.


Manufacturer Evidence Supporting Medical Device ARTG Entries by Certification Type
Japan QMS
0.1%
US FDA
0.1%
Singapore HSA
0.1%
TGA Certification
4%
EU MDR
5%
MDSAP
5%
EU MDD/AIMDD
86%
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%


Manufacturer evidence supporting IVD ARTG entries
(at January 2023)
EU IVD Regulation 2017/746 (EU IVDR)
TGA IVD Conformity Assessment Certification
Directive 98/79/EC (IVDD)
MDSAP
Other ISO 13485
0%
10%
20%
30%
40%
50%
60%
70%

Future

- 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

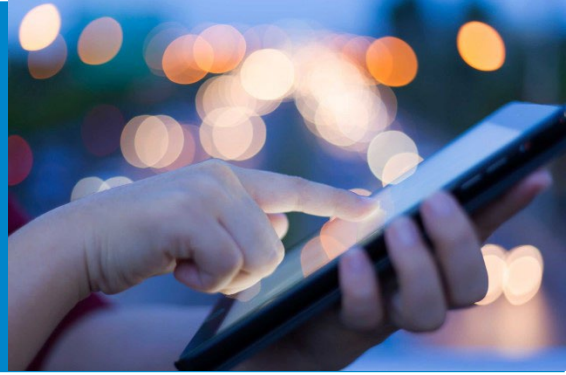
Why reliance?

- Faster access to technology to improve the health of Australians
- 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 and this pays off
- 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

Website references



TGA website	www.tga.gov.au
TGA comparable overseas regulators	www.tga.gov.au/resources/resource/guidance/comparable-overseas-regulators-medical-device-applications
International Medical Device Regulators Forum (IMDRF)	www.imdrf.org

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration