Examples of standards frameworks and regulatory reliance

IMDRF Training
Use of international standards in medical device regulation
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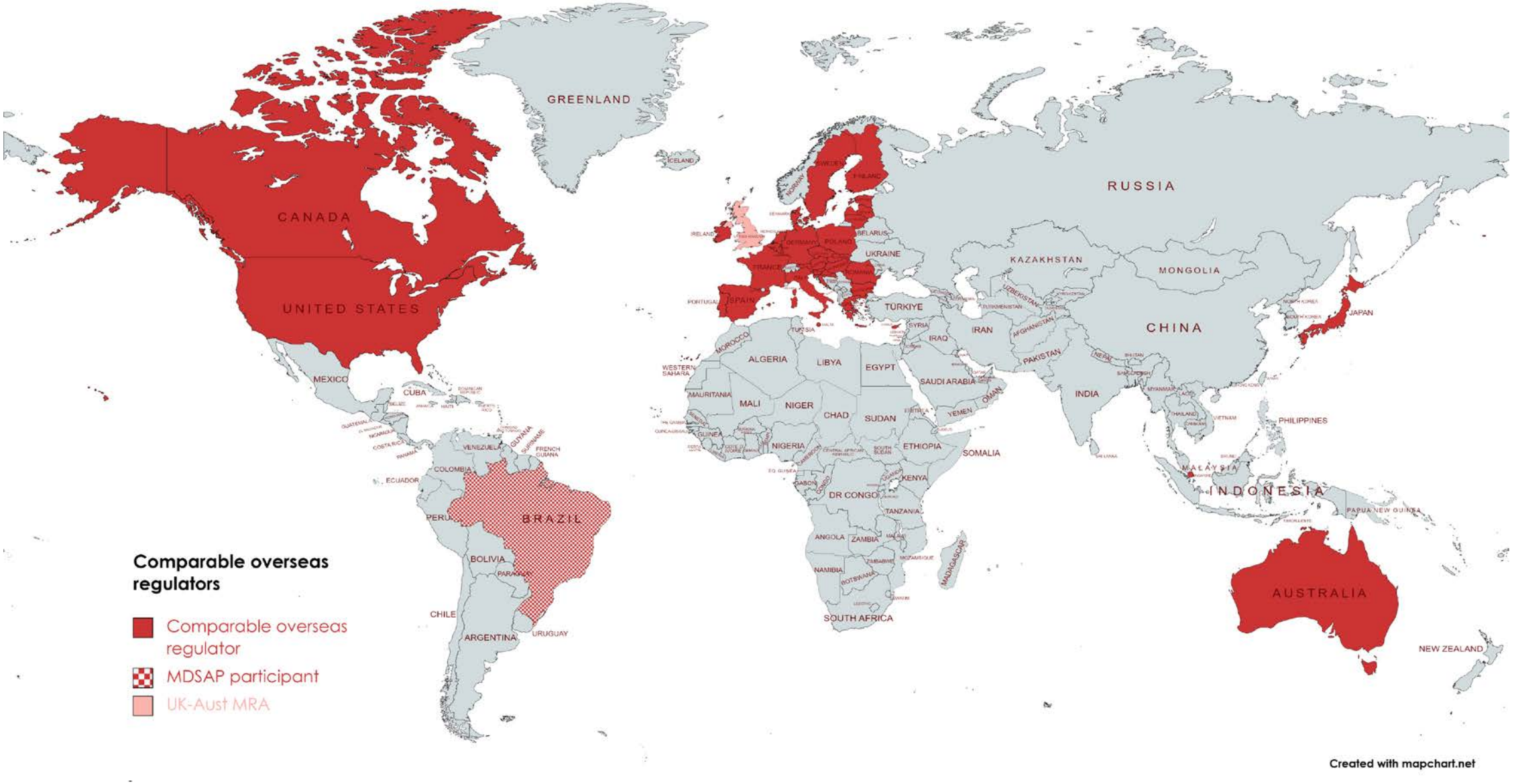
Outline

- Australian reliance framework
- Comparable overseas regulator criteria
- TGA reliance pathways
- Benefits and challenges
- Role of standards in reliance
- Regulatory use of standards
- Quality management systems example
- IVD example
- MDSAP example

Australian medical device reliance arrangements



Comparable overseas regulator criteria

Trust & 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: the Australian Government decides.
The TGA advises the Government based on the above criteria after liaison with the other regulator and the outcome is expressed in a Determination (legal instrument).

Legislation to support reliance

- *Therapeutic Goods (Overseas Regulators) Determination 2018*

  Lists entities that are overseas regulators under the Therapeutic Goods Act

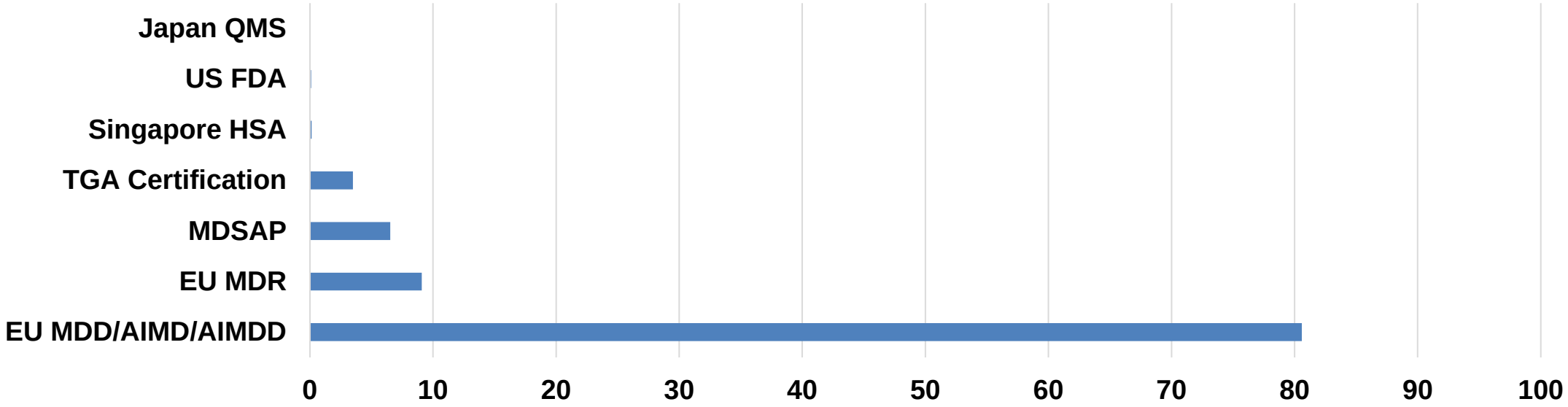
- *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*

  Lists the information (eg certificates and evidence of approval) that must be in a premarket application

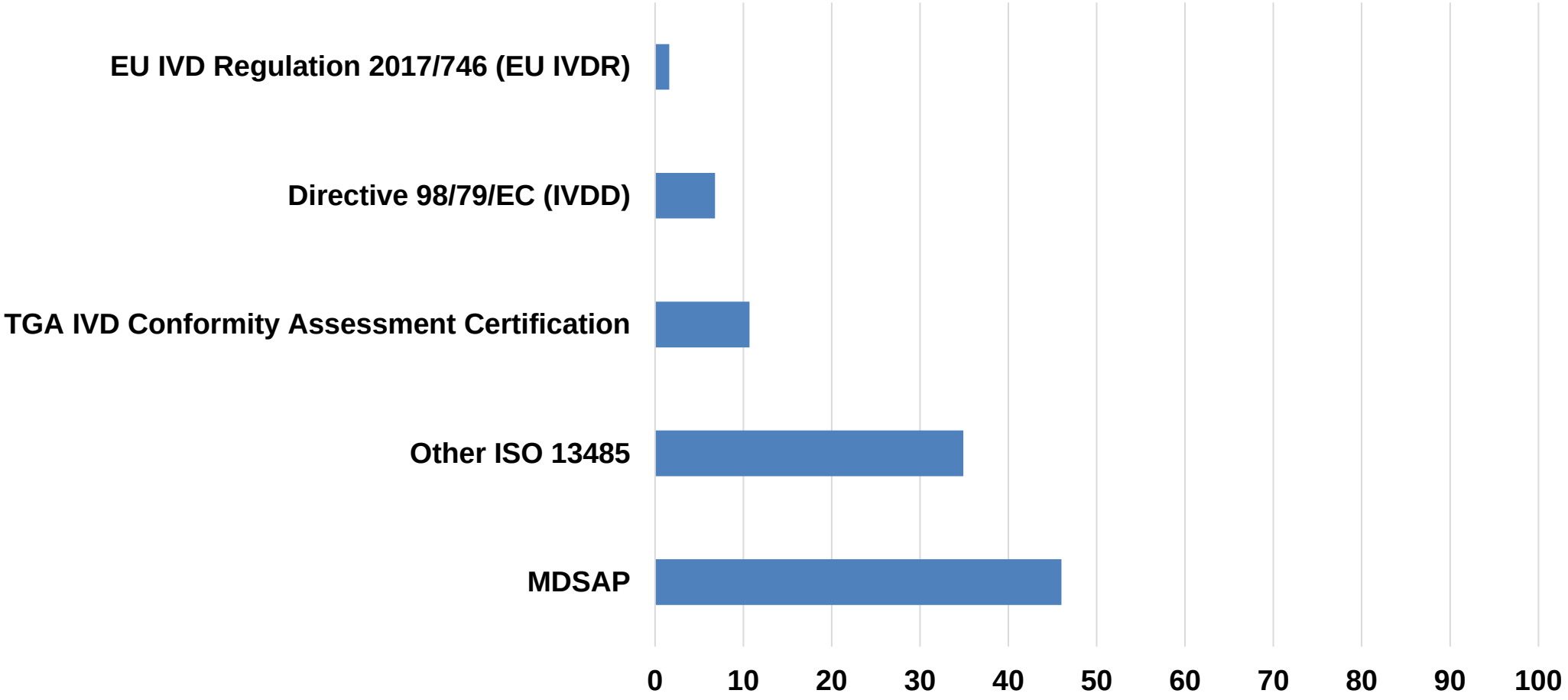
Class III medical device example

Comparable Overseas Regulator	Evidence required to support an application
Health Canada	MDSAP + Medical device licence Class IV
Japan PMDA	MDSAP + Pre-market approval certificate
EU MDR	Annex IX(QMS) + Annex IX (Technical documentation)
EU MDD	Annex II.3 (QMS) + II.4 (design exam)
US FDA	PMA or MDSAP + 510(k)
Singapore HSA	Singapore Register of Health Products Class D medical device

Reliance pathways – non IVD medical devices



Reliance pathways – IVD medical devices



Benefits of reliance

- 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 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 or guidance across jurisdictions
- Other mechanisms such as information sharing agreements, Mutual Recognition Agreements and Memoranda of Understanding

What about standards?

Remember the first criteria?

Comparable overseas regulator criteria

Trust & confidence

1. Comparability of the regulatory framework
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What about standards?

Criteria 1:

Comparability of the regulatory framework

International standards are what allows reliance to work!

Without common standards, regulators cannot “speak the same language”

Australian Regulatory Requirements

Conformity Assessment

QMS (Manufacturer)

Could include:

- Overview of manufacturing stages
- Quality manual
- Purchasing requirements/supplier control
- Process validations and Change Controls
- Procedures for post-market monitoring system

Product Assessment

Could include:

- Device Description and History
- Essential Principles Checklist
- Risk Analysis and Control Summary (e.g. ISO 14971)
- Design and Manufacturing Information
- Clinical Evidence Report
- Performance Evaluation
- Product Validation and Verification
- Stability
- Information to be Supplied with the Medical Device

Essential Principles

1. Use of medical devices not to compromise health and safety
2. Design and construction of medical devices to conform to safety principles
3. Medical devices to be suitable for intended purpose
4. Long-term safety
5. Medical devices not to be adversely affected by transport or storage
6. Benefits of medical devices to outweigh any side effects
7. Chemical, physical and biological properties
8. Infection and microbial contamination
9. Construction and environmental properties
10. Medical devices with a measuring function
11. Protection against radiation
12. Medical devices connected to or equipped with an energy source
13. Information to be provided with medical devices
14. Clinical evidence

Standards – relevance and usage in Australia

- The Australian medical device regulatory framework is “principles based” and does not prescribe compliance with specific standards.
- Manufacturers must demonstrate compliance with the Essential Principles.
- This allows technological advances and changes in the development of new medical devices.
- Manufacturers demonstrate compliance with relevant generally acknowledged state-of-the-art and best-practice, via technical standards, guidelines, or other validated methods.
- The TGA uses international standards as the basis for verifying quality and performance of therapeutic goods when conducting pre- and post-market reviews, investigations and testing.

Standards Orders

- Australian legislation can give manufacturers assurance that certain standards are recognised and accepted.
- Used sparingly and only as needed
- TGA Medical device standards orders
  - *eg Therapeutic Goods (Medical Device Standard – Therapeutic Vaping Devices) Order 2023*
- TGA Conformity assessment standards orders
  - *Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019.*

Standards – QMS example

Manufacturer demonstrating compliance with some of the accepted international standards can claim compliance with Australian regulatory requirements (i.e., conformity assessment and Essential principles) for medical devices.

- Example: If a manufacturer's Quality Management System (QMS) complies with the ISO 13485 standard, the TGA will treat the QMS to comply with the relevant parts of the conformity assessment procedures. This is specified or enforced through the TGA’s Conformity assessment standard order.

Standards – IVD Example

International standards help to establish the state of the art by clearly communicating known hazards relevant to the types of devices they describe and how their potential for impact can be determined. For example: TGA accepts the following as representing state-of-the-art standard for IVD medical devices:

- ISO 14971 addresses principles and processes for risk management of medical devices
- ISO 23640 addresses stability requirements for IVD medical devices

Guidelines from other regulators with comparable evaluation frameworks are adopted by the TGA and considered state of the art. For example:

- WHO guidelines and European Common technical specifications outlining the requirements for Rapid Antigen Tests
- CLSI EP19-ED2:2015 A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures, outlining clinical evidence requirements for IVD medical devices.

Standards – MDSAP example

- The TGA is a founding member of the Medical Device Single Audit Program
- MDSAP allows a manufacturer to have a single quality management system audit that satisfies the requirements of all participating regulatory authorities
- Other official members: ANVISA Brazil, US FDA, Health Canada, Japan PMDA
- A growing number of Observer members and Affiliate members
- The regulatory authorities assess and recognise independent auditing organisations to audit manufacturers under the program

Standards play a critical role

- Auditing organisations must meet ISO 17021:2015 + IMDRF documents
- Manufacturers must meet ISO 13485:2016 + Audit Approach document

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration