APACMed
The voice of MedTech

POSITION PAPER ON

Risk-Based Change Management for Registered Medical Devices

(incl. General Medical Devices, In Vitro Diagnostics and Software as Medical Devices)

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Executive Summary

Change management for registered medical devices is a critical component in the lifecycle of healthcare technologies. It ensures that significant post-market modifications are systematically evaluated, implemented, and communicated to maintain or enhance device safety, efficacy, and compliance with regulatory standards.

As medical devices have become increasingly advanced and integral to patient care, the importance of robust change management practices cannot be overstated. These practices serve as a cornerstone for manufacturers to navigate the challenges of a rapidly changing healthcare environment and an accelerating pace of innovation.

APACMed's Position Paper shares the MedTech industry's perspective on risk-based change management for registered medical devices, a term that encompasses General Medical Devices (GMDs), In Vitro Diagnostic Devices (IVDs), and Software as Medical Devices (SaMDs).

After assessing the divergent practices among APAC markets in their respective change management mechanisms, APACMed proposes the following key recommendations for National Regulatory Authorities' consideration:

Key Recommendations

01 **Adopt a risk-based approach to streamline the change management process:**
Focus regulatory review on significant modifications or changes with substantial impact on safety, performance, and efficacy. This ensures the limited regulatory resources are directed towards changes posing the highest risk to patients.

02 **Harmonise definitions:**
Adopt the World Health Organization (WHO)'s definitions for 'substantial change' (significant or major change) and 'minor change' (non-significant change) to promote better harmonisation and facilitate post-market reliance.

03 **Enhance flexibility in change management submissions:**
- Allow bundling of submissions for identical changes across multiple products or different changes to the same product.
- Permit supplementary submissions to previous change applications.
- Provide a reasonable transition period (6 months as a minimum), during which both updated product versions and those produced before change approval can be manufactured, imported, and distributed.

04 **Implement smart regulation:**
- Utilise regulatory reliance principles.
- Adopt a replacement reagent and instrument family policy.
- Implement a more flexible and streamlined approach for managing changes, which allows regulators to review pre-determined changes during the initial premarket review. This will accelerate the implementation of significant changes.

These recommendations aim to enhance efficiency, promote harmonisation, and facilitate innovation while maintaining rigorous safety standards in medical device regulation across the APAC region.

Note: Some regulators may use the terms 'significant change' and 'substantial change' interchangeably, and likewise for 'non-significant change' and 'minor change' and other similar terms. In this paper, we will use 'significant change' and 'non-significant change' while recognising that different jurisdictions might use different terms for the same meaning.

1 Introduction

Background

The Asia-Pacific (APAC) region, home to 60% of the world's population, stands at a critical juncture in healthcare innovation. Access to cutting-edge medical technologies has the potential to significantly improve health outcomes across the region through early diagnosis, effective treatment, and efficient management of health conditions. Moreover, APAC is emerging as a hub for innovative healthcare technologies that could enhance system efficiency, reduce healthcare disparities, and bolster global health security.

However, the regulatory landscape for post-approval product changes in APAC is highly fragmented. While some authorities employ risk-based methodologies to optimise regulatory resources, others require submissions for all changes regardless of risk level or require new product registrations for modifications that could be managed through established change management pathways.

This inconsistency can lead to:

- Redundant processes and extended approval timelines
- Delayed access to important innovations and safe, effective medical devices
- Inefficient use of regulatory resources

APACMed's observations highlight a critical need for greater harmonisation in change management mechanisms, definitions, and processes across the region. Standardising these procedures could streamline regulatory processes, ensuring an uninterrupted supply of critical devices and improved access to innovations for patients throughout APAC.

Scope and Method

This position paper is intended for regulators and industry stakeholders in the APAC region who manage changes to registered medical devices. The scope encompasses General Medical Devices (GMDs), In Vitro Diagnostic Medical Devices (IVDs), and Software as Medical Devices (SaMDs), collectively referred to as 'registered devices' throughout this document.

The paper offers a comprehensive overview of current change management practices across key APAC markets, benchmarking them against reference markets such as the United States (US), Canada, and the European Union (EU).

Our cross-market analysis focuses on several critical aspects:

- Definitions and categorisations of changes
- Submission pathways and approval timelines
- Transition measures and timelines

The information presented in this paper is based on the source documents listed in Reference Section 5, unless otherwise noted as derived from APACMed members' experiences.

Following this regulatory landscape analysis, we present industry recommendations for risk-based change management approaches. These recommendations are supported by international best practices, drawing on successful models from various markets.

Note: The data and information presented in the position paper reflect the regulatory frameworks and requirements as of the date of publication of this document. Regulatory environments are subject to change, and stakeholders are advised to consult local regulatory authorities for the most current information.

2 Current Landscape

2.1 Definition and Categorisation

Definitions of 'significant change' in medical device regulations vary substantially across jurisdictions. This divergence creates a challenging landscape for manufacturers, as the interpretation of 'significant change' can range from major modifications affecting safety and performance to minor adjustments with minimal impact.

This inconsistency complicates compliance efforts, requiring manufacturers to navigate a complex mosaic of regulatory interpretations to determine the appropriate level of scrutiny and documentation for their product changes.

Similarly, the categorisation of changes to registered devices differs across jurisdictions. Most APAC markets employ a list-based categorisation principle, while reference markets such as Canada, Australia, the EU, and the US tend to favour a risk-based approach enabled by principle-based flow charts.

The following table provides a comprehensive summary of varying definitions of 'significant change', change categories, and categorisation principles.

This summary covers key markets in the APAC region and compares them with Canada, the EU, the US, and the World Health Organization (WHO) guidelines.

Legend:

List-based approach:

National Regulatory Authorities (NRAs) provide a comprehensive list of changes, explicitly categorising them based on their significance. This approach offers clear-cut guidance but may lack flexibility in addressing novel or unforeseen changes.

Flowchart-based approach:

NRAs employ risk-based flowcharts to guide manufacturers in differentiating changes. This method allows for a more nuanced, case-by-case assessment of changes based on their potential impact on safety, performance, and efficacy. While more flexible, this approach requires manufacturers to exercise more judgement in categorising changes.

Table 1: Comparison of the definition of 'significant change', change categories, and categorisation method for changes

Markets	Definition of 'Significant Change'	Change Categories	Categorisation Method
Australia	Term Used: **Substantial Change** • Refers to changes made to Manufacturer's quality management system (QMS) or Medical Devices (inclusive of IVDs) that are expected to impact the quality, safety, or performance of the products	Substantial change, non-substantial change	Flowchart-based
China	No clear definition for Significant Change Substantial modifications to product design, raw materials, manufacturing processes, intended use, and methods of use, that may affect the safety and effectiveness of the medical device, would warrant a change submission (with NRA review/approval needed) for Class II and Class III products	Registerable change (变更注册事项), notifiable change (变更备案事项)	List-based

India	Term Used: **Major Change**
	Changes in respect of following shall be considered as major change in:
	1. material of construction
	2. design which shall affect quality in respect of its specifications, indication for use; performance and stability of the medical device
	3. the intended use or indication for use
	  • Addition of new intended claim
	  • Addition of specimen/samples
	4. the method of sterilisation
	5. the approved shelf life
	6. the name or address of,
	  • the domestic manufacturer or its manufacturing site
	  • overseas manufacturer or its manufacturing site (for import only)
	  • authorised agent (for import only)
	7. label excluding change in font size, font type, colour, label design
	8. manufacturing process, equipment or testing which shall affect quality of the device
	9. primary packaging material
		Major change, minor change	List-based

Indonesia	Term Used: **Significant Change** • Refers to changes that pose a risk to patient that was not previously identified	Significant change, non-significant change	Flowchart-based
Japan	No clear definition for Significant Change	Registrable change (approval is required), notifiable change (approval is not required)	List-based
South Korea	[General Medical Devices] Term Used: **Changes requiring technical file review** • Refers to changes made with intent to significantly affect safety or effectiveness (performance) of a device (incl. changes to Appearance and Structure, Raw materials, Performances, Manufacturing process, etc.) [SaMDs] Term Used: **Software Upgrade** • Refers to analysis algorithms/methods, development language, operating environment, and communication functions) instead [IVDs] Term Used: **Significant (Major) Change** • Changes that affect the safety and effectiveness of an IVD medical device (based on flowchart of change decision and categorisation of significant changes) • Changes related to appearance, raw materials, performance, intended use, performance, method of use, stability and quality control (QC) specification	Changes requiring new product approval, changes requiring technical file review, simple changes that do not require a technical file review, changes requiring minor change notification, and others	Flowchart-based
Malaysia	No clear definition for Significant Change *Category 1 changes refer to changes that affect the safety and performance of the device; these are not in scope for change registration and require new registration	Category 1 Change, Category 2 Change, Category 3 Change	List-based

Markets	Definition of 'Significant Change'	Change Categories	Categorisation Method
Philippines	No clear definition for Significant Change	There is a brief list of variation for filing (QWP-CDRRHR/LRD-11 Annex 00 Rev. No. 00 / 01April 2022), which requires FDA review and pre-approval	List-based
Singapore	No clear definition for Significant Change • Changes that affect the safety, quality and efficacy must be notified to the Health Sciences Authority (HSA) and subject to approval	Technical change, review change, administrative change, notification change	Flowchart-based
Taiwan	No clear definition for Significant Change • Changes requiring prior approval include changes to product names, labelling, product specifications and model, intended use, manufacturer's information, medical device permit licence holder	Not clearly defined	List-based
Thailand	Term Used: **Major Change** • Changes to indication/intended use, product specification, and manufacturing procedure that affects efficiency and safety of medical devices	Major and Minor Change	List-based
Vietnam	No clear definition for Significant Change • Examples of changes allowed are mentioned in Decree 98; changes not mentioned in the Decree will require a new registration	Changes requiring new registration; reviewable changes	List-based

Markets	Definition of 'Significant Change'	Change Categories	Categorisation Method
Canada	Term Used: **Significant change** A change that could reasonably be expected to affect the safety or effectiveness of a medical device. It includes a change to any of the following: • the manufacturing process, facility or equipment • the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device, or of the materials used in its manufacture • the design of the device, including its performance characteristics, principles of operation, specifications of materials, energy source, software, or accessories • the intended use of the device, including any new or extended use, any addition or deletion of a contraindication for the device, and any change to the period used to establish its expiry date	Significant change, non-significant change	Flowchart-based

European Union	Term Used: **Substantial Change**
	There is no clear definition of the term yet, but it was used in the IVDR (e.g. in Annex IX, Chapter 2.4).
	• The requirements to notify changes under the IVD Regulation are linked to certificate(s) issued for the device:
	  • Devices with an EU quality management system certificate must apply the notification requirements under Annex IX section 2.4
	  • Devices with both an EU quality management system certificate and EU technical documentation assessment certificate will need to comply with both sections 2.4 and the applicable part of section 4 or section 5:
	  » Class D devices need to follow Annex IX section 4.11 and section 2.4
	  » Devices intended for self-testing and near-patient testing need to follow Annex IX section 5.1(f) instead of section 4.11 (which has the same wording). Section 2.4 still applies
	  » Companion diagnostics should follow Annex IX section 5.2(f). Section 2.4 still applies
	
	Note: There are guidelines under MDD/ IVDD/ AIMD but no guidelines under MDR and IVDR so far. The European Manufacturer's Association (MedTech Europe) is currently working on a proposal
		Substantial change, non-substantial change	Flowchart-based

Markets	Definition of 'Significant Change'	Change Categories	Categorisation Method
US	Term Used: **Significant Change** <u>For Class II/510(k) Cleared Devices:</u> The following constitute significant changes or modifications that require a premarket notification: i. (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g. a significant change or modification in design, material, chemical composition, energy source, or manufacturing process ii. (ii) A major change or modification in the intended use of the device <u>For High-Risk Devices: PMA</u> If changes affect the safety or effectiveness of the device, an applicant must submit a PMA supplement. A list of changes include, but are not limited to the below: • new indication for use of the device • labelling changes • the use of a different facility or establishment to manufacture, process, or package the device • changes in manufacturing methods, or quality control procedures • changes in sterilisation procedures • changes in packaging • changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device; and • extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by FDA [If the protocol has been previously approved by FDA, a supplement is not submitted but the change must be reported to FDA in the post-approval periodic reports as described in §814.39(b).]	Significant change, non-significant change	Flowchart-based

Markets	Definition of 'Significant Change'	Change Categories	Categorisation Method
WHO	Term Used: **Substantial Change** Changes may range from minor changes (with little potential to impact the safety, performance and/or quality of the medical device) to substantial changes likely to affect the safety, performance and/or quality of the medical device. 'A substantial change is any change that could reasonably be expected to affect the safety or performance of a medical device or its conformity with the essential principles, and would include changes to any of the following: • the manufacturing process, facility or equipment • the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality and sterility of the device, or of the materials used in its manufacture • the design of the device, including its performance characteristics, principles of operation, and specifications of materials, energy source, software or accessories, and • the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication for the device, and any change to the period used to establish its expiry date.'	Substantial change, minor change	N/A

2.2 Change Submission Pathways

Efficient change management for devices is intricately linked to the pathways for notifying regulatory authorities of changes, which vary widely across jurisdictions. Gaining a deep understanding of the variances in submission processes and their corresponding approval timelines across different regions is crucial for manufacturers striving for streamlined regulatory compliance. Moreover, the regulatory policies on consolidating changes — whether they involve similar adjustments across various products or different modifications to the same product — exhibit significant variations across jurisdictions.

Table 2 provides a summary of the varying change submission pathways and approval timeline, in addition to an overview of whether bundling/supplementary submission of changes is allowed and whether reliance pathway for change exists. 'Bundling submission' refers to when the NRA allows the submission of the 'same change' to multiple products, or different changes to the same product, in one single submission to increase efficiency when certain criteria are met.

Table 2: Change submission pathways, timelines, and principles

Change Submission Pathways						
Markets	**Submission Pathways**	**Review/Approval Timeline**	**Is bundling submission allowed for**		**Is supplementary submission allowed to add a new change to a previous change notification?**	**Is reliance pathway applicable?**
			Same changes to multiple products	**Different changes to the same product**		
Australia	• Class III/AIMD variation application form • Device Change Request form • IVD Variation application form • Substantial change notification and application (for devices covered by TGA conformity assessment certificates)	Timelines are not provided by the TGA. Current average experience is between 6–18 months depending on the risk classification of the device and the nature of the change. 12 months for products covered by TGA conformity assessment (Note: Australia TGA practices reliance/recognition for change approval, hence those changes with reference approvals, will get approved by TGA in a much shorter time than what is described above.)	Yes	Yes	No (but can be negotiated with the TGA)	Yes

Change Submission Pathways						
Markets	**Submission Pathways**	**Review/Approval Timeline**	**Is bundling submission allowed for**		**Is supplementary submission allowed to add a new change to a previous change notification?**	**Is reliance pathway applicable?**
			Same changes to multiple products	**Different changes to the same product**		
China	Class II & III: Notifiable Changes	5 Working Days–1 Month	No	Yes	No	No
	Class II & III: Registerable Change (Administrative or License Change)	Class II: 5–6 months Class III: 6–7 months (Note: This is the official review timeline as indicated in the regulation; the actual timeline would vary depending on the company/product on a case-by-case basis)				
India	Major Change Submission	60 days as per MDR 2017 and in case no approval received within stipulated timeline from Competent Licensing Authority (CLA), such changes shall be deemed to have been approved. Note: However, in reality, major change approval will take 3–4 months.	No	No	Yes (a supplementary change application is allowed for any product if the previous change application is still under review with jurisdiction)	No (approval from reference country is required for major change but there is no reduction in in dossier requirements or turnaround time)
	Minor Change Submission	Within 30 days from date of implementation. No prior approval is required in case of minor change. Notification to CLA is required to submit within 30 days. Note: However, in reality, minor change application will need 3–4 months in approval				

Change Submission Pathways

Markets	Submission Pathways	Review/Approval Timeline	Is bundling submission allowed for		Is supplementary submission allowed to add a new change to a previous change notification?	Is reliance pathway applicable?
			Same changes to multiple products	Different changes to the same product		
Indonesia	Change submission for minor change	1–2 months	Yes	Yes	No	No
South Korea (GMDs)	Changes requiring a tech file review	Official review time (working day): Class 2: 20 days Class 3 & 4: 42 days Clinical data review: 60 days	No	Yes	No	No
	Changes that do not require a tech file review	Official review time (working day): Class 1: Immediate Class 2: 5 days Class 3 & 4: 10 days				
	Minor Change Notification	Official review time (working day): Class 3 & 4: Immediate (5 days for checking if it's subject to minor change) Class 1 & 2: Immediate				

Change Submission Pathways

Markets	Submission Pathways	Review/Approval Timeline	Is bundling submission allowed for		Is supplementary submission allowed to add a new change to a previous change notification?	Is reliance pathway applicable?
			Same changes to multiple products	Different changes to the same product		
South Korea [IVDs]	Changes requiring a tech file review (Significant Change)	Official review time (working day): Class 2: 20 days Class 3 & 4: 42 days Clinical data review: 60 days	No	Yes	Yes	No
	Changes that do not require a tech file review (Administrative change)	Official review time (working day) Class 2: 5 days Class 3 & 4: 10 days				
	Minor or Change Notification (only for class 1)	Official review time (working day) Minor Change Class 3 & 4: Immediate (5 working days for checking if it's subject to minor change) Class 1 & 2: Immediate Change Notification: Immediate				

Change Submission Pathways

Markets	Submission Pathways	Review/Approval Timeline	Is bundling submission allowed for		Is supplementary submission allowed to add a new change to a previous change notification?	Is reliance pathway applicable?
			Same changes to multiple products	Different changes to the same product		
Japan	Change approval	2–6 months (depend on contents of changes)	No	Yes	No	No
	Change certification	2–3 months	Yes	Yes	No	No
	Minor change notification	1 day	No	Yes	No	No
Malaysia	Category 2 Change Category 3 Change	Single category Submission: 30 Days Multiple category Submissions: 60 Days	No	Yes	No	No
Philippines	Change Submission	3 Months	No	Yes	No	No
Singapore	Technical Changes	Class C: 75 Working Days Class D: 90 Working Days	Yes	Yes	No	No
	Review Changes	45 Working Days				
	Administrative Changes	30 Working Days				
	Notification Changes	No Approval Required				

Change Submission Pathways

Markets	Submission Pathways	Review/Approval Timeline	Is bundling submission allowed for		Is supplementary submission allowed to add a new change to a previous change notification?	Is reliance pathway applicable?
			Same changes to multiple products	Different changes to the same product		
Taiwan	Change Submission if changes are made specifically to: - Device Name - Contents on registered label and IFU - Ingredients, materials, structure, specifications, or model number - Indications for use or intended use - Manufacturing Name - Manufacturing Address or Country - License Holder	Independent of IVD classification between 3–8 months	Yes, only if the IVDs are registered under the same licence	Yes	No, supplementary submission is not acceptable once the review starts	No
Thailand	Major Changes Minor Changes	35 Working Days 5 Working Days	Not clearly defined	Class 2,3,4: Yes	No	No
Vietnam	Change notification for all medical device classification if changes are made specifically to: a) address of the product owner or registration number holder b) name of the registration number holder or product owner c) the medical device manufacturer's name or address d) packing size e) the warranty centre f) the label or IFU without changing intended use or indication	No approval required (publish immediately on MoH portal)	No	Yes	No	No

Change Submission Pathways

Markets	Submission Pathways	Review/Approval Timeline	Is bundling submission allowed for		Is supplementary submission allowed to add a new change to a previous change notification?	Is reliance pathway applicable?
			Same changes to multiple products	Different changes to the same product		
Canada	• Class II Medical Device Licence Amendment Application Form • Class III Medical Device Licence Amendment Application Form • Class IV Medical Device Licence Amendment Application Form • Medical devices licence amendment minor change form (addition/ deletion/ product name change) • Manufacturer Name address change form F202 • Non-significant changes should be documented in the quality management system and reported at annual renewal	Health Authority (HA) working days (does not include hold times) Class 2 = 19 Class 3 = 79 Class 4 = 94	Yes	Yes	No	No
European Union	Depending on the type of the change (substantial) and the MDR or IVDR classification (e.g. Class III or IIb, Class D, CDx, PoC, lay use, (all products that have a product specific conformity assessment) a change notification is filed to the Notified Body. Note: A new guidance under EU MDR/ IVDR is under development as proposed by MTE, still needs to get accepted by the authority	Depends on change, 1–6 months	Yes	Yes	Yes	No
USA 510(k)	• New 510(k) submission • Documentation	Same timeline as 510(k) submission	Depends on supporting data (if it is similar), division reviewing the documents, indication of use	Yes	Depends on the significance of change that needs to be added: significant changes or modifications that require premarket notification: (i) a change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g. a significant change or modification in design, material, chemical composition, energy source, or manufacturing process; (ii) a major change or modification in the intended use of the device.	No
USA (Premarket Approval (PMA)) Class III Devices	• Panel-Track Supplement • 180-Day Supplement • Special PMA Supplement • 30-Day Notice • Manufacturing Site Change Supplement • Document to File	Depends on the type of Supplement Submission	No	Yes	No	No

Note: The approval timelines stated in the table are mostly based on APACMed member companies' experiences

An analysis of **Table 2** reveals significant divergences in change submission pathways and turnaround times among APAC markets. Encouragingly, several regulatory authorities permit bundled submissions for either identical changes across multiple products or various changes to a single product. However, few authorities allow supplementary change submissions to ongoing regulatory reviews. Regarding reliance pathways for change submissions, Australia's Therapeutic Goods Administration (TGA) stands alone in its current implementation.

Furthermore, some authorities mandate new product registrations for modifications that others process through established change registration pathways. Notably, the approval time for a new registration typically exceeds that of a change registration in most countries.

These inconsistencies underscore the need for harmonised, risk-based approaches to change management in medical device regulations, balancing thorough oversight with timely access to updated technologies. **Table 3** summarises the divergent practices across jurisdictions in defining which types of changes warrant a new registration.

Table 3: Changes that require a new product registration across jurisdictions

Market	What kind of changes are out of scope in the change registration pathway, and instead require a new product registration?	Approval timeline of the new registration
Australia	• Changes to products resulting in re-classification e.g. claim extensions • Changes to products resulting in a new GMDN code • Changes to legal manufacturer with new QMS	1–12 months depending on manufacturer evidence and classification of product
China	• If the risk classification of a registered device has been upgraded from a lower level to a higher level, a new registration is required • According to common questions published by CMDE, if plasticiser of the product has been changed, a new registration is required • For registered Class II and Class III in vitro diagnostic reagents, if there are substantial changes to the product's core technological principles, or if other significant changes occur that have a major impact on the product's safety and effectiveness, essentially constituting a new product, these do not fall under the scope of change registration and a new registration is required	Class II: 5–6 months Class III: 6–7 months (Note: This is the official review timeline as indicated in the regulation; the actual timeline would vary depending on the company/product on a case-by-case basis)
India	• Change in constitutions • Change in address of overseas manufacturer and its manufacturing site • Local agent name and address update	9 Months
Indonesia	• Device design changes that result in addition or expansion of intended use, change in validation, preclinical/clinical data that may affect device safety, quality and performance • Sterilisation process change, or change in sterile packaging • Software changes: including modification of algorithms, addition of new features/applications, alteration in operating system that affect diagnostic or therapeutic functions or patient-care usage • Change in radiation source, drug ingredient/concentration and biological source, processing or material supplier • Changes/transfer of distributors • Changes in manufacturer/producer • Changes in manufacturer/producer location • Changes in product specification changes • Changes/additions of raw materials/formulas that alter device specifications/functions • Changes in claim or indication	Class A = 1–2 months Class B = 2–4 months Class C = 2–4 months Class D = 4–6 months

Market	What kind of changes are out of scope in the change registration pathway, and instead require a new product registration?	Approval timeline of the new registration
Japan	• Change of active ingredients and its concentration • Change of assay type (i.e. qualitative to quantitative) • Change of assay principles • Change of kit release criteria	Class I (notification) (1 day) Class II (certification) (3–4 months) Class III & special cases & new (approval) (7–12 months)
South Korea	[GMDs] • Changes to the mechanism of action or operating principle • Changes to raw materials used for the first time domestically	*Official review time (working day) Class II devices with a Substantial Equivalent: 25 days Class III and IV devices: 65–80 days *Excluding query time and other administrative processes
	[IVDs] • Change of intended use resulting from changes in assay principles • Change of intended use or categorisation/classification resulting from changes in analytes/ detecting methods • Change of classification resulting from changes/addition of clinical significance	Clinical data review: 80 days Technical file review: Class II: 30 days Class III & IV: 65 days *Excluding query time and other administrative processes
Malaysia	All category 1 changes that affect the safety and performance of the devices: • Change to the intended purpose (e.g. new and additional) of a registered medical device, unless it involves a reduction of indications for use not arising due to medical device safety and/or performance concerns • Change to the risk classification of a registered medical device • Addition of devices not considered a permissible variant according to the rules of grouping in Second Schedule of MDR 2012 and MDA/GD/0005, Product Grouping • Addition of variant(s) for Cluster (Class A and B) according to the rules of grouping in Second Schedule of MDR2012 and MDA/GD/0054 Product Grouping for In- Vitro Diagnostic (IVDs) Medical Devices • Change to the type, concentration or drug specifications (DS) of medicinal substance in a medical device that incorporates a medicinal product as an ancillary role shall be refer to National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia • Addition of medical devices with device proprietary names different from the registered devices, into a device listing. Unless the devices with different proprietary names qualify to be listed together under one listing based on MDA guidance documents on grouping criteria for medical devices registration	6–12 months
Philippines	• Change in material code • Change of manufacturer (new formulation and procedure) • Change of intended use (except for additional indication) • Change of risk-classification	12–24 months
Singapore	Some changes that will NOT qualify for Change Notification and require the submission of a NEW Pre-market Product Registration include: • Change to the intended purpose of a registered medical device • Change to the risk classification of a registered medical device • Addition of model(s) that do not fulfil the grouping criteria, including permissible variants, as listed in the GN-12 guidance documents on Grouping of Medical Devices for Product Registration • Change to the medicinal substance in a device that incorporates a medicinal product in an ancillary role • Addition of medical devices with device proprietary names different from the registered devices, into a device listing • Unless the devices with different proprietary names qualify to be listed together under one SMDR listing based on GN-12 guidance documents on Grouping of Medical Devices for Product Registration.	100 working days to 310 working days
Taiwan	• For registered Class II and Class III in vitro diagnostic reagents, if there are substantial changes to the product's core technological principles, or if other significant changes occur that have a major impact on the product's safety and effectiveness, essentially constituting a new product, these do not fall under the scope of change registration and a new registration is required • Change to the risk classification of a registered medical device • Change of intended use from qualitative to quantitative • Physical Manufacturing (if it's an additional site, not transferring to new site)	6–12 months
Thailand	• Change product name but same catalogue number • Change risk classification can be accepted for class II and III (class II change to III or class III change to class II) because this change does not affect the licence type (licence level)	Class 1: less than 1 month Class 2 & 3: 1–3 months Class 4 without local evaluation: 1–3 months (without local evaluation) Class 4 with local evaluation: 6–8 months

Market	What kind of changes are out of scope in the change registration pathway, and instead require a new product registration?	Approval timeline of the new registration
Vietnam	A change other than those specified in list of change notification regulated (table above)	Timeline in regulation - Approval timeline: 10 Working Days without supplement required. - If supplementary submissions are required, a maximum of three supplements may be submitted, with a lead time of three months for each supplement. In reality, average timeline approval is from 12 to 24 months.
Canada	Changes in product (with new catalogue number) • Class 2: Changes to intended use, test principle, composition • Class 3 and 4: Changes to intended use	Health Authority Working days (does not include hold times) - Class 2 = 19 days, Class 3 = 79 days, Class 4 = 94 days
EU	• Changes that clearly change significant performance characteristics of the assay (as outlined in the Instruction for Use) • Changes in measuring principles • Change of product name • (non-exhaustive list, this is not defined and depends on the change specific interaction with the Notified Body)	Class D: 12-18 months Class B or C: 6 weeks (administrative change only unless technical review is indicated)
USA	Changes meet with the criteria in 'Guidance - Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)' will be requested to submit a new 510(k) Traditional 510(k): 90 days Special 510(k): 30 days 180 days for supplemental response	Changes meet with the criteria in 'Guidance - Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)' will be requested to submit a new 510(k) Traditional 510(k): 90 days Special 510(k): 30days 180 days for supplemental response

Note: The approval timelines stated in the table are mostly based on APACMed member companies' experiences

2.3 Transition Measures & Period

In the rapidly evolving landscape of medical technology, the implementation of a transition period is crucial for ensuring a smooth and efficient change management process in medical device regulation due to several interconnected factors. Medical device manufacturing often involves complex production cycles, and a reasonable transition period allows manufacturers to modify production lines, update quality control processes, implement and validate new manufacturing procedures, all of which are essential for maintaining product quality and safety.

The global supply chain requires time to adapt to changes, necessitating communication with suppliers and distributors, adjustments to inventory management systems, and ensuring a seamless transition of components or materials. These efforts collectively contribute to maintaining market stability and preventing product shortages.

Changing product labelling and packaging is a multi-step process that involves designing new labels and packaging, obtaining regulatory approval for label changes, and implementing these changes across all product lines and variants, a process that requires careful planning and execution to ensure compliance and clarity for end-users.

Additionally, a well-structured transition period is vital for market continuity, preventing product shortages and allowing healthcare providers to plan for any necessary adjustments in clinical practice, thereby minimising disruptions to patient care and ensuring the continued availability of essential medical devices.

By providing a reasonable transition period, regulatory authorities can ensure that manufacturers have sufficient time to implement changes effectively, maintain product quality and safety, and minimise disruptions to patient care, ultimately supporting the ongoing advancement of medical technology while safeguarding public health.

Table 4 provides a comparative summary of transition practices across APAC markets and selected reference markets. It highlights the diverse approaches in different jurisdictions, emphasising the necessity for manufacturers to navigate these variations carefully when planning product changes or modifications. Additionally, it identifies opportunities for harmonising transition practices, facilitating more efficient and consistent change management globally, ultimately benefiting both industry stakeholders and patients.

Table 4: Transition measures and timeline for changes of medical devices already imported in the market

Transition Measures & Timeline for Changes		
Markets	**Can the previous version of devices can still be imported after the change approval by the respective jurisdiction?**	**How long can the previous version of devices be sold after the change approval by the respective jurisdiction?**
Australia	Yes	Not defined by the Authority
China	Yes, but the manufacturing date of the previous version of devices has to be prior to the change approval date and the manufacturing date of the new version of devices has to be after the approval date, which poses great challenges to manufacturing and supply chain	Till the product expiry date
India	No	Till the product expiry date Note: For change of name and address of authorised Indian agent, legal manufacturer, site manufacturer, there should be a transition provision of at least 1 year when the products with old labelling/new labelling should be allowed to be imported to consume old stock and to handle labelling implementation of large number of products
Indonesia	No	Not defined by the Authority but there is possibility to apply for a 3-month or 6-month time period to deplete the old stocks and get approval from Authority on a case by case basis
Japan	Yes	Principally till change approval. Exception: In case the transition target date is set at change approval, unchanged products can be released to the market till the target date.
South Korea	General Medical Devices: Yes	6 months for the changes in: 1. Expiry date 2. Sterilisation or packaging methods 3. The name or location of the legal manufacturer (applicable only to products manufactured before the change approval/certification) 4. The name or location of the manufacturer (applicable only to products manufactured before the change approval/certification)
	IVDs: Shifting from No to Yes (Note: As we were drafting this paper, the newly published IVD Act (draft) would allow manufacturing and import or the product version prior to change)	Till the product expiry date
Malaysia	Yes	Not defined by the Authority Manufacturers can propose the change and get approval from the Authority, on a case by case basis
Philippines	Yes	6 months to 12 months exhaustion period for existing inventory

Transition Measures & Timeline for Changes		
Markets	**Can the previous version of devices can still be imported after the change approval by the respective jurisdiction?**	**How long can the previous version of devices be sold after the change approval by the respective jurisdiction?**
Singapore	Yes	Not defined by the Authority Manufacturer should keep traceability procedure and record for the concurrent supply. Manufacturers can propose and get approval from the Authority in the context of changes to product owner, manufacturing and/or sterilisation site.
Taiwan	No	Till the product expiry date
Thailand	Yes	Till the product expiry date
Vietnam	Yes (Note: For label changes, the previous version must be manufactured before the change submission date. No restriction for other changes)	Not defined by the Authority
Canada	Not Indicated	Not defined by the Authority
EU	Not Indicated. A device needs to comply with legislation at the time of placing on the market in the Union market, therefore this will depend on when the device was considered to be placed on the market.	Not defined by the Authority. The MDR and IVDR do not foresee a time limit for continuous availability of a device already placed on the Union market. As long as the device was compliant with the MDR or IVDR at the time of placing on the market and remains within its lifetime, it can continue to be sold.
USA	Yes	Not defined by Authority Manufacturer's decision

Our landscape analysis reveals an emerging trend among regulatory authorities towards greater flexibility in managing product transitions. Increasingly, these authorities are permitting the concurrent import and distribution of both previously approved and newly approved versions of medical devices for a defined period. This approach demonstrates a nuanced understanding of the complex challenges manufacturers face when implementing changes to their products. By allowing this overlap, regulatory bodies acknowledge the intricate balance between introducing improved devices and maintaining uninterrupted supply chains. Such flexibility is crucial in supporting smoother transitions, as it provides manufacturers with the necessary time to adjust production processes, update labelling, and make appropriate supply chain arrangements. Ultimately, this approach serves to minimise market disruptions, ensure continuous availability of essential medical devices, and facilitate the gradual integration of updated products into healthcare systems, thereby benefiting both manufacturers and patients alike.

3 Recommendations

The regulatory authorities and the MedTech industry share a common goal: ensuring patient safety while maintaining an uninterrupted supply of life-saving medical technologies amidst ongoing innovations.

However, the divergent practices among APAC markets in managing product changes have led to potential risks regarding timely patient access. In light of these challenges, APACMed proposes adopting risk-based change management measures to enhance regulatory resource efficiency, minimise disruptions to the supply of critical devices, and accelerate patient access to medical technology innovations, ultimately improving clinical outcomes.

By implementing these recommendations, we aim to address the inconsistencies in regulatory approaches across the APAC region and foster a more harmonised and efficient regulatory environment. This balance between rigorous oversight and the need for rapid innovation in the medical technology sector will benefit patients, healthcare providers, and the industry as a whole.

3.1 Implementing risk-based change management strategies

When considering any change to medical devices, both Regulatory Authorities and Manufacturers must carefully evaluate the potential impact on patients, practitioners, and device users, as well as the implications for the product's intended use and risk classification. It is crucial to assess whether such changes could reasonably be expected to affect the safety or performance of the medical device or its conformity with essential principles.

A risk-based approach to change management offers significant advantages by focusing regulatory scrutiny on modifications with the highest potential impact on safety, performance, and efficacy. This strategy effectively relieves the need for regulators to perform repetitive or unnecessary assessments of lower-risk changes. By allowing for expedited approval of lower-risk modifications, this approach enhances the efficiency of the process for both regulators and manufacturers, ultimately facilitating faster patient access to improved medical devices.

Furthermore, this risk-based methodology is designed to concentrate resources on significant, higher-risk, or higher-impact changes. Such an approach enables global regulatory authority workforces to adapt more effectively to emerging technologies while encouraging alignment with international standards and practices. This alignment contributes to global harmonisation efforts, fostering a more consistent and efficient regulatory environment across different jurisdictions. Ultimately, this streamlined approach benefits all stakeholders by ensuring thorough oversight of critical changes while expediting the introduction of minor improvements that can enhance patient care and outcomes.

3.2 Harmonising definitions and categorising of changes

APACMed recommends regulatory authorities to adopt the WHO's definition on significant/substantial change and non-significant/minor change for better harmonisation.

WHO's Definition

A 'substantial change' is 'any change that could reasonably be expected to affect the safety or performance of a medical device or its conformity with the essential principles'.

A 'minor change' is a change 'with little potential to impact the safety, performance and/or quality of the medical device'.

Adopting this risk-based definition ensures a least burdensome approach that protects patients while enabling timely access to medical devices. A structured framework sets clear expectations, allowing applicants to streamline compliance processes and easily plan for the necessary tests and documentation based on the assigned classification. This approach fosters greater transparency and predictability in the regulatory process.

Furthermore, harmonised definitions and categorisation of changes promote alignment and consistency in regulatory practices across borders and markets. This approach will facilitate the adoption of post-market reliance and allow regulators to focus their regulatory resources on jurisdiction-specific oversight such as adverse event reporting.

3.3 Adopting risk-based change submission pathways

APACMed advocates for the adoption of **risk-based regulatory pathways** for product changes, taking into account **both the risk class of the product and the risk profile of the proposed change.** It is generally recommended that only those modifications that significantly impact the safety or performance of higher-risk devices should necessitate regulatory review. Low-risk devices, by their nature, pose a lower impact on patient health and safety; therefore, they should not require regulatory approval before entering the market.

Changes to low-risk devices should similarly be exempt from National Regulatory Authority review unless the device's risk classification is elevated, such as by making alterations in intended use or changes that increase the risk to patients or users. Allowing manufacturers to document changes internally in accordance with their quality management systems facilitates more rapid innovation and enables regulatory authorities to concentrate their resources on devices and changes that have a meaningful impact on patient health and safety. This approach not only streamlines the change management process but also promotes a more efficient regulatory environment conducive to ongoing advancements in medical technology.

When considering a risk-based approach to managing changes, two key elements come into play: the risk profile of the device and the nature of the change itself. While the device's risk classification provides a baseline for regulatory scrutiny, the significance of the proposed change is equally important. Significant changes that could potentially affect product safety or performance warrant regulatory review and approval prior to implementation.

Table 5 provides a comprehensive summary of the proposed change submission pathways, taking into account both the product risk classification and the significance of the changes. This matrix approach offers a nuanced framework for determining the appropriate regulatory pathway for various types of modifications across different device risk categories, balancing the need for thorough oversight of critical changes with the goal of streamlining processes for changes posing lower risks to patients.

Table 5: Change submission pathways based on products' risk classes and change category

Product Risk Class	Significant Changes	Non-Significant Changes	
		Administrative change/licence amendment	Other non-significant changes
Low Risk	Changes to be self-managed by the manufacturer according to the established Quality Management System		
Low-moderate Risk	Change notification (with no NRA review/ approval needed) with immediate implementation is recommended	No submission required; however, documentation of the changes including records of details and analysis of changes must be maintained and made available to the NRA for review, upon request. Or a simplified notification process for the purpose of Customs clearance	No submission required; however, documentation of the changes including records of details and analysis of changes must be maintained and made available to the NRA for review, upon request
Moderate-high Risk	Change submission (with NRA review/approval needed before implementation)	Change notification (with no NRA review/ approval needed) with immediate implementation is recommended	No submission required; however, documentation of the changes including records of details and analysis of changes must be maintained and made available to the NRA for review, upon request
High Risk	Change submission (with NRA review/approval needed before implementation)	Change notification (with no NRA review/ approval needed) with immediate implementation is recommended	No submission required; however, documentation of the changes including records of details and analysis of changes must be maintained and made available to the NRA for review, upon request

Good Practice Example: Canada

Canada's approach to managing medical devices across Class 1, 2, 3, and 4 is characterised by a risk-based regulatory framework, ensuring that the level of oversight is proportional to the potential risk the devices pose to patients and users. For Class 1 devices, considered the lowest risk, manufacturers are primarily responsible for maintaining compliance records of changes, with minimal direct regulatory intervention. These records should be readily available upon request by Health Canada, but proactive submission is not typically required.

For Class 2 devices, which pose moderate risks, the approach is slightly more stringent. Manufacturers must document significant changes and may need to notify Health Canada for certain modifications that could impact the device's safety or effectiveness, particularly if these changes affect the device's intended use or introduce a significant redesign.

The regulatory requirements intensify for Class 3 and Class 4 devices, which include high-risk and life-sustaining or life-supporting technologies. Any significant modifications to these devices necessitate a comprehensive review process, including the submission of detailed amendments to existing licenses. Manufacturers must provide substantial evidence, such as updated risk assessments, clinical data, and validation studies, to demonstrate that the modifications do not compromise the device's safety or performance.

Overall, Canada's regulatory management of medical devices ensures a balanced approach that prioritises patient safety while fostering innovation. The system is designed to be adaptable, allowing for efficient management of changes across all device classes, with the stringency of regulation increasing with the device's potential risk.

Good Practice Example: South Korea

Korea MFDS simplified change management of Software as Medical Devices. Given the need to frequently update and localise software, a simplified change management framework can enable agile modifications while maintaining a high-level of safety. Changes to SaMD can be managed by restricting the scope that needs regulatory review, limiting it to changes that relate to major functions, such as analysis algorithms (analysis methods), development language, operating environment, or communication functions.

Other changes can be reasonably reported after the modifications have been implemented.

To further enhance regulatory efficiency, APACMed recommends that authorities consider adopting more agile approaches to change management. These could include allowing bundled submissions for multiple scenarios: firstly, when implementing the same change across multiple products, and secondly, when applying different changes to a single product. Additionally, we propose permitting **supplementary change submissions** to be added to previous submissions currently under regulatory review.

3.4 Providing adequate transition periods for regulatory changes

Providing manufacturers with an adequate transition period for implementing changes in medical device regulations is crucial for maintaining product quality, availability, and patient safety. This transition time allows manufacturers to align their production processes, update labelling, and adjust supply chain arrangements without compromising the uninterrupted supply of critical medical devices in the market.

Given the complexity of medical device manufacturing and global supply chains, APACMed recommends that regulators **provide a transition period of at least 6 months.** During this time, both the updated product versions and those produced before the changes should be allowed to be manufactured, imported, and distributed without disruptions.

This 6-month timeframe strikes a balance between the need for prompt implementation of regulatory changes and the practical considerations faced by manufacturers. This transition period would enable manufacturers to:

- Modify production lines and validate new manufacturing procedures
- Communicate changes to suppliers and distributors
- Update quality control processes
- Adjust inventory management systems
- Design and implement new labelling and packaging
- Prepare and submit updated regulatory documentation

Good Practice Example: Singapore

Singapore HSA allows a concurrent supply of both the original registered medical device and the changed medical device (subject of the Change Notification) upon approval of Change Notification application only if both versions of the medical device conform to the Essential Requirements for safety and performance for medical devices as stipulated in the Regulations. Quality Management System (QMS) traceability procedures and records should be in place and made available to Regulatory Authorities upon request.

This concurrent supply of the unchanged original device may not be applicable for changes to medical devices implemented as a consequence of reportable AEs or FSCAs.

3.5 Considering alternative pathways

3.5.1 Considering reliance pathways

The WHO Global Model Regulatory Framework for Medical Devices Including In Vitro Diagnostic Medical Devices recommends that National Regulatory Authorities (NRAs) should, **when feasible, implement reliance and recognition principles in evaluating changes to medical devices.** This approach aligns with the growing trend toward regulatory reliance, as seen in the WHO's Good Reliance Practices Guidance and the increasing use of reliance mechanisms by regulatory authorities worldwide for new product registrations and post-market inspections

Given the global shift toward reliance as a cornerstone of efficient regulation, APACMed recommends that regulatory authorities establish a reliance or recognition pathway specifically for significant changes to registered products. Implementing such a model for approving modified or altered devices would offer several key benefits:

- Accelerated access to innovation, ensuring patients can benefit from improved medical technologies more rapidly.
- More efficient use of limited regulatory resources, allowing authorities to focus on high-risk or novel changes.
- Streamlined compliance processes for manufacturers, reducing redundant evaluations across multiple jurisdictions.

Good Practice Example: Australia

The Australia's Therapeutic Goods Administration (TGA) has adopted a reliance approach to streamline the approval process for changes to medical devices and In Vitro Diagnostic devices (IVDs). This is best exemplified by changes that have already been approved by European Union Notified Bodies (EU NB) under the Medical Devices Regulation (MDR) or the In Vitro Diagnostic Regulation (IVDR).

This approach allows the TGA to leverage the assessment work already conducted by EU NB, facilitating faster approval of device changes within the Australian market. By recognising and utilising the rigorous evaluations performed by EU NB, the TGA can expedite the regulatory process for modifications to devices that have demonstrated compliance with the stringent standards set forth by the MDR or IVDR. This reliance strategy not only speeds up the approval timeline for device changes, ensuring that Australian patients gain quicker access to the latest medical technologies and innovations, but also maintains a high level of safety and effectiveness in line with international standards.

3.5.2 Adopting Replacement Reagent and Instrument Family Policy

The Replacement Reagent and Instrument Family Policy (RRIFP) offers an efficient pathway to expedite the availability of medium-risk assays on instruments within the same family. This concept, as outlined Replacement Reagent and Instrument Family Policy (GHWP/WG2 /F001:2021), facilitates the migration of an assay to additional instruments that are either cleared or members of a previously cleared instrument family.

The US Food and Drug Administration (FDA) has successfully implemented this policy for over two decades. Under this approach, manufacturers can maintain the safety and effectiveness levels demonstrated for the cleared device when applying modifications, provided they adhere to predefined acceptance criteria and utilise proper validation protocols. Notably, this process often eliminates the need for a new premarket notification submission.

Given its proven effectiveness, APACMed recommends that regulatory authorities adopt the RRIFP when evaluating:

- The addition of an approved test kit/assay to a previously approved instrument (Replacement Reagent Policy)
- The introduction of a new instrument family member to a previously approved instrument family (Instrument Family Policy)

Good Practice Example: USA

The US FDA's Replacement Reagent and Instrument Family Policy has significantly streamlined the process for IVD manufacturers to introduce improvements to their products. This policy allows manufacturers to apply a previously cleared assay to a new instrument within the same family without submitting a new 510(k), provided they meet certain criteria and maintain the same level of safety and effectiveness.

One of the key benefits of this policy is the acceleration of market access for improved IVD systems, leading to quicker deployment of innovations and potentially better patient care. It also promotes resource efficiency for both manufacturers and the FDA, allowing companies to allocate resources more effectively towards innovation and validation, while enabling the FDA to focus its review efforts on more substantial changes or novel devices.

Furthermore, this approach encourages continuous innovation in the IVD field by providing a streamlined path to market for certain types of enhancements. Manufacturers are more likely to pursue incremental improvements, fostering a culture of ongoing product refinement and technological advancement. This policy demonstrates how well-designed regulatory frameworks can effectively balance the need for safety with the drive for rapid technological progress, ultimately benefiting patients, manufacturers, and regulatory bodies alike.

3.5.3 Adopting a more flexible and streamlined approach in managing changes to enable innovation

Given the rapid pace of technological advancements in the medical device industry, a more flexible and streamlined approach to managing changes is essential to ensure timely patient access to improved devices while maintaining high safety standards. This applies to all types of medical devices, from traditional hardware to In Vitro Diagnostics reagents, connected devices and SaMDs.

Traditional regulatory frameworks, which often require extensive review for certain post-market modifications, can significantly delay the implementation of important updates. This delay potentially hinders innovation and may compromise patient safety by slowing responses to emerging issues or necessary improvements across all device categories.

APACMed recommends that regulatory authorities consider a more flexible and streamlined approach. This approach would allow regulators to review, during the initial premarket submission:

- A description of specific, pre-planned modifications
- A detailed modification protocol
- An impact assessment including benefit-risk analysis and acceptance criteria for these changes

This concept allows manufacturers to obtain advance authorisation for specific, pre-planned modifications across various device types. If the manufacturer adheres to the agreed-upon protocol for changes within its scope and meets the predefined criteria, modifications could be implemented without further regulatory review.

This approach ensures focused oversight while allowing for necessary flexibility across all device categories. It would significantly reduce delays caused by traditional reviews for significant changes while maintaining regulatory oversight. By adopting a Pre-Determined Change Control Plan (PCCP)-like mechanism, regulatory authorities can facilitate more rapid innovation and timely updates across the entire spectrum of medical devices, ultimately benefiting patient safety and care.

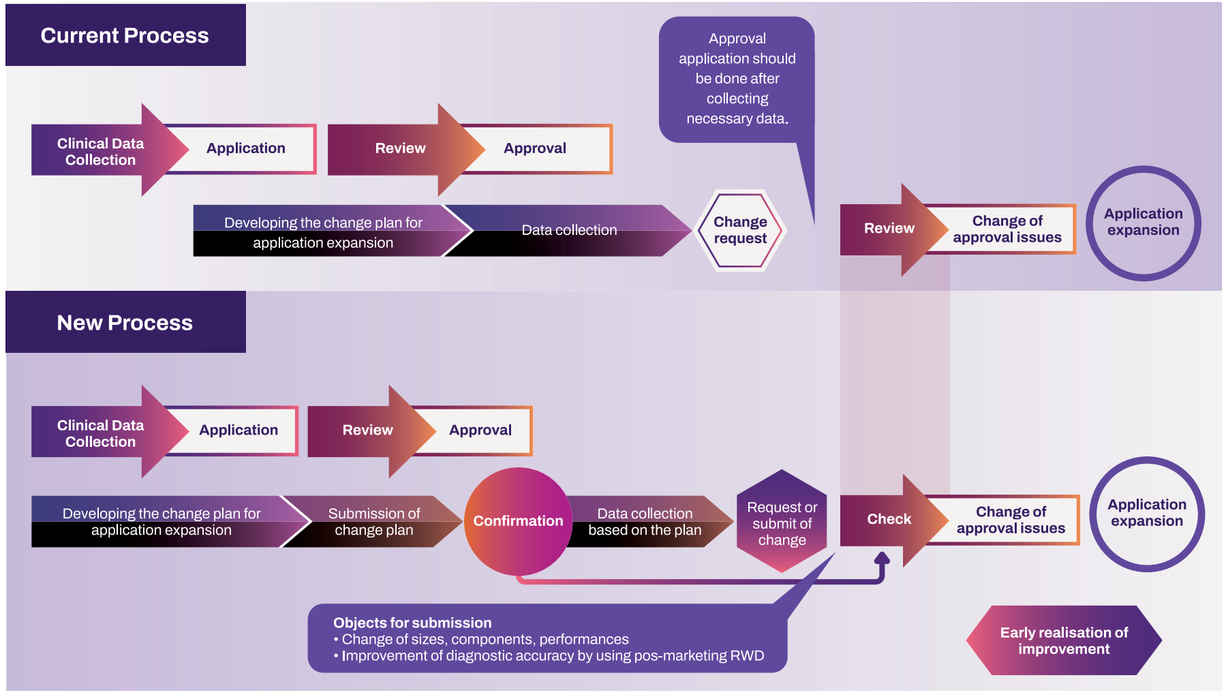
Good Practice Example: Japan

Japan's IDATEN initiative represents a strategic move towards accelerating the review and approval process for changes in medical devices, including SaMDs. This approach is particularly significant for SaMDs, where rapid iterations and updates are crucial for enhancing functionality, security, and user experience.

IDATEN allows manufacturers to submit the change plan (including updates or modifications that are expected to occur post-market) at the time of initial device registration. The regulatory body then reviews these proposed changes and confirms them during the initial approval process. Once the product is on the market, the manufacturer should submit the change, which will trigger a simple check (instead of normal review) by the authority before the change is implemented.

This approach significantly reduces the time and administrative burden associated with submitting separate applications for each change, as it eliminates the need for multiple rounds of review for changes that fall within the agreed-upon scope.

Post-Approval Change Management Protocol will be introduced for medical devices to enable continuous improvements.



"Improvement Design within Approval for Timely Evaluation and Notice (IDATEN)"

Source: https://www.pmda.go.jp/files/000234056.pdf

4 Conclusion

In conclusion, this position paper highlights the critical role of risk-based change management for registered medical devices in ensuring safety and regulatory compliance. Our analysis of APAC market practices reveals opportunities to streamline change management processes while upholding high safety standards.

APACMed is committed to advocating for efficient regulatory practices and collaborating with stakeholders to implement the recommendations outlined in this paper. By fostering dialogue with policymakers and regulators, we aim to create a harmonised environment that ensures timely access to safe and innovative medical technologies for patients across the Asia-Pacific region.

5 References

Market	Change management guidance document (MDs, IVDs, SaMDs)
Australia	Changes affecting TGA-issued conformity assessment certificates https://www.tga.gov.au/how-we-regulate/manufacturing/medical-devices/conformity-assessment/conformity-assessment-bodies/tga-conformity-assessment-certification/changes-affecting-tga-issued-conformity-assessment-certificates Varying entries in the ARTG: medical devices and IVDs https://www.tga.gov.au/resources/resource/guidance/varying-entries-artg-medical-devices-and-ivds Manufacturer Evidence for medical devices including IVD medical devices https://www.tga.gov.au/manufacturer-evidence-medical-devices-including-ivd-medical-devices
China	Regulation for Medical Device Supervision and Administration https://www.nmpa.gov.cn/xxgk/fgwj/flxzhfg/20210318084145148.html Provisions for Medical Device Registration and Filing (SAMR. No. 47) https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210326094015179.html Provisions for IVD Reagents Registration and Filing (SAMR No. 48) https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210326094620192.html

Market	Change management guidance document (MDs, IVDs, SaMDs)
India	Medical Device Rules 2017 - Sixth Schedule (https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzMzNg==). Guidelines not available.
Indonesia	MoH Decree No. 62, 2017: Marketing Authorization for General Medical Device, Invitro Diagnostic Medical Device, Household Health Equipment. (https://regalkes.kemkes.go.id/informasi_alkes/Regulasi%20Lisensi%20Produk.pdf) Change Management Guideline on Medical Device and Medical Device Invitro Diagnostics. 2021. (https://regalkes.kemkes.go.id/informasi_alkes/Pedoman%20Manajemen%20Perubahan.pdf) Guidelines on Medical Device Assessment referring to MoH Decree No. 62, 2017: Marketing Authorization for General Medical Device, Invitro Diagnostic Medical Device, Household Health Equipment. 2019. (https://regalkes.kemkes.go.id/informasi_alkes/Pedoman%20Penilaian%20Alkes%20Permenkes.pdf)
Japan	Notification: PFSB/ELD/OMDE No. 1120/1: Points to Consider when Preparing Manufacturing Marketing Approval Application Documents for Medical Devices (https://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/261120kiki112001.pdf, MD) Notification: PFSB/ELD/OMDE No. 1121/16: On Points to be Reminded for Product Approval Application of In-vitro Diagnostic Agents (https://www.mhlw.go.jp/web/t_doc?dataId=00tc0541&dataType=1&pageNo=1, IVD) Publication of Guidance on Approval Applications for Medical Device Programs (https://www.mhlw.go.jp/web/t_doc?dataId=00tc1785&dataType=1&pageNo=1, SaMD) Notification: PSEHB/MDED No. 0831/14: Handling Application for Confirmation of Medical Device Change Plan (https://www.mhlw.go.jp/content/11120000/000665757.pdf, SaMD)
Korea	Guideline on Minor Changes Reporting Requirements for Medical Devices 식품의약품안전처〉법령/자료〉법령정보〉공무원지침서/민원인안내서〉민원인안내서	식품의약품안전처 (mfds.go.kr) SaMD – Guideline on medical device software registration https://www.mfds.go.kr/brd/m_1060/view. ?seq=15228&srchFr=&srchTo=&srchWord=%EC%86%8C%ED%94%84%ED%8A%B8%EC%9B%A8%EC%96%B4&srchTp=0&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&Data_stts_gubun=C9999&page=1 In vitro diagnostic medical device - Guidelines related to change registration (including minor change cases) _4th revision (식품의약품안전처〉법령/자료〉법령정보〉공무원지침서/민원인안내서〉민원인안내서 - 상세보기	식품의약품안전처 (mfds.go.kr))
Malaysia	Change Notification for Registered Medical Device MDA/GD/0020 https://portal.mda.gov.my/index.php/documents/guidance-documents/2392-guidance-document-change-notification-for-registered-medical-device-4th-edition

Market	Change management guidance document (MDs, IVDs, SaMDs)
Philippines	CHECKLIST OF REQUIREMENTS FOR VARIATION AND REVALIDATION OF CERTIFICATE OF PRODUCT REGISTRATION OF A MEDICAL DEVICE https://www.fda.gov.ph/wp-content/uploads/2022/05/Checklist-Requirements-Variation.pdf
Singapore	GN-21: Guidance on Change Notification for Registered Medical Devices https://www.hsa.gov.sg/medical-devices/guidance-documents
Taiwan	Regulations Governing Issuance of Medical Device License, Listing and Declaration (https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030128)
Thailand	Guidance on Change Notification issued by Thai FDA https://medical.fda.moph.go.th/ivd-head/ivd-03-01-004
Vietnam	Decree 98/2021/NĐ-CP dated 08 Nov 2021 prescribing medical device management
Canada	Draft guidance on how to interpret ‘significant change’ of a medical device: Overview. Date revised: February 7, 2024. Replaces: Guidance for the Interpretation of Significant Change of a Medical Device (2011) https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/interpret-significant-change-medical-device/process-procedures.html#a3 Medical Devices Regulations SOR/98-282 https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/fulltext.html

Market	Change management guidance document (MDs, IVDs, SaMDs)
EU	MDs: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices IVDs: Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices Under MDD, sometimes still used as a reference: NBOG Guide 2014-3 Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System For the transition period from MDD to MDR and IVDD to IVDR: MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR https://health.ec.europa.eu/system/files/2022-05/mdcg_2022-6.pdf MDCG 2020-3 Rev.1 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD https://health.ec.europa.eu/document/download/800e8e87-d4eb-4cc5-b5ad-07a9146d7c90_en?filename=mdcg_2020-3_en_1.pdf
USA	Deciding When to Submit a 510(k) for a Change to an Existing Device https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device PMA Supplements and Amendments https://www.fda.gov/medical-devices/premarket-approval-pma/pma-supplements-and-amendments Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modifications-devices-subject-premarket-approval-pma-pma-supplement-decision-making-process Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices (Guidance for Industry and FDA Staff) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/replacement-reagent-and-instrument-family-policy-in-vitro-diagnostic-devices
WHO	WHO Expert Committee on Biological Standardization (76th report), Annex 3-WHO Global model Regulatory Framework for Medical Devices Including In Vitro Diagnostics Medical Devices (see page 251) https://www.who.int/publications/i/item/9789240074484
GHWP	Replacement Reagent and Instrument Family Policy (GHWP/WG2 /F001:2021) http://www.ahwp.info/sites/default/files/Replacement%20Reagent%20and%20Instrument%20Family%20Policy.pdf

About APACMed

The Asia Pacific Medical Technology Association (APACMed) comprises over 60 Corporate Members with over 600 regulatory professionals in the Regulatory Affairs (RA) Committee. Forming the largest committee in the Association, one of the RA Committee's goals is to promote regulatory convergence by collaborating with key stakeholders.

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About [‘mediPr]

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