IMDRF International Medical Device Regulators Forum

Regulatory Updates Health Sciences Authority Singapore

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Medical Device Legislative Changes – Key Objectives

- To improve clarity and transparency in the scope of regulatory controls
- To improve accessibility to safe medical devices for patients
- To enhance the efficiency of regulatory processes and remove redundancies where appropriate
- To strengthen the post-market compliance monitoring as necessary to balance the life cycle regulatory approach
- To support safe innovation in medical technology to benefit patients

Medical Device Legislative Changes - *In Progress*

- Improving the accessibility to Class A (sterile) and Class B Medical Devices
  - Conformity to International standards (e.g. sterilisation standards)
  - Leveraging on the marketing authorization from reference regulatory agencies* and safe marketing history where applicable
  - Strengthening post-market compliance monitoring for these devices
    - Recalibrating the regulatory controls based on experience gathered
    - Potential faster access to all sterile Class A MDs and an additional 54% of Class B MDs

**Australia's Therapeutic Goods Administration, European Medicines Agency, Health Canada, Japan's Pharmaceuticals and Medical Devices Agency, US Food and Drug Administration*

Medical Device Legislative Changes - *In Progress*

- **Implementation** of the regulatory approach for Telehealth Products
  - A risk-based approach to regulation of these products has since been developed
    - Not all Telehealth products are necessarily regulated as medical devices
    - Products intended for medical purposes (i.e. diagnosis, treatment or patient monitoring) to be regulated as medical devices
    - Products intended for wellness purposes not to be regulated as medical devices (e.g. wearable lifestyle devices, sports performance trackers) if
      - *They are labelled clearly to inform users their intended purpose i.e. not for medical diagnostic or monitoring purposes*
  - Regulatory requirements for stand-alone software and mobile applications (i.e. SaMD)
    - Faster market access pathway for SaMD that have been reviewed and cleared by one of our reference regulatory agency*

**Australia's Therapeutic Goods Administration, European Medicines Agency, Health Canada, Japan's Pharmaceuticals and Medical Devices Agency, US Food and Drug Administration*

Medical Device Legislative Changes - *In Progress*

- Setting up a separate public online database for Class A medical devices imported/supplied in Singapore
  - Currently there is a public online register for all registered medical devices – Singapore Medical Device Register

- Streamlining the submission requirements for post-approval changes to registered medical devices

- Prescribing the quality management system requirements for licensing of manufacturers, importers and wholesalers of medical devices within the legislation

Guidance Documents – Upcoming Updates in 2018

- Guidance on Essential Principles for Safety and Performance of Medical Devices
- Guidance on Labelling for Medical Devices
- Guidance on Medical Device Product Registration
- Guidance on Change Notification

NOTE: Includes changes to the guidance documents that are a consequence of the legislative changes in progress

Thank you!