Australian Government
Department of Health
Therapeutic Goods Administration

What's happening in Europe?

New medical device and IVD regulations

New European regulations came into force on 25 May 2017

3 years to transition*

** Subject to certain exclusions*

5 years to transition*

MEDICAL DEVICES

Notified bodies

- Strengthened designation criteria
- Joint audits
- Unannounced audits

Clinical evidence

- For high risk devices – more explicit requirements
- Publish Safety and Performance data
- Post-market clinical follow-up

Pre-market

- New definitions
- Up-classifications
- European Authorised Representatives – joint responsibility with manufacturers for defective devices

Post-market

- Central database and co-ordination
- Post-market reporting
- Enforcement activities

Transparency and traceability

- Unique Device Identification (UDI) system
- Implant cards

Other

- Some products without medical purpose to be regulated as medical devices (therefore, subject to stricter controls)

IVDs

Notified bodies

- Strengthened designation criteria
- Joint audits
- Unannounced audits

Clinical evidence

- *Scientific Validity*
- *Analytical Performance*
- *Clinical Performance*

Pre-market

- Expanded scope of regulated IVD products
- New risk-based classification system (A to D)
- 80-90% of IVDs will be checked by a notified body (previously only 20%)
- European Authorised Representatives – joint responsibility with manufacturers for defective devices
- Special provision for companion diagnostics

Post-market

- Central database and co-ordination
- Post-market reporting
- Enforcement activities

Transparency and traceability

- Unique Device Identification (UDI) system

In-house IVDs

- Includes regulation of in-house IVDs

Harmonisation with Europe

MMDR Recommendation 20 accepted by Government:

> *"The regulation of medical devices by the Australian NRA is, wherever possible, aligned with the European Union framework…Should the Australian NRA seek to apply specific requirements, there must be a clear rationale to do so."*

Consultation has recently commenced on specific aspects. Further consultations on harmonisation with Europe will be released in 2018

Need more information?

https://www.tga.gov.au/

Need more information? **www.tga.gov.au** **email: devices@tga.gov.au**

TGA Health Safety Regulation