



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

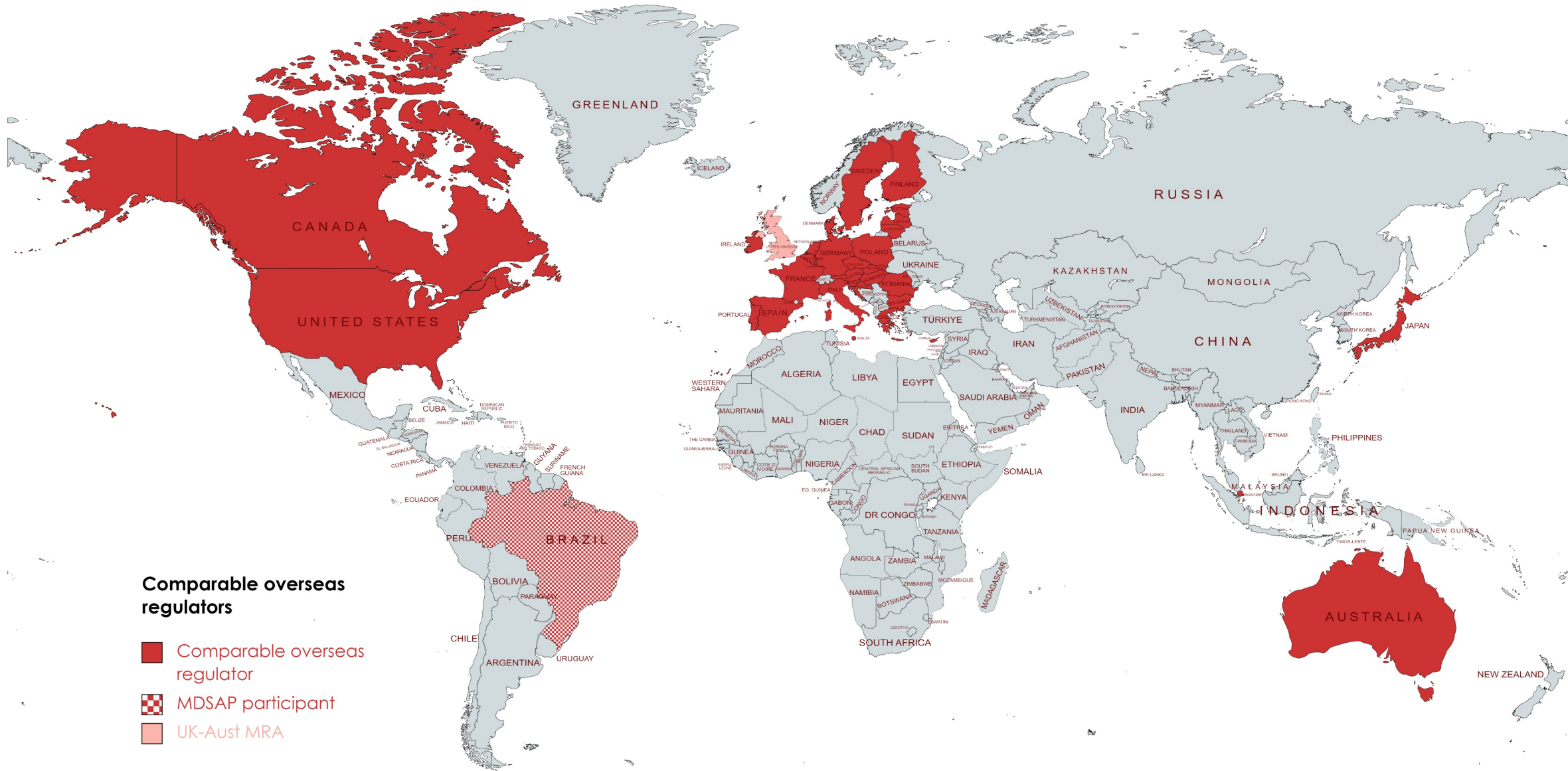
## Reliance in Australia

- 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





# Criteria for comparable overseas regulators



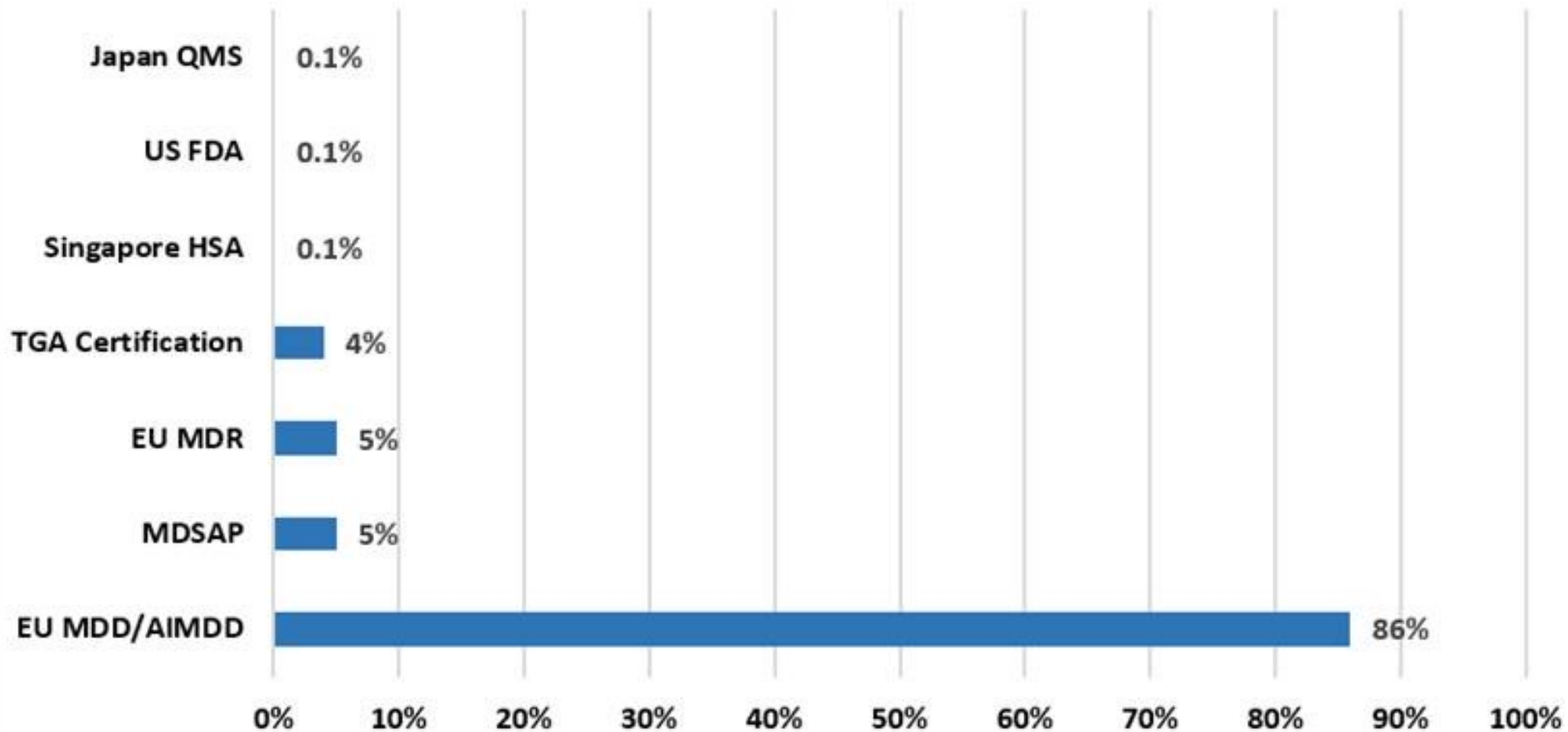
- 1. Comparability of the regulatory framework**
- 2. IMDRF membership**
- 3. Life cycle approach and post-market vigilance**
- 4. Communication and cooperation with overseas regulators**
- 5. Expertise of the overseas regulator**

This is an Australian Government decision.

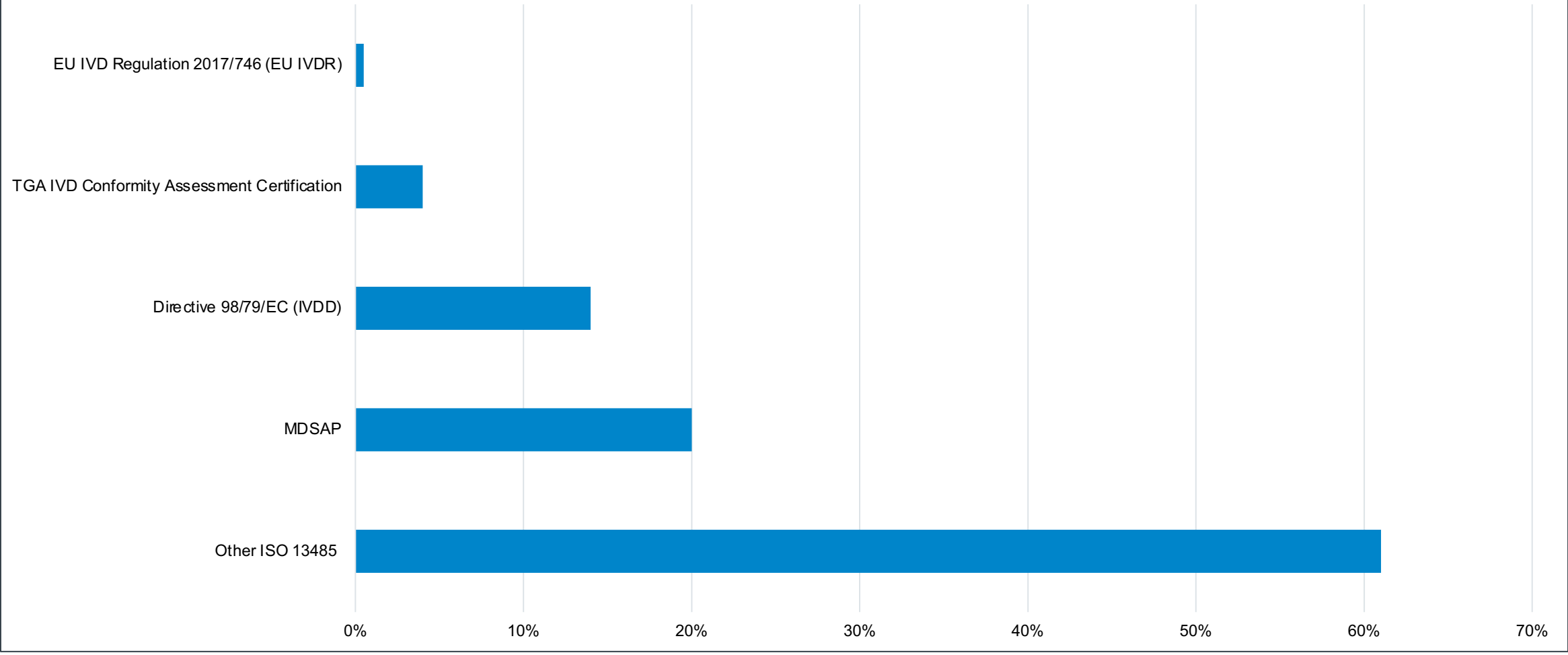
The TGA advises Government based on these criteria after liaising with the other regulator.

The outcome is expressed in a Determination.

## Manufacturer Evidence Supporting Medical Device ARTG Entries by Certification Type



### Manufacturer evidence supporting IVD ARTG entries (at January 2023)



## 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

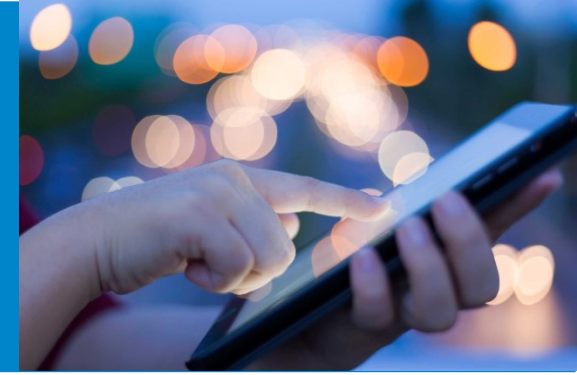


# Lessons and challenges

- 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	<a href="http://www.tga.gov.au">www.tga.gov.au</a>
TGA comparable overseas regulators	<a href="http://www.tga.gov.au/resources/resource/guidance/comparable-overseas-regulators-medical-device-applications">www.tga.gov.au/resources/resource/guidance/comparable-overseas-regulators-medical-device-applications</a>
International Medical Device Regulators Forum (IMDRF)	<a href="http://www.imdrf.org">www.imdrf.org</a>



**Australian Government**

---

**Department of Health and Aged Care**  
Therapeutic Goods Administration