Australian Government
Department of Health
Therapeutic Goods Administration

Regulatory Update

An Action Plan for Medical Devices

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TGA Health Safety Regulation

The biggest changes to medical device regulation in 20 years – Why ?

- Need for greater flexibility in getting products to market
- Avoid duplicating work of other regulators
- Changes in Europe to device regulation
- New technologies have reshaped what medical devices are, and how they are used
- Software, cybersecurity, personalisation
- Blurring of product boundaries
- Device safety “crises”
- Consumer demands for more transparency and confidence in product safety

MMDR reforms:
New evaluation pathways established for devices

- **Multiple pathways** for Class II, III, AIMD devices and Class 2–4 IVDs:
  - **Conformity Assessment** in Australia **by TGA** (existing pathway)
  - **Conformity Assessment** in Australia by a body **designated by TGA**
    - No bodies yet designated
  - **Utilisation of overseas approval** where the device has been:
    - **Conformity Assessed** by a body designated by a comparable overseas Designating Authority; or
    - **Approved** by a comparable overseas regulatory authority
- **Priority review** for certain novel devices

Using evidence from comparable overseas regulators or assessment bodies in:

1. Requests for **abridgement of TGA conformity assessments**, OR
2. Applications for **inclusion of medical devices** in the ARTG:
   - Certificates issued by EU-designated notified bodies
   - Decisions of the US FDA
   - Approvals and licences issued by Health Canada
   - Pre-market approvals from Japan
   - Certificates and reports issued under the MDSAP

- **Documentation** should be for same design, intended purpose, and indications
- **Detailed guidance** specifies what documentation can be utilised for what purpose and where TGA fees can be reduced

Consultation Updates

Consultations that have closed	Current Status
UDI	Approval received to amend legislation
Software as a Medical Device	Approval to proceed
Personalised Medical Devices	Approval to proceed
Reclassification of certain devices eg. spinal implants etc	Process to amend regulations initiated
Definitions and scope of products without medical purpose	Approval to proceed; consult more on beauty products
Current and Future consultations	
Disability Products Essential Principles Medical Device System and Procedure Packs	Consultations underway
Conformity Assessment Procedures	Forecast for October
Device Clinical Trials	Forecast for October
Devices containing nanomaterials	Forecast for end 2019

Unique Device Identification System (UDI)

Potential benefits

- Accurate reporting and analysis of **adverse events**
- Faster, accurate identification of **device problems**
- **Reducing medical errors** by enabling health care professionals to precisely trace the device
- **Documenting device** use in electronic health records, clinical information systems and registries
- More effectively **management of device recalls**
- More **secure global distribution chain**
- Better **international device information sharing**

Implementation of a UDI system agreed in principle, but an Act change is required

- TGA to **manage the UDI database**
- Class I (non-measuring, non-sterile) and custom made devices will **be exempted**
- **A range of external agencies will be able to seek accreditation by TGA to issue unique device identifiers**

Still to be finalised

- **international system** that the Australian UDI aligns with
- **transitional timeframes** for each class of device
- **Core data elements to be** entered into the AusUDID
- Linkages to the **National Product Catalogue** or **My Health Record**
- **Information to be shared** between the ARTG and UDI databases

Software as a Medical Device (SaMD)

*How to regulate so many **apps** ?*

Regulatory changes

- New rules to more **appropriately classify software medical devices** according to the potential harm they could cause to patients
- **Exclude software from TGA personal importation provisions** so that SaMD will be required to be included in the ARTG and have an Australian sponsor
- **Essential principles** for medical devices to include clear requirements for demonstrating the safety and performance of software

It will be important to set some boundaries

- **What software should be regulated** as a medical device by TGA ?
- **When would TGA regulation be unnecessary** ? e.g.
  - Very low risk ?
  - Unclear if product is a device ?
  - Where other systems are well established (e.g. hospital information systems)
- We are **currently consulting** on this
- A **national strategy** for managing apps is also under development as developers are often not familiar with regulation

Proposed new SaMD classification rules

- Will cover **SaMD that is intended to be used to process data** for:
  - providing a diagnosis
  - recommending a treatment or intervention
  - monitoring a condition
- **Classification levels** will depend on
  - Whether the SaMD will provide therapy through direct interaction with a patient
  - Whether the information is intended to be acted upon directly, or instead a clinician will make the decision
  - The condition the information is intended to treat/monitor/diagnose
  - The potential for the therapy to cause harm to the patient

Device Cyber Security

- **Increasing number** of medical devices connected to networks, but many outdated operating systems
- Cybersecurity is already covered through application of the **Essential Principles**, but new vulnerabilities
  - Mobile devices
  - Hospital, admin and IT service staff all need access
  - Patient confidentiality issues as well as cybersecurity
- **TGA** will develop capacity to undertake penetration testing, threat analysis and signal analysis
- **New regulatory guidance** explains how industry and users should more overtly consider cybersecurity issues

Personalised / 3D printed devices – changes to regulation

Don't want to hinder innovation but enable adequate safety oversight

- **Definitions** for personalised devices (align with IMDRF)
- Changed requirements for **custom-made devices**
- **Healthcare providers** can produce lower risk personalised devices for treating patients **without the need for manufacturing certification**
- Wider range of **devices used for recording diagnostic images** regulated e.g. 3D-printed anatomy models
- 3D-printed devices containing **human cells and tissues now regulated as devices**
- **Adaptations** to personalise an already supplied device can only be made as intended by the device's manufacturer

Types of personalised devices

- **Custom-made medical device – EXEMPT from ARTG inclusion**
  - intended for the sole use of a particular individual
  - it is intended to address the specific anatomo-physiological features or pathological condition of that individual
  - made in accordance with a written request of a health professional
- **Patient-matched medical device – must be on ARTG**
  - matched to a patient's anatomy within a specified design envelope
  - produced in a batch through a process that is capable of being validated and reproduced
  - designed and produced under the responsibility of a manufacturer
- **Adaptable medical device – must be on ARTG**
  - Mass-produced and adapted, adjusted, assembled or shaped at the point of care to suit an individual patient's specific anatomo-physiological features

Proposed reclassification of some medical devices

to consider current risks, advances in technology and alignment with international (especially EU) regulation

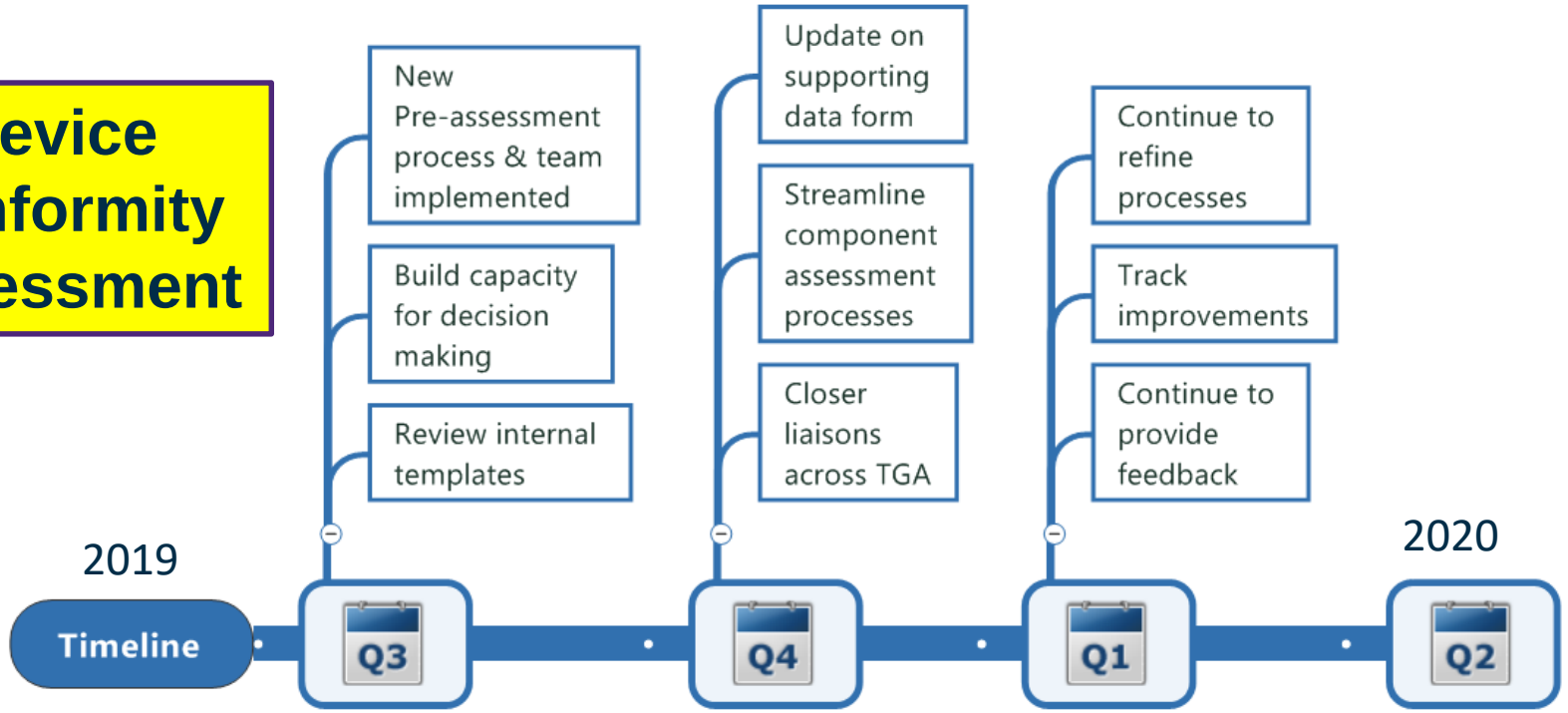
- **Active medical devices** for diagnosis and patient therapy
- **Spinal implantable medical devices** that are motion-preserving (disc replacements) or that come into direct contact with the spinal column
- Active implantable medical devices and their **accessories**
- Devices that **administer medicines by inhalation**
- **Substances introduced into the body** via body orifice or applied to the skin
- Human cell, tissue and organ storage solutions, IVF media
- Devices used in **direct contact with the heart, central circulatory or central nervous system**

Changes to definitions and regulation of some products without medical purpose

- **Some products carry considerable risk** and are not adequately regulated, e.g.
  - e.g. decorative contact lenses
  - equipment for liposuction, lipolysis or lipoplasty
  - lasers and intense pulsed light equipment for skin resurfacing, tattoo or hair removal or other skin treatment
  - equipment intended for brain stimulation
- Plan to **align Australia with the EU** to regulate as medical devices
- **Some questions** about need for regulation of products for beauty therapy (e.g. personal IPL)

We are also improving business processes

Device Conformity Assessment



What you will see

- Faster initial processing and invoicing
- Regular updates and education sessions
- Reduced no. of rounds of requests for information
- Improvements in processing timeframes

Strengthening post market monitoring

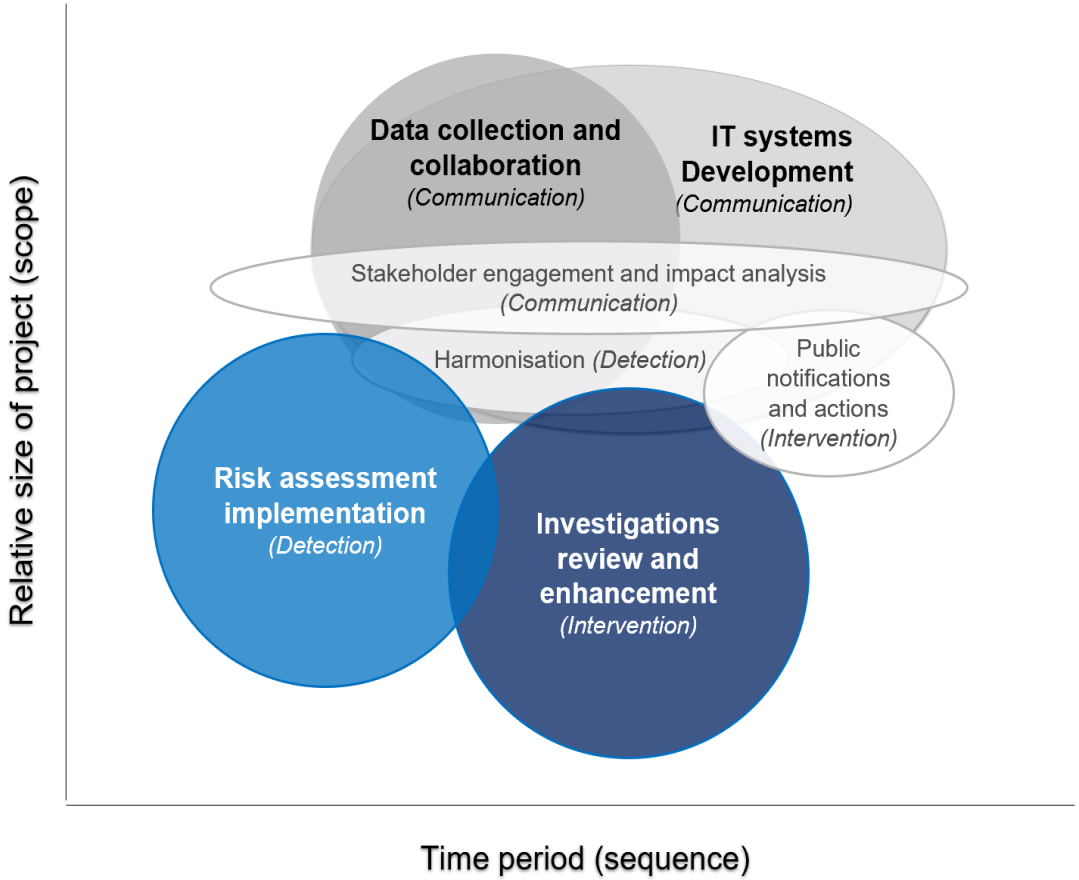
- **Enhanced Post Market Monitoring and Analytics**
  - Review underway of TGA's **risk assessment processes**
  - **Improved business systems** to manage post market reviews
  - New, **simpler reporting** forms for consumers, health professionals, sponsors
  - Better integration and timely **analysis of available datasets**
- **Electronic reporting** of adverse events
- **Enhanced information-sharing** with overseas regulators
- **Consultations in 2019/20** on:
  - Periodic Safety Update Reporting
  - Electronic submissions by manufacturers and sponsors
  - Exemption Rules
- And more "hubs" on the TGA website – **consolidating patient safety information** and joint publications with patient groups

Strategies to improve post-market monitoring

Improved ***detection***

More timely ***intervention***

Better ***communication***



22 TGA post market medical device reviews underway in 2019

- **Examples include:**
  - Veritas mesh use in breast reconstruction
  - Mammary tissue expanders and BIA-ALCL
  - External Defibrillators
  - Self-inflating resuscitation bags for neonates
  - Heater Cooler devices for cardiac surgery
  - Ventilators used in Intensive Care Units
  - Spinal fusion devices

Recommendations of the Senate Inquiry into urogynaecologial mesh 2017-2018

- Provide **information to patients** receiving implantable devices
- Ensure **informed patient consent**
- Establish **implantable devices registries** including for meshes
- **Gynaecological Clinical Committee** report release
- Increase and simplify **adverse event reporting**
- Treatment guidelines - **use transvaginal mesh as a last resort**
- **Credentialing and training** of implanting surgeons
- Awareness by surgeons and gynaecologists of **information** resources
- States and territories to **audit all mesh procedures ever performed**
- Review **services for use and/or removal of mesh**
- Review **ethical standards** on industry payments to doctors

Responsibility for implementation

- Commonwealth Health Department (including TGA)
- State and Territory Health Departments
- Australian Commission on Safety and Quality in Health Care
- Clinical and surgical groups
- Individual surgeons
- Public and Private Hospitals
- The medical device industry

Actions to date: Patient Information cards and leaflets

To help informed consent - required now for all new meshes, and for all devices by Dec 2021

- **Patient cards must include:**
  - ✓ Name and model of the device
  - ✓ Batch code, lot number or serial number
  - ✓ Unique device identifier of the device (if any)
  - ✓ Manufacturer's name, address and website
- **Information leaflets must include:**
  - ✓ Information identifying the device
  - ✓ The intended purpose of the device
  - ✓ Information on how to use the device safely
  - ✓ Other information useful for patients

Actions to date: Device registries

- **Clinical quality registry for pelvic floor procedures,** 3 year pilot from June 2019
- Will **provide longitudinal health outcome data** for all undergoing pelvic surgery procedures
- Will **complement other registries**
- **Cost recovery basis** to be considered in medium term
- **A National Clinical Quality Registry Strategy** to be considered by COAG Health Council in early 2020

AUSTRALIAN Breast Device REGISTRY

AOANJRR Australian Orthopaedic Association National Joint Replacement Registry

Australian Government

The safety of Australian patients comes first

An Action Plan for Medical Devices

Improving Australia's medical device regulatory framework

April 2019

STRATEGY 1: IMPROVING HOW NEW DEVICES GET ON THE MARKET

STRATEGY 2: STRENGTHEN MONITORING AND FOLLOW-UP OF DEVICES ALREADY IN USE

STRATEGY 3: PROVIDE MORE INFORMATION TO PATIENTS ABOUT THE DEVICES THEY USE

STRATEGY 1:
Improve how devices get on the market

TGA will:

- **Better assess new technologies for safety -** e.g**.** 3D printed devices and software apps, and device cybersecurity issues
- Clarify and **strengthen the regulatory requirements** for particular devices e.g. first aid kits, single use surgical procedure packs, contact lenses, lasers, brain stimulators and dermal fillers

Government will consider, after public consultation:

- Whether more applications for **class IIB devices** should require TGA audits
- Whether **greater levels of clinical evidence** for certain devices be required
- **More onsite inspections** of manufacturers for very high risk devices
- If certain devices should be reviewed by TGA **before use in clinical trials**

STRATEGY 2: Strengthen monitoring and follow-up of devices already in use

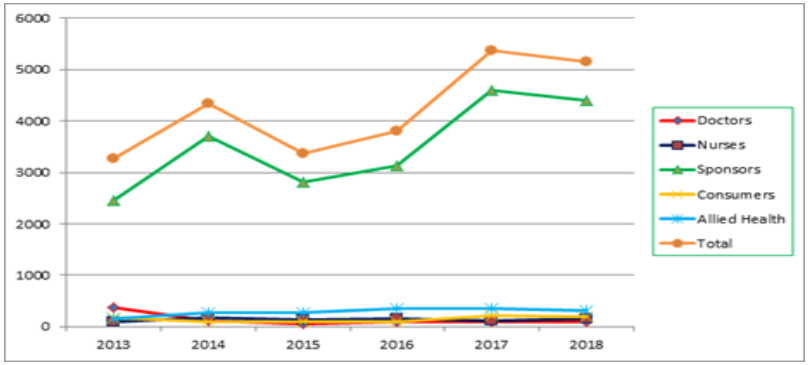
TGA will:

- **Enhance IT systems and analysis capability** for adverse events
- Develop **simpler ways for consumers to report adverse events**
- Publicise how **reporting of adverse events helps improve product safety**
- Increasing information sharing on device incidents with **state and territory hospital systems**
- Develop education programs and systems to **help healthcare professionals and hospitals identify and report device incidents**

To increase reporting of adverse events:

Government will consider, after public consultation:

- Whether it should **be mandatory for healthcare facilities** to report device adverse events
- **Removing some exemptions** to improve reporting of incidents by industry
- Whether TGA should have **enhanced recall powers over cancelled devices**
- Implementing a **Unique Device Identifier system**
- **Onsite auditing** of sponsor reporting of adverse events, as per medicines



Numbers of medical device incidents reported annually

STRATEGY 3: Provide more information to patients about the devices they use

Government will consider, after public consultation:

- Publishing more information about **decisions made** and the higher risk **devices regulated by the TGA**
- **Strengthening consumer awareness** of how safety and performance of medical devices are assessed
- Ways to help **consumers report concerns about a medical device more easily**
- Wider **engagement with 'everyday' consumers –** e.g. evaluating current processes and integrating patient experience, road test proposals and documentation
- Establishing more a**dvisory groups with consumer representation**

And finally, with the Devices action plan ...

- **The Action Plan will accelerate reform activities** currently underway
- **There will be further public consultations** to seek feedback on new approaches
- **But decisions** on new policies/regulations will be made by government
- **Regulation impact statements** would need to be prepared for some measures (e.g. mandatory healthcare facility reporting)
- Need to determine **how to fund implementation o**f some reforms