Reminder:

Kindly rejoin the zoom webinar with your name and company (eg: Lee An / HSA), if you have not done so.

INDUSTRY BRIEFING:
Change Management Program for SaMD*

Medical Devices Cluster

21 AUGUST 2024

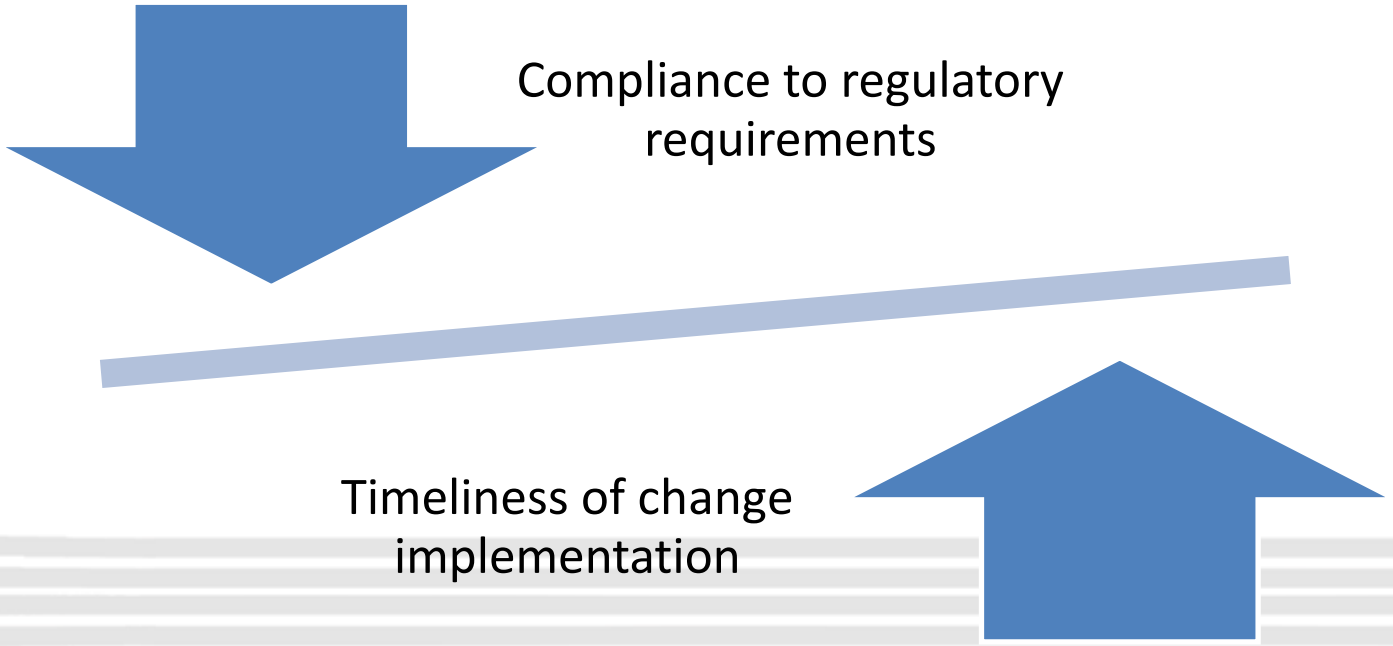
Standalone Medical Mobile Application
a software and/or mobile application that is intended to function by itself and are not intended for use to control or affect the operation of other hardware medical devices.

NOTE: *Standalone Medical Mobile Application is intended to run on general computing device (e.g. laptop, tablet, desktop and etc.).* These are commonly referred to as **Software as Medical Devices (SaMD)**

Background

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:



Background

Adoption of modern regulatory framework that embraces agile methodologies and risk-based assessments is necessary to expedite the approval process for certain types of changes, especially those aimed at improving the effectiveness and safety of SaMD.

Optional regulatory pathway for SaMD:

Change Management Program (CMP)

Objective

Streamline the SaMD TPLC-based regulatory framework to:

i) facilitate timely implementation of software changes for SaMD

ii) reduce redundancy in dossier submission

- Establishing confidence in PO's good quality management system practices
- Pre-specified changes concept

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.

Pre-requisites

Conformance with the following standards:

1) ISO 13485

Medical devices — Quality management systems — Requirements for regulatory purposes

- SaMD product owner shall possess a valid ISO 13485 certificate, with approved scope of activity applicable to the SaMD and related development activities.

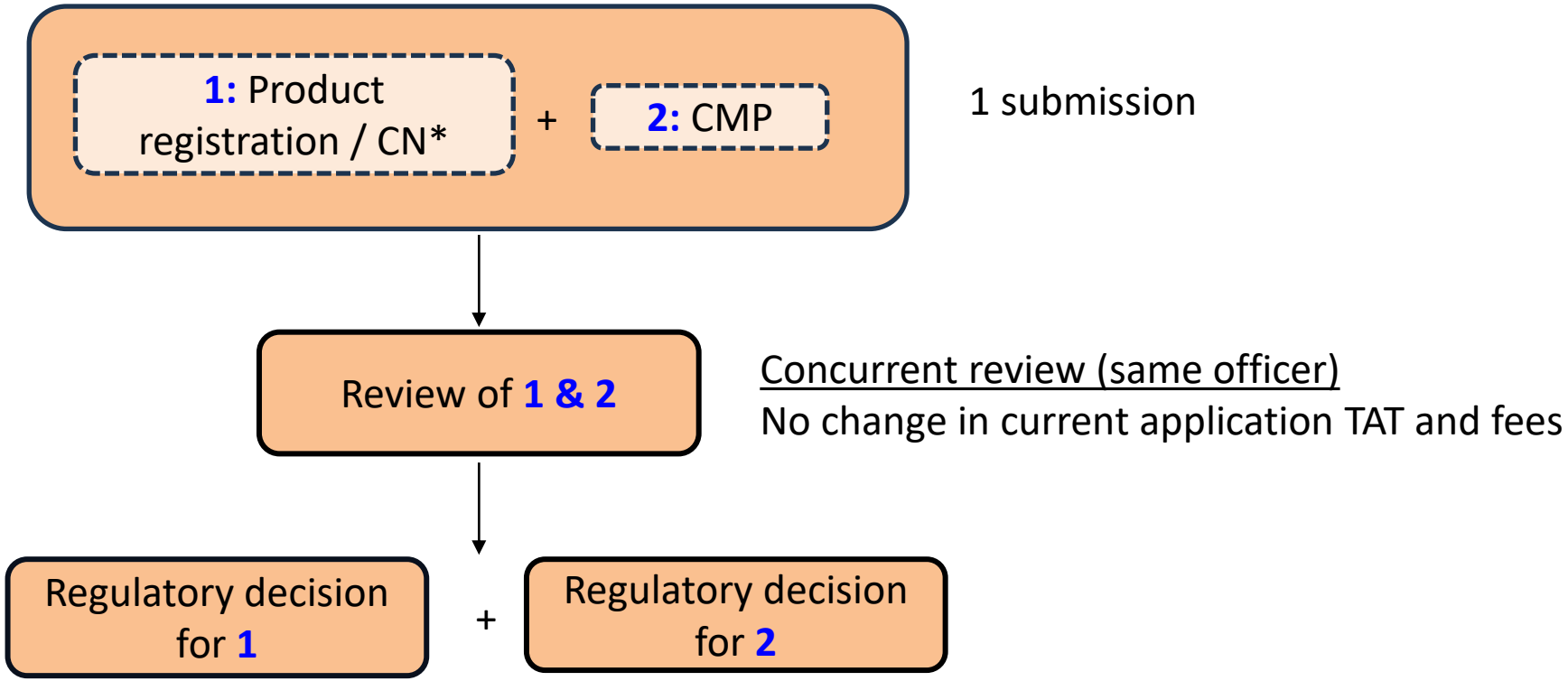
2) IEC 62304

Medical device software — Software life cycle processes

- SaMD product owner may either possess IEC 62304 certificate issued by accredited third-party certification body or in-house assessed summary report conforming to IEC 62304, etc

** NOTE: SaMD product owners are required to conform to the latest standard version and conformance shall remain valid throughout the SaMD total product life cycle (TPLC).*

Application process



**CN change type: Review change for Class B SaMD; Technical change for Class C SaMD*
1: Documentary requirement per GN-15 (product registration) or GN-21 (CN)
2: Documentary requirement per slide 7 & 8

Documentary requirement: Quality assurance processes

Description on how conformity to the following processes can be demonstrated by the applicable SaMD:

- Timely review of recognized standards throughout SaMD TPLC
- SaMD versioning and traceability processes throughout the SaMD TPLC, including 3rd party and / or open-source software if applicable
- Cybersecurity and data safety management
- Safety issues management, including effective AE and FSCA reporting;
- Processes related to risk management of 3rd party and open-source software
- Post-market data analysis
- Change management processes

Documentary requirement: Pre-specified changes

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

Exclude: Changes resulting in change in SaMD **intended use**, **indication for use** and **method of use**, **SMDR device information**

- Also applicable for ML-SaMD (excluding continuous learning (CL) & generative AI)

Information to be submitted:

- **Description of change:** what are the changes, how the changes take place, expected implementation timeline
- **Implementation protocol:** how changes will be implemented and managed
- **Performance verification and validation protocol,** including re-training dataset selection, protocols for ML-SaMD
- **Post-implementation impact analysis** – Risk and benefits of implementing the pre-specified changes, as well as the mitigations of the identified risks

Post-CMP approval

Post-CMP approval	
Implementation of approved Pre-specified changes	**No CN is required.** Annual declaration - no further review from HSA.
Change to previously approved Pre-specified changes	**CN Notification**
Addition of pre-specified changes to CMP listing	

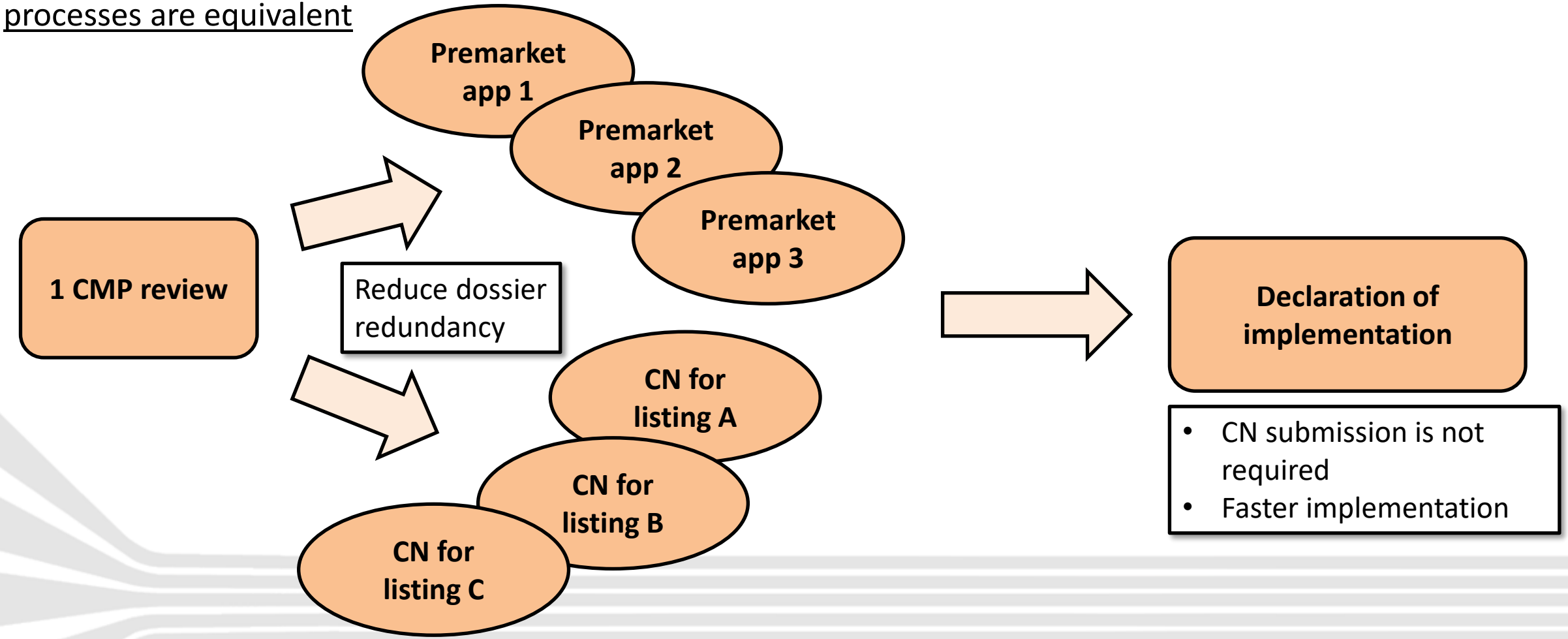
**CN change type: Review change for Class B SaMD; Technical change for Class C SaMD*

1: Documentary requirement per GN-15 (product registration) or GN-21 (CN)

2: Documentary requirement per slide 5 - 7

Leveraging on approved CMP

Manufacturers may leverage on the approved CMP documentation (except Pre-specified changes) in the subsequent Product Registration on similar SaMD or CN of existing listing, if the quality management processes are equivalent



Summary of CMP submission requirements

CMP documentary requirements	1st CMP application	With approved CMP	
		PMA/CN* leveraging on approved CMP	Changes / addition of pre-specified changes
Evidence of conformity to ISO 13485 & IEC 62304	√	√	
Quality assurance processes	√	Justification of relevance only	
Pre-specified changes	√	√	√
Declaration letter from PO on Equivalent Quality Management Processes		√	
Referenced CMP-approved SaMD device name and SMDR listing number		√	
Annex 2 to GN-21: Summary Table of Change Notification			√

**CN change type: Review change for Class B SaMD; Technical change for Class C SaMD*

Industry consultation

Draft guidance will be published for consultation after briefing, alongside with excel template for stakeholders to input their feedback.

Email: HSA_MD_Info@hsa.gov.sg

Subject: Feedback on Guidance on CMP for SaMD

Consultation period:

26 August 2024 – 21 Oct 2024

Target launch date: tentatively Nov 2024 (pilot trial).

Step 1: Upload all required documents on MEDICS

Step 2: Email us at HSA_MD_Info@hsa.gov.sg

Email subject: CMP enrolment

- MEDICS job reference number
- Company name
- Submission date
- Device name

CMP will eventually open up to devices other than SaMD (eg: software medical devices, etc)

Any questions?

Please click on the raise hand icon and wait for us to un-mute you.

State the company you are from before you commence with your query.