Regulatory Update from TGA – Australia

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IMDRF International Medical Device Regulators Forum

Medical Device Reforms

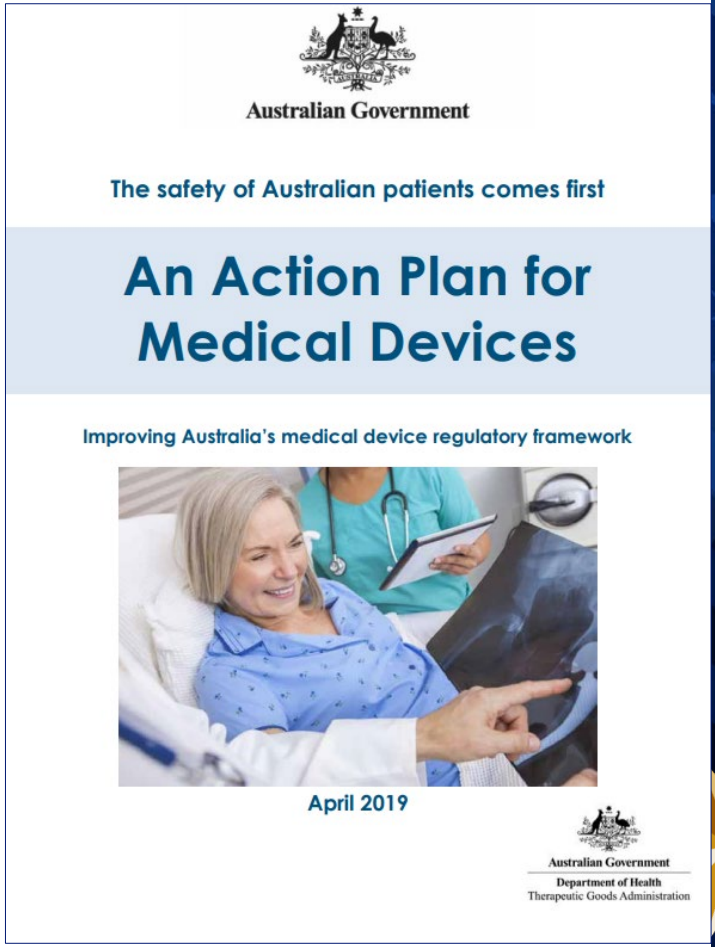
- An Action Plan for Medical Devices
- Impact of European Union Medical Device Regulations (EU MDR)
- Mandatory Reporting of Adverse Events
- Medical Device Vigilance Program
- Point of Care Manufacturing
- Unique Device Identifier (UDI)

An Action Plan for Medical Devices

Continues to guide medical device reforms, taking into account international harmonisation efforts, that:

- strengthen our regulatory system
- remains patient focused
- provides greater transparency and
- increases public confidence in Australia's medical device regulatory system.

Strategy 1	**Pre-market medical device reforms** Improve how new devices get on the market (focus until 2022)
Strategy 2	**Post-market medical device reforms** Strengthen monitoring and follow-up of devices already in use (focus for 2022-2024)
Strategy 3	**Consumer focused reforms** Provide more information to patients about the devices they use



Impact of European Union Medical Device Regulations (EU MDR)

- **Devices subjected to reclassification** – Regulatory amendments made in November 2023 to extend the transition deadline for some transitional devices to 1 July 2029.
- **Patient matched medical devices** - Regulatory amendments made to extend the transition for patient-matched medical devices to 1 July 2029, and notification period for existing patient-matched medical devices to 1 November 2024.
- **UDI** – continued discussions about the differences and impact on the Australian implementation.
- **Software based medical devices** - Transitional arrangement for software based medical devices will not change and the transition ends on 1 November 2024.
- **IVD Classification and Definitions** – Policy work is underway to review and align with European requirements

Mandatory Reporting of Adverse Events

- Mandatory reporting by healthcare facilities (hospitals) Regulations by March 2025
- Conducted six roundtables with states and territories in 2023
- Established inter-jurisdictional steering committee in 2024
  - Provides governance of the mandatory reporting framework
  - Facilitates policy and implementation discussions
- Working towards
  - Data definitions, data fields and classifications
  - Improved interoperability between health care facilities systems and the TGA
  - Hospital Standards Accreditation and guidelines will support compliance (Australian Commission on Safety and Quality in Health Care)

Medical Device Vigilance Program

- Reviews compliance of post market regulatory requirements
- Pilot commenced of a self-assessment tool (SAT) as an educational resource
- Used as a screening tool by the TGA, alongside other intelligence
- Complements existing post-market surveillance activities

Point of Care Manufacturing

- Established steering committee and sector-specific working groups (dental, allied health, in-hospital and complex manufacturing)
- Work underway to map existing regulatory frameworks
  - Identify gaps, overlaps and potential refinements
  - Use of 3D printers for complex manufacturing within healthcare facilities
- Co-designing and developing educational and training materials with sector specific working groups to uplift regulatory knowledge and understanding
- Scope of practice for clinicians, hospital standards, licensing options?

Unique Device Identifier (UDI)

- **Our approach in Australia**
  - Accepting EU and US compliant labels to minimise burden on manufacturers and support global alignment
  - Leveraging international standards and solutions such as the National Product Catalogue and HL7 to minimise administrative burden
  - Engaging with hospitals to support adoption
- **Progress update**
  - Australian UDI Database in pre-production, and includes functionality for patient information leaflets (PILs) and electronic instructions for use (eIFUs)
  - Identified an initial set of learnings on UDI adoption from pilot
- **Challenges**
  - Practical approach for managing changes to UDI data for devices with more than one Australian supplier
  - The level of change to the regulatory environment is delaying finalisation of the regulation changes
  - High operational demands on hospitals limiting our ability to increase understanding and readiness for adoption

International Engagement

- **International Engagement Strategy 2021-2025**
- **Recent/Ongoing Activities**

International Engagement Strategy 2021-2025

- **Advancing Australia's health through international regulatory engagement**
  - **Global policy alignment**
    - **IMDRF guidance, Mutual Recognition Agreements**
  - **Pre-market global collaboration**
    - **IMDRF, WGs, workshops, MDSAP, conferences**
  - **Post-market global monitoring**
    - **IMDRF, WGs, workshops. MDSAP, conferences**
  - **Regional regulatory capabilities**
    - **Regulatory Strengthening Program**
    - **Pacific Medicines Testing Program**

Challenges

Software and AI

Boundary and Combination Products

Therapeutic and Recreational Vapes

Software and AI

General challenges

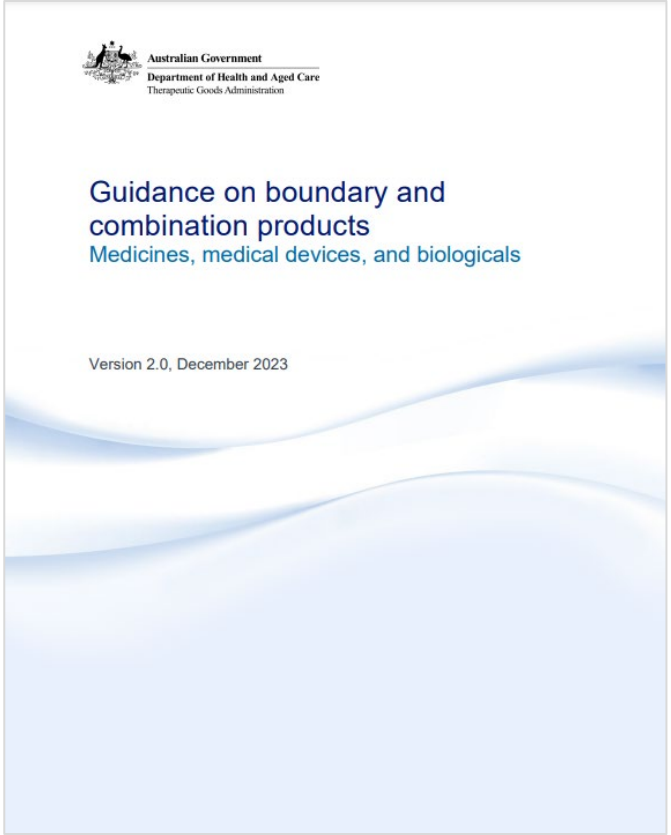
- Rapid development and **diversity** of AI products – including generative AI like ChatGPT, Bard etc
- Often the use of AI is **not transparent** – unable to verify performance and manage risks
- Anecdotal reports of errors in AI – **validation** is critical to ensure **accuracy** and **generalisability**
- Massive data lakes being collected – **privacy** and **consent** continue to be significant

Regulator specific challenges

- Plenty of entities wanting to be a part of the AI solution - where does the regulator fit in the overarching national AI strategy?
- What does post-market monitoring look like to manage risks of unintended bias, model performance degradation and off-label use?
- Observations on applications that include AI:
  - Training and testing data sets not clearly demarcated – risk of overfitting
  - Inadequate assurance that all “borderline” cases within intended use can be accurately classified
  - Intended use does not specify specimen type, equipment (source of input data) type, and how output is integrated into clinical decision making

Boundary and Combination Products

- **Boundary products**
  - *"Products with attributes of two or more therapeutic good categories with different intended actions or effects, and the appropriate regulatory pathway is not immediately obvious."*
  - Published updated guidance in December 2023
  - Some challenging examples:
    - Head and body lice treatment products
    - Sensitive toothpaste
    - Moisturisers and emollients
  - Seeking to clarify regulatory pathways through instruments and consult on transitional timeframes for affected products
- **Combination products**
  - *"Products containing more than one type of therapeutic good with more than one therapeutic action or effect."*
  - Reviewing current regulatory approaches



Vaping Reforms - Devices

- **From 1 March 2024 there will be:**
  - a ban on the importation of all vapes without an import licence and permit
  - a requirement for therapeutic vape importers and manufacturers to notify the TGA about compliance with the relevant product standards before importation to Australia or release for supply in Australia
  - some changes to the quality requirements for therapeutic vapes for smoking cessation and the management of nicotine dependence, including restrictions on flavours to mint, menthol and tobacco
  - a new medical device standard for therapeutic vaping devices that were previously excluded from the therapeutic goods framework.
- **Further reforms**
  - a domestic ban on the manufacture, supply, advertising, and commercial possession of disposable vapes, and non-therapeutic vapes to ensure comprehensive controls across all levels of the supply chain
  - product standards for therapeutic vapes will also be strengthened, including to reduce permissible nicotine concentrations, require plain packaging, and enhance the regulatory requirements for vaping devices

Thank you

Therapeutic Goods Administration, Australia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