IMDRF International Medical Device Regulators Forum | 26th Session

Regulatory Updates Health Sciences Authority, Singapore

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NextGen MD Initiative

- A new initiative for next generation devices to tap on previously reviewed data by HSA for the predecessor devices

- MDs often undergo numerous iterations. Next generation devices typically rebranded but share common characteristics and validation data with their predecessors

In effect since **1 July 2024**

Initiative is **optional** and can be enrolled through premarket registration process

NextGen MD Initiative

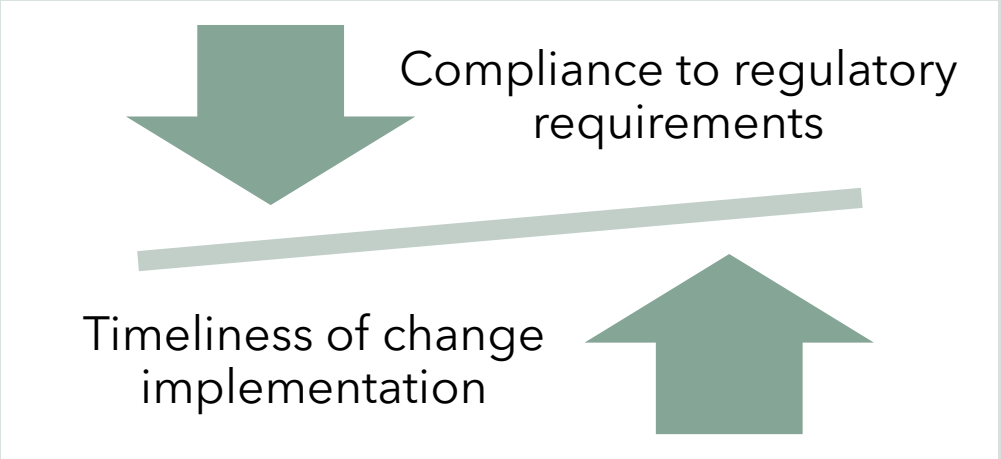
- Applicable for Class B, C and D (except MD-drug combination) device submitted under **FULL** evaluation route
  - Leveraged device must be from the same product owner, and registered with HSA
  - Required to leverage on the same dataset as the registered devices due to product similarity

- Potential to enhance the efficiency of the review process for faster market access

Change Management Program (CMP) for SaMD

SaMDs are rapidly evolving devices in which prevailing regulatory framework may not be suited to accommodate their rapid iterative innovation cycles while ensuring their safety and effectiveness

Manufacturers often face challenges in balancing the act



NEW **optional** regulatory pathway for SaMD:

Change Management Program (CMP)

Change Management Program (CMP) for SaMD

- A new pathway to facilitate timely implementation of SaMD software changes*, including AI related software changes, after device registration

  * **Pre-specified changes** : Upcoming anticipated-changes (e.g. improvement in existing features / specifications, bug fixes, etc) that would otherwise require a new change application

- Establishing confidence in manufacturer's good quality management practices. This provide assurance that the SaMD is designed, developed, and maintained in a manner that ensures its safety and effectiveness, which allow us to gain confidence that proactive management of SaMD changes is in place

- Enrolled through premarket registration process – **Concurrent review** of application and CMP

Change Management Program (CMP) for SaMD

- Post-CMP approval
  - Company may proceed to implement the approved Pre-specified changes without a change application to HSA
  - Annual declaration of implementation

- Manufacturers may leverage on the approved CMP (except Pre-specified changes) in the subsequent SaMD registration, if the quality management processes are equivalent. This reduces redundancy in dossier submission

- CMP will eventually open up to other device types (e.g. software in medical devices (SiMD), IVD etc.)

Draft guidance currently published for consultation

Tentative launch date for Pilot: **Nov 2024**

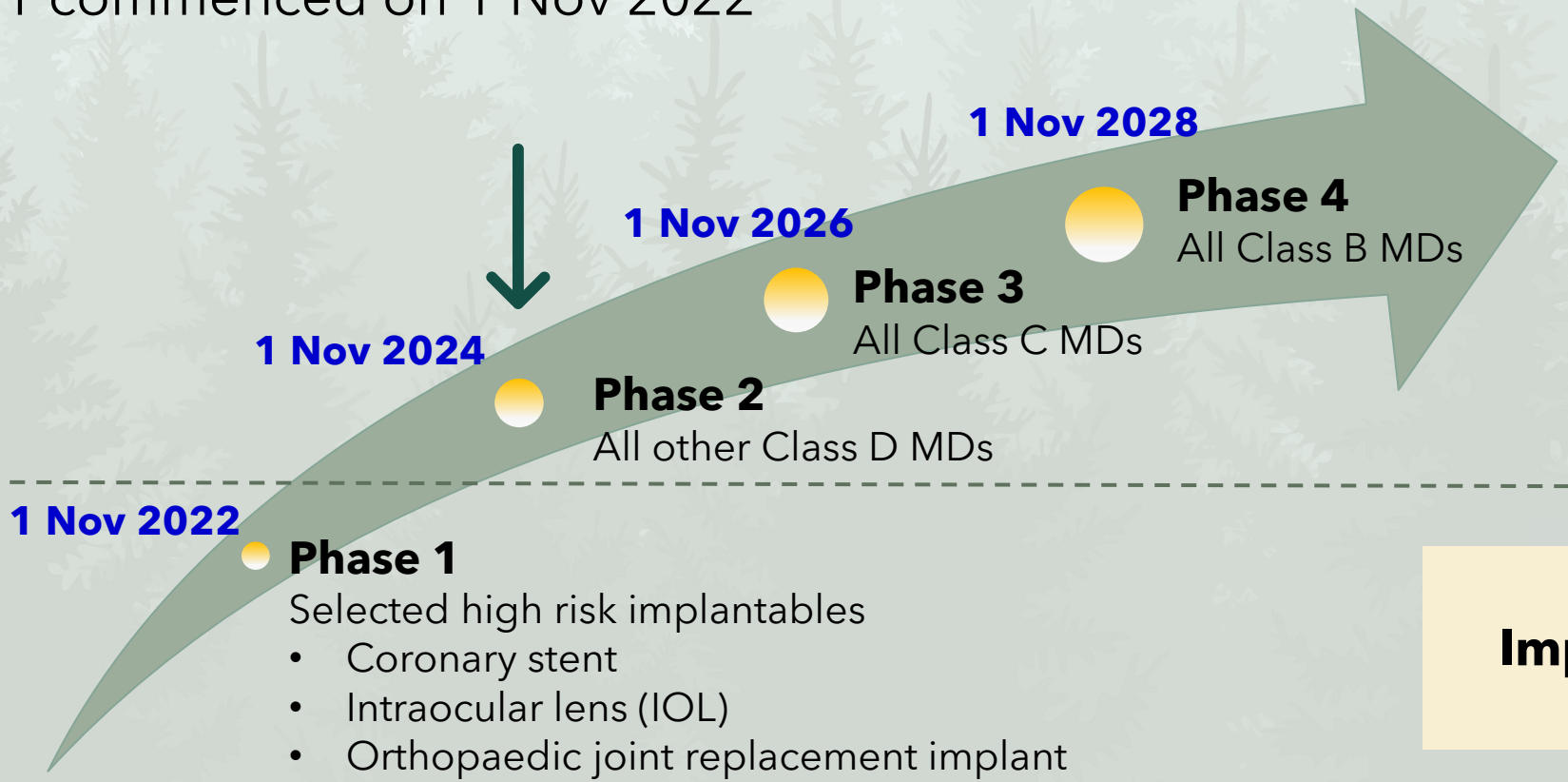
UDI Implementation

A least burdensome approach to Unique Device Identification (UDI) implementation in Singapore

- **Aligned to internationally harmonized principles** outlined in the IMDRF guidance
- **Phased** implementation approach
- **Risk calibrated.** Only medium-high risk MDs will require UDI label. Not mandatory for Class A MDs
- **Leveraging existing UDI barcodes** that manufacturers have applied on their MDs for US and/or EU markets. No Singapore specific UDI is required
- UDI is publicly available on the **Singapore Medical Device Register (SMDR).** No new database is required

Progress of UDI Implementation

- UDI **phased** implementation - Four phases with 2 years apart for each phase
- Phase 1 commenced on 1 Nov 2022



Implemented

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IMDRF 2024 Chair

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THANK YOU