IMDRF International Medical Device Regulators Forum

Australian Jurisdictional Update
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Government

2015 review medicines and medical device regulation

- Government accepted recommendations and TGA is developing new pathways for pre market approval:
  - Designation of Australian bodies
  - Utilisation of approval from comparable regulators
  - Expedited approval in certain circumstances

- Consultation and policy development progressing

Current Focus

- Clinical Evidence Guidelines published February 2017
  - communication strategy developed
  - webinars for international manufacturers

- Other guidance materials being developed
  - implant labelling and patient cards
  - electronic IFUs for implantable devices
  - 3D printing

- About to publish outcomes of TGA Laboratories testing

- Transition of in-house IVDs to be completed by mid-2017