Regulatory Updates
Health Sciences Authority
Singapore

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Regulatory approach for Telehealth Products

• Paradigm shift in healthcare sector
  o 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**
  o 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
  o 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
## Guidelines on regulation of Telehealth Products

<table>
<thead>
<tr>
<th>Scope of Regulatory Controls</th>
<th>Risk Mitigation Measure</th>
<th>Regulatory Approach</th>
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<tbody>
<tr>
<td>Only Telehealth products with intended medical purpose (e.g. diagnosis, treatment, patient monitoring) to be subject to regulatory controls.</td>
<td>Telehealth products for monitoring physiological parameters &amp; 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.</td>
<td>Confidence based approach – Immediate market access to standalone mobile applications approved in a reference regulatory agency*</td>
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*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.

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*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
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!