



28 MARCH 2018
HEALTH SCIENCES AUTHORITY

PUBLIC CONSULTATION ON THE PROPOSED AMENDMENTS TO HEALTH PRODUCTS (MEDICAL DEVICES) REGULATIONS

Introduction

The Health Sciences Authority (HSA), a statutory board of the Ministry of Health, invites stakeholders to provide feedback on the proposed amendments to the Health Products (Medical Devices) Regulations 2010. This consultation will start from 28 March 2018, and end on 11 Apr 2018.

2. The proposed amendments seek to further simplify and provide legal clarity on current policies and requirements. This is intended to ensure the robustness and continued relevance of the medical device (MD) regulatory framework to cater for different operational and emerging business models and to facilitate access and innovations, while safeguarding consumer health and safety.

Proposed Key Legislative Changes

3. This consultation covers the proposed legislative amendments with the objectives of:

i. Streamlining requirements to facilitate access to MDs

a) Facilitate faster access to lower risk MDs.

- Product registration for all Class A (low risk) MDs will no longer be required. Dealers' licensing and listing of Class A devices on

a Public Online Database are still applicable to ensure an appropriate quality management system and traceability.

- Class B (low-moderate risk) MDs with no safety issues globally and either 2 independent reference¹ agencies approval or 1 reference agency approval plus 3 years of marketing history, will be eligible for immediate market access.
- b) Immediate market access for standalone mobile medical applications with prior approval from at least one reference regulatory agency and no safety issues globally at the point of submission.
 - c) A licensed manufacturer will no longer require an Importer's Licence for the purpose of manufacturing its own products.
 - d) Currently, an application to HSA has to be made for any changes concerning registered medical devices. With this amendment to the Regulations, non-significant changes (such as changes to the colour, font size of device labels without any change in content) may be implemented by the company without the need for prior approval by HSA.

ii. Clarification on scope of regulatory controls

- a) With the diverse range of telehealth devices, there is a need to clarify the scope of telehealth² devices that are regulated as a MD. The Telehealth Guidelines was published in 2017, following a public consultation from 17 October 2016 to 30 November 2016. The proposed amendments will align the legislation to the Guidelines, to provide clarity that only telehealth devices with intended medical purpose will be subject to HSA's regulatory control.
- b) Telehealth wellness devices intended solely for well-being or lifestyle purposes and not for any medical purpose will not be subject to medical

¹ HSA's reference agencies are (i) Australian Therapeutic Goods Administration, (ii) European Union Notified Bodies *and the corresponding approvals indicated in GN-15*, (iii) Health Canada, (iv) Japan Ministry of Health, Labour and Welfare (MHLW), (v) United States Food and Drug Administration.

² 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.

device regulatory controls, if a “clarification statement”³ (or equivalent) is included on their labels (including advertisements) to inform consumers.

- c) The proposed amendments also seek to provide clarity on the scope of regulatory controls of devices used for modification of appearance or anatomy by identifying a positive list of such high risk devices. The list may be expanded in future when new risks are identified.

iii. Safeguarding consumer health and safety

- a) For safe and effective use of the medical device, it is important to ensure that medical devices are supplied and used by appropriately “trained user” as intended by the manufacturer, where applicable.
- b) “Trained user only” (TUO) medical device is defined in the Regulations. Supply of these TUO devices shall be limited to persons who have been trained on the safe and efficacious use of the medical device as the manufacturer of the device determines as necessary.
- c) For medical devices with recommended user training from the manufacturer, the local registrants/dealers of such medical devices should work with the manufacturers/product owners to arrange for the appropriate training of local users, where applicable at the point of supply of the device.

Feedback Sought

4. HSA welcomes your comments and feedback on the proposed amendments to the Health Products (Medical Devices) Regulations 2010. This consultation will start from 28 March 2018, and end on 11 April 2018.

³ Clarification statement: “This device or software is intended for use only for general well-being purposes or to encourage or maintain a healthy lifestyle, and is not intended to be used for any medical purpose (such as the detection, diagnosis, monitoring, management or treatment of any medical condition or disease). Any health- related information provided by this device or software should not be treated as medical advice. Please consult a physician for any medical advice required.”

5. 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.
6. Where possible, you should highlight the specific regulation in the proposed draft you are providing your comments on.
7. 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.
8. Please email your feedback using the prescribed feedback form to hsa_feedback@hsa.gov.sg by **11 April 2018**.

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