The Rise of Digital Health Innovation and what it means for the Regulators?

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HSA Within the Public Service

A Statutory Board of the Ministry of Health

The Singapore Public Service

HSA
Health Sciences Authority

Vision

To be the **LEADING INNOVATIVE AUTHORITY**
protecting and advancing **NATIONAL HEALTH** and **SAFETY**

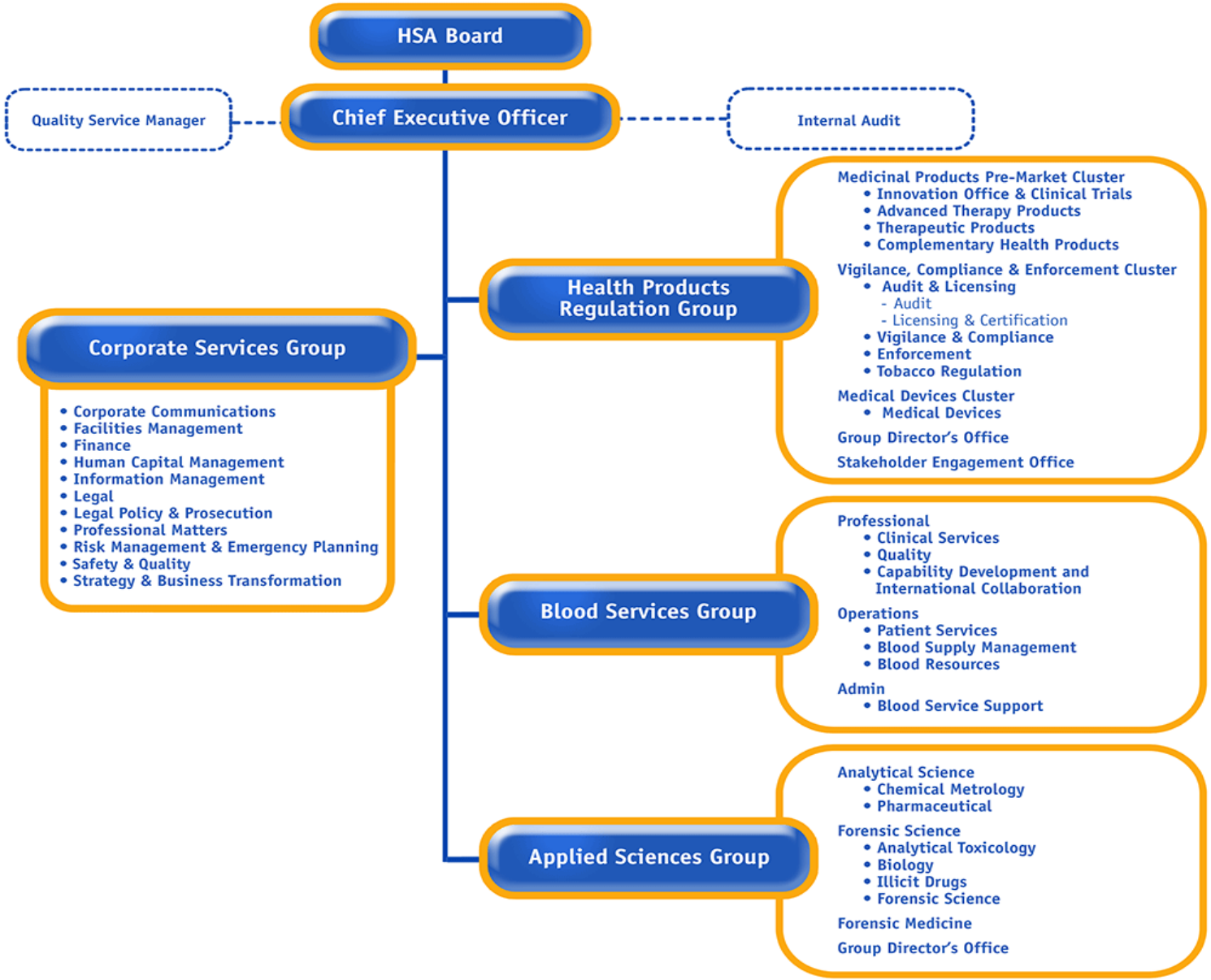
Mission

- To **wisely regulate** health products
- To **serve** the administration of justice
- To **secure** the nation's blood supply
- To **safeguard** public health

Corporate Headquarters • Health Products Regulation Group • Blood Services Group • Applied Sciences Group

A Statutory Board of the Ministry of Health | The Singapore Public Service : Integrity • Service • Excellence

Organisation Structure



Regulatory Scope – Diverse Range of Products

Outline

- Singapore MD Regulatory Framework
- Telehealth Guideline
- MD Cybersecurity Requirements
- MD with Artificial Intelligence (AI)/ Machine Learning (ML)
- Software Life Cycle Guidance
- Other Initiatives
- Challenges & Considerations

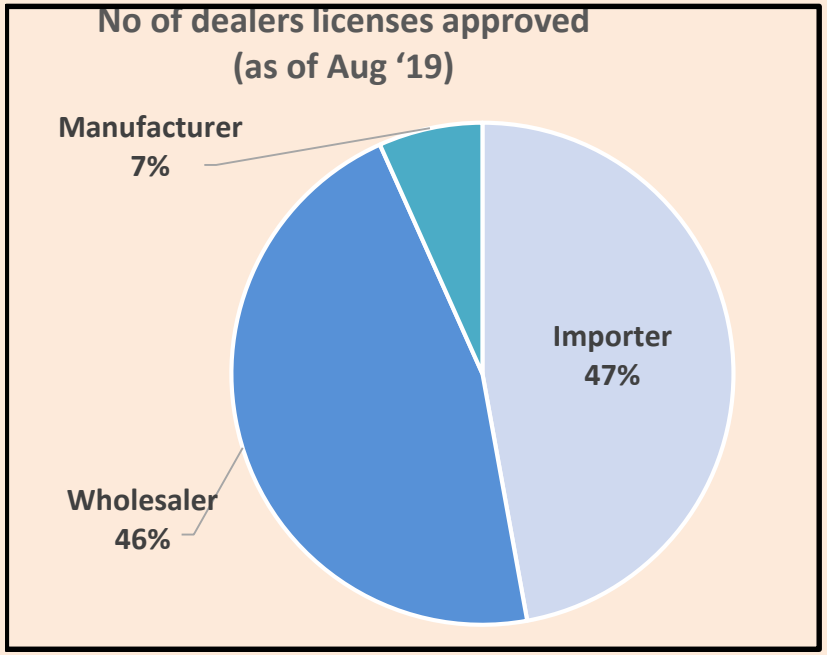
Singapore's Demographic

Imported Medical Devices

For Singapore, majority of medical devices are imported:

~ 3000 importers & wholesalers

~ 200 local manufacturers



Innovative R&D Ecosystem

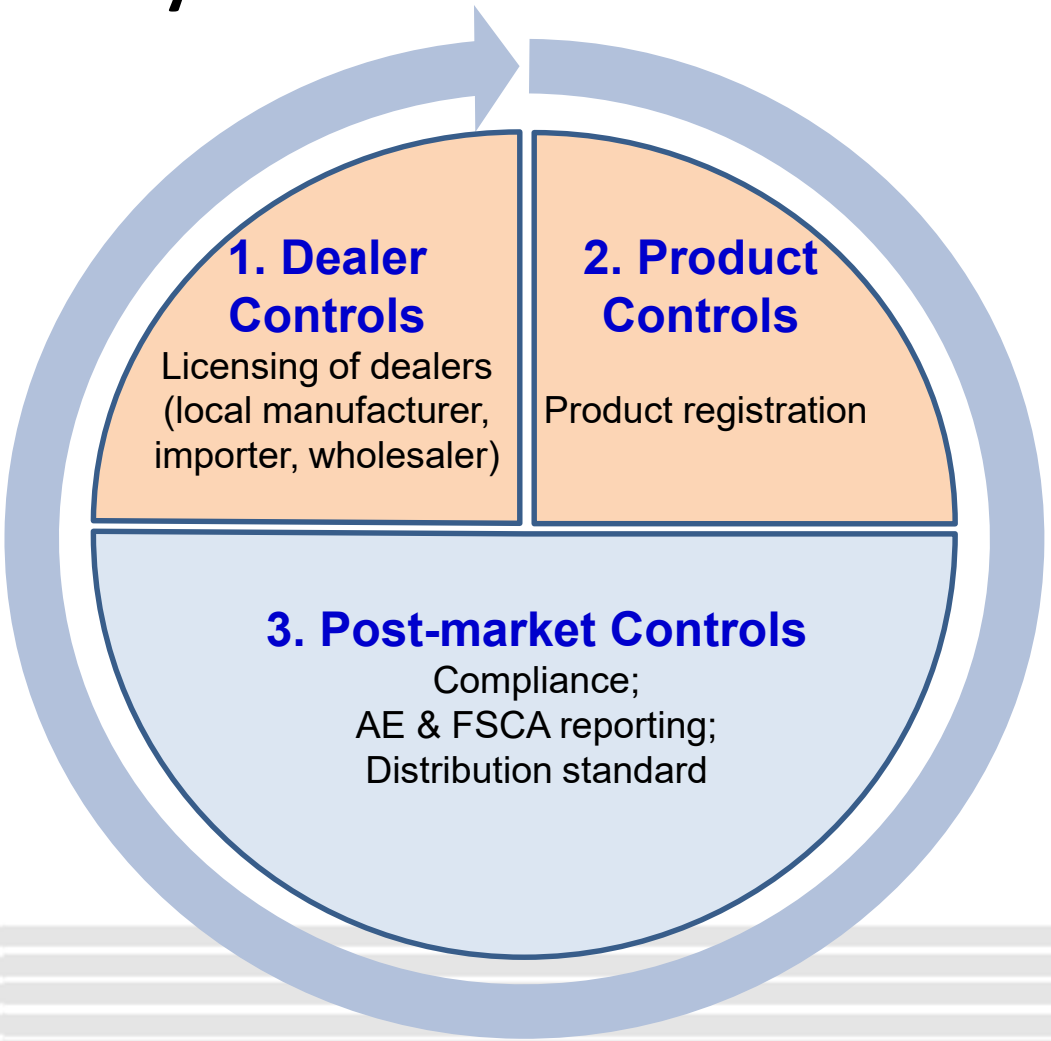
Singapore's network of top universities, research institutions and innovative start-ups enable MedTech companies to tap on a vibrant open innovation ecosystem.

- More than 25 R&D centres
- 50 regional headquarters
- Over 220 MedTech start-ups and small-medium enterprises

Source: https://www.edb.gov.sg/en/our-industries/medical-technology.html

Entering the Singapore Market

Key regulatory controls in line with the MD lifecycle



Pre-market stage

Post-market stage

Definition of “Medical Device” (MD)

HP Act First Schedule
http://sso.agc.gov.sg/

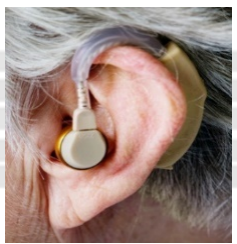
“Medical Device” means

Any instrument, apparatus, implement, machine, appliance, implant, in vitro use, **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, mainly for medical purposes;
d) supporting or sustaining life;
e) control of conception;
f) disinfection of medical devices; or
g) providing information by means of in vitro examination of specimens derived from the human body, for medical or diagnostic purposes,

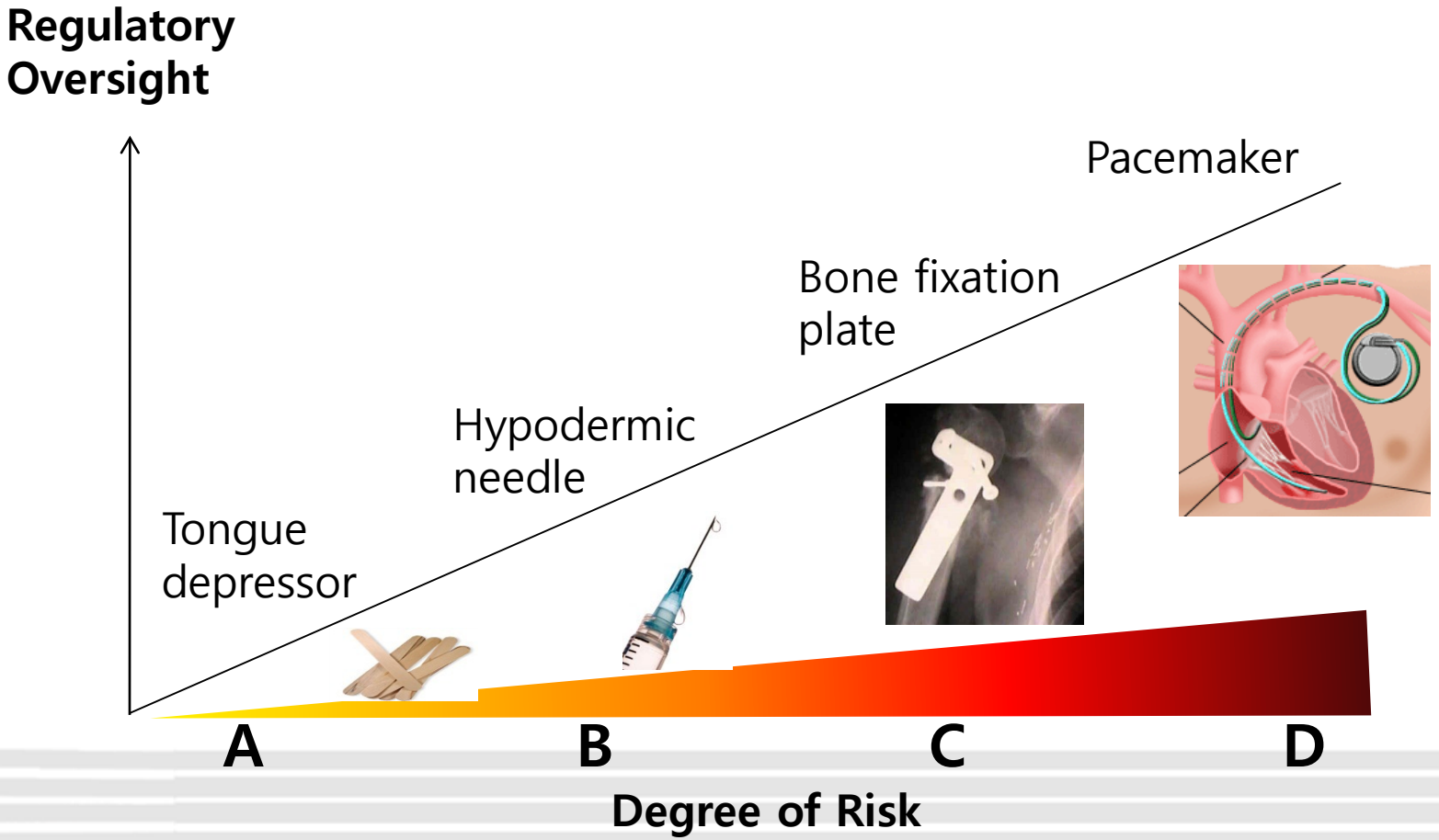
and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.



Risk Classification

Medical Devices are categorized into 4 risk classes which are aligned with the international rule-based classification system



Inherent Challenges

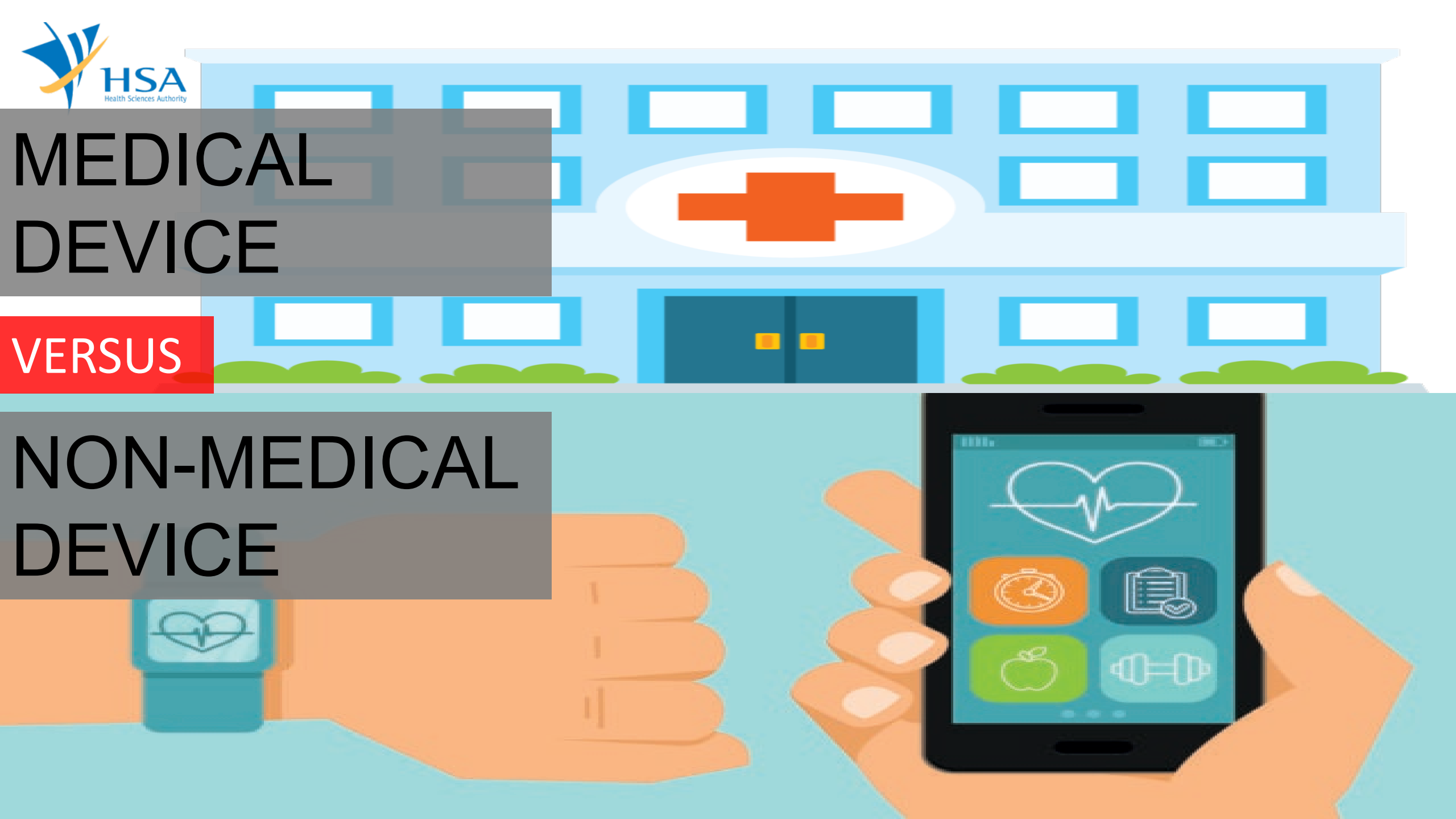
- Ensuring Product Quality
- The Internet of Things
- Cybersecurity
- Regulatory Compliance and Controls

HSA's Initiatives

HSA's Initiatives

Digital Health Market Size to Grow at Over 25.9% CAGR to Reach $379bn by 2024

SOURCE: Global Market Insights Inc.


HSA
Health Sciences Authority
MEDICAL DEVICE
VERSUS
NON-MEDICAL DEVICE

Telehealth Guidelines

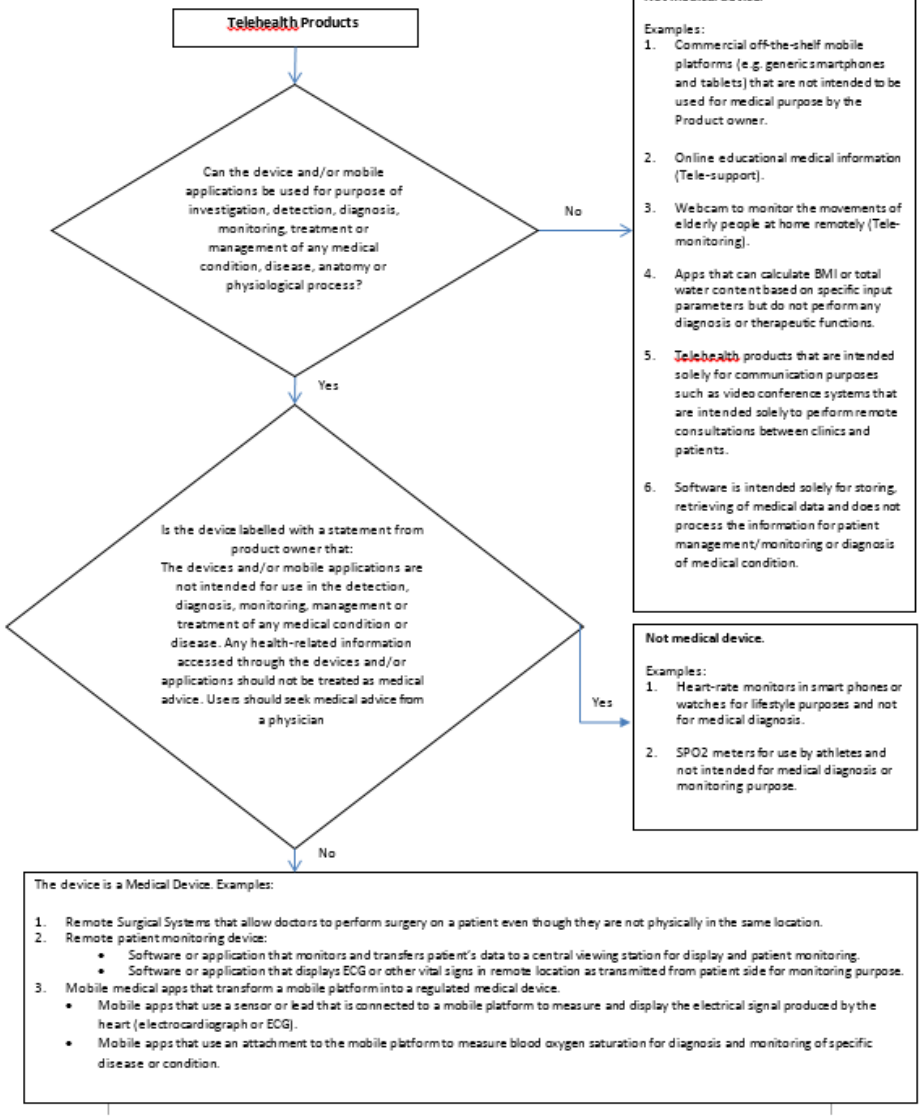
1.3 Scope

This document applies to all Telehealth products which include hardware devices, software and mobile applications, specifically on the classification and regulation of such products.
It does not cover the practice of Telehealth services as this falls out of HSA's purview.

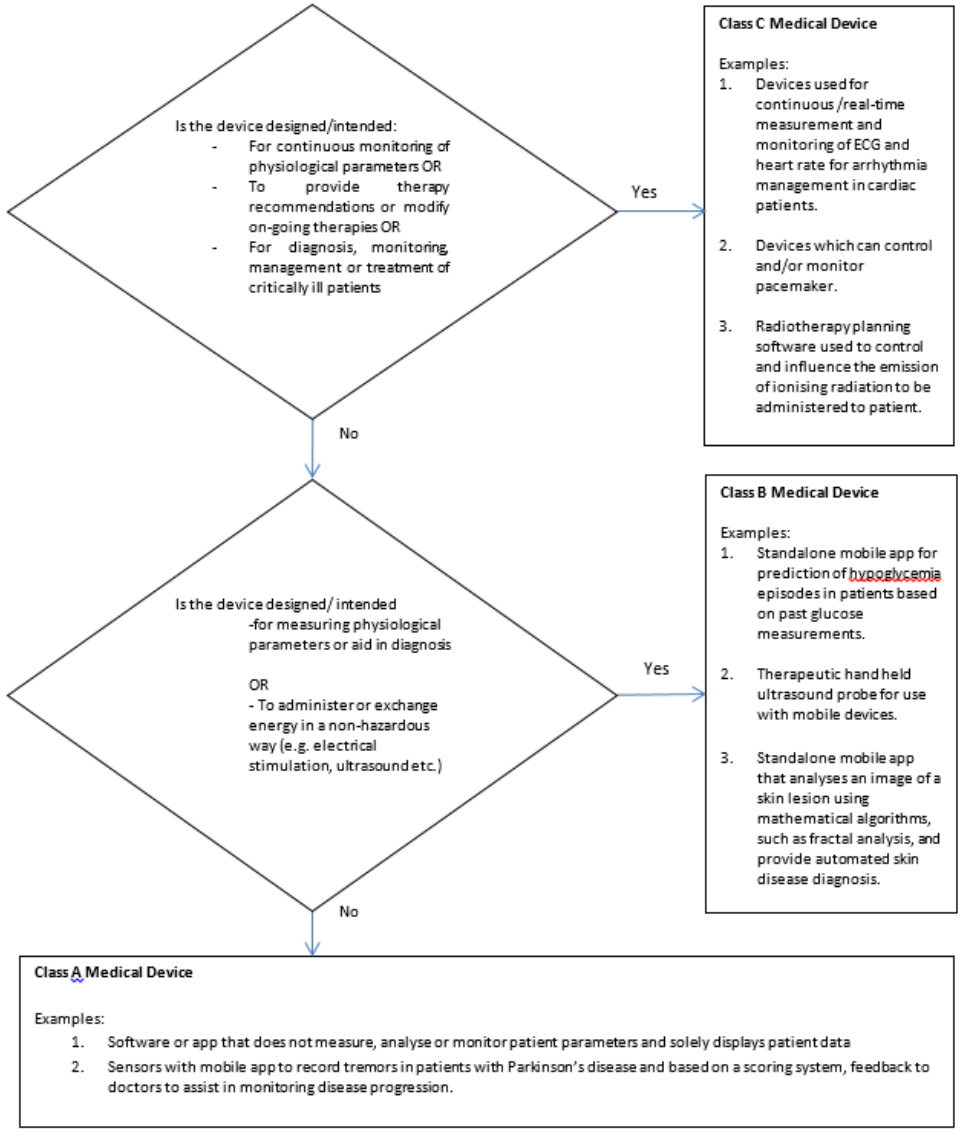
1) Introduction | 2) Categorisation | 3) Risk Classification | 4) Regulatory Controls | 5) Standalone Mobile Apps

Telehealth Guidelines

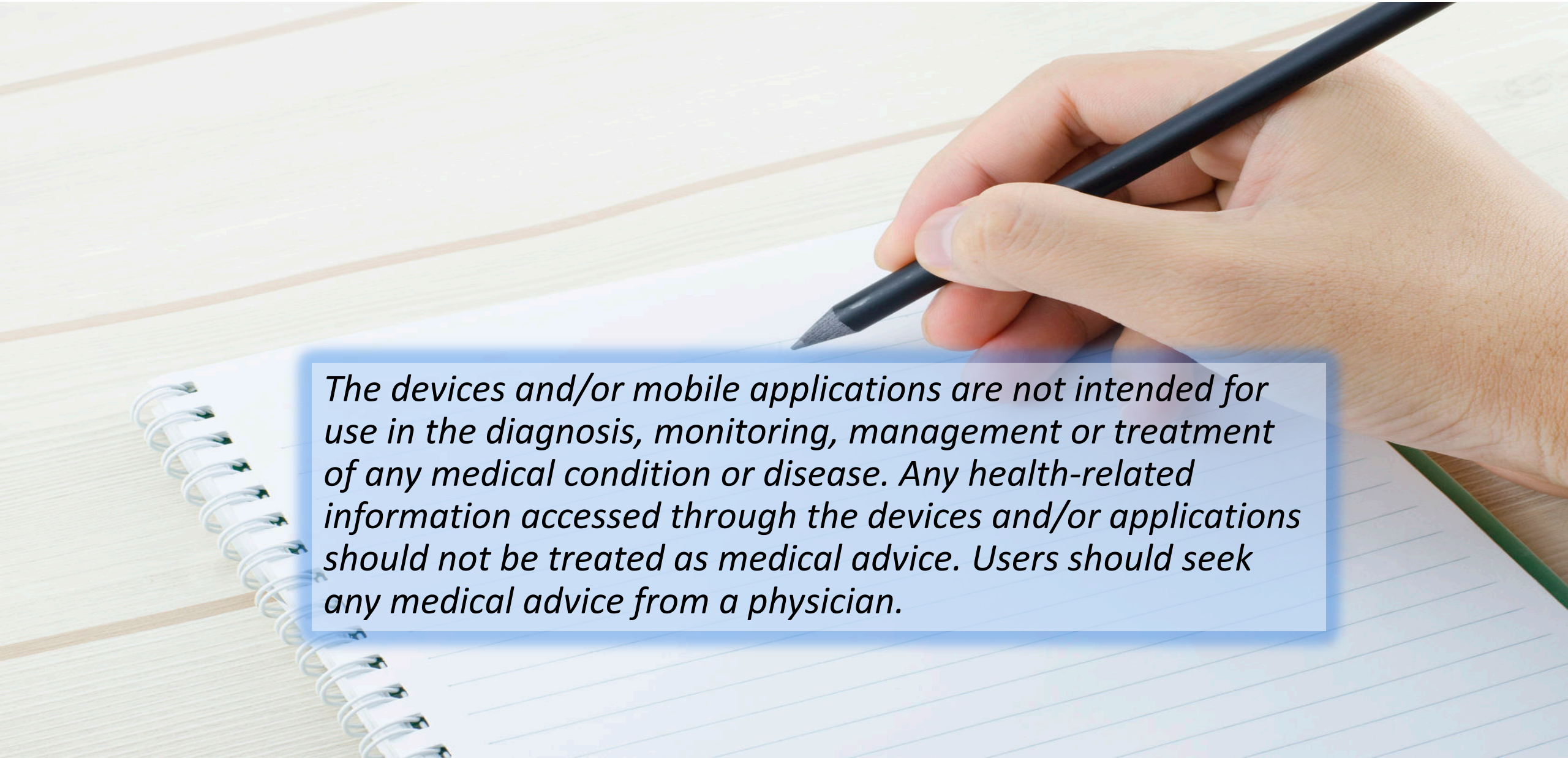
Flowchart 1: Is a Telehealth product a Medical Device?



Flowchart 2: Risk Classification of Telehealth Medical Devices

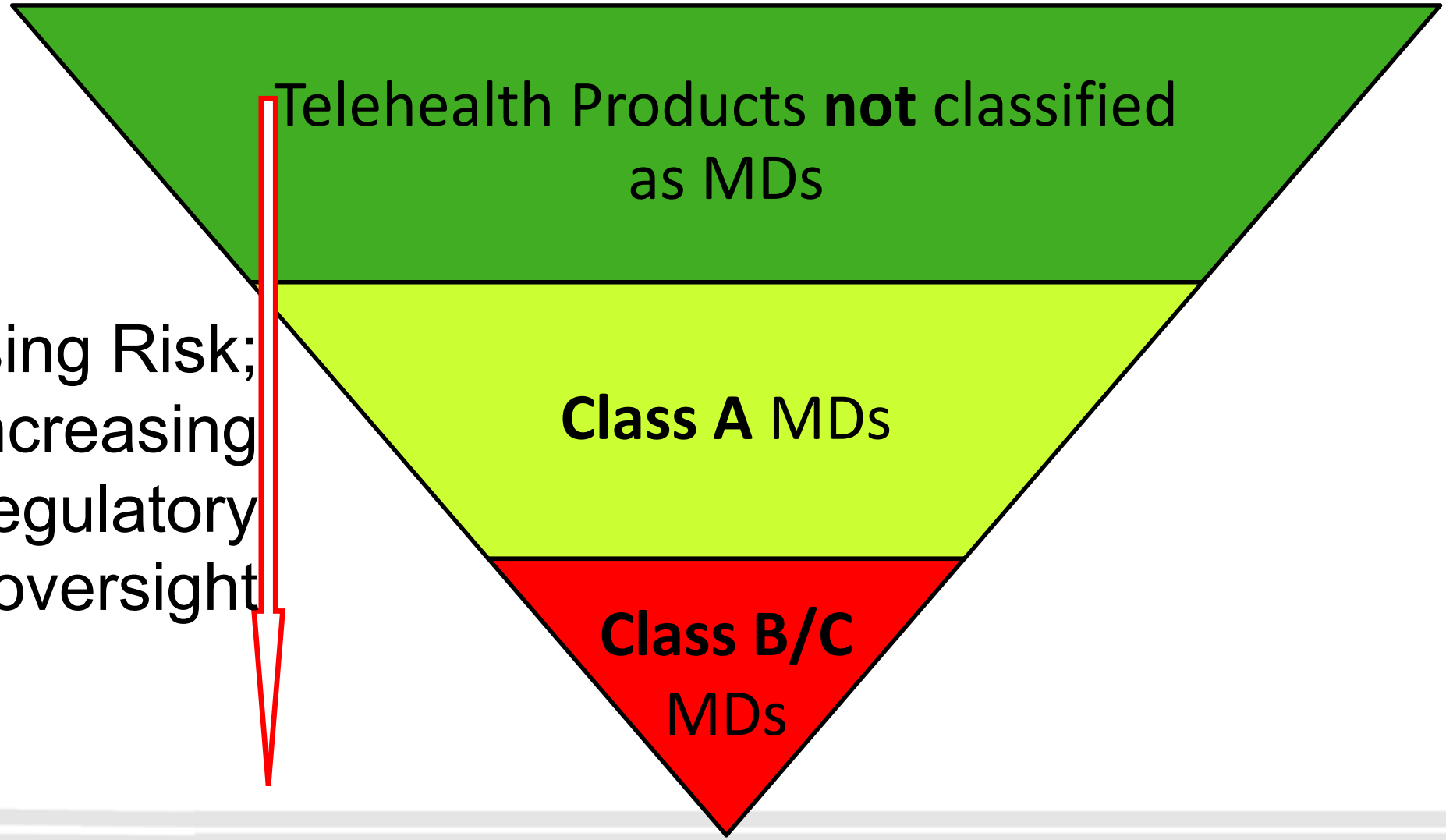


Telehealth Guidelines – Clarification Statement



The devices and/or mobile applications are not intended for use in the 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 medical advice. Users should seek any medical advice from a physician.

Risk based Regulatory Approach



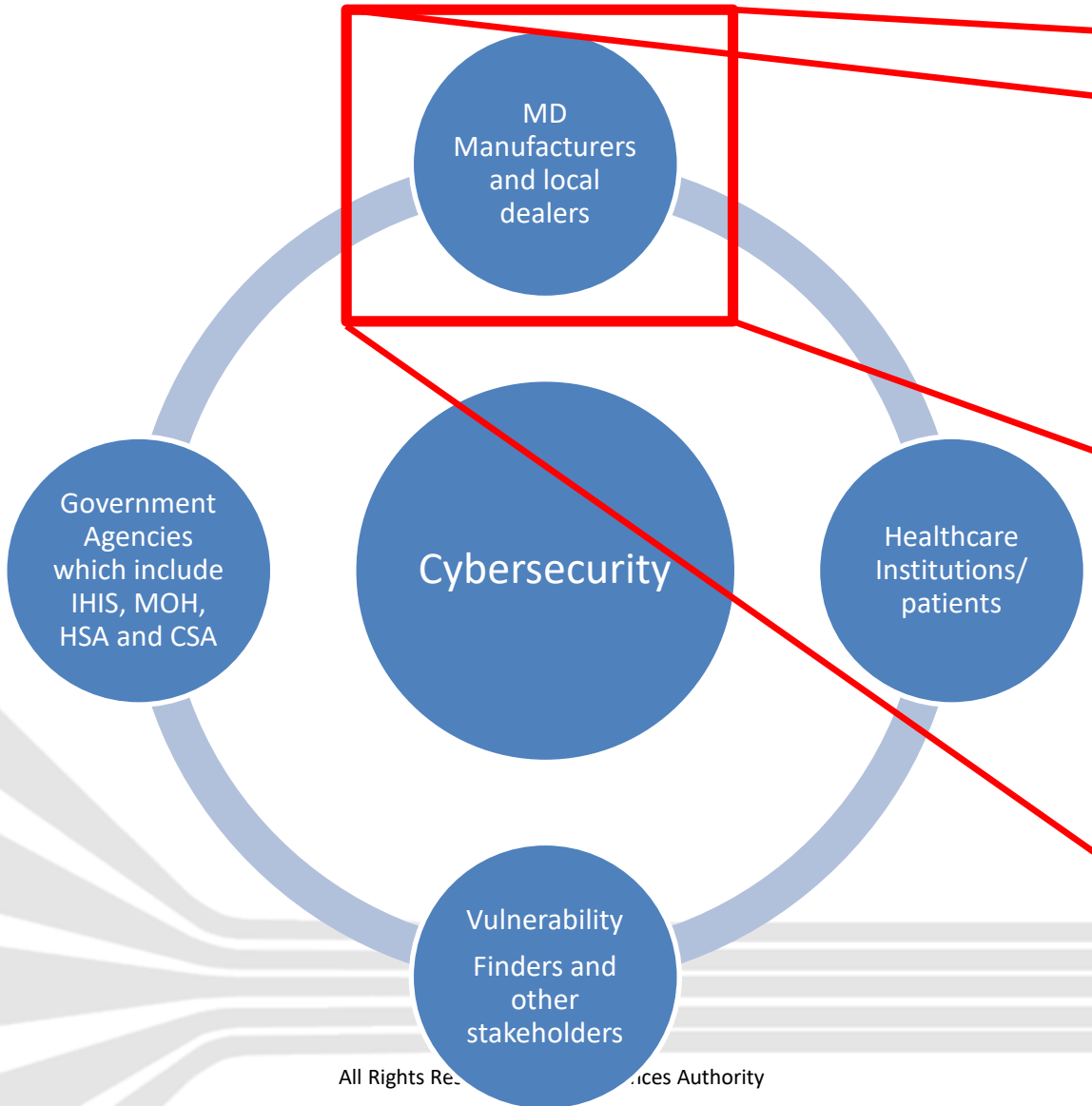
Immediate access for Standalone Mobile Medical Device application with at least **1 Reference Agency approval (i.e. US, EU, Japan, Canada, Australia)**

HSA's Initiatives

Current Cybersecurity Landscape

- Healthcare industry is a major target for cybercriminals who may have malicious intention to cause patient harm and steal private/confidential healthcare data
- Threat landscape is ever-evolving and attacks are getting more sophisticated
- Increased use of wireless, Internet, IoT, and network-connected devices
- The environment where the devices are operating in [hospital vs. community care (home use)]
- Lack of global harmonised approach in regulating MD cybersecurity

To address cybersecurity risk, it has to be a shared responsibility among all the stakeholders which include HCI, MD Manufacturers, Government Agencies and end users to ensure that the MDs are cyber-secure



Cybersecurity requirements to be fulfilled by MD Manufacturers

- **Pre-market requirements**
  - **Secured by design** – Manufacturers should consider cybersecurity threats and vulnerabilities by incorporating cybersecurity features at the early phase of device development
  - **Risk Mitigation** - Risk management system should be utilised to address any cybersecurity risks

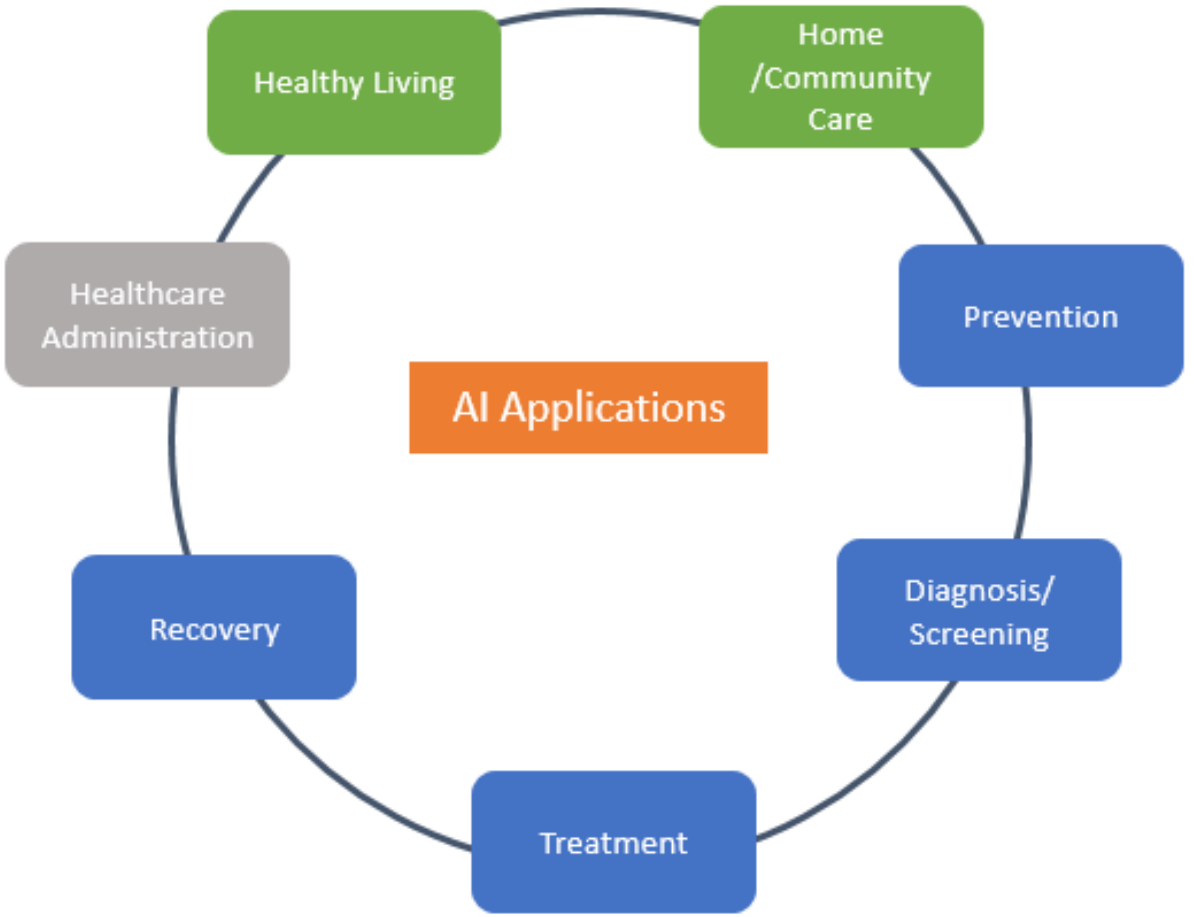
- **Post-market requirements**
  - Evidence must be provided to demonstrate that they have an **on-going plan** for surveillance, timely detection and management of the cybersecurity related threats during the useful life of the device

HSA's Initiatives

AI in Healthcare and its Benefits

- AI can bring about the following benefits in healthcare:
  1. Faster and more consistent diagnosis/treatment outcomes
  2. More efficient allocation of manpower
  3. Expanding coverage of healthcare

- AI has potential use-cases throughout healthcare, stretching across 3 broad interfaces:
  1. Interactions between patient and healthcare practitioners
  2. Pre-/Post-patient interactions with healthcare practitioners
  3. Back-end administrative processes of healthcare institutions



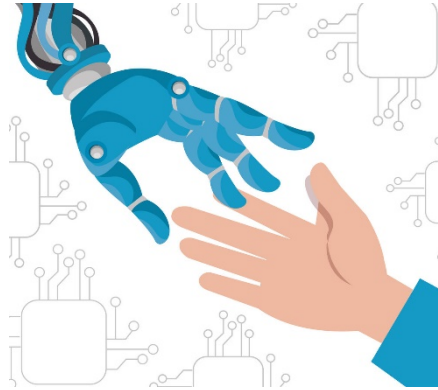
Source: AI in Healthcare – Regulatory Challenges and Approaches [For Discussion]

AI in Healthcare: Regulatory Challenges

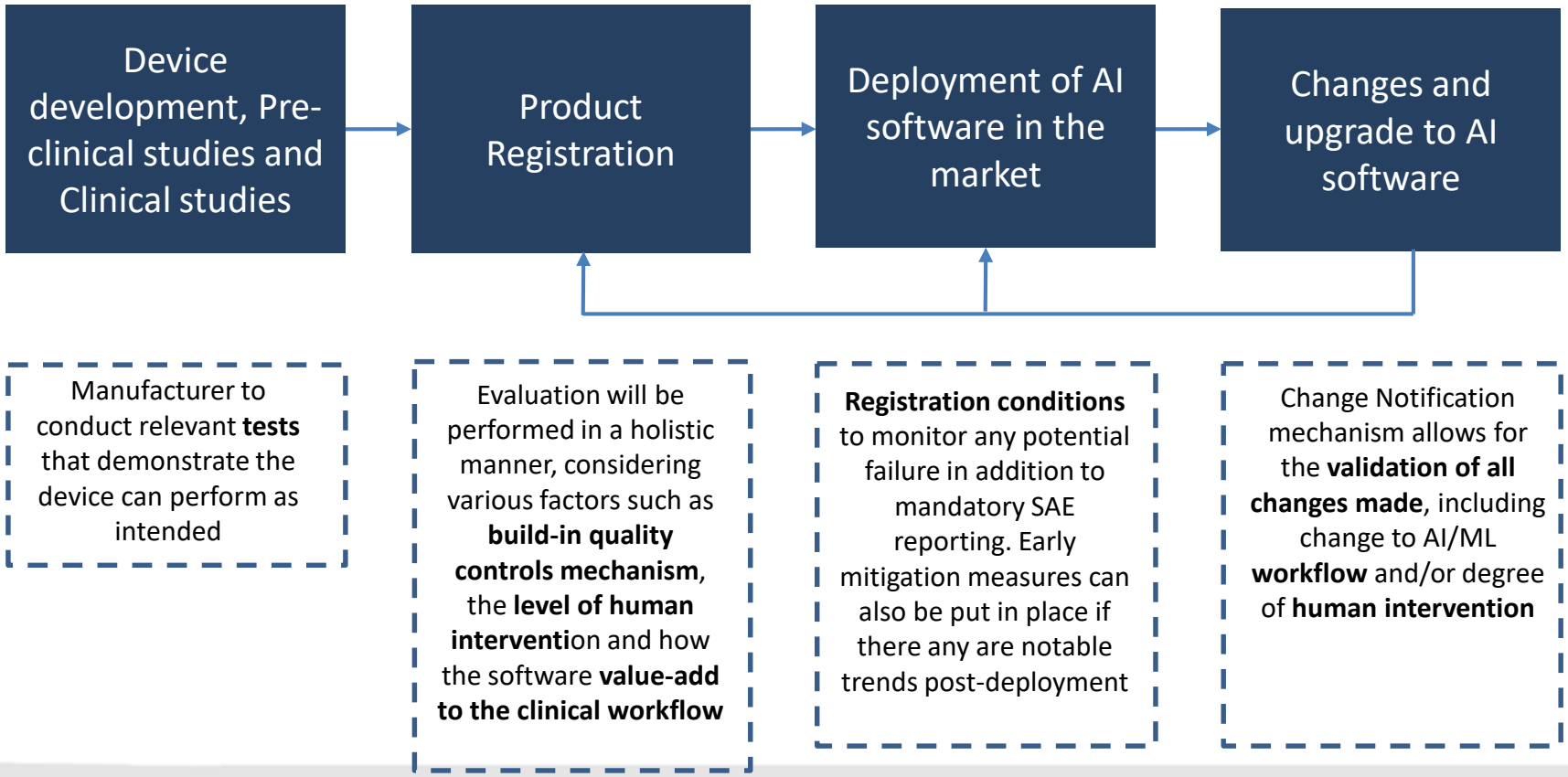
- AI/Machine Learning performance is dependent on the quality of the learning data set that is used in training the engine
  - Good quality data will improve the performance while poor quality data or inaccurate data may affect the device performance

- AI/Machine Learning, unlike other software, has the ability to continuously learn post-deployment, during use
  - With continuous learning, the performance of the machine learning/AI changes from what it was originally validated
  - May provide a different set of output/result

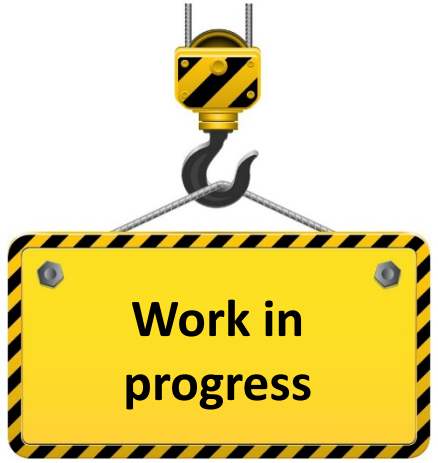
AI in Healthcare: HSA's Regulatory Approach



- Product life cycle approach



HSA's Initiatives

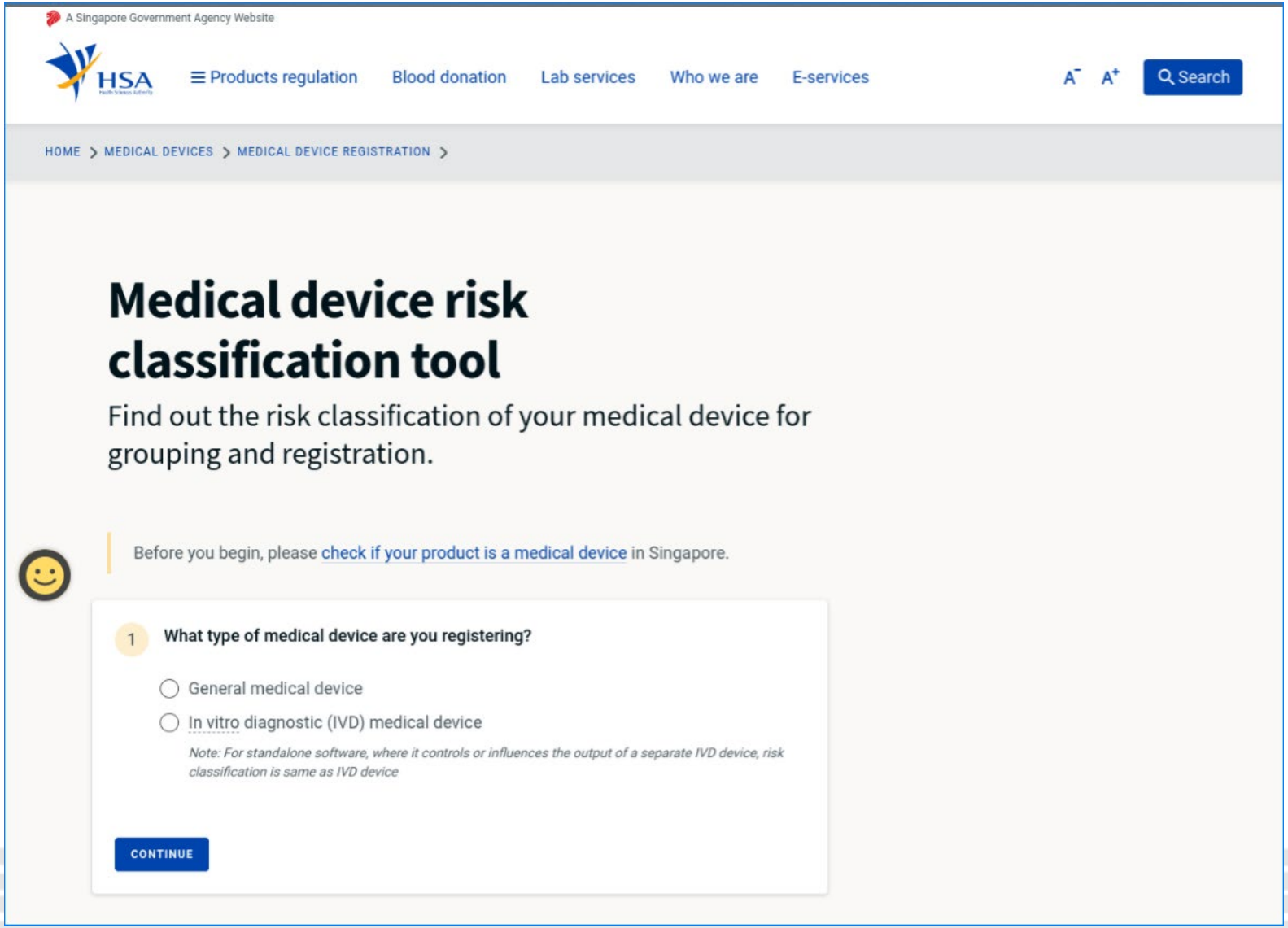


- Aug 2010 — Software Requirements
- 2017 — Telehealth Guidelines
- 2017 — Cybersecurity Requirements
- 2019 — Received 1st MD with AI/ML for product registration
- 2020 — Software Life Cycle Guidelines

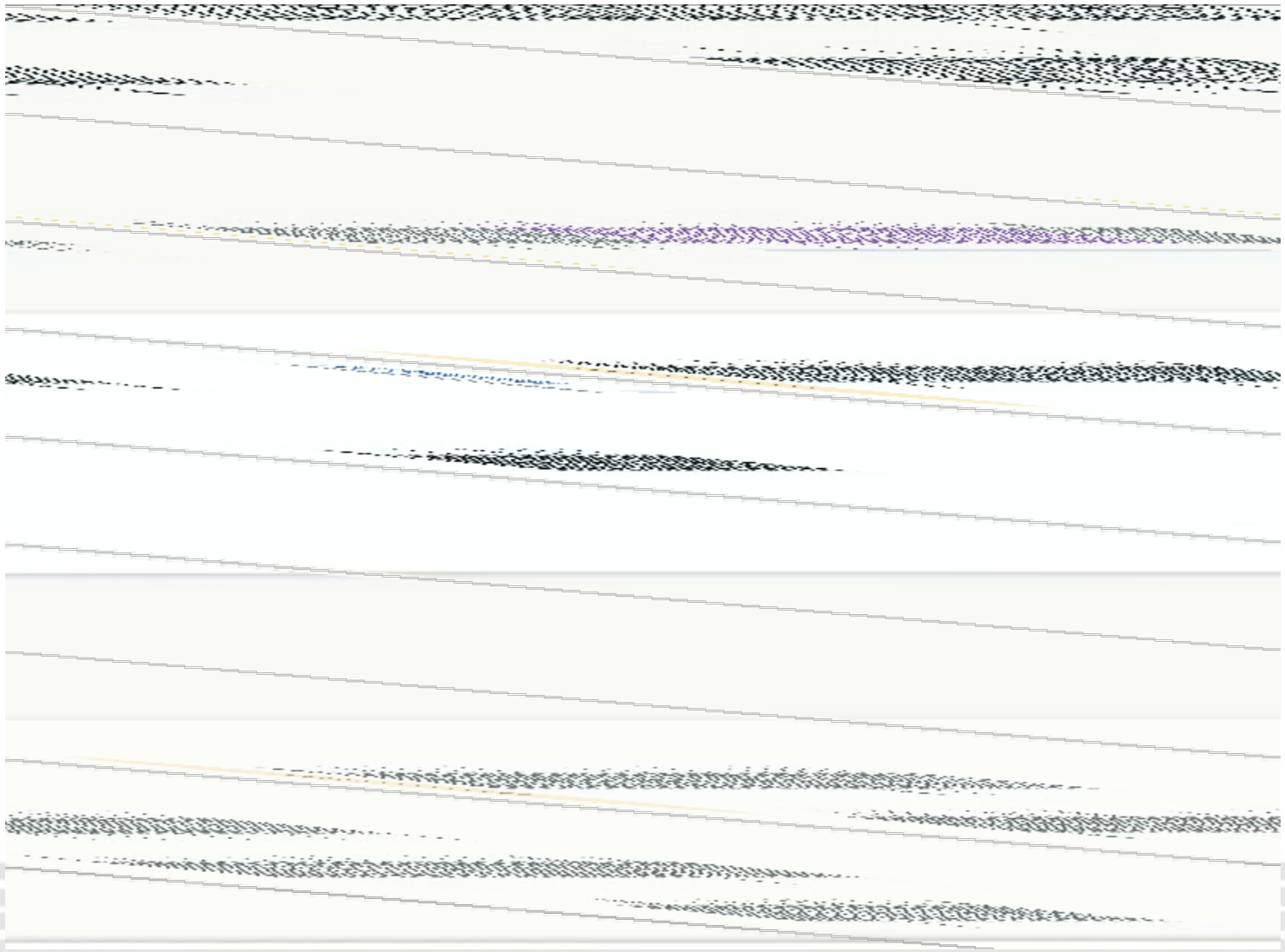
Other Initiatives

- MD Risk Classification Tool
- Pre-Market Consultation and Priority Review Schemes

Medical Device Risk Classification Tool



Medical Device Risk Classification Tool



Medical Device Risk Classification Tool

- Results can be saved and printed

04/11/2019 HSA | Medical device risk classification tool

Medical device risk classification tool

This summary is for MyMDSoftware

1. What type of medical device are you registering?

General medical device

2. Does the device have an integral part which is a registrable medicine (therapeutic product) that only functions to act on the human body with action ancillary to that of the device?

Examples: bone cements with antibiotic, wound dressings incorporating antimicrobial agents to provide ancillary action on the wound

No

3. The device was manufactured from or has incorporated any of the following:

- ○ Derivatives of cells or tissues of human origin, rendered non-viable
- ○ Cells, tissues or their derivatives of animal origin (rendered non-viable) or recombinant origin
- ✓ **None of the above**

4. What is the intended use of the device.

- ○ Sterilise or disinfect medical devices (including contact lenses), or hydrating contact lenses
- ○ Contraceptive or used to prevent the transmission of sexually transmitted diseases
- ✓ **None of the above**

5. Is the device invasive?

No

6. Is the device an active medical device?

Yes

https://www-hsa-gov-sg.cwp.sg/medical-devices/registration/risk-classification 1/2

04/11/2019 HSA | Medical device risk classification tool

7. Is the device an active therapeutic device intended to administer or exchange energy to or with the human body, or is a software?

Yes

8. Considering the nature, density and site of application of the energy, could the administration or exchange of this energy be done in a potentially hazardous manner, including exposure to ionising radiation?

Examples: lung ventilators, baby incubators, electrosurgical generators, external pacemakers and defibrillators, surgical lasers, lithotriptors, therapeutic xray and other sources of ionising radiation

***Note:** The term 'potentially hazardous' is in relations to the type of technology involved and the intended application.*

No

Your device's risk classification is Class B.

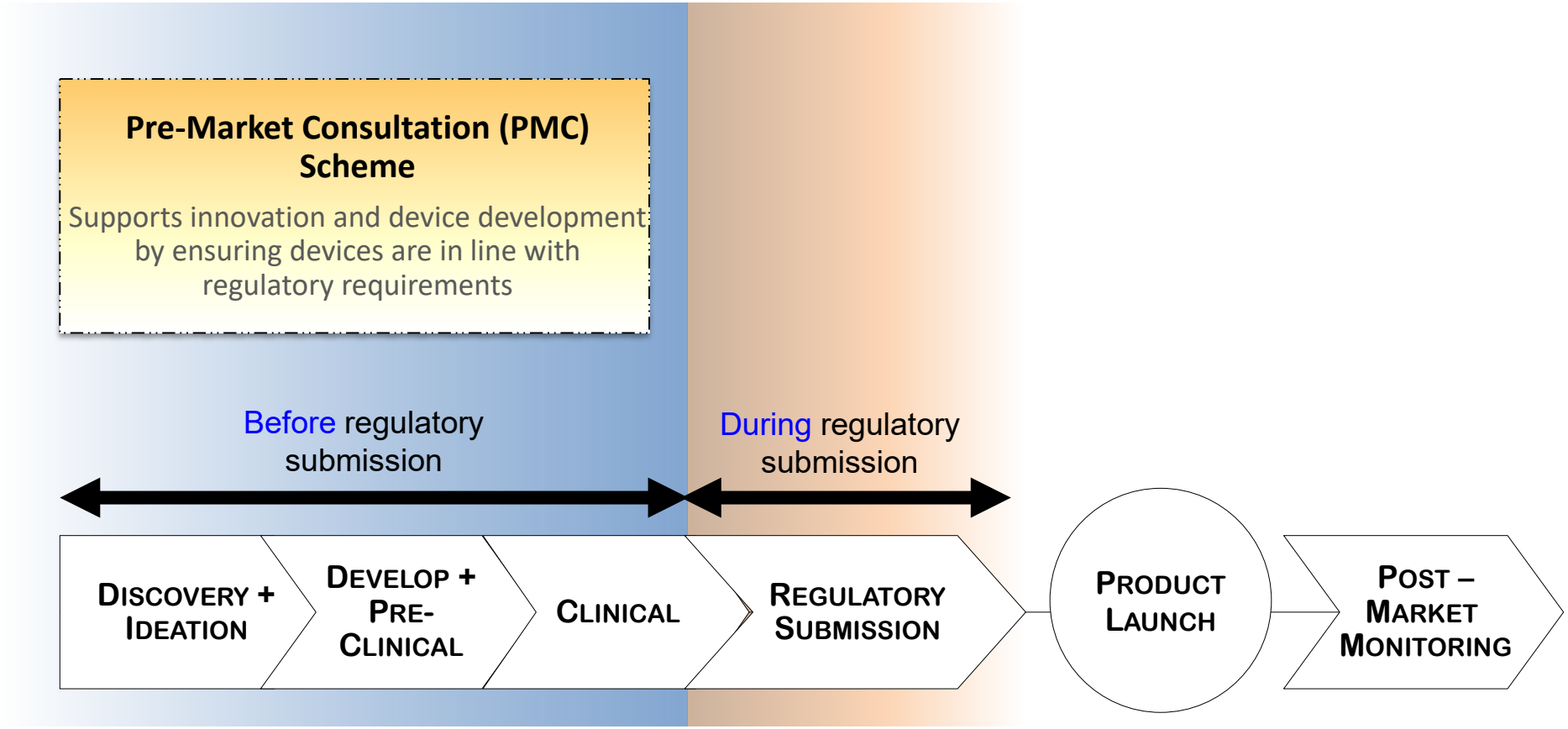
Examples: muscle stimulators, Transcutaneous Electro-Neuro Stimulator (TENS) devices, powered dental hand pieces, hearing aids, neonatal phototherapy equipment, ultrasound equipment for physiotherapy.

The risk classification above is based on GN13 rule 9i.

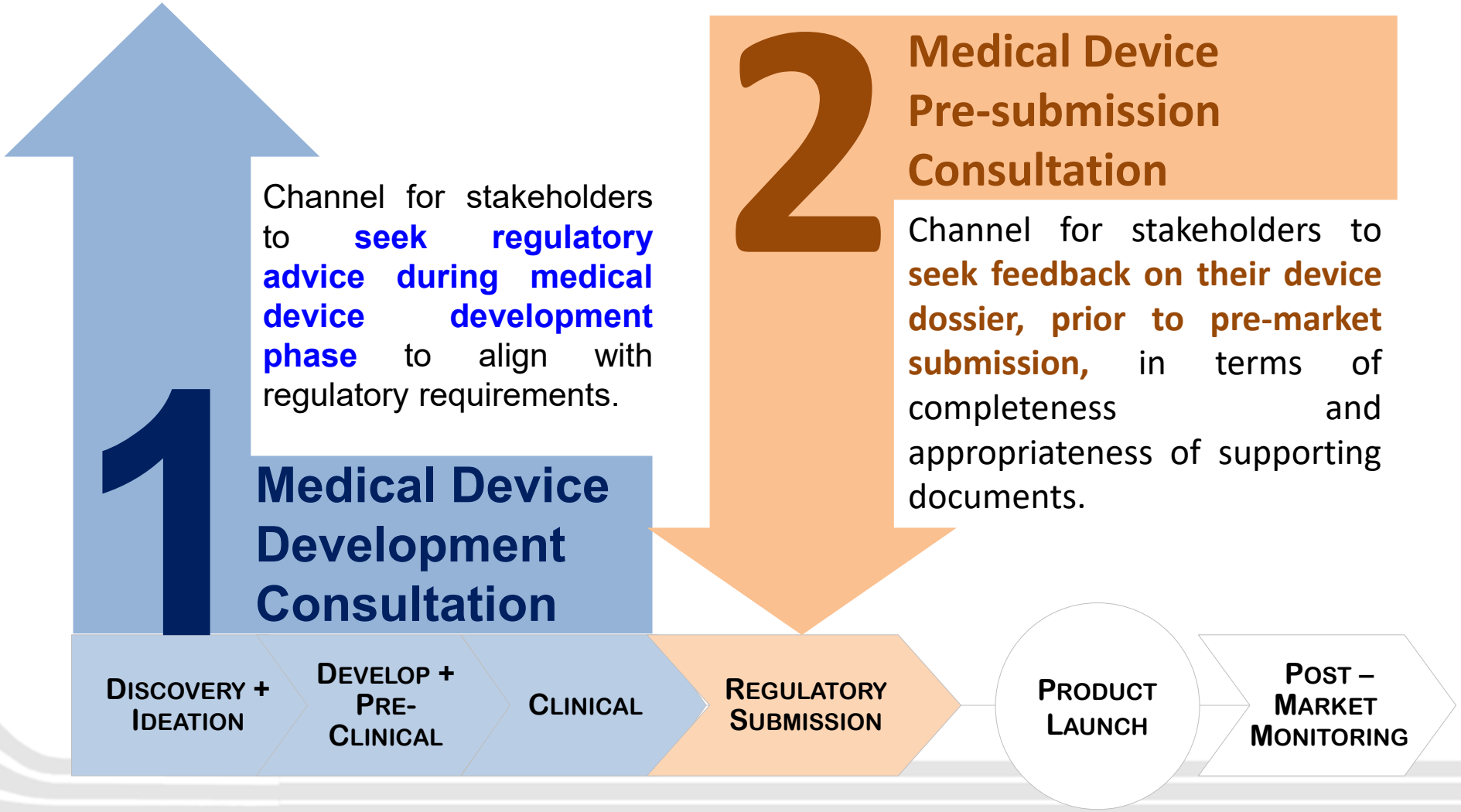
To continue registering your medical device, you may check the registration and licensing requirements for your device.

Pre-Market Consultation (PMC) Scheme

- To provide support through the device development lifecycle

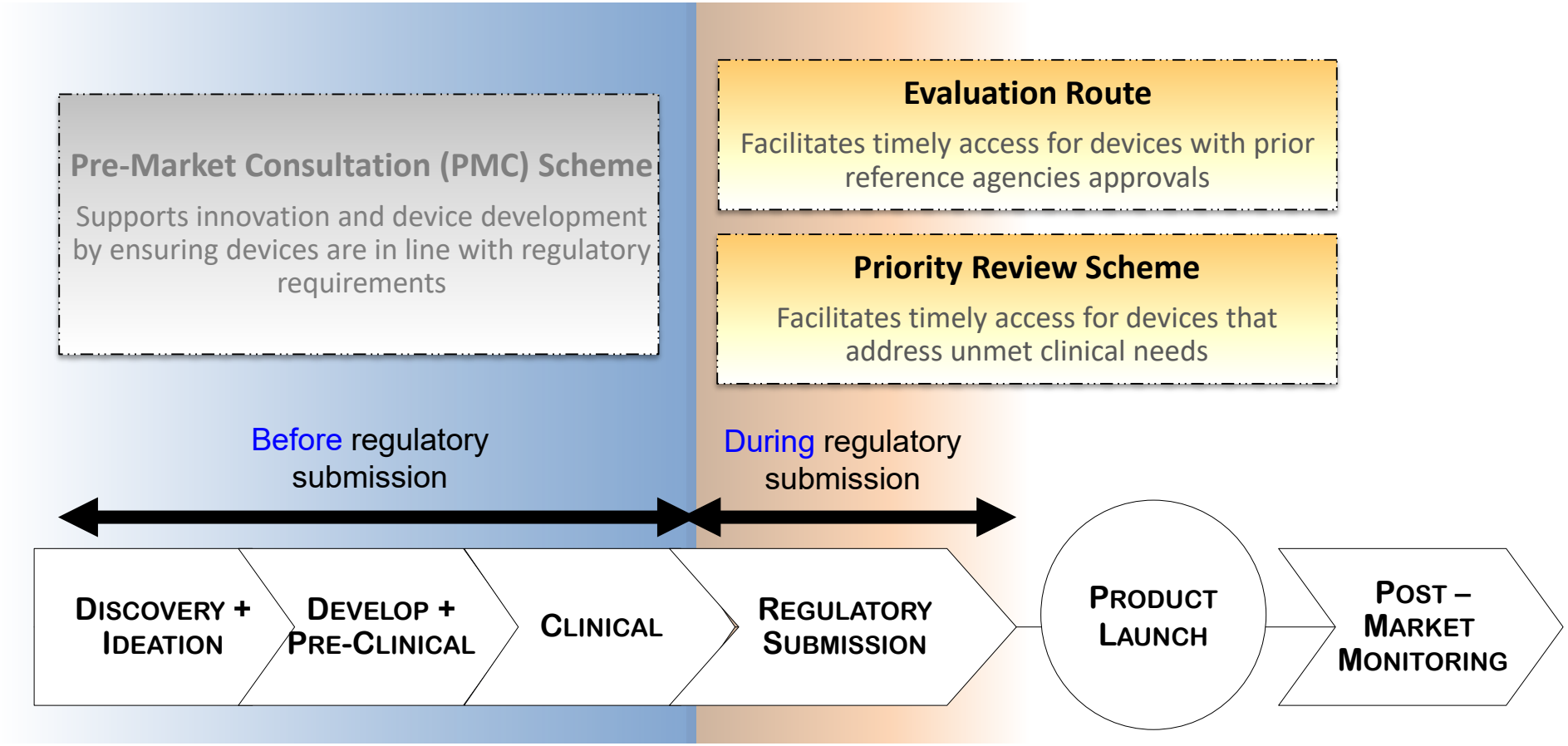


Pre-Market Consultation (PMC) Scheme



Priority Review Scheme

- To provide support through the device development lifecycle



Priority Review Scheme

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

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

- 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

**Excluding devices incorporating registrable medicinal products*

Conclusion: Keeping Up with Innovative Technologies

As a Regulator:

- Patient safety and user safety are paramount consideration
- Be acquainted with the emerging trends in our ecosystem
- Forward-looking and agile
- Strive to constantly improve both technical and regulatory knowledge
- Balance the need for regulation (in ensuring safety and performance) with the need to enable businesses and innovation to grow