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Singapore Medical Devices Regulatory Updates

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Health Sciences Authority

Health Products Regulation

Ensures health products are safe, of good quality and efficacious

- PRISM
- MEDICS
- Bringing personal medication into Singapore

Medicines | Medical Devices
Complementary Health Products
Tobacco Control |
Clinical Trials

VIEW MORE

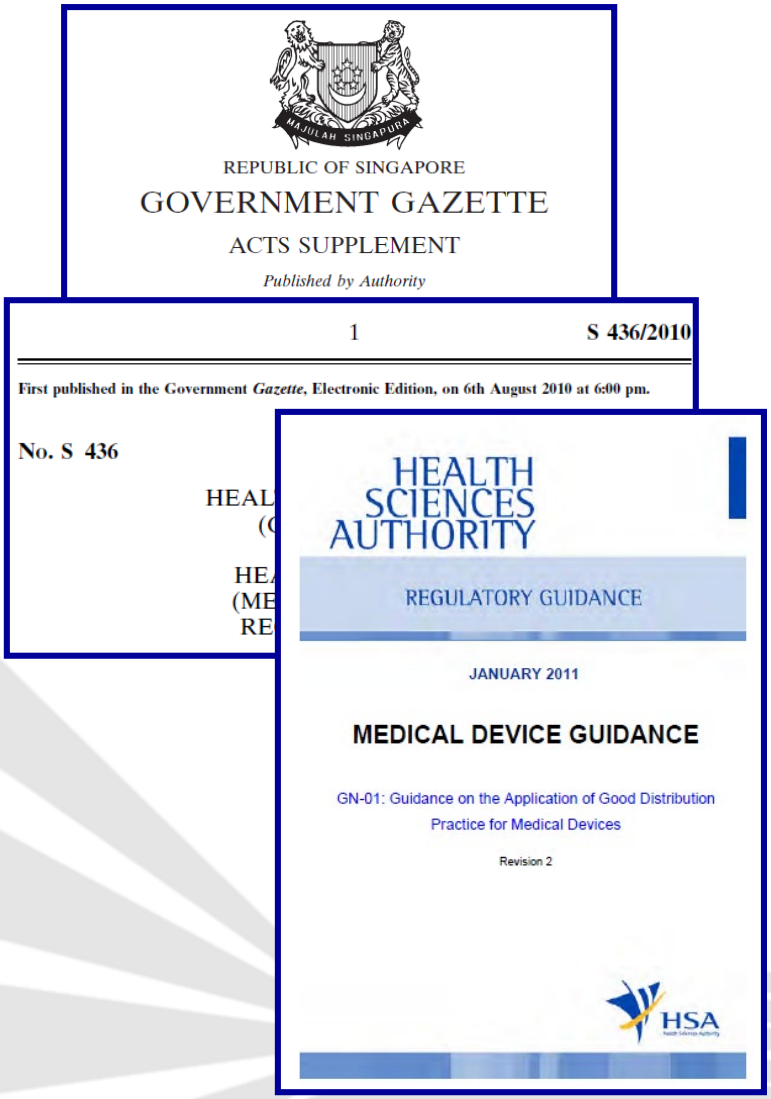
Blood Services

Provides a safe and sustainable national blood supply

Applied Sciences

Provides forensic and analytical testing to support law enforcement and the courts

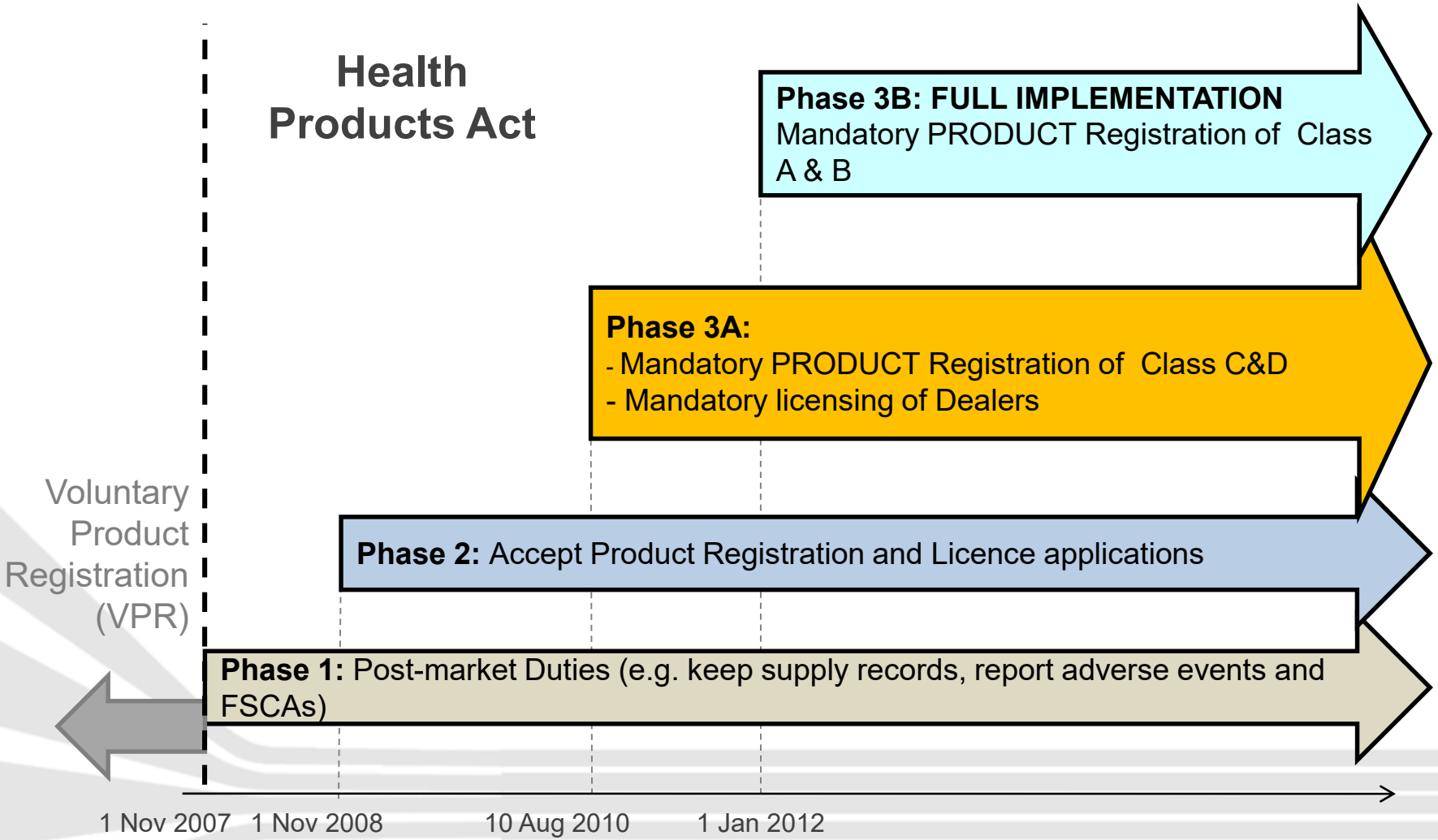
Regulatory Requirements Hierarchy



- **Act** *(Health Products Act)*
- **Regulations** *(Health Products (Medical Devices) Regulations 2010)*
- **Guidance Documents** *(Public information available on the web)*

http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices/regulatory_guidances.html

Implementation Milestones



Regulatory Changes

I. Regulatory requirements for Class A and B medical devices
II. Regulatory requirements for Stand-alone mobile applications
III. Clarifying the scope of the medical device regulatory framework
IV. Pre-Market Consultation and Priority Review Scheme

I. Regulatory requirements for Class A and B medical devices

Regulatory requirements for Class A MDs

Before 01 June 2018

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***)

From 01 June 2018

Class A MDs
- **Sterile and Non-sterile** - Product registration not required

- Importers/ manufacturers are required to list all Class A MDs (sterile and non-sterile) 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 which includes
    - ensuring compliance with appropriate sterilisation standards for the sterilisation process for their Class A sterile MDs

Regulatory requirements for Class A MDs

DEALERS CONTROL – For solely Class A dealers

Dealer Licences	Pre-requisite Before 1 June 2018	Pre-requisite From 1 June 2018
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

Regulatory requirements for Class B MDs

Before 01 June 2018

- Immediate Class B Evaluation Route (IBR)
- ~~Expedited Class B Evaluation Route (EBR 2)~~
- Abridged Evaluation Route
- Full Evaluation Route

From 01 June 2018

- Immediate Class B Evaluation Route (IBR) (Expanded scope)

75% of Class B

- Abridged Evaluation Route
- Full Evaluation Route

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

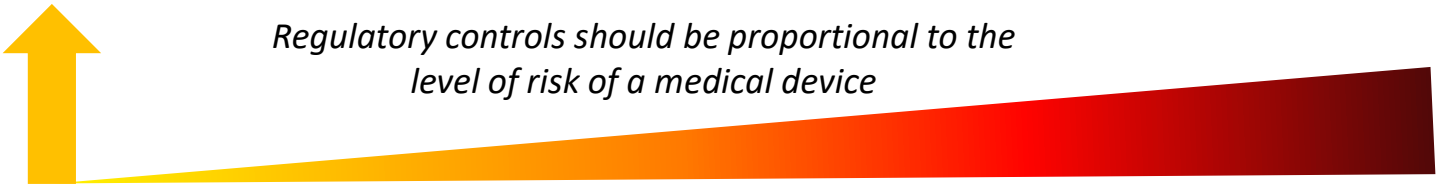
- ❑ 2 reference agencies approvals **<u>and</u>** 3 years marketing history

<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

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 •Immediate market access for Class B MDs that qualify for IBR •Immediate market access for Class C standalone apps that qualify		
Manufacturer License (Pre-requisite)	QMS Declaration	ISO13485 certification		
Importer/Wholesaler License (Pre-requisite)	QMS 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			

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

- Final Telehealth Guidelines published in 2017

HSA Telehealth Guidelines:

https://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/REGULATORY%20GUIDELINES%20FOR%20TELEHEALTH%20PRODUCTS%20Rev%202.0.pdf

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.*

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.

III. Clarifying the Scope of the Medical Devices Regulatory controls

a. Devices for wellness purposes

b. Devices for aesthetic-related purposes

Devices for wellness purposes

- 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.

HSA Telehealth Guidelines:

https://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/REGULATORY%20GUIDELINES%20FOR%20TELEHEALTH%20PRODUCTS%20Rev%202.0.pdf

Devices for wellness purposes

- 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**) → **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.

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

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

Devices for wellness purposes

- 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.*

Devices for modification of appearance or anatomy

- Need for clarity on the scope of medical device regulatory controls for devices intended **solely** for *modification of appearance or anatomy (e.g. treatment of wrinkles, improving skin texture, body contouring)

- HSA to focus regulatory oversight on **high risk** devices intended solely for *modification of appearance or anatomy:
  - with known or reported serious adverse events globally
  - which pose **comparable risks** to other regulated medical devices (e.g. foreseeable hazards)

Device Types	Examples of Reported Serious Adverse Events
Gluteal implants, breast implants	Rupture, capsular contracture (scar tissues that forms around the implant and squeeze the implant), infection
Collagen/ hyaluronic dermal fillers, lip fillers	Injection site necrosis, nodules, allergic reaction
Lipoplasty/ liposuction equipment	Infection, pulmonary embolism, visceral perforation

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

HSA Aesthetic-related Guidelines:
https://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/Aesthetic-Related%20Guidelines_2018.PDF

Risk-based approach

Annex A: Positive list of **high risk** devices intended for modification of appearance or anatomy* to 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"*

VI. Premarket Consultation and Priority review scheme

QR code for information on Priority Review scheme & Pre-market Consultation (PMC) schemes:

Pre-Market Consultation (PMC) Scheme

1 Medical Device Development Consultation

Channel for stakeholders to **seek regulatory advice during medical device development phase** to align with regulatory requirements.

2 Medical Device Pre-submission Consultation

Channel for stakeholders to **seek feedback on their device dossier, prior to pre-market submission** in terms of completeness and appropriateness of supporting documents.

Medical Device Priority Review Scheme

Qualification Criteria

Medical devices* to be registered via FULL Evaluation Route → **Route 2**

1 **Falls under 1 of the 5 healthcare focus area**

- Cancer
- Diabetes
- Ophthalmic diseases
- Cardiovascular diseases
- Infectious diseases

+

2 **Designed & validated to meet unmet clinical needs**

Intended for a medical purpose with **no existing alternative** treatment or means of diagnosis

OR

Represents a breakthrough technology that provides a **clinically meaningful advantage** over existing legally marketed technology

→ **Route 1**

**** Devices incorporating registrable medicinal products are not eligible for the Priority Review Scheme.***

Medical Device Priority Review Scheme

Turn-Around-Time (TAT)

Risk Class	TAT for Registration Routes (in working days)				
	R7 ► **Immediate** ◄	**Expedited**	**Abridged**	**Full**	**Full (Priority Review Scheme)**
Class B	Immediate Registration upon Submission		100	160	120
Class C	R7 ► Immediate registration upon submission (for Class C standalone medical mobile application only) ◄	120	160	220	165
Class D		180	220	310	235
Class D (devices incorporating medicinal products)			220	310	

Faster Access to Lower Risk Medical Devices

Approval Timeline

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

Faster Access to Lower Risk Medical Devices

Approval Timeline

Current	From 1 June 2018
Expedited Route **60** working days	Immediate Route **0** working days

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

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

Clearer Regulatory Controls

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**

Thank you