Australian Government
Department of Health
Therapeutic Goods Administration

EU Medical Device Regulation: Implications for the TGA and Australia

Adj. Professor John Skerritt
Deputy Secretary, Australian Department of Health
AusMedtech Conference, 18 May 2021

TGA Health Safety Regulation

Why did the EU regulations change?

- **Outdated:** did not keep up with technological developments (and regulatory challenges)
- **Lack of consistency:** MDD are directives so don't supersede laws of individual countries
- **Focus on premarket approval but not postmarket performance:** this was not tracked consistently and continued clinical assessment was not mandatory
- **Narrowly focused accountability:** Liability for safety fell on the original manufacturer, without accounting for other companies in the supply/distribution chain
- **Insufficient scrutiny on notified bodies:** Notified bodies contracted by manufacturers focused on premarket assessments and approval
- **Limited and unclear clinical evidence requirements**
- **Exclusion of most IVDs** from regulation, despite serious impacts on personal/public health

BMJ

BMJ 2012;345:e7090 doi: 10.1136/bmj.e7090 (Published 24 October 2012)

FEATURE

MEDICAL DEVICE REGULATION

How a fake hip showed up failings in European device regulation

Deborah Cohen investigates how EU authorities would be prepared to allow a fake hip prosthesis with dangerous design flaws onto the market

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. FOOD AND DRUG ADMINISTRATION

May 2012

Unsafe and Ineffective Devices Approved in the EU that were Not Approved in the US

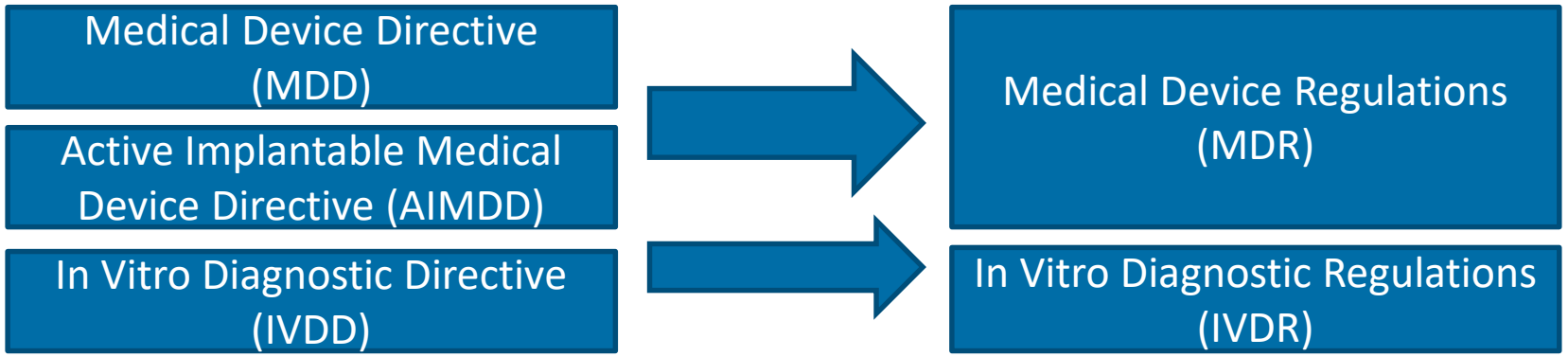
The dilemma for Australia

EU MDR commences 26 May 2021 – but EU have not yet published all the relevant guidance

Aligning with a moving, incomplete and delayed target

And we had to go earlier on some reforms

Main EU changes for Medical devices and IVDs



New EU Medical Device Regulations (MDR 2017/745) and IVD Regulations (IVDR 2017/746)

replace the previous (now very dated)

Medical Device Directive (MDD 93/42/EEC), AIMD Directive (AIMDD 90/385/EEC) and IVD Directive (IVDD – 98/79/EC)

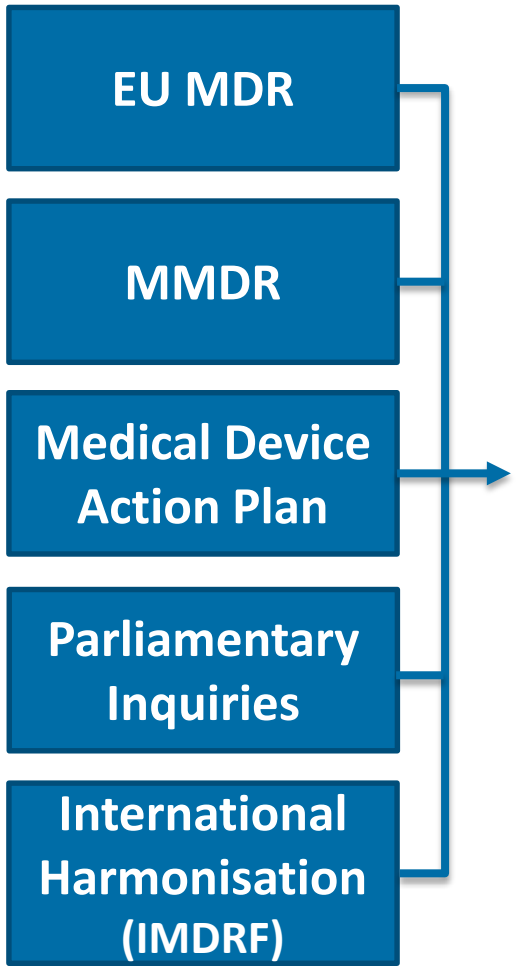
Systemic redesign of the EU regulatory framework

- **Definitions** - new and refinement of existing definitions
- **Scope** – e.g regulation of cosmetic contact lenses, lasers for tattoo or hair removal
- **Reclassifications**
  - Ø spinal implants, active medical devices for therapy with diagnostic function
  - Ø active implantable medical devices and their accessories
  - Ø devices that administer medicines or biologicals by inhalation, skin or body orifice
  - Ø devices in direct contact with the heart, central circulatory or CNS
  - Ø software
- **Notified body designation, governance, use of clinical panels and laboratories**
- **Eudamed database for all devices – premarket and postmarket data/ traceability**
- **Conformity assessment procedures, General Safety and Performance Requirements**
- **Unique Device Identification (UDI) and Packaging labelling and instructions**

Current Australian situation

- Current Australian medical devices framework differs from EU in legislative structure, but the intent is the same
  - Ø EU MDR and IVDR are more prescriptive
  - Ø Australian legislation is principles / outcomes based
- **Greater emphasis** on:
  - Ø application audit
  - Ø clinical evidence requirements of manufacturers; and
  - Ø strengthening of post market surveillance
- Challenges associated with **timing of changes**

Australian regulatory changes



Australian **Conformity Assessment Bodies**

Comparable overseas regulators

Priority pathway for novel devices

Review of **low risk devices** and other therapeutic goods

Alignment with EU MDR

Reforms to IVDs (companion diagnostics, self tests)

Software as a Medical Device (SaMD)

Personalised Medical Devices/ Device Production Systems

Unique Device Identifiers (UDIs)

Enhancement to post market processes

Reclassification of surgical meshes and other devices

Patient materials (implant cards and information leaflets)

Reclassification of non-IVD devices in the EU

Alignment warranted in many **but not all cases?**

- Active devices for diagnosis and therapy
- Spinal implants
- Human cells, tissue, organ storage solutions and IVF media
- Devices in direct contact with heart, CNS, central circulatory system
- Devices that administer medicine by inhalation, body orifices or skin
- Active implantable devices and their accessories
- Devices containing nanomaterials

In parallel, the EU also changing

- Essential Principles and Conformity Assessment Procedures
- Review requirements for Clinical Trials

Australian regulatory changes

Aim to align with EU changes as first principle - but government decisions also based on:

- Best practice from other countries – IMDRF, FDA, comparable regulators
- Input from stakeholder consultations
- Immediate safety concerns – e.g. earlier implementation of patient information materials, mesh up-classifications

Reform process typically includes:

- Public consultations and government policy approval
- Legislative, regulatory and / or instrument amendments
- Implementation – guidance, process re-design, upskilling of personnel, IT changes, communications, transitional arrangements

Reforms as we align with new EU requirements

Amendment to the *Medical Devices Regulations* (Dec 2019)

- Software-based medical devices
- Personalised medical devices
- IVD companion diagnostics
- Reclassification of certain devices

Amendment to the *Therapeutic Goods Act* (June 2020)

- Definitions in the medical device regulatory framework
- Clarifying system or procedure pack requirements
- UDI

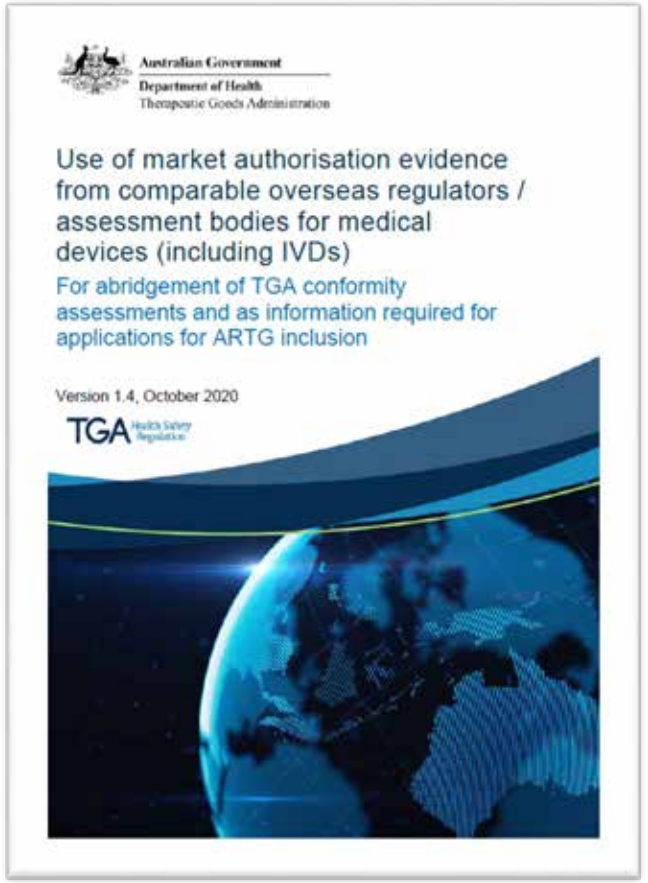
Further work underway on

- Essential Principles and conformity assessment procedures
- Strengthening postmarket monitoring and surveillance

Changes in Australia usually run slightly after EU dates, to allow flow into the Australian system

Comparable overseas regulators

- **Over 90% of medical device entries** on the ARTG needing third party certification or approval currently rely on CE mark certification
  - Ø But with TGA application audits in some cases
- European changes require that **all these devices must be recertified** under the MDR by May 2024
  - Ø will flow through to the certificates supporting Australian supply
  - Ø will as many application audits be needed after all devices have transitioned as rigour of review will be higher ?
- We also allow industry to use evidence from applications from a **wider range of countries** to support ARTG inclusion applications



Whither Mutual Recognition Agreements (MRAs)?

- An MRA is in place between Australia and the EC, and provides for the **mutual acceptance of conformity assessment** for devices under the current EU MD directives (except for high risk medical devices after 1 Jan 2013)
  - Ø But the current MRA does not reflect new EU regulations, so TGA cannot issue CA certification against the new regulations
  - Ø The Australian Government is negotiating with the European Commission on updates to the MRA
  - Ø MRA with European Free Trade Association (Iceland, Liechtenstein and Norway) also needs to be updated
- Australia and the UK have already signed an MRA for recognition of conformity assessment certification

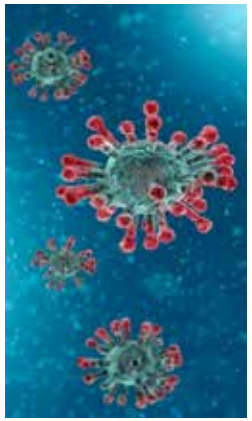
EU delays from COVID-19

Europe delayed MDR transition date from May 2020 to May 2021

So Australia delayed a number of reforms in line with this:

Reclassification of certain devices *Spinal implants, AIMDs, substances, direct contact with central circulatory system or the central nervous system*	25 Aug 2020	→	25 Nov 2020
Medical device **software**	25 Aug 2020	→	25 Feb 2021
Personalised medical devices	25 Aug 2020	→	25 Feb 2021
Systems or procedure packs	25 Aug 2020	→	25 Nov 2020
Amendments to the **Essential Principles**	After commencement of EU MDR (May 2023)		
IVD Medical Device Regulations	Two years after commencement of IVDR (May 2022)		

EU notified body availability

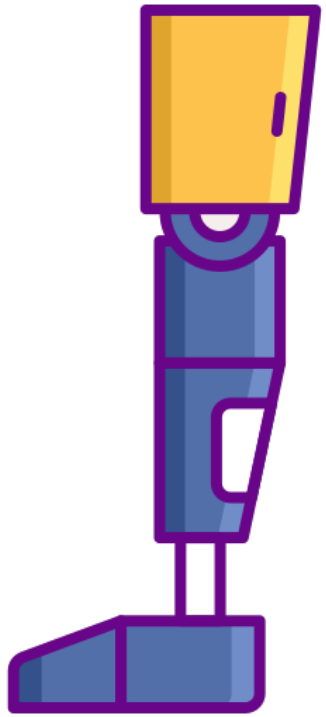


- **MDR led to rationalisation**, delayed re-designation of some EU notified bodies
- Some UK notified bodies 'relocated' to Europe and required redesignation
  - Ø resulting in a backlog of manufacturers waiting to transition
  - Ø backlog may impact on lapsing CE certificates

- Impacts on **supply and reclassification of devices in Australia**
  - Ø TGA guidance Jan 2021 www.tga.gov.au/resource/tgas-approach-delays-medical-device-conformity-assessment-recertification
  - Ø Advise TGA as early as possible about **lapsing** CA documentation and we will consider whether sponsor has taken reasonable steps to mitigate, and issue is due to EU delays
  - Ø If EU CA was instead **suspended, cancelled or revoked** we will take regulatory action
  - Ø **You cannot supply devices that have never had CA** or comparable procedures

Personalised medical devices

- On 25 Feb 2021 a new framework for the **regulation of personalised (including custom-made) medical devices** commenced in Australia
  - Ø Based on definitions and concepts established by the International Medical Devices Regulators Forum (IMDRF)
- **EU and Australia do not fully align here**
  - Ø EU adopted IMDRF definitions for custom-made and patient-matched devices
  - Ø **But the** EU excludes devices manufactured by/for healthcare professionals for use in their clinical practice
- TGA is continuing to engage with industry to **determine whether some carve outs of lower-risk products** are required
  - Ø Even if we aligned with EU we would be out of step with the US and elsewhere



Software based medical devices

- **Recent changes further align with EU**
  - Ø Changed classification rules to better reflect risk
  - Ø Boundary clarification and “carve out” of low risk software products
  - Ø Exemption for some clinical decision support software
- **Slight differences** between Australia and EU device classifications may result in a **lower** classification in Australia
  - Ø if intended user is a health professional, or
  - Ø low-moderate health risk devices that monitor progression of a condition or disease
  - Ø But any EU CA for a higher classification will also be accepted by the TGA
- **Awaiting publication of UK guidance on SAMD** to understand whether they will have any differences from the EU

Australian Conformity Assessment Bodies

- The Australian Government accepted MMDR recommendation to allow Australian third party conformity assessment bodies
  - Ø Provides an alternative pathway to market
  - Ø TGA determines scope of accreditation of Australian CA bodies

- Will accept **applications from Australian companies from July**
  - Ø Applicants must demonstrate they have adequate processes in place to conduct audits of manufacturers, and required expertise to undertake product assessments
  - Ø Aligned with EU requirements for notified body designation, and Medical Device Single Audit Program (MDSAP) Auditing Organisations

Unique Device Identification (UDI)

- Recently, *Therapeutic Goods Act 1989 was* changed and Government approved TGA to invest $ 7.7 m **to establish an Australian UDI database**
  - Ø Two public consultations, ongoing discussions with other regulators
  - Ø Engagement with manufacturers and sponsors, hospitals, consumers, health purchasers/payer , states and territories, registries and software developers
- But **we won't directly adopt the EU system**
  - Ø TGA is **not planning to implement Australian UDI** before the EU compliance dates
  - Ø Will make compliance with requirements from different jurisdictions as seamless as possible
  - Ø EU developing its own device nomenclature while Australia and USA require GMDN
- Manufacturers who supply devices to several countries with UDI systems are already having to **comply with different regulatory requirements**

Changes to IVD regulation start May 2022

- **The EU will move many IVDs** from a default Class A classification (self assessed) to higher classifications (Class B, C and D) (requiring independent certification)
- **Australia** has had a similar system of IVD classification for some years (introduced 7/10, transition to 7/15) and the new EU system is similar
- **EU changes will also require**
  - Ø More independent certification of many more IVDs, with new Declarations of Conformity
  - Ø Greater clinical evidence and more postmarket surveillance
  - Ø Labelling changes – UDI, or if single use, near patient or self test
  - Ø IFU – information on intended purpose, proper use, precautions

Regulatory challenges and more information

- Complex due to lack of detailed information on some reforms from the EU
  - Ø EU are still developing guidance for MDR
  - Ø Delivery of Australian reforms that may need refinement once EU release information
  - Ø Need to update Mutual Recognition arrangements
  - Ø Need to consider whether fewer application audits will be required post full MDR implementation

More details on reforms at www.tga.gov.au/medical-devices-reforms

Medical Devices Information Unit devices@tga.gov.au or 1800 141 144

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