Update on Australian regulatory framework for medical devices

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The Medical Technology Association of Australia (MTAA) is the national association made up of 70+ medical technology industry manufacturers, researchers, suppliers and distributors from across the country.

Majority of MedTech companies (head offices) are located in:
- New South Wales (55%)
- Victoria (24%)
- Queensland (12%)

50% of foreign MedTech ownership is from the U.S., Europe and Asia make up the next 35%
What’s been happening in Australian regulatory space?

Major regulatory reforms – “the most comprehensive change” since Therapeutic Goods Act 1989*

TG Amendment (2016 Measures No. 1) Bill – March 2017:

1) Allow faster access for new therapeutic goods addressing unmet needs for life-threatening conditions
2) Allow notification for low-risk medicine variations
3) Enable 3rd party conformity assessment bodies for medical devices to operate in Australia
4) Enable HCPs more timely access to unapproved therapeutic goods in certain circumstances
5) Review and appeal mechanisms for sponsors applying to include new ingredients for complementary medicines
6) Set legislative timeframes for decisions on complementary medicines
7) Strengthen post-market monitoring
8) Streamline TGA statutory advisory committees
9) Other amendments

*Dr John Skerritt, Head of TGA, at the Senate Community Affairs Legislation Committee Hearing of 17 March 2017
What’s been happening in Australian regulatory space?

Timeline

**MMDR Review Recommendations**
- Medicines, medical devices – 32 recommendations **R1 – R32**
- Complementary medicines, advertising – 26 recommendations **R33 – R58**
  - March & July 2015

**Government’s response**
- 56 of 58 recommendations accepted(*)
  - September 2016

**TG Amendment (2016 Measures No. 1) Bill**
- May 2017

**TG Amendment (2017 Measures No. 2) Bill**
- 2018?

(*) Recommendations rejected by the Government:
- R29 – Chief Medical Officer (CMO) to become ‘the’ decision maker for inclusions into ARTG
- R30 – Advisory Committee on Medicines Scheduling (ACMS) to become a sub-committee of Advisory Committee for Medicines (ACM)

Medical Technology for a healthier Australia
Let’s delve into some details...

#1 Allow faster access for new therapeutic goods addressing unmet needs for life-threatening conditions

**Accelerated assessment/ Priority Review pathway for novel medical devices (R15, R19)**

- Applications go to the front of the queue, dedicated coordinating assessor to supervise timely assessment & assignment of suitable experts
- **Same** level of scrutiny, thorough review
- **Eligibility criteria:**
  - Prevention, diagnosis or treatment of a **life-threatening or seriously debilitating** condition
  - Unmet clinical need in Australian patients
  - Novel/ breakthrough technology, major **clinical** advantage over existing technology/ existing alternatives included in the ARTG; or
  - Major public health benefit - for IVDs only
Let’s delve into some details...

#1 Allow faster access for new therapeutic goods addressing unmet needs for life-threatening conditions

**Priority Review pathway and Provisional Approval pathway for medicines (R3, R8, R10)**

**Priority Review** = Applications go to the front of the queue, flexible business processes

**Eligibility criteria:**
- Prevention, diagnosis or treatment of a life-threatening or seriously debilitating condition
- Unmet clinical need in Australian patients
- **Priority Review**: Substantial evidence of major therapeutic advantage in efficacy and/or safety over existing treatments registered in Australia

**Provisional Approval** = early access, provisional registration limited in duration and will automatically lapse unless specified conditions are met

**Provisional Approval**: Promising evidence from early data of major therapeutic advantage in efficacy and/or safety over existing treatments registered in Australia
Let’s delve into some details...

#2 Allow notification for low-risk variations for medicines (R13)

- Low-risk variations to medicines = do not impact quality, safety or efficacy
- Allow straightforward low-risk changes to product details (e.g. a change in box size) to be notifiable rather than requiring the approval of the Secretary of the Department of Health
Let’s delve into some details...

#3 Enable Australian-designated 3rd party bodies to perform conformity assessments for medical devices (R15, R16)

Currently the only Australian-based CAB

Potential candidates for 3rd party CABs:
- Australian subsidiaries of EU NBs
- Local university technology spin-offs
- Research organisations
- Commercial entities
Let’s delve into some details...

#3 Enable Australian-designated 3rd party bodies to perform conformity assessments for medical devices (R15, R16)

Accreditation Body/Designating Authority

Conformity Assessment Body

Manufacturers/Sponsors

TGA designating authority

TGA device evaluation 3rd party CABs

TGA Product inclusion in the ARTG

Competition is not neutral! ... unless there is complete separation between the TGA designating and device evaluation functions.
Let’s delve into some details...

#4 Enable HCPs more timely patient-specific access to unapproved therapeutic goods in certain circumstances (R24, R25, R26)

- From ~ 20,000 Special Access Scheme (SAS) Category B applications per year, only 0.3% of them are rejected ⇒ high administrative burden spent on low risk
- Streamlines the SAS B process: notify TGA instead of applying for pre-approval for certain products which will be included on a pre-approved SAS B list, online, TGA-administered
- Eligibility criterion for including unapproved therapeutic goods in the notifiable SAS B list: Established history of safe use for a given indications for use
- Streamlines the Authorised prescriber (AP) Scheme: notify TGA instead of applying for pre-approval; approval only by either ethics committee or specialist medical college
- Duration of AP approval extended from 1 year to up to 3 years for devices; from 2 years to up to 5 years for medicines;

Patients needing access to unapproved products:
- Category A - seriously ill
- Category B - other
#4 Enable HCPs more timely patient-specific access to unapproved therapeutic goods in certain circumstances (R24, R25, R26)

- SAS and AP schemes are not a back door for unapproved therapeutic goods!
- Unapproved products should only be accessed in exceptional circumstances where therapeutic goods on the ARTG are not clinically suitable for a patient
- If there are already therapeutic goods on the ARTG that are approved for the indications for use/ intended use, SAS and AP will most likely be rejected
Let’s delve into some details…

#7 Strengthen post-market monitoring for medicines and medical devices (R27)

- Greater collection of adverse events information through system improvements and enhancements – linking to PBS, MBS;
- Signal detection – *is this a coincidence or a real association between an adverse event and a therapeutic product?*
- Increased powers for ‘authorised persons’ (e.g. TGA medical officers) to check sponsor compliance with post-market obligations;
- Increased powers for the Secretary of Health to require the person responsible for undertaking a recall to provide more information about the recalled goods and the circumstances of the recall to the public.

Medical devices
*Tip balance more in favour of post-market!*
Where can I find more information about the reforms?

TGA consultations related to the Medicines and Medical Devices Regulation review

The Expert Review of Medicines and Medical Devices Regulation – Department of Health
Clinical evidence guidelines for medical devices – 24 Feb 2017

- 160 pages document
- Covers medical devices including IVDs
- Aligns with relevant international guidelines (GHTF/IMDRF) and EU MEDDEV 2.7/1 rev. 4
- Includes specific information on the clinical evidence requirements for the following types of devices:
  - Total and partial joint prostheses
  - Cardiovascular devices to promote patency or functional flow
  - Implantable pulse generators
  - Heart valve prostheses
  - Supportive devices - meshes, patches and tissue adhesives
- Section 10 contains requirements specific to implantable medical devices in the magnetic resonance environment
Thank you!