IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority
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Regulatory approach for Telehealth Products

- Paradigm shift in healthcare sector
  - Surge in development of Telehealth products
    - Remote monitoring of patients with chronic illness and online consultation with physicians
    - Greater access to technology for consumers (e.g. smart phones)
    - Enabler for efficient use of the limited healthcare resources and infrastructure

- Regulation of **Telehealth products**
  - With the current definition of “medical devices”, majority of the Telehealth products (i.e. devices, software and mobile applications) will fall within the scope of our regulatory controls
  - A risk-based approach to regulation of these products has since been developed
    - Not all Telehealth products are necessarily regulated as medical devices (e.g. wearable lifestyle devices, sports performance trackers)
    - Products intended for medical purposes (i.e. diagnosis, treatment or patient monitoring) to be regulated as medical devices

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Guidelines on regulation of Telehealth Products

Scope of Regulatory Controls	Risk Mitigation Measure	Regulatory Approach
Only Telehealth products with intended **medical purpose** (e.g. diagnosis, treatment, patient monitoring) to be subject to regulatory controls.	Telehealth products for monitoring physiological parameters & not intended for medical purposes (e.g. heart rate monitor for sportspersons) to include a "**clarification statement**" on their labels, to inform users and consumers that the **product is not** to be used **for medical conditions**.	Confidence based approach – Immediate market access to standalone mobile applications approved in a reference regulatory agency* Risk stratified approach – Regulatory requirements commensurate with risk class of the product

Decision trees to aid in determining regulatory controls applicable and also risk class of the regulated product

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

Key Benefits:

- Regulatory oversight stratified based on the intended purpose of the product
- A labeling requirement in the form of a “clarification statement” is required to adequately inform users of the appropriate use of the product
  - Address any potential misuse of products and applications that may not meet medical device standards
- Clarity on regulatory controls and transparency – also for non medical device stakeholders (e.g. mobile app developers)
- Provide early guidance to industry on regulatory requirements – facilitate regulatory compliance

→ Faster access to innovation to benefit our healthcare system and the patients

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Current Status:

a. The regulatory approach for Telehealth products has been approved

b. Draft guidelines has been developed

c. Completed public consultation (20 October – 30 November 2016)

- Over 150 comments have been received from diverse stakeholders (e.g. medical device industry members, mobile application developers including Apple, healthcare institutions, MOHH, MOH)
- **Review of comments in progress**
- Guidelines to be updated based on comments received and to be published with FAQs and responses to comments (2Q 2017)

Implementation pending legislative update to the Health Products (Medical Devices) Regulations.

Guidance Documents – 2016 Key Updates

- Guidance on Change Notification for registered medical devices
- Guidance on Grouping of Medical Devices for Product Registration – General Grouping and Device Specific Grouping Criteria
- Guidance on Medical Device Field Safety Corrective Action

Upcoming Documents

- Update to the Guidance on Preparation of the ASEAN CSDT* for Medical Devices and In Vitro Diagnostics (IVDs)

- Registration and listing of IVD analysers and instruments

**** Common Submission Dossier Template***

Thank you!