Proposed Amendments to the Health Products (Medical Devices) Regulations

Briefing on the proposed key updates

28 February 2018

Medical Devices Branch
Health Products Regulation Group
Health Sciences Authority

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Key Regulatory Changes

I. Regulatory requirements for Class A and B medical devices
II. Faster access to stand-alone mobile applications
III. Clarifying the scope of the medical device regulatory framework
IV. Trained user only (TUO) medical devices
V. Changes to registered medical devices
VI. Requirements for Dealers' licences

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I. Regulatory requirements for Class A and B medical devices

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CLASS A MDs PREMARKET CONTROLS - PRODUCT REGISTRATION

CURRENT APPROACH

Class A MDs **(sterile)** – Require product registration

Class A MDs **(non-sterile)**

- Product registration not required
- Declaration of all Class A non-sterile MDs under Class A exemption list (***public online database effective from August 2017***)

- Dealers of Class A MDs are required to ensure
  - The intended use/ claims for their devices are based on scientific evidence
  - Devices comply with the essential requirements for safety and performance (**GN-16** Guidance document) which includes

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Class A MD Public Online Database

From: HSA MD Info (HSA)
Sent: Monday, 7 August, 2017 6:18 PM
Subject: Class A Medical Device Register

Dear Industry Stakeholders,

With reference to our earlier email dated 1 June 2017, we wish to thank all stakeholders for the effort in updating the Class A Exemption List. We are pleased to announce that we will be implementing the Class A Medical Device Register for public access on 10 August 2017.This register allows members of the public to search for importers/local manufacturers as well as imported/manufactured Class A medical devices that are exempted from product registration.

All devices on the Class A Exemption List have been transferred to the Class A Medical Device Register. After implementation of the register on 10 August 2017, you may access the register via the link below:
https://eservice.hsa.gov.sg/medics/md/mdEnquiry.do?action=loadClassA

Please verify that all the Class A (non-sterile) devices are updated and the information is accurate.

With the implementation of the Class A Medical Device Register, there will be no change to the declaration procedure. Please be reminded that it is the dealers' responsibility to ensure the information declared under the importer/manufacturer licences are accurate and complete. Dealers may proceed to update the Class A Exemption List via the MEDICS e-service below at any time point prior to the import of the Class A Exempted Medical Devices.

- Amendment for Dealer's license/Submission of update of Class A Medical Device Exemption List
- Amendment procedure E-guide

All updates will be reflected on the Class A Medical Device Register in real time and only entries with 'ACTIVE' status will be shown on the Register for public view.

We look forward to your partnership in ensuring the smooth implementation of the Class A Medical Device Register.

For any further enquiries, please email us at HSA_MD_Info@hsa.gov.sg or call us at 6866 1111.

Thank you.

Yours Sincerely

MEDICAL DEVICES BRANCH
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

Public Online Database

Implemented for Class A non-sterile MDs on 10 August 2017

Currently dealers may proceed to update the Class A Exemption List via the MEDICS e-service below at any time point prior to the import of the Class A Non-sterile Medical Devices.
Amendment for Dealer's license/Submission of update of Class A Medical Device Exemption List

Amendment procedure E-guide

With legislation update, this database to be applicable for Class A sterile MDs too.

NOTE: *Operational details on next steps to be communicated with stakeholders at a later date*

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CLASS A MDs PREMARKET CONTROLS - PRODUCT REGISTRATION

CURRENT APPROACH

Class A MDs **(sterile)** – Require product registration

Class A MDs **(non-sterile)**

- Product registration not required
- Declaration of all Class A non-sterile MDs under Class A exemption list ***(public online database effective from August 2017***)

PROPOSED APPROACH

Class A MDs

- **Sterile and Non-sterile** - Product registration not required

- Importers/ manufacturers are required to list all Class A MDs i.e. Class A sterile MDs together with their Class A non-sterile MDs on the public online Class A database as and when prior to import/supply in Singapore

- Dealers of Class A MDs are required to ensure
  - The intended use/ claims for their devices are based on scientific evidence
  - Devices comply with the essential requirements for safety and performance (**GN-16** Guidance document) which includes
    - Ensuring compliance with appropriate sterilisation standards for the sterilisation process for their Class A sterile MDs

NOTE: *Operational details on next steps to be communicated with stakeholders at a later date*

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CLASS A MDs PREMARKET CONTROLS

DEALERS CONTROL – For solely Class A dealers

Dealer Licences	Current Pre-requisite	Proposed Pre-requisite
Manufacturer's licence	ISO13485 certification	Declaration of conformity to a Quality Management System (QMS) i.e. Third-party certification no longer required
Importer's/ Wholesaler's licence	Goods Distribution Practice for Medical Devices (GDPMDS) **OR** ISO13485 certification	

- Dealers of solely Class A MD are still required to be licensed by HSA
- As pre-requisite to their licences, dealers of solely Class A MD are required to establish and maintain an appropriate quality management system in their facilities
  - Third-party audit and certification is no longer required

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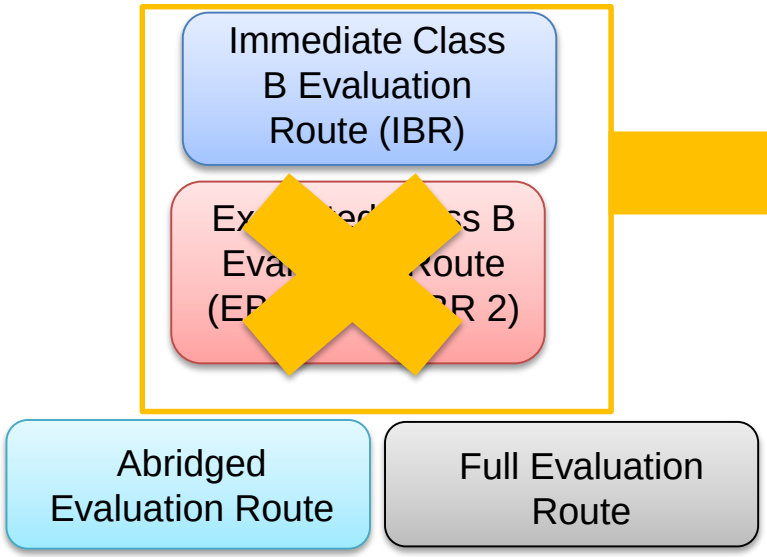
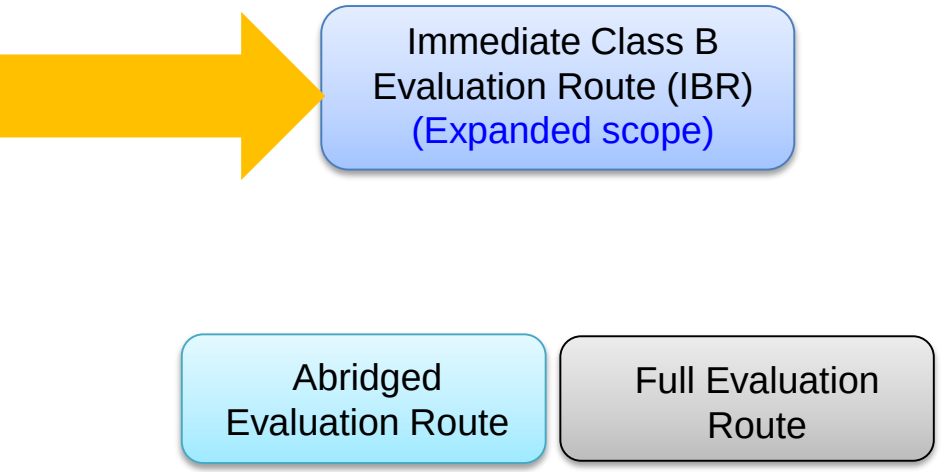
CLASS B MDs EVALUATION ROUTES

CURRENT APPROACH



PROPOSED APPROACH



<u>Immediate market access</u> for Class B MDs with no safety issues globally that have:

- ❑ 2 reference agencies approvals **<u>and</u>** 3 years marketing history

<u>Immediate market access</u> for Class B MDs with no safety issues globally that have:

- ❑ 2 reference agencies approvals; **OR**
- ❑ 1 reference agencies **<u>and</u>** 3 years marketing history

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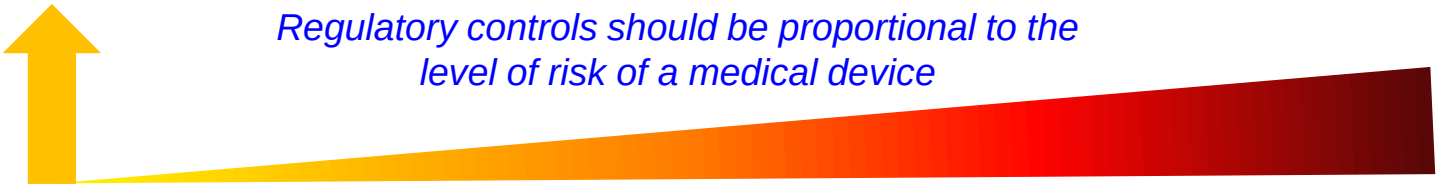
MD REGULATORY FRAMEWORK OVERVIEW

Increasing regulatory requirements



Regulatory controls should be proportional to the level of risk of a medical device

Risk Class	Class A	Class B	Class C	Class D
PREMARKET CONTROLS				
Product registration	Not required	Required		
Manufacturer's License (Pre-requisite)	Quality Management System Declaration	ISO13485 certification		
Importer's/ Wholesaler's License (Pre-requisite)	Quality Management System Declaration	GDPMDS certification		
POST-MARKET CONTROLS				
AE/FSCA Reporting	Mandatory reporting of Adverse Events (AE) and Field Safety Corrective Actions (FSCA) to HSA			
Maintenance of records	Maintaining distribution records and complaint records			
Advertisement	Prohibition against false and misleading advertisements			

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Life-cycle approach to Regulation

- To continue to balance our pre-market and post-market regulatory controls to enhance patient safety
  - Post-market oversight for Class A devices and dealers to ensure continued safety, quality and efficacy of these devices
- Random compliance checks/monitoring to be put in place
  - To verify compliance with quality management systems on the part of Class A dealers
  - To verify continued conformity to the essential requirements for safety and performance of the Class A and Class B medical devices supplied locally (e.g. compliance to sterilisation standards as appropriate)
- Public online database of all Class A MDs supplied locally
  - To be updated by the local importers/manufacturers
  - Access to information on Class A MDs on the market for users
  - Improves traceability

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II. Faster access to Standalone Mobile Applications that are medical devices

- Final Telehealth Guidelines published in 2017

HSA Telehealth Guidelines:
http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/Telehealth%20Guideline%20-%20Aug%202017.pdf

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Standalone Mobile Applications

- 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
  - Typically these include algorithm based calculators of parameters for use in clinical practice or for use in diagnosis or managing a disease or condition
  - Designed based on formulae with established scientific evidence and clinical utility

- Such Standalone Class B or Class C mobile medical device application if reviewed and approved by at least one of HSA's reference regulatory agencies, will qualify for Immediate Registration Route
  - Immediate Class B Registration Route for Class B Standalone Mobile Applications with one reference regulatory agency approval*
  - New Immediate Class C Registration Route for Class C Standalone Mobile Applications with one reference regulatory agency approval*

***** *The reference regulatory agency approval must be within the list of approval types listed in our GN-15 Guidance document on medical device registration to qualify for current abridged, expedited and immediate registration routes.*

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Immediate Registration Route – Standalone Mobile Applications

- The eligibility criteria for the Immediate Registration Route at the point of submission are:
  - Approval by at least one of HSA's reference regulatory 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 indicated in 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
    - No reported deaths;
    - No reported serious deterioration in the state of health of any person; and
    - No open field safety corrective actions (including recalls) at the point of submission.

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III. Clarifying the Scope of the Medical Devices Regulatory controls

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Devices for wellness purposes

HSA Telehealth Guidelines:

http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/Telehealth%20Guideline%20-%20Aug%202017.pdf

- Telehealth products are involved in the provision of healthcare services over physically separate environments via infocomm technologies
- The intended use of the Telehealth product as determined by the manufacturer will determine whether it will be regulated as a medical device
- If the Telehealth product is intended to be used for investigation, detection, diagnosis, monitoring, treatment or management of any medical condition, disease, anatomy or physiological process, it is a Telehealth medical device and is subject to HSA's regulatory control.

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Devices for wellness purposes

HSA Telehealth Guidelines:

http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/Telehealth%20Guideline%20-%20Aug%202017.pdf

- If the Telehealth product is not intended by the manufacturer to be used for the aforementioned medical purposes (e.g. intended for fitness tracking), but is able to perform such function/purpose (e.g. monitoring heart rate), such products are required to be labelled to clearly inform the users of the product's appropriate use (i.e. not for medical purpose) → Included under Devices for "Wellness purposes"

- This information should be presented clearly to the users, where practicable (e.g. Packaging, Instructions for use (IFU) or splash screen/loading screen in a mobile application). This is necessary to ensure that users do not misconstrue any health-related information accessed through these devices as medical advice.

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Devices for wellness purposes

- Wellness device includes devices or software intended by its manufacturer to be used
  - solely to enable or encourage the user to adopt or maintain a healthy lifestyle; or for the user's general well-being; but
  - not to be used for any medical purpose
    - e.g. Fit bit watches, heart rate measuring devices for fitness purposes
- Wellness device refers to devices that are not intended for medical purpose i.e. intended for wellness purposes.
  - Includes the category of Telehealth products not intended for medical purpose
- Wellness devices not to be subject to medical device regulatory controls if
  - The device is labelled as not for medical purpose and is supplied with the clarification statement on the device presentation and advertisements
  - Clarification statement refers to the following text or equivalent
    - *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.*

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Devices for modification of appearance or anatomy

Background

- Devices could be intended by the manufacturer for medical purposes and/or for modification of appearance or anatomy * of an individual
- As long as the intended purpose of a device includes one or more medical purposes, the device is subject to the medical device regulatory controls
- Need for clarity on the scope of medical device regulatory controls for devices intended for modification of appearance or anatomy* only (e.g. treatment of wrinkles, Improving skin texture, body contouring)

Key Review Considerations

- Post-market surveillance data globally and locally related to these devices
- Other regulatory oversight in place locally:
  - Professional bodies (e.g. Singapore Medical Council (SMC)) governs the use of devices which are intended for use by doctors only
    - *Guidelines on Aesthetic Practices for Doctors (Allowed aesthetic procedures, premises and training requirements to conduct aesthetic procedures)*
  - NEA has licensing requirements for individuals or facilities handling ionizing/non-ionizing radiation emitting equipment
    - *Radiation Protection Act (Use of ionizing and non-ionizing radiation)*

**** Devices intended for modification of appearance or anatomy refers to "devices for cosmetic/aesthetic related purpose"***

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Risk-based approach

- For devices intended for modification of appearance or anatomy * only, HSA to focus our regulatory oversight on high risk devices under this category
  - High risk devices with known or reported serious adverse events globally
  - High risk devices that pose **comparable risks** to other regulated medical devices (e.g. foreseeable hazards)

Device Types	Known Serious Adverse Events - Examples
Gluteal implants, breast implants	Rupture, capsular contracture (scar tissues that forms around the implant and squeeze the implant)
Collagen/ hyaluronic dermal fillers, lip fillers	Injection site necrosis, nodules, allergic reaction

**** Devices intended for modification of appearance or anatomy refers to "devices for cosmetic/aesthetic related purpose"***

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Risk-based approach

List of high risk devices intended for modification of appearance or anatomy* only that will be regulated as medical devices

i. any implant for the modification or fixation of any body part (e.g. breast implant, gluteal implant)

ii. any injectable dermal filler or mucous membrane filler (e.g. soft tissue fillers, wrinkle fillers)

iii. any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means (e.g. liposuction devices)

NOTE: *Above list may be expanded in the future when new risks are identified (e.g. New technology, New application/use for existing technology, New risks surface from wide-spread use)*

**** Devices intended for modification of appearance or anatomy refers to "devices for cosmetic/aesthetic related purpose"***

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Devices for modification of appearance or anatomy

- Devices intended for modification of appearance or anatomy* that also have medical claims are already regulated as medical devices
  - Hence the devices in the positive list are currently subject to medical device regulatory controls

- Where devices intended solely for modification of appearance or anatomy are not within the high risk list of devices to be regulated as medical devices (e.g. cryolipolysis equipment, laser devices for skin tightening)
  - Some of these devices will still be subject to other local regulatory controls (e.g. NEA controls) where applicable
  - No impediment to market access
  - Operational details on any follow-up actions required from dealers will be communicated at a later date

**** Devices intended for modification of appearance or anatomy refers to "devices for cosmetic/aesthetic related purpose"***

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IV. Trained user only (TUO) medical devices

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Trained user only (TUO) medical devices

- Medical Device technology is rapidly advancing with increasing complexity in design, operation, application, usability etc.
  - Manufacturers intend such devices for users trained as appropriate in order to ensure device safety and efficacy
  - Manufacturers determine the appropriate and necessary training for their device where applicable (e.g. hands on user training, online tutorials, briefing, technical demonstration)
  - The intended user for the device is typically indicated by the manufacturer on the IFU/user manual/product insert accompanying the medical device

- For safe and effective use of the medical device, it is important to ensure that such medical devices are supplied and used by appropriately “trained user” as intended by the manufacturer where applicable

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Trained user only (TUO) medical devices

- "Trained user only" (TUO) medical device to be defined in the Regulations

  "trained user only" medical device means a medical device that is to be used only by an individual who has undergone such training on the safe and efficacious use of the medical device as is necessary."

- Supply of these TUO medical 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 medical device determines is necessary
  - No other restrictions to be imposed (e.g. advertisement controls)

- 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
  - Registrants/Dealers are encouraged to continuously work with users and user facilities to support training of new users in the facilities during the life time of the device

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Trained user only (TUO) medical devices

- For both Professional Use only* (PUO) medical devices and TUO medical devices,
  - Whether a medical device is “PUO” or “TUO” medical device, the determination will be based on the manufacturer’s intent as presented on the IFU/user manual/Product Insert
  - HSA will only step in, where we disagree with the manufacturer’s intent and may require additional measures in the interest of device safety or efficacy (e.g. label update)
  - Applicable to all medical devices supplied in Singapore including unregistered medical devices supplied via special authorization routes
- Unlike for PUO devices, TUO devices will not have additional registration condition during registration of the device
  - It is the responsibility of all suppliers to ensure that the medical devices are supplied to appropriate users (e.g. doctors, trained users) based on manufacturer’s intent with reference to the IFU/user manual/product insert, where applicable

* *PUO medical devices are intended by the manufacturer for use by or under the direct supervision of doctors or dentists.*

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V. Changes to registered medical devices - Change Notification

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Changes to registered medical devices

- HSA organised an Industry focus group session in 2016 on change notification
  - Majority of the feedback from these sessions have already been implemented except those that required legislative changes
  - One such feedback was that it is onerous to submit non-significant changes to registered medical devices (e.g. change in layout, colour, font size of device labels without any change in content) via the online system

- Current Regulations require any change to registered medical devices to be submitted to HSA

- Regulations to be updated to allow for certain specific non-significant changes to not require notification to HSA
  - Guidance GN-21 on change notification to be updated to indicate the types of changes for which notification will no longer be required
  - These changes to be identified from the industry feedback from the focus group session
  - Updated guidance once ready will be posted on our website for industry consultation

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Changes to registered medical devices

- Fourth Schedule of the current Regulations to be updated with reference to the "**description**" of change notification categories
  - To update the description of the change notification categories to reflect the scope of the "Technical" "Review" "Administrative" and "Notification" change categories
  - Technical changes (Class C and D) and Review Changes (Class B) – Changes that affect the safety, quality and efficacy of the registered medical devices
  - Administrative change refers to a change that does not affect the safety, quality and efficacy of the registered medical device that involves change to any information entered on the SMDR in respect of that medical device except changes to delete or remove such information from SMDR.
  - Notification change refers to any change other than administrative change that does not affect the safety, quality and efficacy of the registered medical device.
- No change to the existing 4 categories of change notification
- Guidance GN-21 on change notification to be updated as necessary
  - Updated guidance once ready will be posted on our website for industry consultation

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VI. Requirements for Dealers' licences

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Requirements Dealers' Licences

- The current pre-requisites in place for the medical device dealers' licences will be included within the Regulations
  - Manufacturer's Licence – able to comply with the requirements of ISO 13485 in relation to the manufacture of the medical device
    - ISO 13485 to be defined in the Regulations to cover both the current 2016 edition and the previous 2003 edition of the standard to enable compliance
  - Importer's and Wholesaler's Licences – able to comply with the requirements of the Good Distribution Practice Standard for Medical Devices (GDPMDS) or ISO 13485
    - GDPMDS standard for medical devices to be defined to include current TS-01 GDPMDS Requirements (before 9 November 2020) and the Singapore Standard for GDPMDS (SS 620)

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Thank you

Send in your Feedback via email to
hsa_md_info@hsa.gov.sg

Please indicate in the subject of the Email:
Feedback on MD legislative amendments

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