Update 2024
Medical Devices Authorisation

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Clinical trials

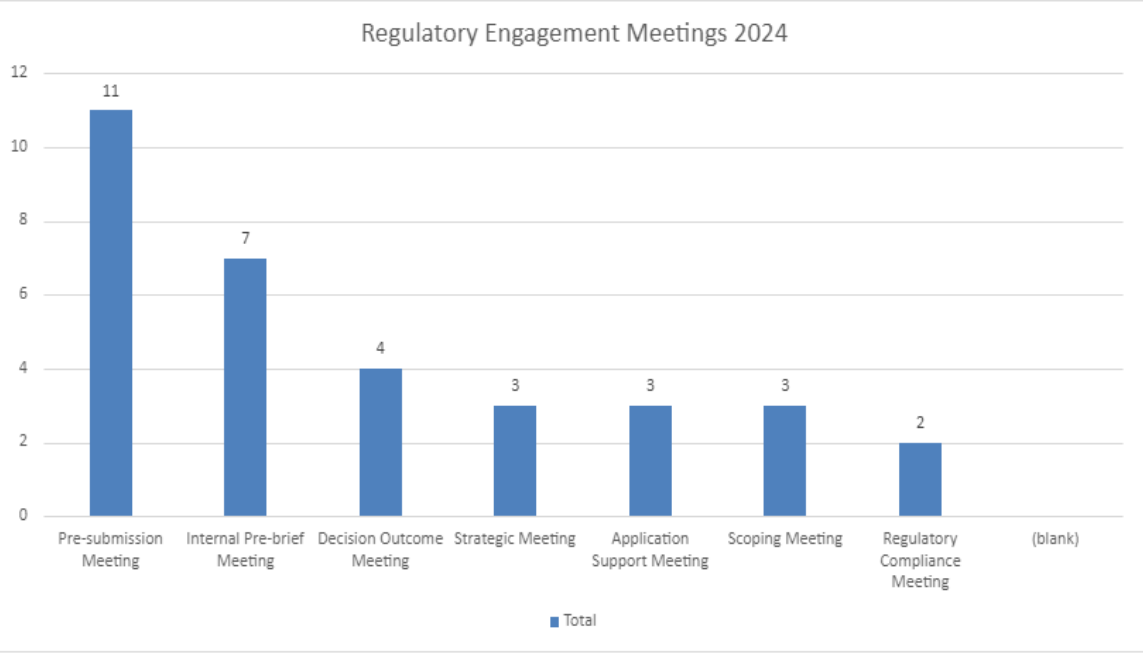
- Legislative changes in November 2023
  - Strengthened powers to request information about devices used in clinical trials
  - Inclusion of medical device trials Good Clinical Practice Inspection Program (GCPIP)
- Clinical Trials Notification (CTN) form updates in April 2024
  - To collect more accurate data about devices studied in clinical trials
- Proactive monitoring of medical device trials, with a focus on first-in-human trials of the highest risk implantable and cardiac invasive devices

Regulatory engagement meetings

(e.g. pre-submission meetings)

The TGA received Government funding for public good activities such as industry engagement and education.

Since February 2024, we started developing improved processes and resourcing to support regulatory engagement meetings of various kinds.



Meeting Type	Description
Scoping	Early days - development of a medical device
Application Support	Questions about how to progress an application
Pre-submission	Sponsor or manufacturer have some final questions before they apply
Decision Outcome	Discussion about a proposed outcome of an application
Regulatory Compliance	Enquiry or concern about regulatory compliance - public, companies
Strategic	Regular meeting with sponsor, manufacturer, peak body or stakeholder

Devices with animal, microbial or recombinant substances

Public consultation closed July 2023

- reviewed the risks for these products
- reviewed microbial and recombinant materials specifically
- reviewed reliance on comparable overseas regulators.

Changes planned to start 1 July 2024

- remove microbial and recombinant materials from Class III (rule 5.5) and associated labelling requirements in Essential Principle 13.4
- exclude other low-risk animal-origin materials from Rule 5.5 e.g. milk, silk, etc.
- aligns with comparable overseas regulators
- rely on all comparable overseas regulators for these devices (not just the EU, also US FDA and others)
- 2-year transition for existing approved devices

TGA conformity assessment certification

New process, timeframes and guidance

If no comparable overseas regulatory approval (EU, US FDA, MDSAP etc.) the TGA can certify the manufacturer.

Refer to newly published guidance for details

Application type	**Target timeframe** business days with TGA	**Maximum Timeframe** business days with TGA	**Applicant days** business days with applicant (contingent on number of questions raised per round)	**Estimated total timeframe** (includes total applicant days)
New or substantial change	160 business days	200 business days	40-100 business days	10-15 months total (~300 – 445 days)
New or change applications with ACMD* advice OR requiring on-site TGA audit of facilities	190 business days	225 business days	40-100 business days	12-16 months total (~330 – 480 days)
Recertification	80 business days	150 business days	40-60 business days	6-10 months total (~185 – 310 days)

* Advisory Committee on Medical Devices (ACMD)

Application audit framework

Public consultation closed September 2023

- criteria for mandatory audits
- reliance pathways and comparable overseas regulators
- risk factors informing non-mandatory audits
- TGA communication and case management processes.

Changes planned to start 1 July 2024

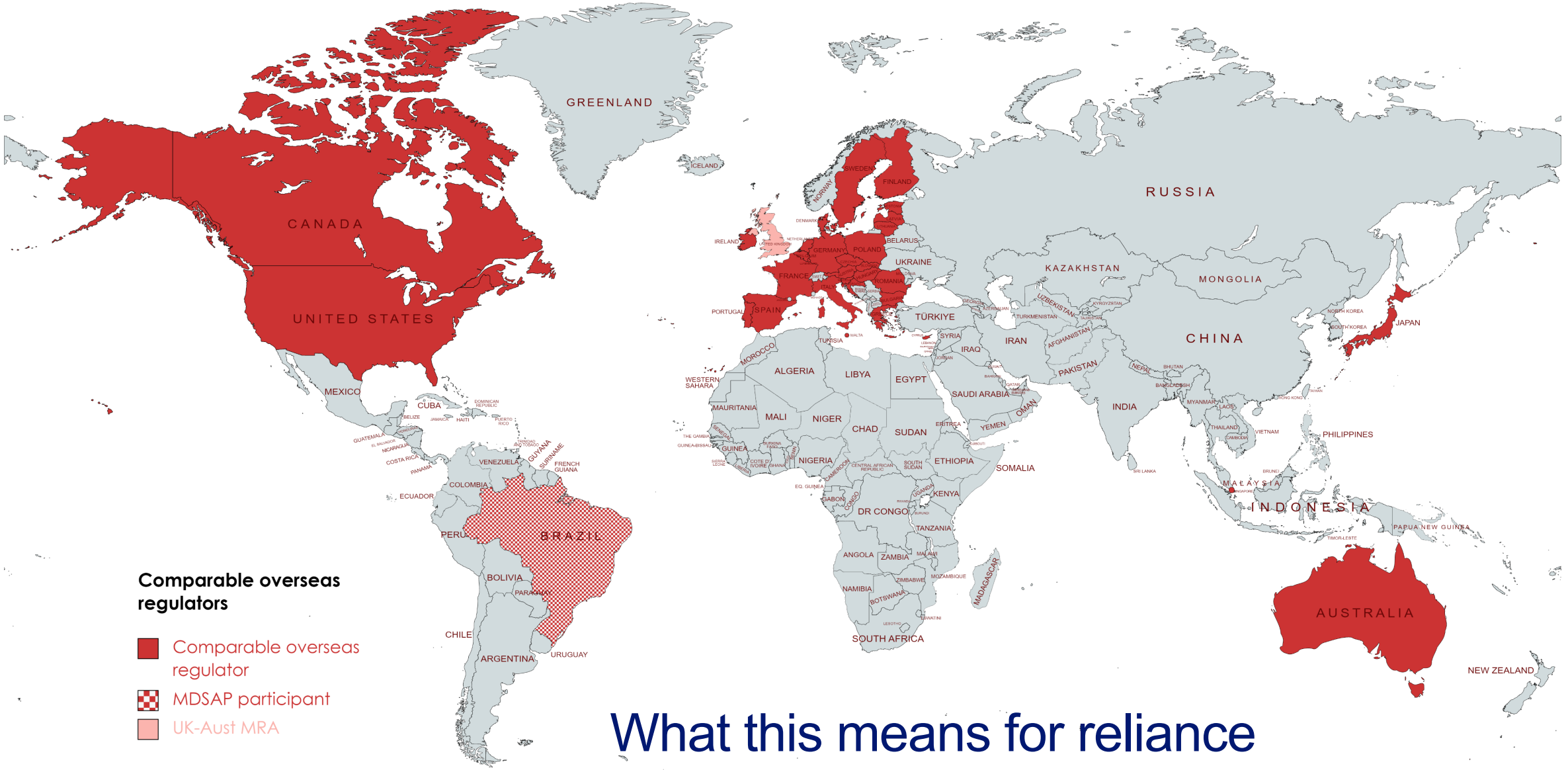
- limit mandatory audits to Class III (no more mandatory audits of class IIb disinfectants, intra-ocular lenses etc.)
- limit IVD mandatory audits to Class 4, Class 3, point-of-care & self-tests
- no mandatory audits for most comparable overseas regulator approvals
- new MDSAP + US FDA 510(k) mandatory audit pathway for Class III medical devices
- On 1 June, we stopped checking the quality of clinical evidence as a risk factor for class III EU MDR devices extend to other comparable overseas regulators on 1 July.
- More work on risk factors and case management (e.g. target timeframes) with an industry working group

Medical Device Single Audit Program (MDSAP)

The TGA chairs the MDSAP Regulatory Authority Council for 2 years

Strengthening the program with the other members:

- new MDSAP website in development
- new members (e.g. HSA Singapore is now an Observer)
- engaging with the EU and UK MHRA
- improving Auditing Organisation designation
- improved experience for Australian sponsors
  (we worked with industry on a revised Audit Approach document)
- look to strengthen support of MDSAP in our Regulations
- hoping to grow beyond 7,000 manufacturers globally
- we encourage manufacturers to use MDSAP



What this means for reliance

Reliance pathways after 1 July 2024

- Medical devices with animal origin or medicinal substances
  - Reliance pathway for all comparable overseas regulators for these devices
  - not just the EU - also US FDA, Japan PMDA and others
- No more mandatory audits of applications with US FDA PMA, Health Canada licence, HSA Singapore approval, Japan PMDA/MHLW approval
  - the same reliance pathway as EU MDR and EU IVDR certification
- Mandatory audits remain for Class III medical devices:
  - with EU MDD certificates, during the EU MDR transition
  - new MDSAP certificate + US FDA 510(k) approval pathway
- Mandatory audits remain for Class 3, 4, point-of-care and self-test IVD medical devices:
  - with EU IVDD certificate, or IAF ISO 13485 certificate + IVDD Declaration of Conformity, during the EU IVDR transition
  - with MDSAP certificate and no product approval from comparable overseas regulators
- TGA conformity assessment certification remains available

Therapeutic Goods Administration (TGA)

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