APPENDIX- FAQ

Telehealth Product

1. What are Telehealth products?

   Telehealth products are instruments, apparatus, machines or software (including mobile applications) that are involved in the provision of healthcare services over physically separate environments via infocomm technologies (including mobile technology), categorised into four broad domains:
   - Tele-collaboration;
   - Tele-treatment;
   - Tele-monitoring;
   - Tele-support.

   Examples of Telehealth products:
   - Tele-collaboration: An online platform that facilitates sharing of information between physicians for peer consultation purpose.
   - Tele-treatment: Robotic surgery system that allows a surgeon to perform surgery on a patient even though they are not physically in the same location.
   - Tele-monitoring: Portable SpO2 patient monitoring system that is intended for spot-checking or continuous monitoring of oxygen saturation of arterial hemoglobin. The readings can be transmitted to the physician for monitoring.
   - Tele-support: A mobile application that provides educational information to patients on diseases, medications and etc.

2. Are all Telehealth products considered as a Medical Device?

   Not all Telehealth products are medical devices. A Telehealth product intended for medical purposes by the Product Owner (PO), will be classified as a medical device and are regulated by HSA. Such Telehealth products are also known as **Telehealth Medical Devices**.

   It is understood that certain Wellness Devices achieve its intended purpose by encouraging users to improve or maintain a healthy lifestyle. Such products are not medical devices.

3. How are Telehealth Medical Device regulated?

   All medical devices to be supplied in Singapore are subject to the following medical device regulatory controls:
   i. Product Registration;
   ii. Dealer's licence requirements;
   iii. Post-market obligations.

   Similarly, these controls apply to Telehealth Medical Devices as well. For an understanding of the product registration and licensing of dealers process and requirements, you can download the Quick Guide at this **link**.

4. What is the purpose of the clarification statement to be included on the label for Telehealth Wellness Device?

   It is not easy for a user to ascertain whether a Telehealth Wellness Device falls under the definition of a Medical Device solely based on the product labelling (For example: smart watch that measures/monitors the user's heart rate or SpO2 for general fitness tracking).

   For Telehealth Wellness Devices that are not intended by the Product owner (PO) for medical purpose, but are able to perform such function/purpose, PO has to ensure that the product's labelling claims is conveyed clearly and does not mislead the users on its intended function. Hence the clarification statement or equivalent will be required to ensure that users do not mistakenly use the product for medical purpose.

5. Are there any differences in the risk classification of Telehealth Medical Devices as compared to other form of medical devices?

   There are no differences between the risk classification of Telehealth Medical Devices and other forms of medical device. Please refer to GN-13 Guidance on the Risk Classification of General Medical Devices to determine the Medical Device risk classification.

   Alternatively, you may refer to Flowchart 2 (Risk Classification of Telehealth Medical Devices) to determine the risk classification of Telehealth Medical Devices. The flowchart is based on the current risk classification rules as per GN-13 and is meant to provide guidance and clarity in layman terms.

6. Will commercial off-the-shelf smartphone/tablet be regulated by HSA?

   Generic mobile platforms (e.g. smartphones and tablets) on their own are unable to perform a medical purpose without the aid of a mobile application. Hence they will not be regulated by HSA. The “Clarification statement” is also not required to be labelled on such products.

Standalone Medical Mobile Application

1. What are Standalone Medical Mobile Applications?

   Standalone Medical Mobile Applications refer to software and/or mobile applications with medical purpose that are intended to function by themselves and are not intended for use to control or affect other hardware medical devices (e.g. medical sensors).

   An example would be a standalone software that predicts low blood glucose level episodes in patients based on past glucose measurements and diet input into the software. These are required to be designed based on established scientific evidence and known clinical utility.

If the standalone mobile applications are not intended for medical purpose (e.g. fitness tracking) but are able to perform such function/purpose (e.g. heart rate monitoring), PO of the mobile applications is required to include the "clarification statement" or equivalent (refer to page 4 of the Telehealth Guidelines) in the mobile application (e.g. splash screen or loading screen).

2. How are Standalone Medical Mobile Applications regulated?

Regardless of where the physical server of the Standalone Medical Mobile Application is located (overseas or locally), the Standalone Medical Mobile Applications will fall under HSA's jurisdiction if the application is distributed in Singapore via the local online platforms (e.g. Apple Store, Google Play Store and etc.). Like all other medical devices, the Standalone Medical Mobile Applications are subject to the following medical device regulatory controls:

i. Product Registration;
ii. Dealer's licence requirements;
iii. Post-market obligations.

3. Are there any differences in the risk classification of Standalone Medical Mobile application as compared to other form of medical devices?

There are no differences between the risk classification of Standalone Medical Mobile Application and other forms of medical device. Please refer to GN-13 Guidance on the Risk Classification of General Medical Devices to determine the risk classification of such Medical Devices.

4. What is the rationale for implementing the new Immediate Registration Route for standalone mobile medical device application?

For Standalone Medical Mobile Applications that have been approved in the reference agencies (Health Canada; Japan's Ministry of Health, Labour and Welfare; United States Food and Drug Administration; Australian Therapeutic Goods Administration; European Union Notified Bodies), the software algorithm and clinical utility would have been reviewed by a recognized regulatory body. HSA is utilising a confidence-based approach by leveraging on the reference agency's approval to facilitate access for such Standalone Medical Mobile application into the Singapore market.

This new route is not intended to encompass other medical device as there may be other considerations (For example: Electromagnetic compatibility, electrical safety and device durability) that require review by HSA.