Medical device regulation - an update on the latest

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Therapeutic Goods Administration

A/g Deputy Secretary

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

“With sweeping reforms occurring across the globe in medical device regulation, this session focuses on how the TGA is supporting the industry through these changes, along with the challenges of regulating new and emerging technologies and what this means for Australian patients."

- **Australian Medical Device Reforms**
- **Supporting Industry through Regulatory Changes**
- **Emerging Technologies - challenges**
- **HPRG Transformation**
- **Collaboration with International Partners**

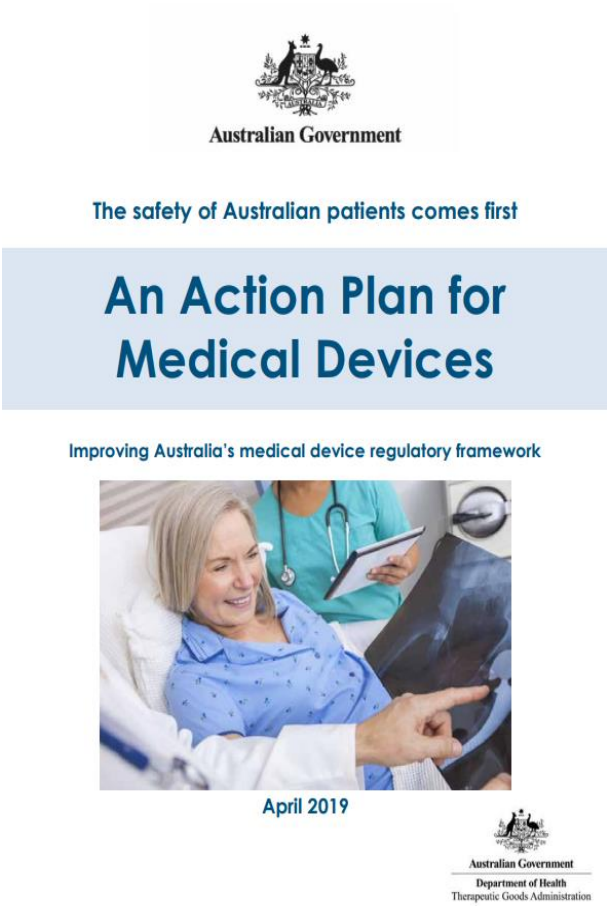
An Action Plan for Medical Devices

A blueprint about medical device reforms that:

- strengthens our regulatory system
- remains patient focused
- provides greater transparency: and
- increases public confidence in Australia's device regulatory system

Three strategies:

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



Strategy 1: Pre-market medical device reforms

❖ **Reclassification of certain medical devices (non IVD)**

- Due dates for applications 1 November 2024; proposal for further delay subject to Government approval; guidance published; workshops held
- Review of exemption framework; potential refinement of certain changes now that more detail is available from the EU

❖ **Streamlining TGA processes and timeframes**

- Recognition and agreements with other regulators (recent Singapore)
- Proposed risk based application audit framework - fewer mandatory audits
  - Workshops late 2022 – early 2023 to co-design the framework – public consultation

❖ **European Union Medical Device Regulation (MDR) and IVDR**

- Amended regulations to align where possible; streamline device change requests; variation to fees and retrospective refunds; extension of transition timeframes; website updates; accepting extended MDD and IVD certification; communication to healthcare system and supply chains; voluntary publishing service on website

Strategy 1: Pre-market medical device reforms

❖ Software-based medical devices

- Bedding down refinements and “carve outs” – digital mental health tools, some clinical decision support systems
- ARTG software entries – searchable on software name, version, build numbers etc
- More guidance on specific types of products; collaboration on mhealth apps
- Industry support through ANDHealth to assist new developers and start-ups

❖ Personalised medical devices

- Webinars, guidance, fact sheets, conferences, industry meetings, stakeholder emails
- Recognition that refinements are required, for transition timeframes and for Point of Care manufacturing and Medical Device Production Systems
- Consultations, surveys underway, more collaboration with other regulators

❖ Unique Device Identification system

- Webinars, consultation, workshops, help desk, database open to all stakeholders to test
- Guidance being developed in collaboration with industry, engagement of healthcare system and supply chains, engagement with international stakeholders to reduce differences; technical working group; early adopters
- Implementation dates revised 2023-25, subject to Government approval; regulatory workshops 9 and 16 June

Companion Diagnostics (CDx)

- Transition arrangements extended to 26 May 2026
- 8 assays approved under the new framework
- Ongoing work:
  - Education of / for stakeholders
  - Targeted information program for various sectors including medicines and pathology
  - Updating guidance with new descriptors and examples
  - Guidance for those with digital components
  - Publish list of approved CDx on TGA website

IVD medical device	Proprietary medicine generic name
VENTANA PD-L1 (SP142) Assay	TECENTRIQ® (atezolizumab)
PD-L1 IHC 22C3 pharmDx	KEYTRUDA® (pembrolizumab)
Therascreen KRS RGQ PCR Kit	LUMAKRAS® (sotorasib)
PD-L1 IHC 22C3 pharmDx (Dako Omnis) /GE006	KEYTRUDA® (pembrolizumab)
VENTANA PD-L1 (SP263) Assay	IMFINZI™ (durvalumab), KEYTRUDA® (pembrolizumab), OPDIVO® (nivolumab), TECENTRIQ® (atezolizumab)
Cobas® 4800 BRAF V600 Mutation Test	ZELBORAF® (vemurafenib) COTELLIC® (cobimetinib)
VENTANA HER2 Dual ISH DNA Probe Cocktail	Herceptin (trastuzumab)
VENTANA anti-ALK (D5F3) Rabbit Monoclonal Primary Antibody	XALKORI® (crizotinib), ZYKADIA® (ceritinib) or ALECENSA® (alectinib)

Strategy 2: Post-market medical device reforms

❖ **Adverse event reporting arrangements**

- Improved reporting forms and internal TGA analysis processes (patient feedback)
- Changes to existing exemptions - consultation
- Mandatory reporting by healthcare facilities – required change to legislation and partnership with other governments/ agencies (implementation 2025)
- Introduction of a pilot vigilance program including self-assessment tool, desk top review and onsite inspection focus on ensuring post market obligations are being carried out (e.g. adverse event reporting). Guidance, industry input to tools, call for pilot participants

❖ **Recall processes consultation**

- Greater transparency of supply chains; simplified terminology; ability to share information quicker, review of powers – consultations, workshops

Strategy 3: Consumer focused reforms

❖ **Five working groups with consumer representation**

Eg: Medical Device Consumer Working Group

- Comprises of 21 consumer organisations that provide the consumer voice in the Action Plan
- Review of website materials and processes for improved consumer awareness and engagement, including co-development of fact sheets (eg: software fact sheets) and adverse event reporting forms and processes
- Feedback on electronic IFUs and PILs for consumer facing medical devices and consumer needs

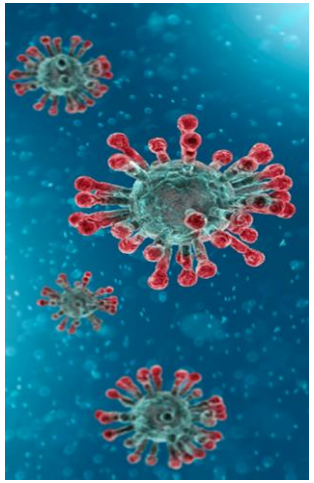
Eg: Women's Health Products Working Group

- Provides advice to the Minister and the TGA on the regulation of health products that relate to women's health

Not a reform – but still important to reflect on

Strategies for Rapid Antigen Test application backlog

- Detailed guidance and checklists on website, publishing of IFUs to assist consumers and performance information to build confidence
- Communication to sponsors on status and website updates
- 2 requests for information, refund mechanism where no assessment had commenced
- Queue reduced from 330 to 154 on hand
- Enquiries reduced enquiries to average 715 per month



Statistics

- More than 110 COVID-19 rapid antigen tests approved (self-tests and PoC tests)
- 62% of over 900 completed RAT applications were unsuccessful
- Also approved a number of combination COVID-19 + Influenza + RSV tests

Challenges regulating IVD software and genomics

- Rise in digitally enabled models of testing and treatment tailored to patients, involving IVD software and genomic sequencing and analysis
- Increase in complexity of genomic testing resulting in hybrid models of testing and service provision
    - regulatory and reimbursement challenges components or whole processes performed overseas
    - tension between expectation that services are wholly provided within Australia when access can be provided to laboratories for the use of bioinformatics software and genomic databases (e.g., cloud based with no physical location)?

TGA Transformation Program - Purpose

- Reduce regulatory burden by making it easier and simpler to do business with the TGA
- Modernised and streamlined websites to access regulatory information
- A new single portal for regulatory and reimbursement applications
- Improved search facilities for the ARTG
- **Medical Device IT specific projects**
  - Electronic IFUs / PILs for consumer facing devices
  - EU MDR / IVDR forms and fee reductions
  - Exempt devices database
  - Data integrity in ARTG, including flags for software devices

International Medical Device Regulators Forum (IMDRF)

- **Participating in the following IMDRF Working Groups**
  - Adverse Event Terminology
  - Artificial Intelligence Medical Devices
  - Good Regulatory Review Practices
  - Medical Device Cybersecurity Guide
  - Personalized Medical Devices (WG Chair)
  - Regulated Product Submission
  - Software as a Medical Device
  - Medical Devices Single Review Program

Regulatory convergence to support Industry

- Implementation of IMDRF technical documents where Australian regulatory framework allows.

Recent amendments to the Therapeutic Goods Act

- Mandatory reporting involving medical devices by hospitals
- Export only biologicals pathway
- Strengthened information gathering powers and release of information provisions
- Extension of time to pay infringement notices and retain seized goods
- Reduce regulatory burden for advertisers (more exemptions)
- Withdrawal of approvals for restricted representations
- Some others…..

Recent budget measures for the TGA

- $61 million over 4 years for public good activities
  - Compliance and enforcement of unregulated products and entities
  - Management of device and medicine shortages
  - Consumer and healthcare professional enquiries and public education
  - Assistance to industry and applicants particularly emerging technologies
    - Expanded support to sponsors bringing new products to market, restoring staff to evaluation areas, expanding capacity for engagement with industry, other regulators or standards bodies (collaboration, alignment)
- $10 million for medicines repurposing function
- Stronger vaping controls (devices and pods)

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration