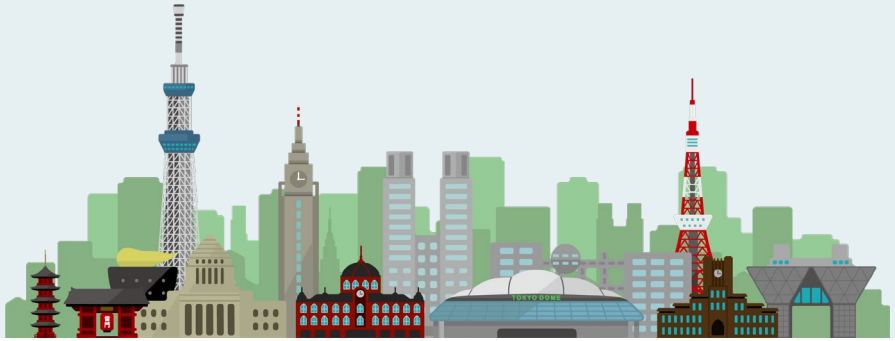
IMDRF International Medical Device Regulators Forum



Sharing jurisdictional case studies and challenges in expanding reliance

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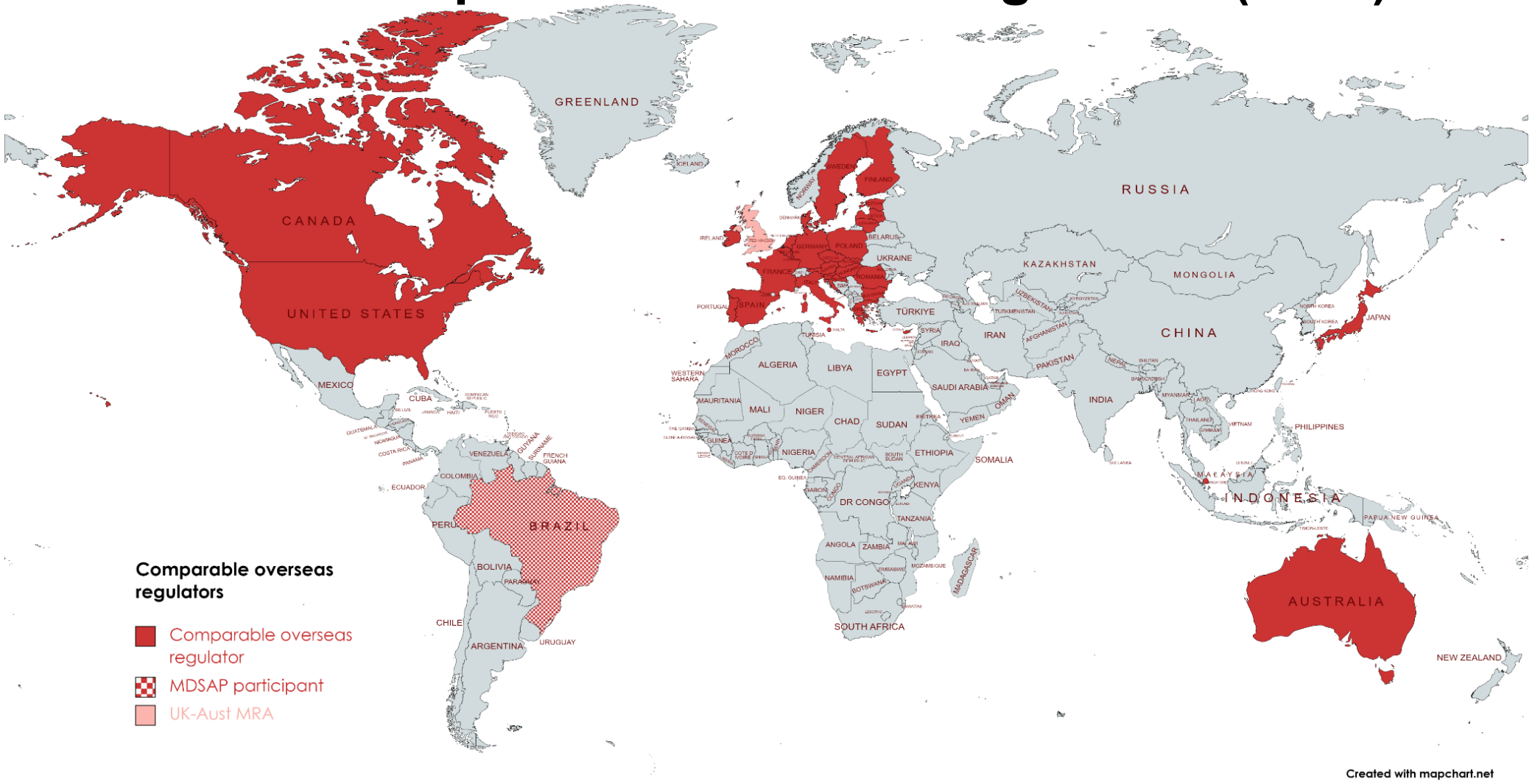
Joint Workshop March 2025

IMDRF International Medical Device Regulators Forum

Australia – Comparable Overseas Regulators (COR) framework



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

- Decision is made by the Australian Government
- The TGA advises the Government based on the above criteria after significant liaising with the other regulator
- 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)

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Australia – Expanding pre-market reliance through recognising Comparable Overseas Regulators

Oct 2018	Sep 2022	Oct 2024	Discussions underway
EU Notified bodies Health Canada Japan PMDA, MHLW MDSAP Auditing Organisations US FDA	Singapore HSA	US FDA*	UK MHRA Brazil ANVISA

*Expanded reliance pathways:

- Class III devices: MDSAP Certification + USFDA 510(K) clearance
- Class IIa devices exempt from USFDA regulation: MDSAP Certification + evidence of exemption from USFDA 510(K) regulation

Pre-market reliance example – Types of acceptable COR evidence* for Class III medical devices

Comparable Overseas Regulator	Documents accepted by TGA to support a Class III Medical Device application
Health Canada	MDSAP + Medical device licence Class IV
Japan MHLW/PMDA	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 HSA	Form supporting entry in Singapore Register of Health Products as a Class D medical device

*The TGA remains independent in reaching its own decision, even when relying on decisions, assessments and information from other regulatory authorities

Post-market reliance – MDSAP

Auditing Organisation reports

- Auditing Organisations audit manufacturers annually – reports are shared through the electronic platform REPs (Regulatory Exchange Platform – secure)
- Regulatory Authorities can access reports on REPs

Australia's post market reliance implementation

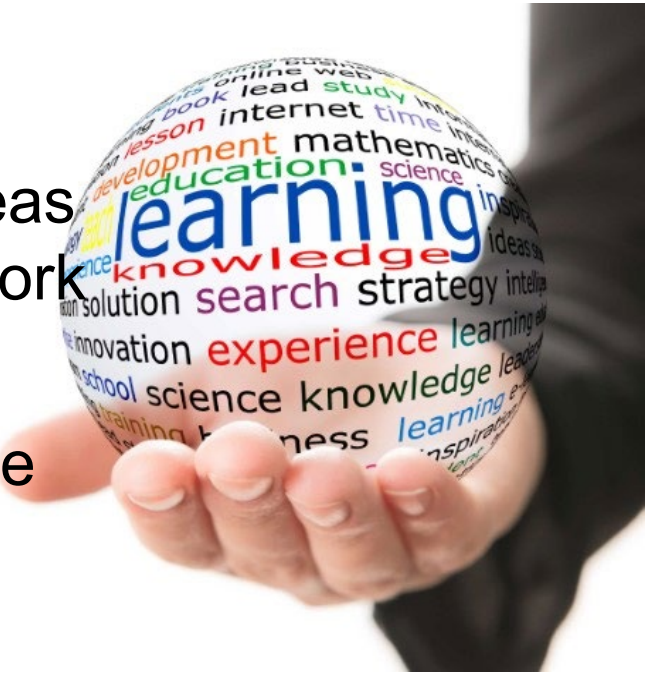
- Auditing Organisation reports are utilized in post market reviews and investigations
- E.g., adverse event reports may trigger an investigation. Auditing Organisation reports are then utilized, alongside other intelligence, to assess risk and determine appropriate compliance actions.

Benefits

- Faster access to safe, effective, innovative medical devices
- Reduced duplication of regulatory effort
- Regulation costs less and lets the TGA do more with what we have
- Quicker identification of post market issues
- 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 – takes time and lots of conversations!!
- Changes to regulatory requirements for a comparable overseas regulator means we need to review them against our framework to ensure we are still comparable (e.g. EU MDR/IVDR)
- Pressure from industry to accept marketing approval evidence from comparable overseas regulators where certain aspects differs (e.g. exemption, classification differences)
- Differing interpretation of legislation and/or guidance within and across jurisdictions, different codes used to identify medical devices



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

OUR KNOWLEDGE OF EU MDR WAS CRITICAL

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 (ACCESS TO CONFIRMATORY INFORMATION WAS CRITICAL).
- 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. (CLEAR INFORMATION FOR MANUFACTURERS IS CRITICAL FOR THEM TO UNDERSTAND WHAT DOCUMENTATION IS REQUIRED)

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
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 this specific use.
- Adverse events poorly reported by surgeons outside of clinical trial.

Outcome:

- Approvals based on a number of changes required for product
- 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.

(SOVEREIGN DECISION FOR SPECIFIC PRODUCT BASED ON INFORMATION PROVIDED)

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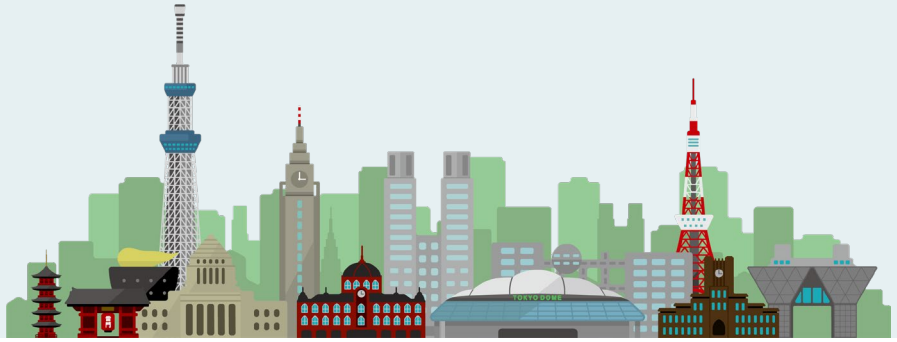

Thank you / Questions

Therapeutic Goods Administration
Australia