MTAA

Update on Australian regulatory framework for medical devices

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Medical Technology for a healthier Australia

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

Who is MTAA?

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%

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What's been happening in Australian regulatory space?

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

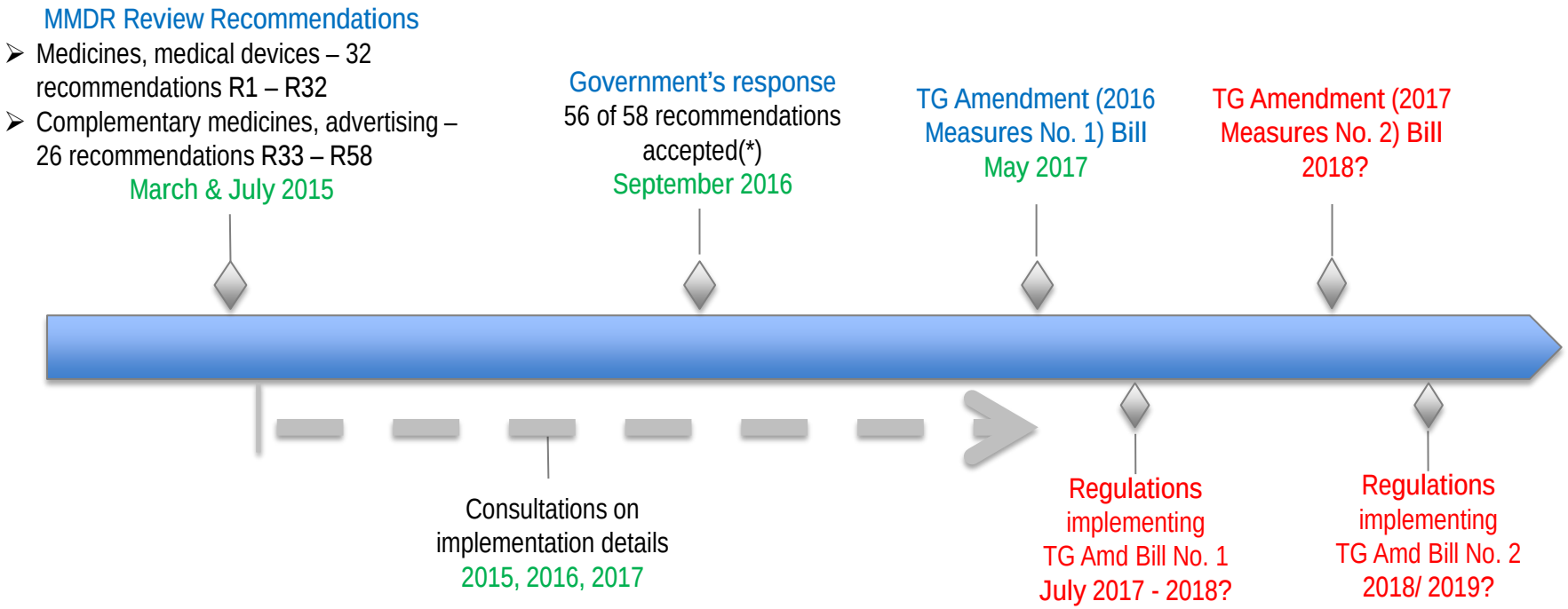
TG Amendment (2016 Measures No. 1) Bill – March 2017:

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



(*) 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)

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

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

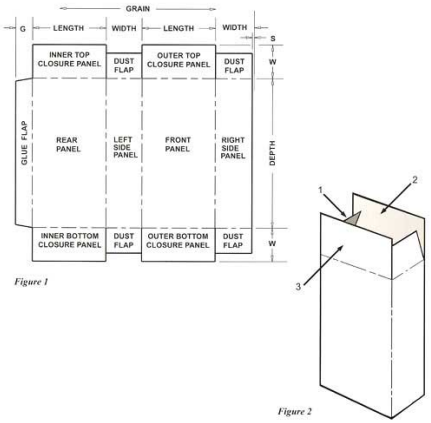
Eligibility criteria:

- 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: 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)

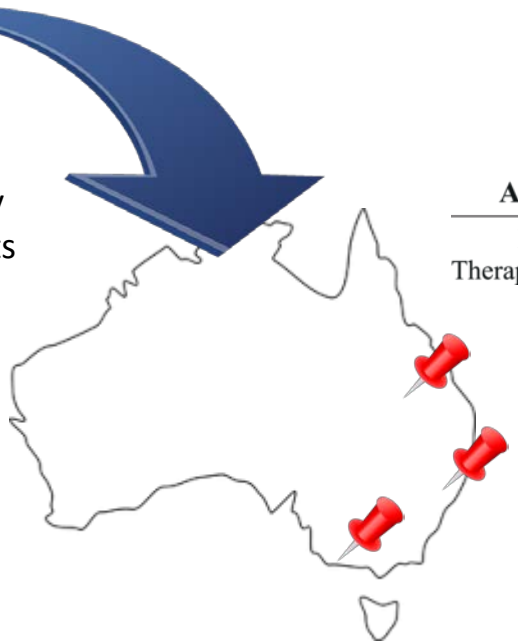
- Low-risk variations to medicines = do not impact quality, safety or efficacy
- Allow straightforward low-risk changes to product details (e.g. a change in box size) to be notifiable rather than requiring the approval of the Secretary of the Department of Health



Let's delve into some details…

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

90-92% of conformity assessments by EU NBs



Australian Government
Department of Health
Therapeutic Goods Administration

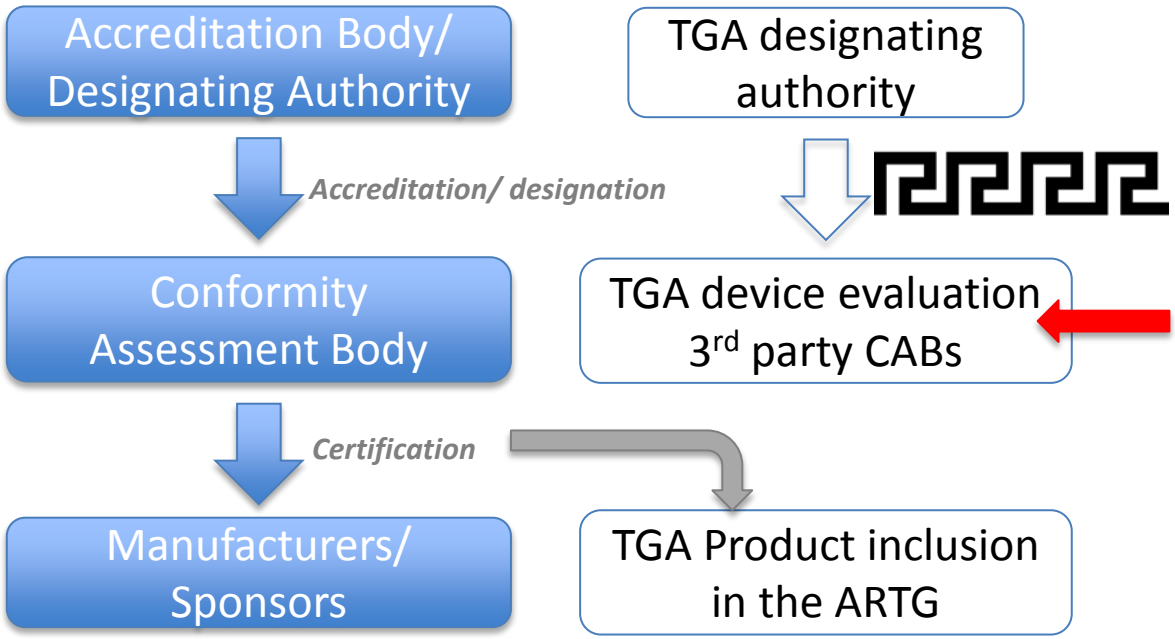
Currently the only Australian-based CAB

Potential candidates for 3rd party CABs:

- **Australian subsidiaries of EU NBs**
- **local university technology spin-offs**
- **research organisations**
- **commercial entities**

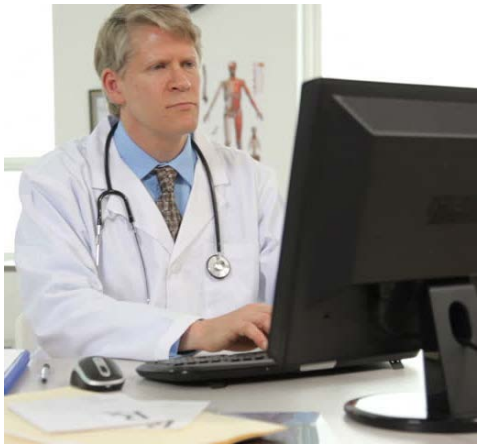
Let's delve into some details…

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



Let's delve into some details…

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



Patients needing access to unapproved products:
Category A - seriously ill
Category B - other

- 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;

Let’s delve into some details…

#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)

Medical devices

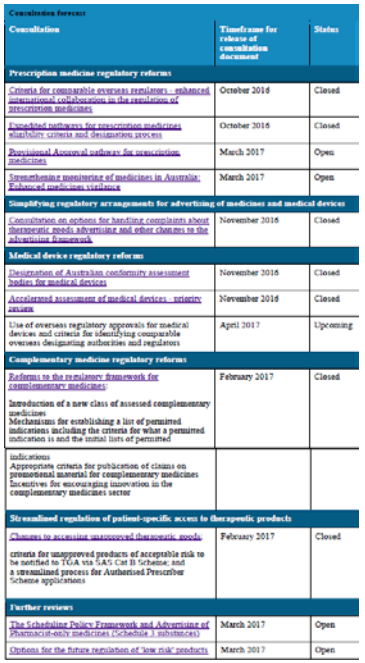
Tip balance more in favour of post-market!

- 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.

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]



Consultation forecast

Consultation	Timeframe for release of consultation document	Status
Prescription medicine regulatory reforms		
Criteria for comparable overseas regulators – enhanced international collaboration in the regulation of prescription medicines	October 2016	Closed
Expedited pathways for prescription medicines: eligibility criteria and designation process	October 2016	Closed
Provisional Approval pathway for prescription medicines	March 2017	Open
Strengthening monitoring of medicines in Australia: Enhanced medicines vigilance	March 2017	Open
Simplifying regulatory arrangements for advertising of medicines and medical devices		
Consultation on options for handling complaints about therapeutic goods advertising and other changes to the advertising framework	November 2016	Closed
Medical device regulatory reforms		
Designation of Australian conformity assessment bodies for medical devices	November 2016	Closed
Accelerated assessment of medical devices – priority review	November 2016	Closed
Use of overseas regulatory approvals for medical devices and criteria for identifying comparable overseas designating authorities and regulators	April 2017	Upcoming
Complementary medicine regulatory reforms		
Reforms to the regulatory framework for complementary medicines: Introduction of a new class of assessed complementary medicines Mechanisms for establishing a list of permitted indications including the criteria for what a permitted indication is and the initial lists of permitted	February 2017	Closed
indications Appropriate criteria for publication of claims on promotional material for complementary medicines Incentives for encouraging innovation in the complementary medicines sector		
Streamlined regulation of patient-specific access to therapeutic products		
Changes to accessing unapproved therapeutic goods: criteria for unapproved products of acceptable risk to be notified to TGA via SAS Cat B 'scheme; and a streamlined process for Authorised Prescriber Scheme applications	February 2017	Closed
Further reviews		
The Scheduling Policy Framework and Advertising of Pharmacist-only medicines (Schedule 3 substances)	March 2017	Open
Options for the future regulation of 'low risk' products	March 2017	Open

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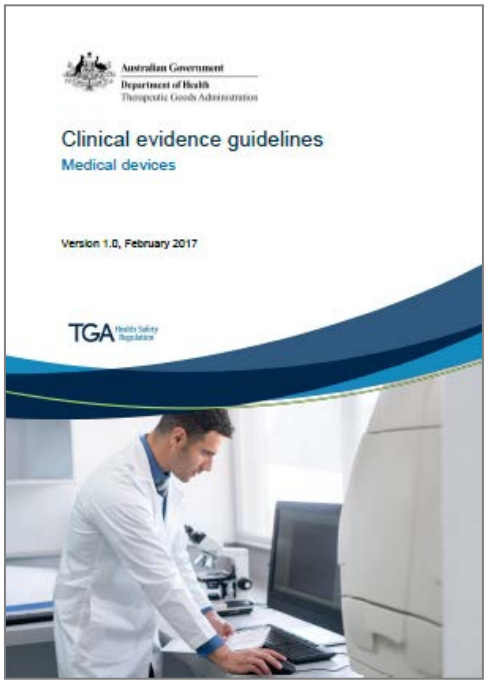
One more thing…

NEW!

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

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