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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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Singapore Medical Devices Regulatory Updates

Dr Rama Sethuraman,
Deputy Director, Medical Devices Branch, HSA

22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

4-8 December, 2017 I New Delhi

MAKE IN INDIA

Regulatory Framework

- **Medical Devices** (MD) are regulated under the **Health Products Act**
  - ❑ *Health Products (Medical Devices) Regulations 2010*
- Hierarchy of regulatory requirements

- ❑ ***Act*** *(Health Products Act)*
- ❑ **Regulations** *(Health Products (Medical Devices) Regulations 2010)*
- ❑ **Guidance Documents** *(Requirements available on the web, HSA website)*

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

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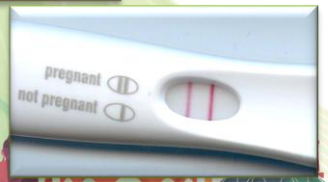
Regulatory Objectives



- **SAFEGUARD PUBLIC HEALTH**
  - Ensure appropriate safety, quality, technical and efficacy standards are met
  - Facilitate recalls, product withdrawals
- **FACILITATE**
  - Support development of a high quality healthcare system
- **ASSURE**
  - Instill trust, confidence and credibility of products at home and abroad

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Phased Implementation of Regulatory Controls

2002

2007

Mandatory Post-market duties

1 Nov 2007

HP ACT

1 Nov 2008

Accept product registration & dealer licence applications

Mandatory Dealer Licensing
Mandatory PRODUCT Registration of Class C&D devices

10 Aug 2010

HP (MD) Regulations

1 Jan 2012

Full Implementation
Mandatory PRODUCT Registration of Class A&B

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Definition of "Medical Device"

- HP Act First Schedule

Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is **intended by its manufacturer** to be used, whether alone or in combination, **for humans** for one or more of the specific purposes of —

a) *diagnosis, prevention, monitoring,* treatment or alleviation of any disease;
b) *diagnosis, monitoring, treatment,* alleviation of or compensation for an injury;
c) *investigation, replacement,* modification, or support of the anatomy or of a physiological process;
d) *supporting or sustaining life;*
e) *control of conception;*
f) *disinfection of medical devices; or*
g) *providing information for medical* or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

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Definition of "*In-Vitro Diagnostic (IVD)* Medical Device"

- HP (MD) Regulations 2010

(a) means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its product owner to be **used *in vitro*** for the **examination of any specimen, including any blood or tissue donation, derived from the human body**, solely or principally for the purpose of providing information —

(i) concerning a physiological or pathological state or a congenital abnormality;

(ii) to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or

(iii) to monitor therapeutic measures; and

(*b*) **includes a specimen receptacle**;

NOTE: Products for general laboratory use are not classified as IVD products, unless that product, in view of its characteristics is specifically intended by its manufacturer to be used for in vitro diagnostic examinations.

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Risk Classification of MDs

- MDs are classified into **4 risk classes** based on international rule-based classification system
  - **Class A** (low risk), **Class B** (low-moderate risk), **Class C** (moderate-high risk) and **Class D** (high risk) devices
  - Key considerations in determining the risk class of MD

Risk class of General medical devices (Non-IVDs)

- Intended Purpose of the MD
- Degree of invasiveness of the MD
- Duration of use
- Whether the device produces a systemic or local effect
- Whether the device is active or non-active.

Risk class of *IVD* medical devices

- Intended purpose of the IVD
- Based on risk to public health
- Risk to individual health

GN-13: Guidance on Risk Classification of General Medical Devices
GN-14: Guidance on Risk Classification of In Vitro Diagnostic Medical Devices

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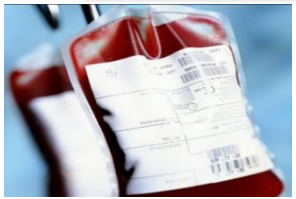
Risk Classification of MDs

RISK

Class D	High Risk	**GMD:** Absorbable sutures, implantable cardiac pacemaker, heart stents. **IVD:** HIV Diagnostic tests, ABO Blood grouping system.
Class C	Moderate-High Risk	**GMD:** Lung ventilator, orthopaedic implant, IOLs, blood bags. **IVD:** HLA typing, Cyclosporine assay, PSA screening kit.
Class B	Low-Moderate Risk	**GMD:** Hypodermic needles, contact lenses, digital blood pressure monitors. **IVD:**: Pregnancy test kits, Urine test kits.
Class A	Low Risk	**GMD:** Tongue depressor, bandage, gauze dressings, wheelchair. **IVD:** Prepared general culture media, Sample collection kit.



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Risk Classification Online Tool

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/risk-classification-tool.html

Medical Devices Risk Classification Tool

The Medical Device Risk Classification Tool is a query tool to help you
device. It is designed in accordance to the risk classification rules of G
of General Medical Devices and GN-14 Guidance on the Risk Classifi
Devices.

You are advised to verify the risk classification results derived from th
medical device. However, if in doubt, you may contact the Medical De

This classification tool may take you 10 minutes to complete.

Medical Device Classification

To begin, please select the type of medical device below

General Medical Devices

In Vitro Diagnostics (IVD) Medical Devices

x

Non Invasive Devices

Q1

Does the non-invasive devi

Y

< Ba

1 2 3

Summary

Print

NO	QUESTION	ANSWER
1	Does the device incorporate as an integral part a substance which if used separately can be considered to be a medicinal product and which is liable to act on the human body with action ancillary to that of the device?	✓ Yes
2	Is the device manufactured from or incorporating animal or human cells tissue and/or derivatives thereof rendered nonviable or cells tissues and/or derivatives of microbial or recombinant origin?	✗ No
3	Is the device manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin?	✓ Yes

Class A IVD, Rule 5

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Regulatory approach for MDs

- Risk-based Regulatory Approach

Pre-market control & Post-approval conditions, Change Management

Post-market surveillance, compliance, vigilance & enforcement

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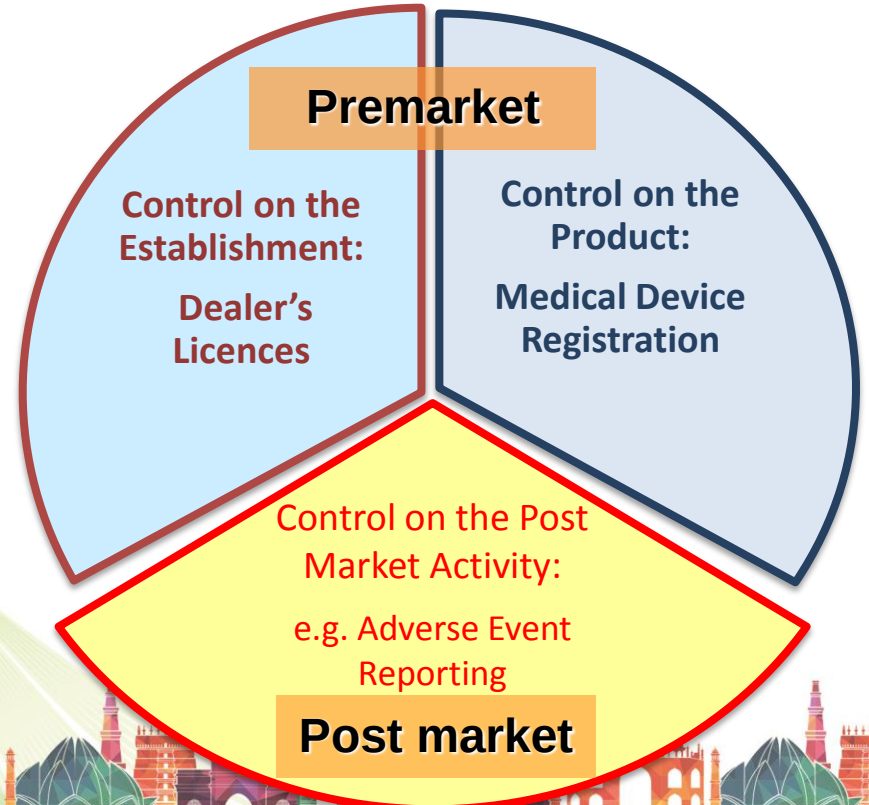
Regulatory Controls



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Pre-market Registration

Device Class	Regulatory Requirements
Class A non-sterile	Exception from device registration
Class A sterile	Device registration required
Class B, C & D	Device registration required

MD Pre-market Review – Key considerations

- Is this MD of good **quality** and manufactured under appropriate quality systems?
- Is this MD **safe** for the proposed intended use, user and patient population?
- Is this MD **efficacious** for the intended purpose? Does the MD perform to what it claim(s)?
- Have all relevant foreseeable risks associated with the use of the MD been minimized to the lowest possible?
- Are there procedures in place to continuously monitor, detect and manage new or evolving risks associated with the medical device post marketing of the device?
    - Post-market surveillance
    - Risk detection and management procedures

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Dealers' Licensing

Licensing requirements depend on company's activities

GDPMDS:
Good **D**istribution **P**ractices of
Medical **D**evices in **S**ingapore
→ **Singapore Standard** on GDPMDS

Activity	Licence Type	Licence Requirements
Manufacture	Manufacturer's Licence	ISO 13485 certificate for finished medical device manufacturing
Import	Importer's Licence	ISO 13485 certificate with scope of storage & distribution; or GDPMDS certificate
Wholesale (includes export)	Wholesaler's Licence	ISO 13485 certificate with scope of storage & distribution; or GDPMDS certificate

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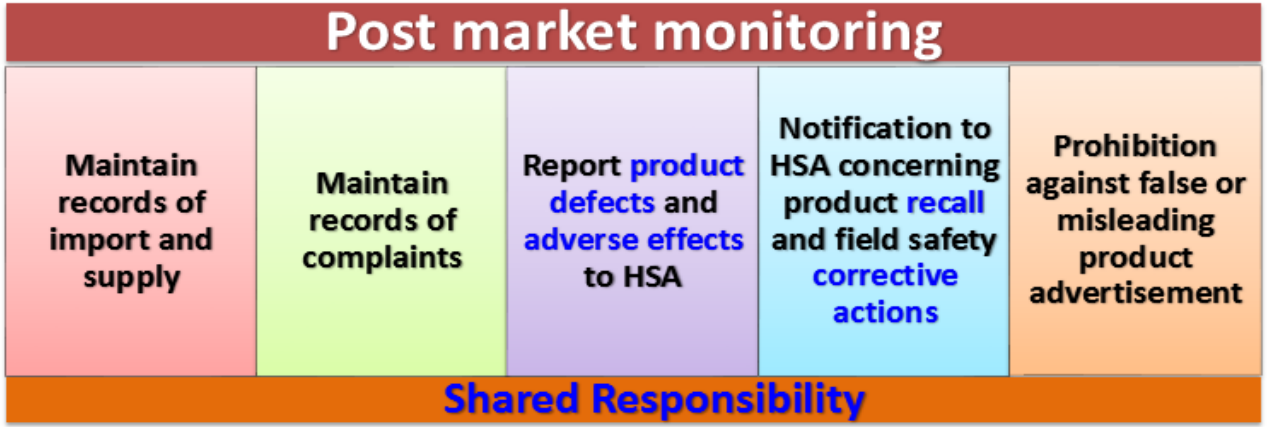
Post market Controls



Implemented since 1 Nov 2007

- Risks associated with the real-world use of medical devices
  - New Risks are identified
  - Existing Risks evolve
- Timely intervention is necessary to ensure continued safe and effective use of the device
  - Monitor, Detect and Manage Risks through out the device life cycle
- Significant changes to the registered MDs would require approval from HSA prior to implementation

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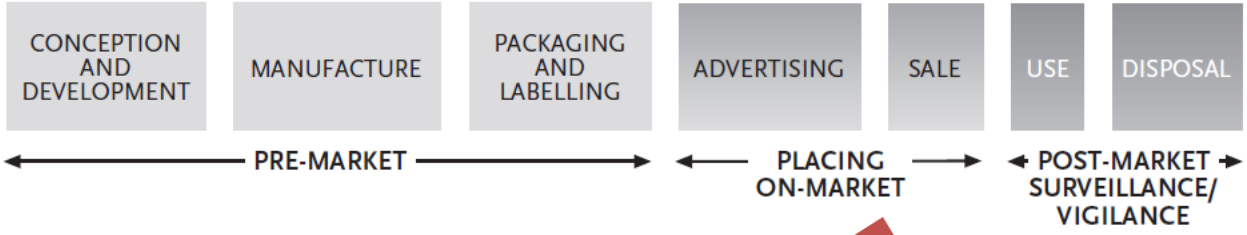
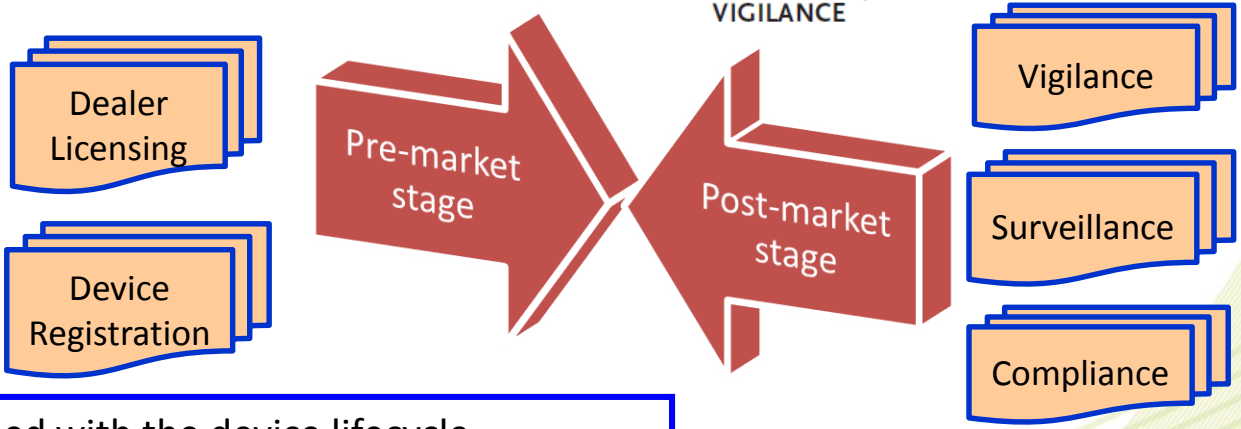
Regulating the MD life-cycle





- Regulatory Controls are aligned with the device lifecycle
- Post-market controls complement pre-market product controls

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Regulatory Updates:
Clarifying our Regulatory Approach for Telehealth Devices

Telehealth Devices refers to all forms of devices, including hardware devices, software and mobile applications, used in the remote delivery of healthcare services over distance (e.g. network or connected devices)

Telehealth Products: Regulatory Approach

- Majority of Telehealth products are within the scope of the current “Medical Devices” Regulatory controls
  - Products intended for medical purposes e.g. diagnosis, treatment
    - Validated to meet appropriate medical standards of measurement/ specifications e.g. accuracy, sensitivity
  - Products intended for general well-being purposes e.g. fitness trackers
    - Typically may not meet medical standards

- To titrate the regulatory approach for Telehealth products based on their intended purpose

- To provide better clarity and transparency regarding the applicable regulatory controls for telehealth products in Singapore

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Well-being Devices: Need for Clarification Statement

Labelled Intended Use:
Intended to track and trend Blood Oxygen & Pulse Rate in patients

Intended for patient monitoring and medical diagnostic use → Telehealth Device

Regulated as Medical Device

Labelled Intended Use:
For athletes or anyone who wants to gain a greater understanding of how their bodies work during activities (e.g.) hiking

Intended for use by individuals during activities; Not for medical diagnostic use → Well-being device

Potential Risk: Product measures SpO2. Possible inappropriate use by consumers for medical diagnosis/ patient monitoring

→ Required to add "**clarification statement**" or equivalent to inform users of the appropriate use of the product on the labels/ product presentation as appropriate.

Not Regulated as Medical Device

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Telehealth Guidelines

Guidelines on regulation of Telehealth Products

Scope of Regulatory Controls

Only Telehealth products with intended **medical purpose** (e.g. diagnosis, treatment, patient monitoring) to be subject to regulatory controls.

Risk Mitigation Measure

Telehealth products for monitoring physiological parameters & not intended for medical purposes (e.g. heart rate monitor for sportspersons) to include a "**clarification statement**" on their labels, to inform users and consumers that the **product is not** to be used **for medical conditions**.

Regulatory Approach

Confidence based approach – Immediate market access to standalone mobile applications approved in a reference regulatory agency*

Risk stratified approach – Regulatory requirements commensurate with risk class of the product

Decision trees to aid in determining regulatory controls applicable and also risk class of the regulated product

**Australia's Therapeutic Goods Administration, European Medicines Agency, Health Canada, Japan's Pharmaceuticals and Medical Devices Agency, US Food and Drug Administration*

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Telehealth Guidelines

Key Benefits:

- Clarity on regulatory controls and transparency – also for non medical device stakeholders (e.g. mobile app developers)
- Provide early guidance to industry on regulatory requirements – facilitate regulatory compliance

→ Faster access to innovation to benefit our healthcare system and the patients

Final Guidelines and FAQs have been published on our website at:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Regulatory_Updates.html

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Regulatory Updates:
Launch of New Schemes for Medical Devices

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New Schemes for Medical Devices

HSA's Initiatives

1. Pre-Market Consultation Scheme

Support innovation and device development by ensuring devices are in line with regulatory requirements

2. Priority Review Scheme

Facilitate timely access for devices that address unmet clinical needs

To provide support through the device development lifecycle

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Pre-market Consultation 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.

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Priority Review Scheme

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

Qualification Criteria

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

- Cancer
- Diabetes
- Ophthalmologic 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**

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