Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1927-2017 FICCI @90

22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

MAKE IN INDIA

4-8 December, 2017 I New Delhi

Medical Devices & IVD's
An Australian Update

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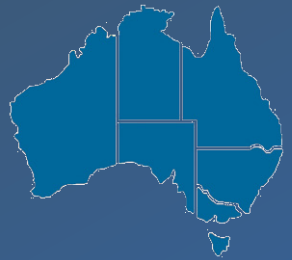


A Little History .....

1985 – Regulation of some high risk devices using the Customs Act

1989 – First therapeutic device regulations introduced

1992 – GHTF first meeting

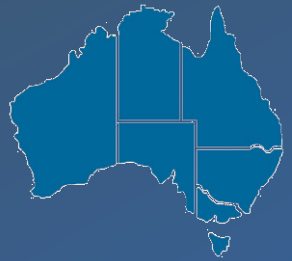
1996 – Commenced development of new regulatory framework

2002 – New medical device regulations introduced

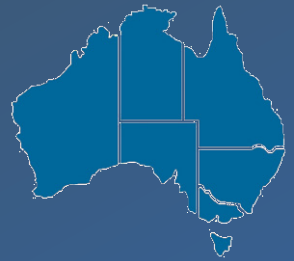
2007 – Medical device regulations fully in place

2010 – IVD regulations introduced

2017 – IVD regulations fully in place



- GHTF Based framework
  - Essential Principles
  - Classification
  - Conformity Assessment
  - Quality Management Systems
  - Registration
  - Postmarket monitoring



But then.....

2011 - TGA reforms: a blueprint for TGA's future

2013 - Change of Government

Mission .....cut the red tape !!

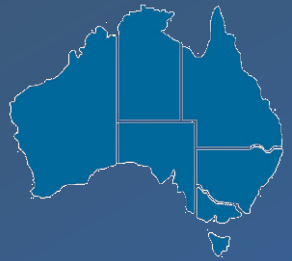
.....for every new regulation.....one had to go !!

2014 - Review of medicines and medical device regulation

2016 - Government response to the review

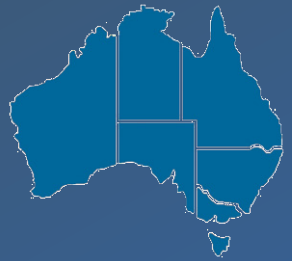
.....accepts nearly all recommendations....

2017 - Commence implementation.....



So, what can we expect…….

- Over-arching principles –
  - TGA will maintain capacity to undertake assessments
  - TGA will retain responsibility for decision making regarding marketing approvals
  - Greater flexibility in approval pathways
  - Enhanced postmarket monitoring



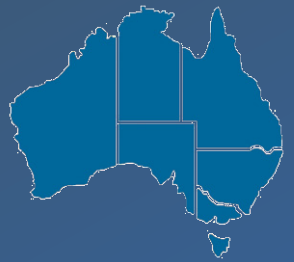
Greater flexibility in approval pathways

- Conformity Assessment within Australia
  - AU manufacturers must use TGA…….removed 2014
  - By TGA designated bodies……not yet, but on the way
- Utilisation of overseas marketing approvals
  - CAB must be designated by a '*comparable*' overseas designating authority; or
  - Approved by '*comparable*' overseas regulatory
- Expedited Review process for certain '*novel*' devices

Conformity Assessment within Australia

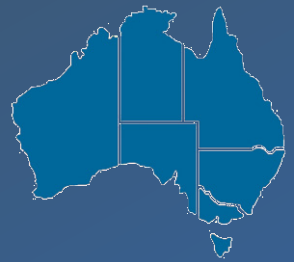
- Bodies designated by the TGA will be able to undertake conformity assessment certification
  - Consultation Nov 2016
    - TGA Designating Authority function
    - Designation process
    - Designated Conformity Assessment Bodies
- Some changes to Act already passed, some still in the process……..

- Delivery Date – January 2018 (promised)
- Regulation changes…….. not yet sighted…….



Conformity Assessment within Australia

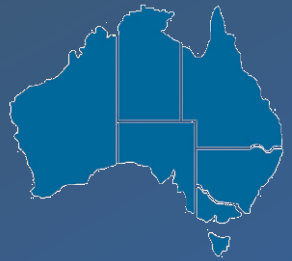
- Issued to be resolved –
  - Fees…….set by CAB's, not the TGA
  - TGA Cost/resources of designation process
  - Impact on TGA Conformity Assessment Revenue
  - Competitive neutrality
    - Competition between public and private businesses
    - ? Any TGA advantage as a government business
      - Taxation…….
      - Cost neutrality, not for profit …….no shareholders….
      - Insurance costs……..
      - Etc……



Conformity Assessment within Australia

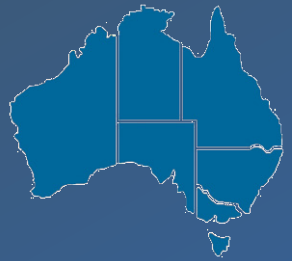
'Australian Conformity Assessment Bodies.....
we will build it.....but will they come?'

Adj Prof John Skerritt
Deputy Secretary, Health Products Regulation Group
Australian Department of Health



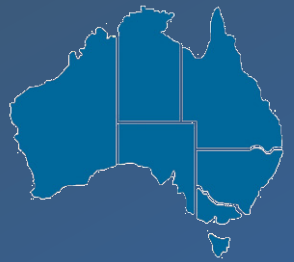
Utilisation of overseas marketing approvals

- AU already accepts EU NB EC Certificates for devices up to class Iib
- Uses application audit process for most class III devices
- Often abridges Conformity Assessment based on EU NB audit reports and assessments
- Potential for greater use of Canadian and US assessments
  - Frameworks are different
  - Applicant would have to provide full assessment report
- Consultation – May 2017
- Changes currently before Parliament
- Regulations still to be drafted
- Watch this space ……
- The big question…….
  - what is '…..*comparable*….'



Expedited Review Processes

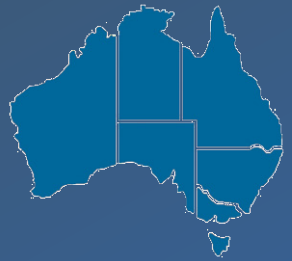
- Priority assessment……..'front of queue' priority
- No reduction in evidence or assessment requirements
- Faster processing of conformity assessment and ARTG inclusion
- Conditions –
  - Answer questions in timely manner……or to the back of the queue
- Extra fees !!



But it's not that easy…….

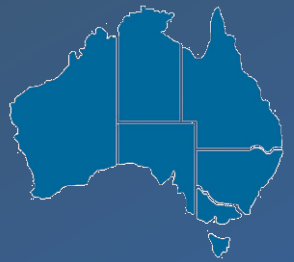
- Devices intended for the prevention or treatment of a **life threatening or seriously debilitating** disease or condition; **AND**
- Device addresses an **unmet clinical need** in Australian patients; **AND**
- Breakthrough technology/clinical advantage/public health need (IVD's only)

- Meets at least one of the following –
  - Device represents a major technological (not just engineering) advantage over existing; **OR**
  - Device offers a major clinical (not just engineering) advantage over existing alternatives; **OR**
  - Early availability will result in a major public health benefit (IVD's only)



Enhanced postmarket monitoring

- Better analysis of available datasets
  - Device Registers
  - AOA National Joint Replacement Register
- Electronic Reporting of Adverse Events
- Public Reporting of TGA Laboratory sampling and testing results
- Information sharing with overseas regulators
- Continued roll out of InSite Hospital program

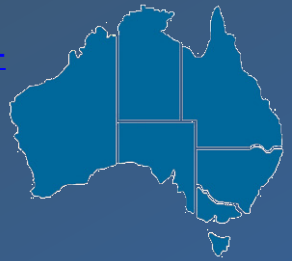


And if that wasn't enough……

- November 2017
  - *Proposed regulatory changes related to personalized and 3D printed medical devices*

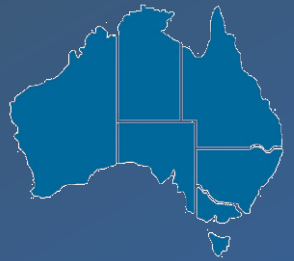
- Released for comment last week
- Comment closes 22 December 2017

https://www.tga.gov.au/consultation/consultation-proposed-regulatory-changes-related-personalised-and-3d-printed-medical-devices



Proposed regulatory changes related to personalized and 3D printed medical devices

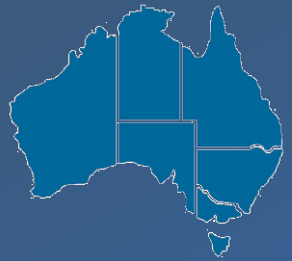
- First serious attempt by a regulator to move into unchartered territory
- Will be closely watched by others……..
- Proposes moving into regulation of ‘practice of medicine’…… typically ‘set aside’ or ‘off limits’ to regulators
- Concerns largely based around 3D implants……
  - But have the potential to impact seriously on devices such as external prosthetics, etc…….



Proposed regulatory changes related to personalized and 3D printed medical devices

- Recommendations –
  - Take the time to review,
  - Comment……good, bad or indifferent….

- Because it may make difference for all in the longer term.



Questions, comments, thoughts ……

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