Initiatives to Accelerate Medical Devices Access – *Singapore regulatory perspective*

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Overview

1) **Regulatory Initiatives in Supporting Innovation**

2) **Regulatory Initiatives in Facilitating Device Access**

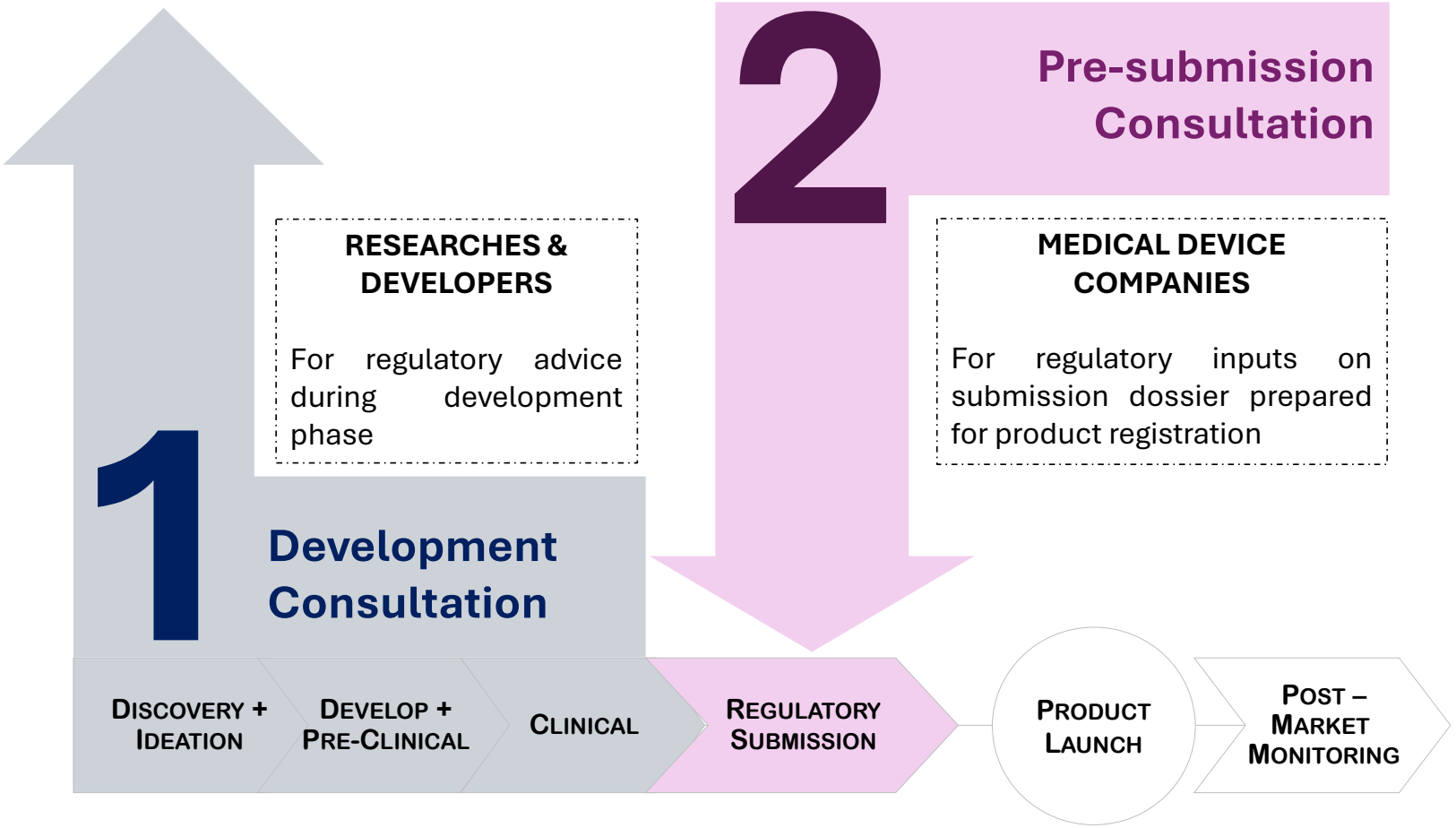
Regulatory Initiatives in Supporting Innovation

Pre-market Consultation (PMC) Scheme: Early guidance on regulatory alignment during development or pre-registration submission phase

Priority Review Scheme: Accelerated evaluation for breakthrough technologies. Facilitate timely access for devices that address unmet clinical needs

Since 2017, we have supported 250 consultations & 140 priority review applications, through which market access of innovative devices was facilitated

Pre-market Consultation (PMC) Scheme



Scan for more information

Priority Review Scheme

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**

Scan for more information

* *Exclude devices incorporating registrable medicinal products*

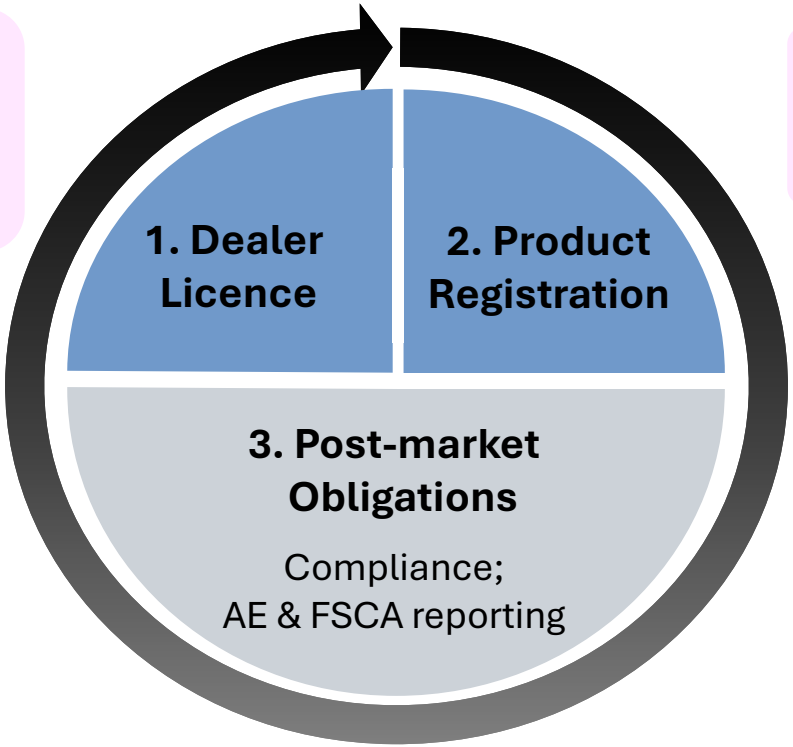
Regulatory Initiatives in Facilitating Device Access

Harmonised & Confidence-based Approach

Overview of Singapore Regulatory Framework

Local companies who **manufacture, import or supply** devices by wholesale are required to be licensed by HSA

All MDs, **except Class A**, required registration with HSA



Pre-market

Post-market

REGULATION VIA LIFECYCLE APPROACH

Adopting Harmonised Approach & International Standards

Internationally aligned Classification

- Risk-based system (Class A, B, C, D)
- Adopted from GHTF framework, in line with the ASEAN Medical Device Directive (AMDD)

Grouping rules to allow submission of multiple devices in a single application

Harmonized submission format

- IMDRF Table of Contents (ToC)
- ASEAN Common Submission Dossier Template (CSDT)

Adoption of harmonized guidelines & international standards

Risk Class	**Dealer Licence** (Manufacturer/Importer/ Wholesaler Licence)	**Product Registration**
Class B, C, D	Accepts MDSAP certificate / ISO 13485 certificate as evidence of conformity for licence application	Accepts dossier submission in IMDRF ToC / ASEAN CSDT format Documentary requirements aligned with international guidelines (e.g. IMDRF guidelines) & international standards

Confidence-based Approach

Leverages on	
Prior approval with **indications aligned** in jurisdiction(s) from • HSA's **reference agencies (RAs)**, or  • **Medical Device Regulatory Reliance Programme** – *Malaysia Medical Device Authority (MDA)* *Type of recognized approvals can be found in GN-15 Guidance*	**Safe history of use** in these jurisdictions

Devices may go through evaluation route(s) with
Shorter timeline + Lower cost + Lesser dossier requirements

Value outcomes

- Effective resource management, reduce duplication of review scope → Regulators
- Decrease regulatory burden → Industry
- Faster access → Patients/users

Evaluation Routes

	Risk Class	Qualifying Criteria	Turn-Around-Time (TAT) *depends on risk class*
Full	B, C, D	Not prior approved in any RA	160 - 310 working days
Full (Priority Review)			104 - 202 working days (↓ 35% TAT reduction)
Abridged	B, C, D	1 RA approval **OR** under Medical Device Regulatory Reliance Programme	100 - 220 working days
Expedited*	C, D	2 RA approval **OR** 1 RA approval with 3 years safe marketing history in RA (only for Class B & C) + no rejection & global safety issues	120 - 180 working days
Immediate	B		Immediate registration

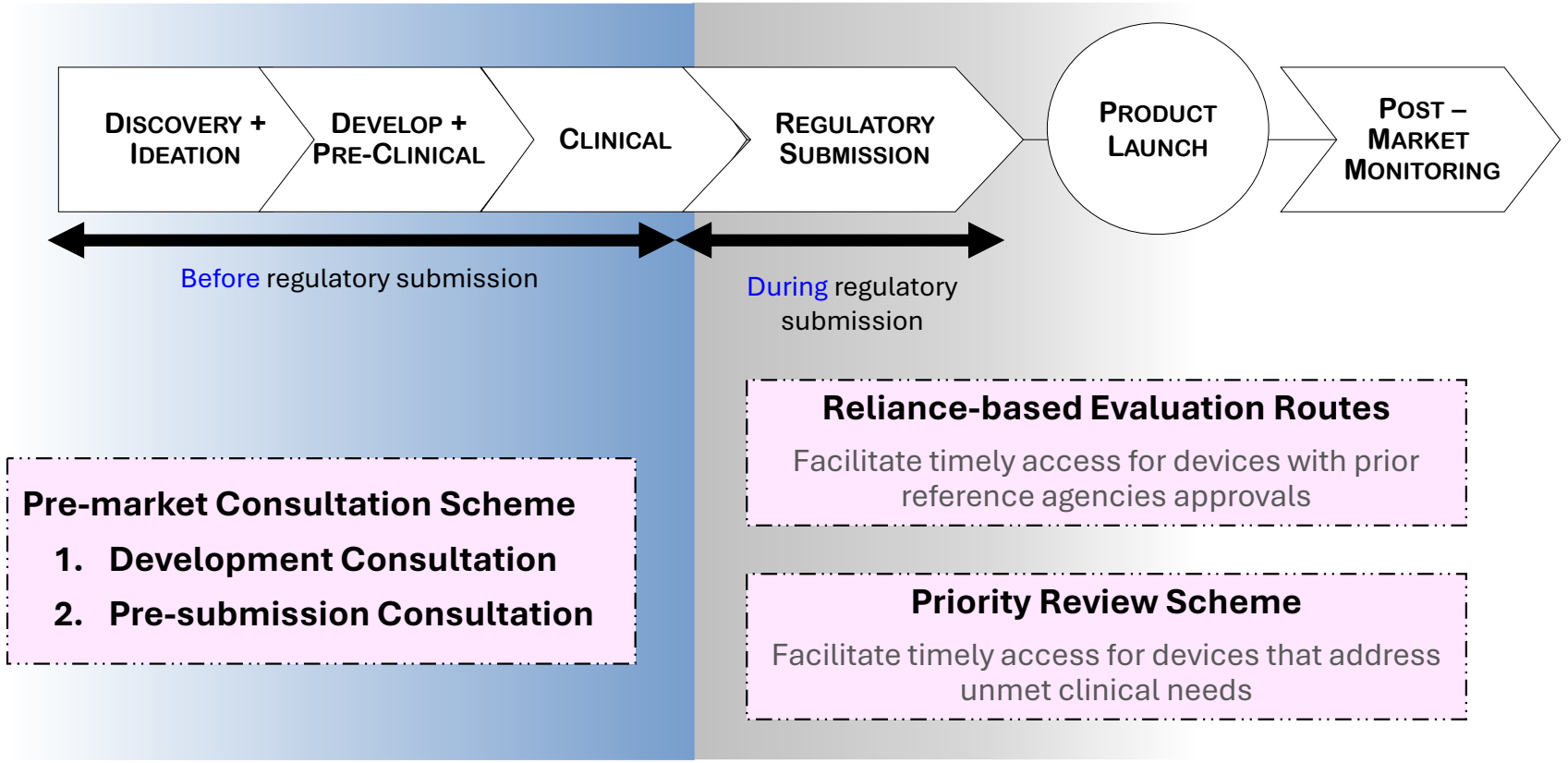
** Not within device group in exclusion list*

EU & TGA approval via Mutual Recognition Agreement (MRA) considered as 1 RA approval

Reference:

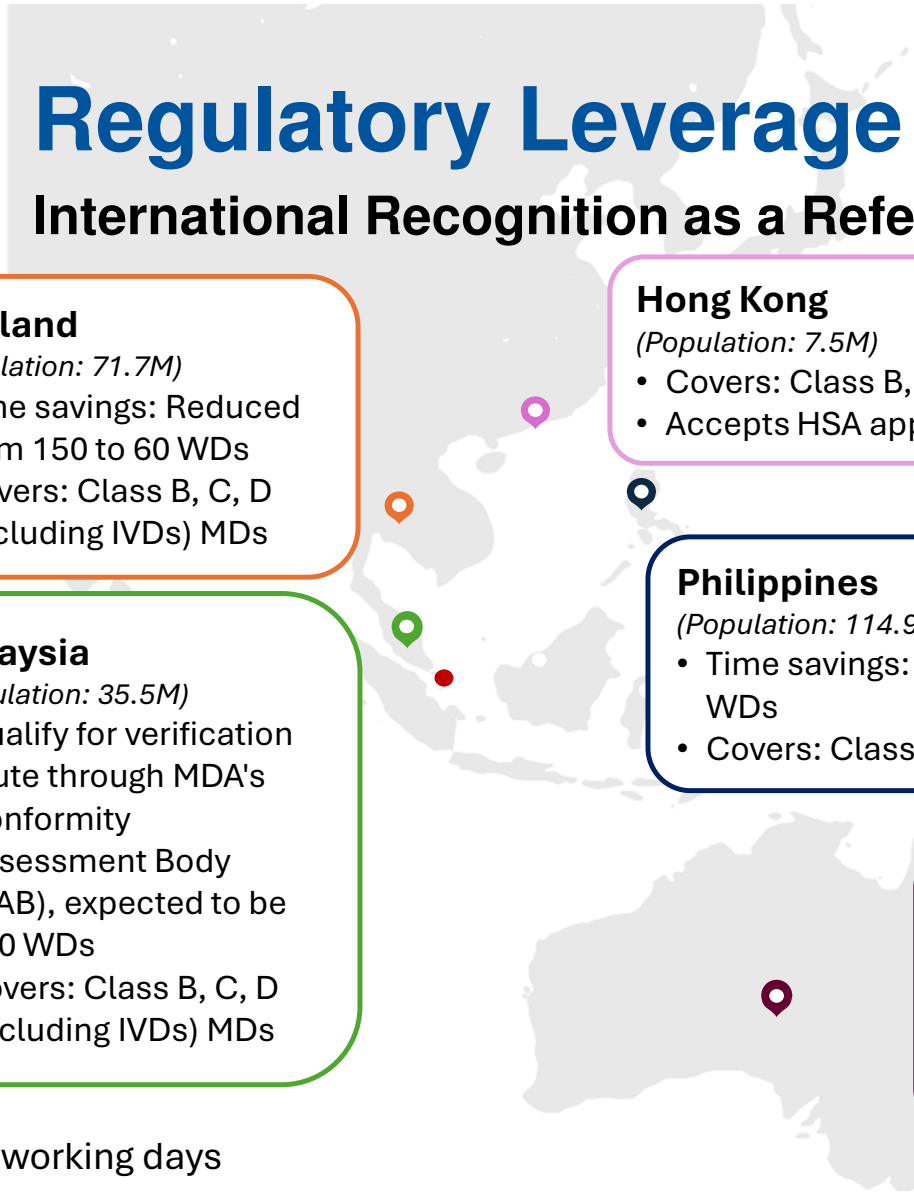
GN-15 Guidance on Medical Device Registration

Facilitating Device Access Across the Product Lifecycle



Regulatory Leverage

International Recognition as a Reference Authority



Thailand
(Population: 71.7M)
- Time savings: Reduced from 150 to 60 WDs
- Covers: Class B, C, D (including IVDs) MDs

Malaysia
(Population: 35.5M)
- Qualify for verification route through MDA's Conformity Assessment Body (CAB), expected to be ~30 WDs
- Covers: Class B, C, D (including IVDs) MDs

Hong Kong
(Population: 7.5M)
- Covers: Class B, C, D (including IVDs) MDs
- Accepts HSA approval as compliance evidence

Philippines
(Population: 114.9M)
- Time savings: Reduced from 90-180 to 30 WDs
- Covers: Class B, C, D (including IVDs) MDs

WHO
- Recognized as WHO Stringent Regulatory Authority (SRA)
- Accepts HSA approval as evidence for abridged prequalification assessment
- Covers: high risk (Class C & D) IVDs

Australia
(Population: 26.7M)
- Estimate time saved based on the exemption from TGA full review process (i.e. TGA conformity assessment certificate) is ~255 WDs, and MDs can be listed in ARTG
- Covers: Class B, C, D (including IVDs) MDs

WDs: working days

Market Access Opportunities

Singapore as a Gateway

- HSA registration as reference for expedited ASEAN market entry
- Singapore's position as regional medical device innovation & research hub
- Potential reach to over 660 million population across ASEAN

Harmonized approach under the ASEAN Medical Device Directive (AMDD)

- Harmonized MD definition and risk classification framework
- Common submission format:
  Single dossier preparation can support regional ASEAN market submission
- Reduced time and regulatory resources

Online Resources

Access to all published guidances
https://www.hsa.gov.sg/medical-devices/guidance-documents

Access to **Quick Guide**

Thank You