CONSULTATION ON PROPOSED REGULATORY GUIDELINES FOR TELEHEALTH DEVICES

1. Introduction

1.1 Objective

The Health Sciences Authority (HSA) invites feedback and comments from our stakeholders to review the proposed regulatory guidelines on Telehealth devices.

As not all Telehealth devices in the market are medical devices, this guideline is intended to provide clarity on the types of Telehealth devices that are medical devices, as well as the proposed regulatory approach and requirements for such Telehealth devices regulated by HSA.

1.2 Background

Telehealth devices are instruments, apparatus, machines or software (including mobile applications) that are involved in the provision of healthcare services over distance via infocomm technologies, categorised into three broad service areas:

- Clinical services e.g. Tele-radiology, Tele-consultation
- Education e.g. Educational web portals
- Administration e.g. Care management systems

Depending on the Telehealth device's intended purpose, it may be classified as a medical device. Therefore, this document serves to provide clear guidelines on identifying a Telehealth medical device.

As a general rule, a Telehealth device **intended for medical purposes** such as i) the diagnosis of disease or medical conditions, or ii) the cure, mitigation, treatment, or iii) prevention of disease, or iv) is intended to affect the structure or any function of the body of humans; will be classified as a medical device that falls under the purview of the HSA.

In recent years, Telehealth technology has advanced at a rapid pace of innovation and introduced a myriad of benefits and potential risks to public health. As part of Singapore's Smart Nation initiatives, HSA aims to refine and streamline its regulatory framework for Telehealth medical devices, so as to promote better innovation and efficiency in our healthcare sector.

This regulatory approach adopted will be largely similar to the 2 regulatory principles in the regulations of the other medical devices – they are:

- Risk-based regulation – HSA employs a rule-based approach (GN-13: Guidance on Risk Classification of General Medical Devices) to classify medical devices into four risk classes (A, B, C & D), according to the nature of the device and its intended functions. The level of scrutiny and regulatory requirements on a medical device will in turn commensurate with its risk class.

- Confidence-based regulation – The evaluation routes (e.g. Immediate Class B Registration route, Expedited Class B/C/D Registration routes and etc.) for medical devices are set out according to a confidence based approach by leveraging on the approvals of HSA's reference regulatory agencies and/or prior safe marketing history of the medical devices. The submission requirements are titrated according to the evaluation routes that the device qualifies.

This will allow faster access to new and innovative Telehealth medical devices to provide high quality Telehealth services to healthcare professionals, patients and consumers, whilst safeguarding public health.

1.3 Scope

This document applies to all Telehealth devices with or without medical intent, which include hardware devices, software and mobile applications.

1.4 Definitions

PRODUCT OWNER (as stated in the Medical Device Regulations): in relation to a health product, is defined as a person who —

- supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
- is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

TELEHEALTH: The provision of healthcare services over distance via infocomm technologies, categorised into three broad service areas:

- Clinical services e.g. Tele-radiology, Tele-consultation

- Education e.g. Educational web portals
- Administration e.g. Care management systems

TELEHEALTH DEVICES: All forms of devices, including hardware devices, software and mobile applications, used in the delivery of Telehealth services.

2. Classification of Telehealth Devices as Medical Devices

The **intended use** of the Telehealth device will determine whether it will be classified as a medical device. The intended use is reflected on the specifications, instructions and information provided by the Product Owner or manufacturer of the device.

When the intended use of a Telehealth device is for i) the diagnosis of disease or medical conditions, or ii) the cure, mitigation, treatment, or iii) prevention of disease, or iv) is intended to affect the structure or any function of the body of humans, then it is a medical device and is subject to HSA's regulatory control.

For a step by step decision tree if a Telehealth device is or is not a medical device, please refer to Flowchart 1 for more details.

3. Telehealth devices intended for general well-being purposes

In recent years, there is an increased adoption of general well-being/lifestyle devices among the general population with the rapid growth of the Telehealth technology. A general well-being device is typically intended to encourage users to maintain and track their healthy lifestyle which include the following:

- A wireless wearable pedometer that counts each step a person takes as an everyday exercise counter;

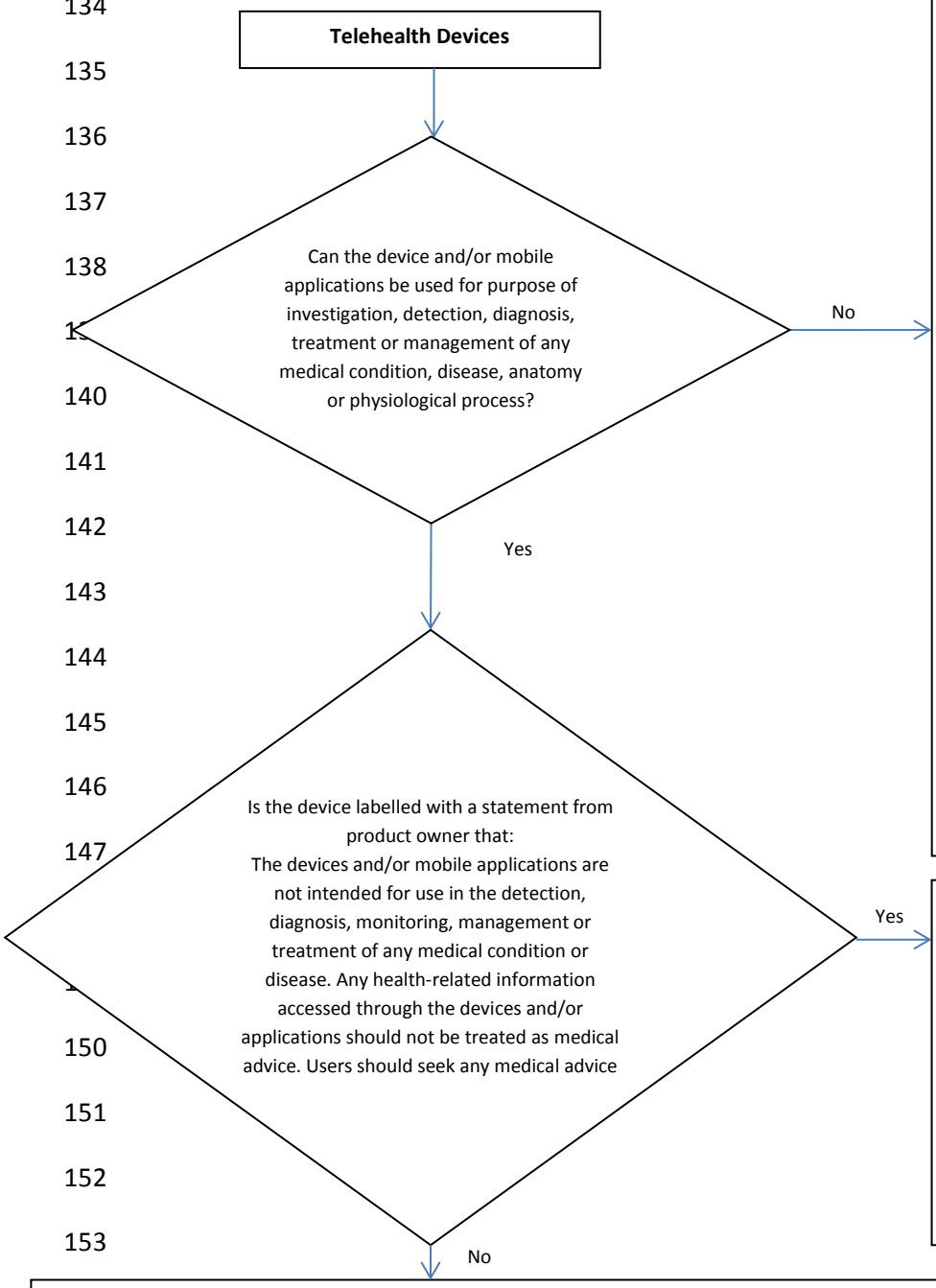
- Heart-rate monitors in smart phones or watches that is meant for tracking of general fitness.

Please note that such Telehealth devices intended for well-being or lifestyle purposes will **not** be regulated as medical devices. For such devices, manufacturers are required to include the following "clarification statement" (or equivalent) on their labels:

"The devices and/or mobile applications are not intended for use in the detection, diagnosis, monitoring, management or treatment of any medical condition or disease. Any health-related information accessed through the devices and/or applications should not be treated as medical advice. Users should seek any medical advice from a physician."

HSA would like to emphasise that users should not misconstrue any health-related information accessed through these devices as medical advice. Users should still seek proper medical advice from a physician regarding any health-related issues.

Flowchart 1: Is a Telehealth Device a Medical Device?



Not medical device.

Examples:

1. Online educational medical information (Tele-support).
2. Webcam to monitor the movements of elderly people at home remotely (Tele-monitoring).
3. Apps that can calculate BMI or total water content based on specific input parameters but do not perform any diagnosis or therapeutic functions.
4. Commercial off-the-shelf mobile platforms (e.g. generic smartphones and tablets) that are not intended to be used for medical purpose by the Product owner.
5. Telehealth devices that are intended solely for communication purposes such as video conference systems that are intended solely to perform remote consultations between clinics and patients
6. Telehealth devices that is intended solely to automate administrative operations in a health care setting such as automated billing system.

Not medical device.

Examples:

1. Heart-rate monitors in smart phones or watches for lifestyle purposes and not for medical diagnosis.
2. SPO2 meters for use by athletes and not intended for medical diagnosis or monitoring purpose

The device is a Medical Device

1. Remote Surgical Systems that allow doctors to perform surgery on a patient even though they are not physically in the same location.
2. Remote patient monitoring device:
   - Software or app that monitors and transfers patient's data to a central viewing station for display and active patient monitoring.
   - Software or app that displays ECG or other vital signs in remote location as transmitted from patient side.
3. Mobile medical apps that transform a mobile platform into a regulated medical device.
   - Mobile apps that use a sensor or lead that is connected to a mobile platform to measure and display the electrical signal produced by the heart (electrocardiograph or ECG).
   - Mobile apps that use an attachment to the mobile platform to measure blood oxygen saturation for diagnosis of specific disease or condition.

4. Risk Classification of Telehealth Devices that are Medical Devices

As with all other medical devices, the Telehealth devices can also be classified into either one of the four Class A-D devices, depending on the nature of the device and its intended functions. If the device intends to monitor or predict any disease or medical conditions, then it will be in a higher risk category compared to a device which just displays a data. This is because of the greater impact on patient health and safety if the patient uses the Telehealth device and if it should not function as intended.

Hence, in lieu of the higher risk profile, the level of scrutiny and regulatory requirements by HSA will also vary accordingly. Below are examples of Telehealth devices of various risk classes.

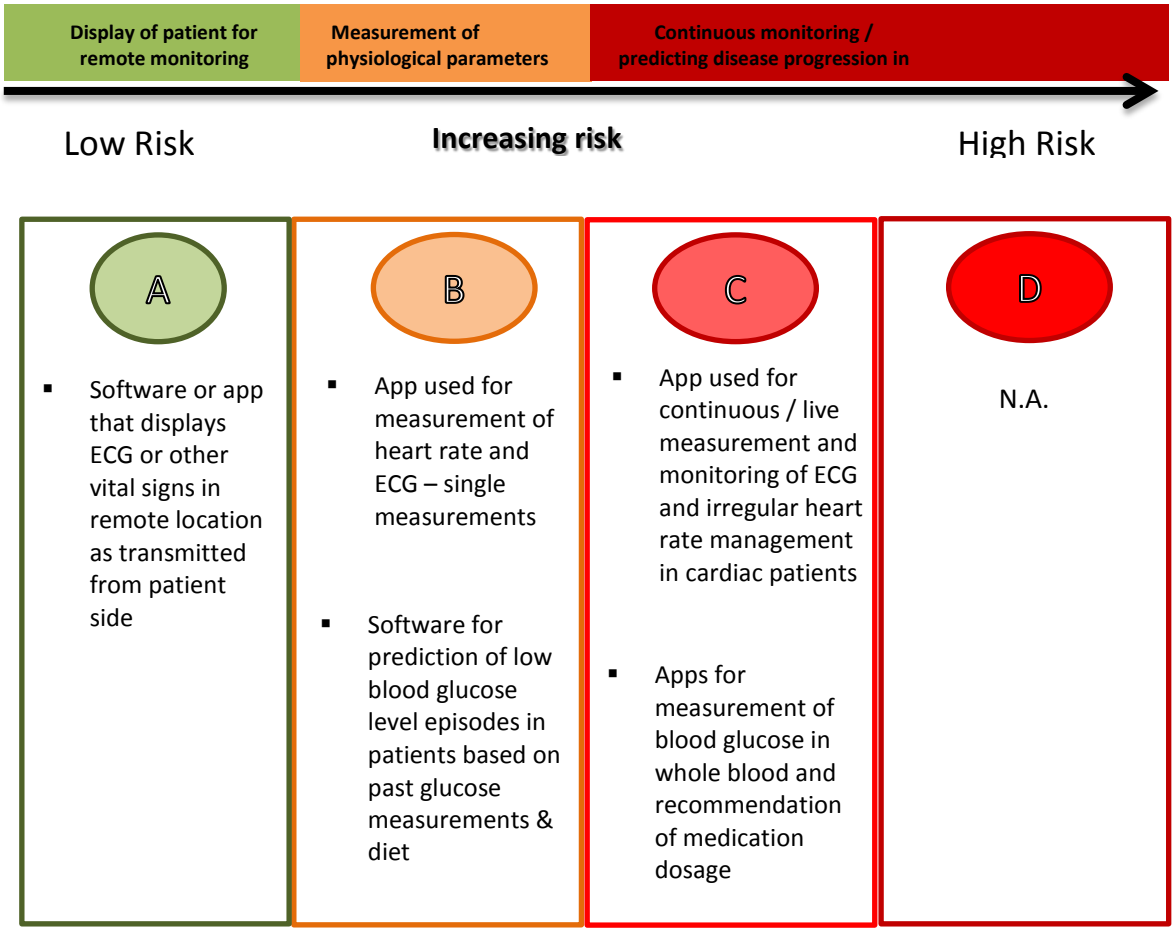
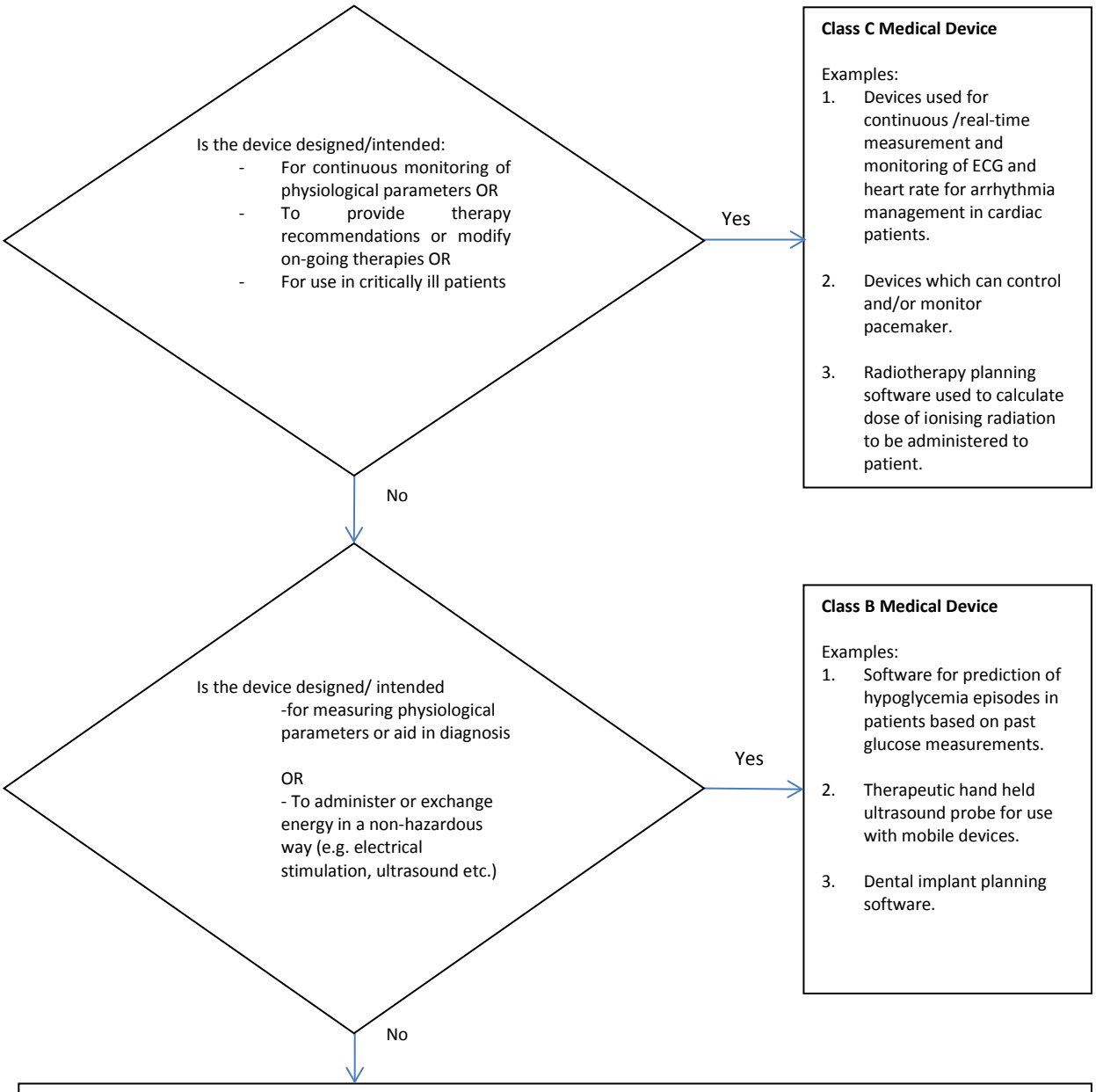


***Table 1**: Examples of Telehealth Medical Devices of various risk classes.*

To determine the risk classification of Telehealth devices that are classified as medical device, please refer to Flowchart 2 (Risk Classification of Telehealth Medical Devices) for more details.

The following sections are applicable to industry members that are dealing with Telehealth medical devices and standalone mobile applications that are medical devices.

Flowchart 2: Risk Classification of Telehealth Medical Devices



5. Proposed Regulatory Controls for Telehealth Devices

Telehealth devices that are "medical devices" are subject to the following medical device regulatory controls:

a) Product Registration;
b) Dealer's licence requirements;
c) Post-market obligations.

(A) **Product Registration:**

If you want to market a Telehealth medical device in Singapore, you will need to obtain marketing clearance from HSA via Product Registration before import and supply of the devices in Singapore. The submission requirements and process, depending on the risk class of the Telehealth medical device, will follow as per GN-15: Guidance on Medical Device Product Registration.

Immediate Route (Only Class B MDs and Standalone Mobile applications)	Expedited Route (Class B, C and D MDs)	Abridged Route (Class B, C and D MDs)	Full Evaluation (Class B, C and D MDs)
Criteria: Class B MDs •2 Reference agency approvals •3 years marketing history •No major safety issues Standalone Mobile application (New) • 1 Reference agency approval • No major safety issues globally	Criteria: •2 Reference agency approvals Or •1 Reference agency approval •3 years marketing history •No major safety issues globally	Criteria: 1 Reference agency approval	No Reference agency approval
Note: HSA's reference agencies: Health Canada, US FDA, Australian Therapeutic Goods Administration, European Union and Japan Ministry of Health, Labor and Welfare.			

***Table 2**: The eligibility criteria for evaluation routes.*

Please note that low risk (i.e. Class A) Telehealth medical devices will be exempted from Product Registration with HSA. Therefore, such devices are able to be marketed immediately.

Manufacturers and importers that are dealing with such Class A exempted Telehealth medical devices only will be required to declare these devices in the list of their non-

sterile Class A medical devices under the importer's and manufacturer's licences and update the list periodically.

(B) **Dealers' Licence requirements**:

If you want to engage in the manufacture, import and/or wholesale of Telehealth medical devices in Singapore, you will need to obtain the appropriate required dealer licences from HSA. The submission requirements and process will follow as per GN-02: Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices. This licensing requirement is to ensure proper traceability and post-market monitoring of Telehealth medical devices marketed in Singapore.

For importers and wholesalers dealing with only Class A medical devices (sterile or non-sterile), they may opt for the Quality Management System for Class A Medical Devices (QMS CAD) scheme administered by HSA in-lieu of GDPMDS certification. For more information, please refer to GN-31: Guidance on Quality Management System Requirements for Licensing of Importers and Wholesalers of Class A Medical Devices.

(C) **Post-market obligations**:

Dealers of Telehealth medical devices are obliged to perform post-market duties, including but not limited to reporting of adverse events, defects and recall to HSA and ensuring appropriate investigation, so as to assure the continued safe use of the devices.

Healthcare professionals and users of Telehealth medical devices may also report any adverse events related to the use of a medical device or device failure related issues to HSA on a voluntary basis.

6. Regulatory Controls for Standalone Mobile Applications* that are Medical Devices

**Standalone Applications refers to applications that are intended to function by themselves and are not intended for use with other hardware devices*

Please note that only standalone mobile applications that are distributed on local online platforms will be regulated.

With the widespread growth and adoption of Telehealth technology, HSA is applying a regulatory approach that is similar to other medical devices to facilitate faster access to standalone mobile applications.

If a Class B and C standalone mobile application has been registered by one of HSA's reference agencies, they may qualify for Immediate Registration Route. The eligibility criteria at the point of submission are:

- Approval by at least one of HSA's independent reference agencies for intended use identical to that submitting for registration in Singapore

[HSA's independent reference regulatory agencies are i) Health Canada, ii) Japan's Ministry of Health, Labour and Welfare, iii) United States Food and Drug Administration, iv) Australian Therapeutic Goods Administration v) European Union Notified Bodies and the corresponding approvals listed under Section 5.1 Evaluation Routes of GN-15.]

- no safety issues globally associated with the use of the medical device(s) when used as intended by the Product Owner, defined as
    a. No reported deaths;
    b. No reported serious deterioration in the state of health of any person; and
    c. No open field safety corrective actions (including recalls) at the point of submission.

Please note that other standard regulatory controls (i.e. Dealers' Licence and Post-Market obligations) are still applicable to standalone mobile applications that are medical devices.

7. Feedback Sought

HSA welcomes your comments and feedback on the definitions, classification, clarification statement and proposed regulations.

This consultation will be held from 17 Oct 2016 to 30 Nov 2016.

Please provide your name, the organisation you represent, mailing address, contact number and email address to enable us to follow up with you to clarify any issues, if necessary.

Where possible, you should highlight the specific regulation in the proposed draft you are providing your comments on.

Please note that the contents of any written feedback submitted, and the identity of the source, may be disclosed at the conclusion of this consultation. You may request for the feedback provided to be treated with confidence on grounds that the information is proprietary, confidential or commercially-sensitive. Such requests will be taken into consideration.

Please email your feedback using the prescribed template to **hprg_feedback@hsa.gov.sg** by **30 Nov 2016**.