Personalised Medical Devices

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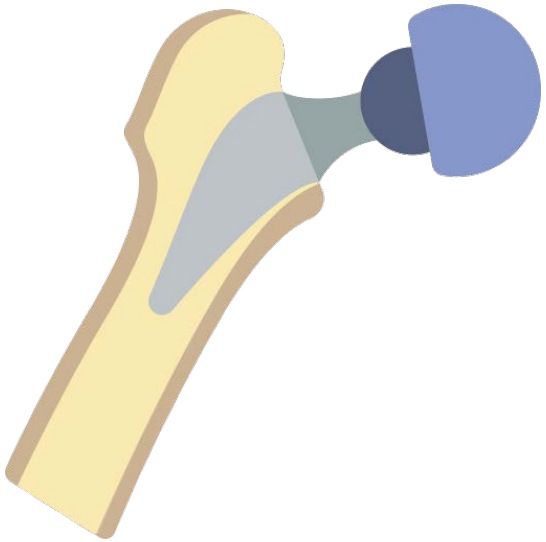
The challenge

- Easier access to technology (eg: 3D printers) presents new challenges for patient safety / confidence
  - Use of these technologies is increasing
  - Higher risk custom-made medical devices
  - New manufacturers entering the market
- On 25 February 2021 a new framework for the regulation of personalised medical devices commenced



PMD Framework – key features

- Reduced in scope
- Exempt from ARTG inclusion
- Low numbers of supply
- Intended for rare, bespoke devices where no other device is available

Custom-made Medical Devices

- Can be validated, verified and reproduced
- Manufactured within a design envelope
- Included in the ARTG
- Intended for consistent methods and materials

Patient-matched medical devices

- End-to-end system for manufacture of a personalised device
- Used by practitioners and professionals
- Within healthcare facilities
- Included in the ARTG
- Devices made using an MDPS are part of the ARTG inclusion for the MDPS

Medical Device Production Systems (MDPS)

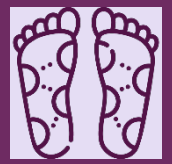
Stakeholders in healthcare sectors

More than 50,000 stakeholders

3,000+ Audiologists

24,000 Dental practitioners

3,000+ Dental laboratories and technicians



4,600 Podiatrists

5,000+ Orthotists and prosthetists

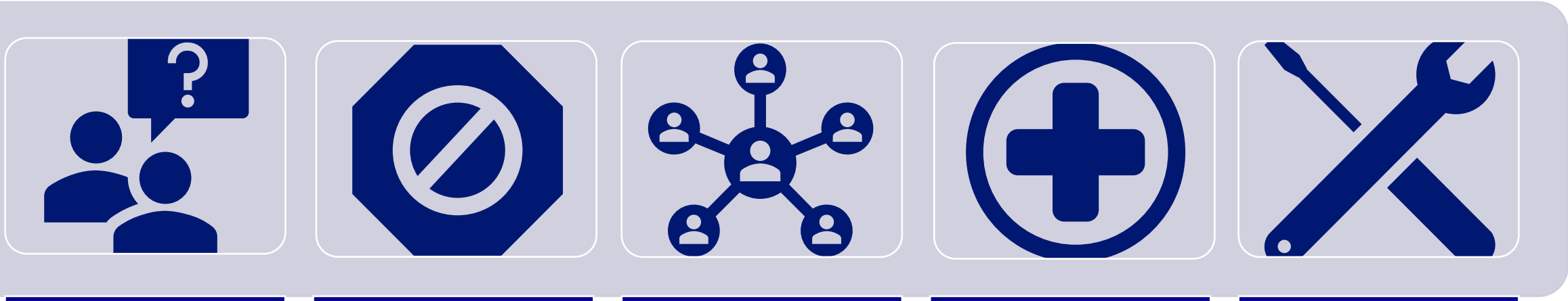
6,000 Optometrists

23,000 Occupational therapists

17,000 Medical radiation practitioners

2,700 Osteopaths

Feedback from healthcare stakeholders



Healthcare practitioners are not sure whether they are regulated and what their regulatory responsibilities to the TGA are

Existing regulation may present a barrier to supply through clinical practice

Point-of-care manufacturing hubs already exist and operate very differently to the concept of an MDPS

The lines between clinical practice and device manufacture are blurring as technology improves

There is an appetite for regulatory amendments that recognise the role of clinical practice and encourage innovation

Feedback from industry stakeholders

The elements of device design and manufacture are (increasingly) no longer the responsibility of one entity

Manufacturers of MDPSs will not take responsibility for devices made in a system they do not directly operate

Pathways to reimbursement need to be considered when introducing new frameworks or refinements

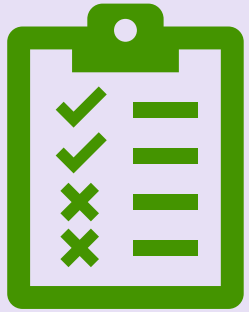
Traditional pre-market approval processes are not always appropriate for personalised medical devices

There is an appetite for regulatory amendments recognising new methods of manufacture and streamlining approval processes

Point-of-care manufacturing

Establish clear boundaries between regulators

Effectively communicate roles and responsibilities



Appropriate regulation to ensure risks are adequately met

Reduction in unnecessary financial and administrative burdens

Positive patient outcomes through timely access to the most appropriate medical devices

Collaboration and consultation

- Australian Health Practitioner Regulation Agency
- National Alliance of Self Regulating Health Professions
- Australian Commission on Safety and Quality in Health Care
- NDIA/NDIS Commission
- State/territory governments
- Private hospitals
- Healthcare practitioners/clinicians

Point-of-care manufacturing

1. • Data collection (surveys)
2. • Analysis of the responses
3. • A national symposium to discuss
4. • Public consultation of refinements if required
5. • Consideration of impacts to the regulatory frameworks
6. • Implementation, communication and education

Looking ahead

1. IMDRF – Personalized Medical Devices Working Group remains open
2. In Australia:
    a. Public consultation – exempt devices framework
    b. National symposium with regulators and state/territory governments
    c. Potential refinements to the legislation
    d. Education, communication and guidance

Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

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Questions?

www.tga.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration