FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
22 MAY 2018

HSA ENHANCES LEGISLATION FOR FASTER ACCESS TO MEDICAL DEVICES AND IMPROVED CLARITY ON REGULATORY CONTROLS

The Health Sciences Authority (HSA) announced today that its regulatory legislation will be enhanced to facilitate faster access for certain lower risk medical devices (MDs) and standalone mobile applications. HSA will also provide greater clarity to existing policies and requirements for telehealth devices and high risk devices for the modification of appearance or anatomy. The changes will take effect from 1 June 2018.

2 The changes seek to cater to different operational and emerging business models in the medical device industry and facilitate access and innovations, while safeguarding consumer health and safety.

FASTER MARKET ACCESS

3 Today's medical devices comprise a very diverse group of products, with varying complexities and risk profiles. HSA regularly reviews our regulatory framework to ensure that it remains relevant and effective. From 1 June 2018, the regulations for the following devices will be enhanced as follows:

a. Class A sterile medical devices, such as sterile examination gloves and sterile intravenous sets, will not need to be registered with HSA. Previously, these devices were subjected to registration to ensure that they comply with the requisite standards on sterility. To ensure safety and facilitate post-market surveillance and monitoring, importers/manufacturers will be required to list all their Class A medical devices on the public online Class A database with HSA.

b. The current expedited[1] Class B registration route, which currently takes 60 days for the product registration, will be subsumed under the immediate[2] registration route if they meet the following criteria:

- No safety issues associated with the device globally
- Two independent regulatory agencies' approval
  or
  One reference agency's approval plus three years of marketing history

With this, 75% of Class B applications, will be granted immediate market access.

c. Class B and C standalone mobile medical applications[3] (e.g. standalone application for calculation of insulin dosage, or live monitoring of ECG for cardiac patients) that are approved by at least one reference regulatory agency[4] without safety issues globally will be eligible for immediate market access under the immediate registration route.

4 "HSA constantly reviews our regulatory framework to ensure that it stays relevant and forward looking. Having obtained a better assessment of the safety profile of MDs in the Singapore market, our moves to allow immediate entry of these lower risk devices would enable us to focus our attention on newer and higher risk devices." said Assoc Professor Chan Cheng Leng, Group Director, Health Products Regulation Group, HSA.

[1] **Expedited Class B registration route:** a medical device that has been approved by at least one of HSA's independent reference agencies and marketed for at least 3 years or approved by at least two of HSA's independent reference agencies

[2] **Immediate Class B registration route:** a medical device that has been approved by at least two of HSA's independent reference agencies and marketed for at least 3 years.

[3] **Standalone mobile application** refers to a software and/or mobile application that is intended to function by itself and are not intended for use to control or affect the operation of other hardware medical devices

[4] **The 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.

MAKING REGULATORY CONTROLS CLEARER

5 Through this regulatory enhancement exercise, HSA is also making existing controls clearer by specifying in the legislation that:

a. Telehealth devices intended by its manufacturer for medical purpose will be regulated as MDs. Those intended by the manufacturer solely for well-being or lifestyle purpose (e.g. smart watch to track heart rate and heart rate measuring devices in smart phones for fitness purposes) and not intended for medical purpose[5] will not be subjected to regulatory controls. However, a clarification statement[6] has to be included on their labels and advertisements that these products are not meant for medical purpose.

b. High risk devices used for modification of appearance or the anatomy are subjected to regulatory controls. To provide clearer guidance to industry players, HSA has developed a Positive List to help industry players identify if their products are regulated. These products are implants, injectable dermal or mucous membrane fillers, and invasive devices for fat removal or fat degradation purposes.

c. For more complex MDs that require users to have the relevant skills and knowledge to use them safely and effectively, HSA will require manufacturers to provide training for the users of these devices. Example of such devices are implantable devices where physicians need to undergo training on implantation technique before using the device on the patients.

[5] **Medical purpose:** For investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process.

[6] **Clarification statement refers to the following text or equivalent:** 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 a medical advice. Users should seek medical advice from a physician

EXTENSIVE CONSULTATION WITH INDUSTRY

6 The above enhancements are the result of regular and extensive engagement with the medical industry. As the time-to-market for new medical devices is shortened, consumer access to these lower risk products will become faster. HSA will continue to engage its stakeholders to further enhance the medical device regulatory framework, while still ensuring that consumers' safety is safeguarded.

7 Mr Eugene Yoo, Chairman of the Medical Technology Industry Group of the Singapore Manufacturing Federation shares, “HSA continues to be a leading innovative regulator and advancing with the changing healthcare landscape. By putting patients’ health and safety as its core mission, the amendments to the medical device regulations will provide clarity and simplify the work flow for the industry. This will certainly accelerate patients’ access to innovative therapy and technologies; further enhancing the health and wellness of the Singapore population.”

GREATER EMPHASIS ON POST-MARKET MEASURES

8 HSA will continue to strengthen post-market surveillance, which include checks and monitoring of product compliance in the market, as well as close monitoring of overseas alerts and local safety signals. These activities will enable HSA to detect safety signals from the market early and investigate adverse events promptly, safeguarding public health and safety.

HEALTH SCIENCES AUTHORITY
SINGAPORE
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About the Health Sciences Authority (HSA)
The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and

analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.
For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

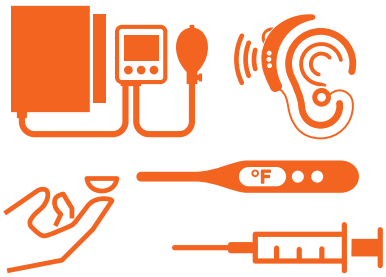
The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

HSA
Health Sciences Authority

Faster Access to Lower Risk Medical Devices

Approval Timeline

	Current	From 1 June 2018
Class A Sterile Devices	30 working days	**0 working days**

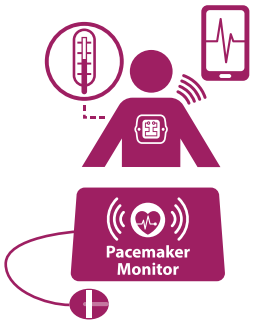


Approval Timeline

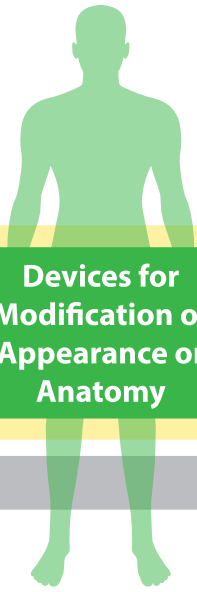
	Current	From 1 June 2018
Class B Devices with: 1. No safety issues globally 2. Two independent regulatory agencies' approval or One reference agency's approval and 3 years of marketing history	Expedited Route 60 working days	Immediate Route **0 working days**

HSA
Health Sciences Authority

Clearer Regulatory Controls



	Regulated	Not Regulated
Telehealth Products	• For medical purpose	• Not for medical purpose • Wellness devices *To include a clarification statement that the product is not for medical purpose



Devices for Modification of Appearance or Anatomy

Regulated as Medical Device

Positive list of high risk devices:

- Implants
- Injectable dermal or mucous membrane fillers
- Invasive devices for fat removal or fat degradation purpose

*List may be expanded in future