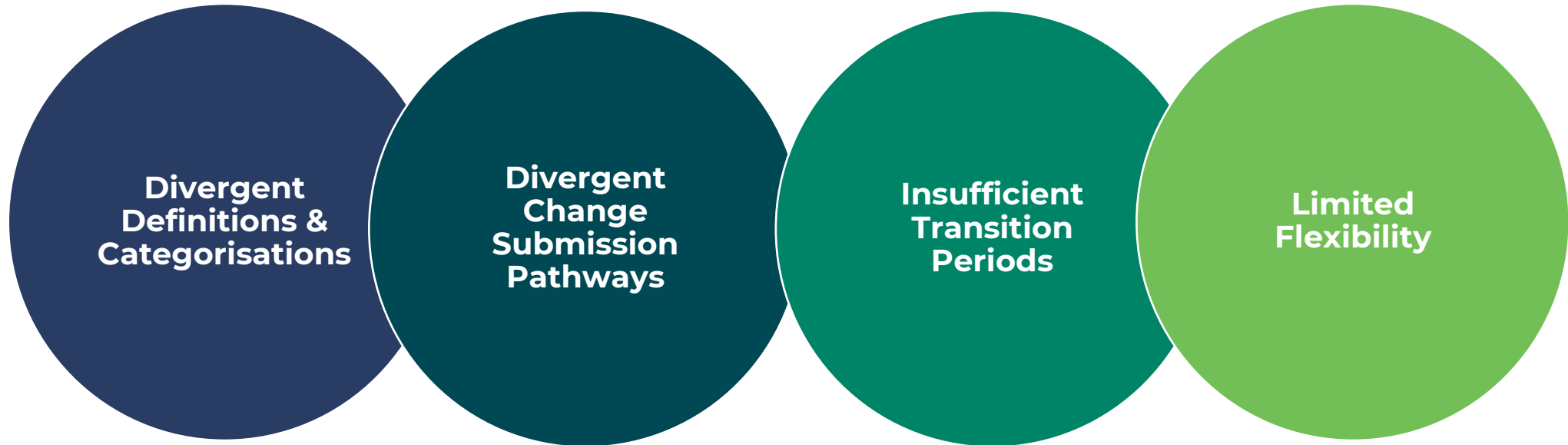
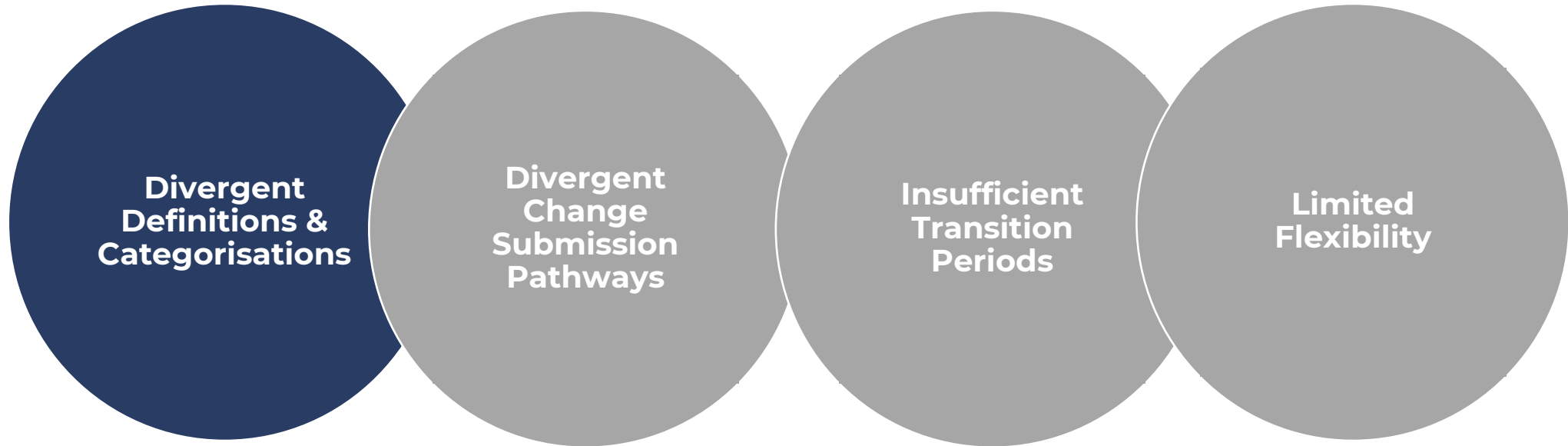


Risk-Based Change Management for Registered Medical Devices

Why this topic matters?



Why this topic matters?

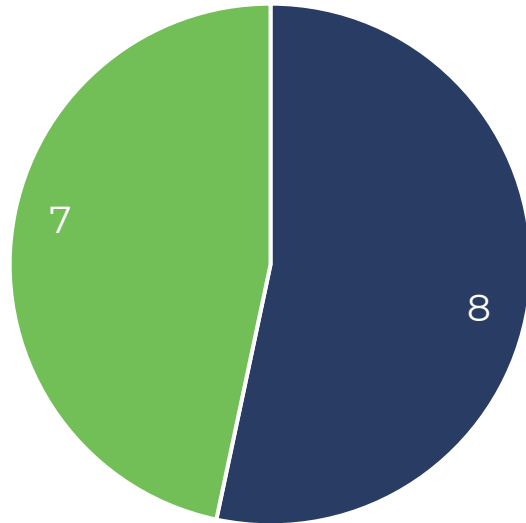


Divergent Definitions & Categorisations

Definitions of "significant change" and categorisations of change vary widely across APAC markets:

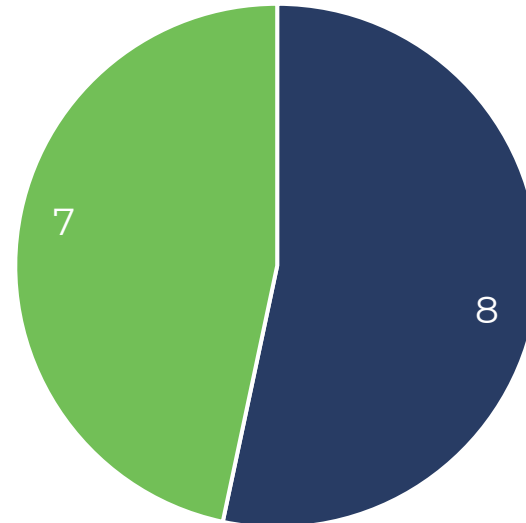
- Not all markets have a clear definition of signification change
- Some markets use **lists** and others, **flowcharts** approaches

Clear definition of change



■ Yes ■ No

Type of change categorisation



■ List Based ■ Flowchart-Based

Divergent Definitions & Categorisations

The lack of standardisation creates delays access to medical devices and complexity for manufacturers



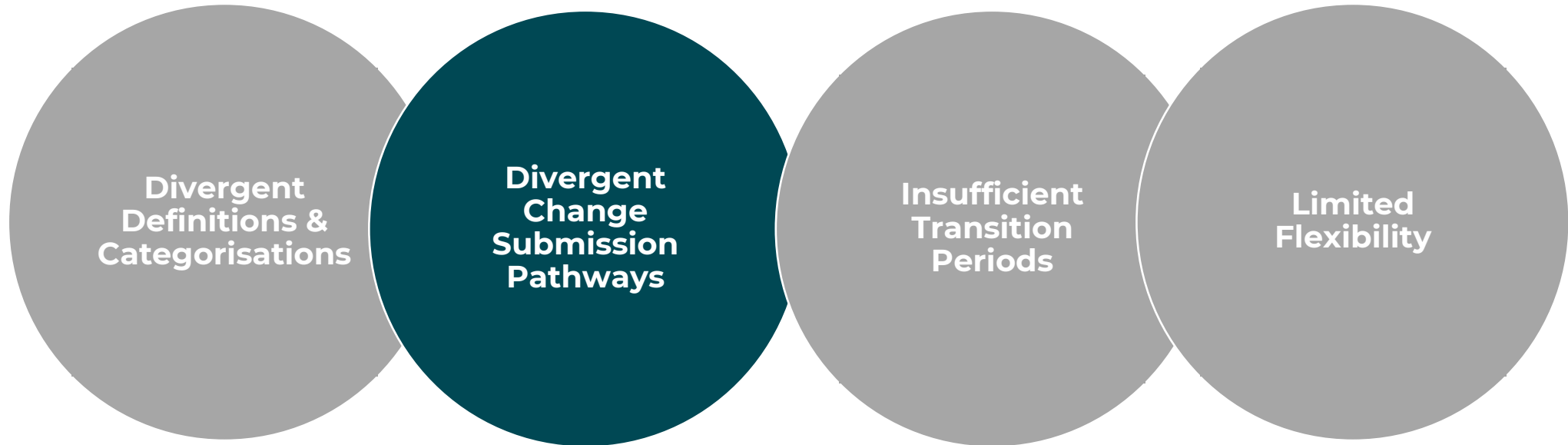
Adopting the WHO's definitions of change and harmonising categorisations of changes to reduce regulatory inconsistencies and accelerate access to medical devices

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'.

Why this topic matters?

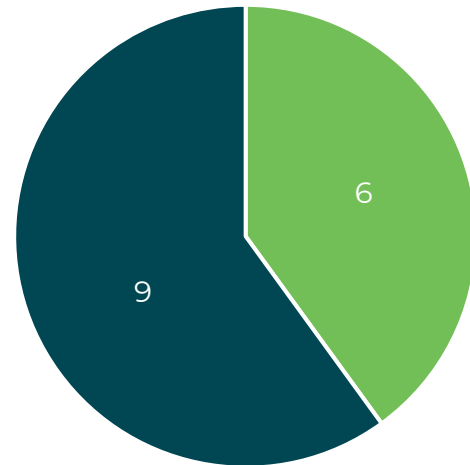


Divergent Change Submission Pathways

Approval timelines and submission pathways vary significantly across jurisdictions:

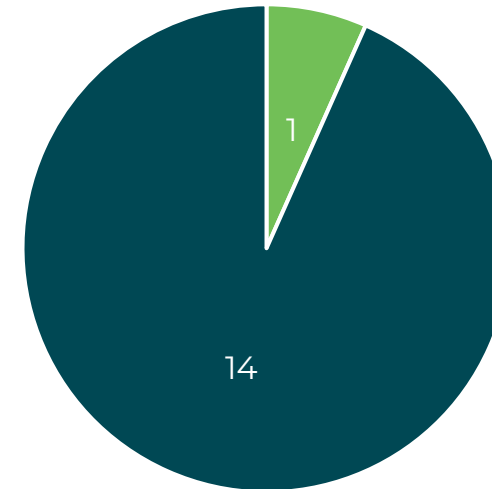
- Most APAC markets require individual submissions even for similar changes across multiple products, prolonging timelines by up to 6-12 months.
- Only Australia allows for reliance pathways

Is bundling of submissions permitted for the same changes applied to multiple products?



■ Yes ■ No

Reliance Pathways are allowed for Change Submissions



■ Yes ■ No

Divergent Change Submission Pathways

Approval timelines and submission pathways vary significantly across jurisdictions, creating delays and additional administrative burdens for manufacturers.



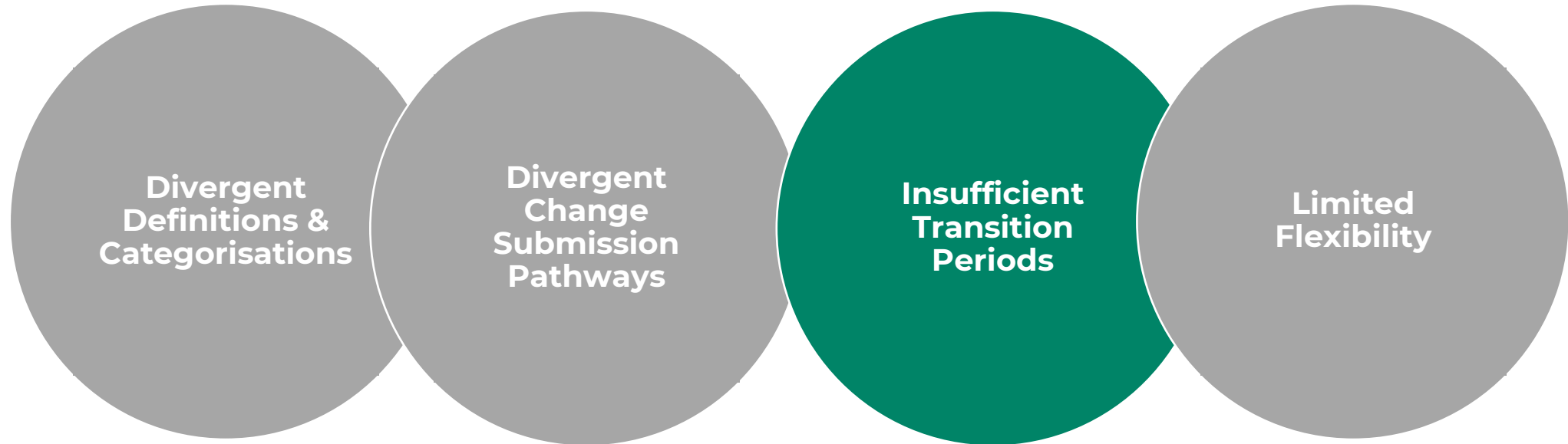
Streamline change submission pathways by implementing reliance mechanisms and bundling options.



Best practice

Australia's TGA has adopted a reliance approach to streamline the approval process for changes to MD and IVDs. The TGA accepts changes that have already been approved by European Union Notified Bodies (EU NB) under the MDR/IVDR.

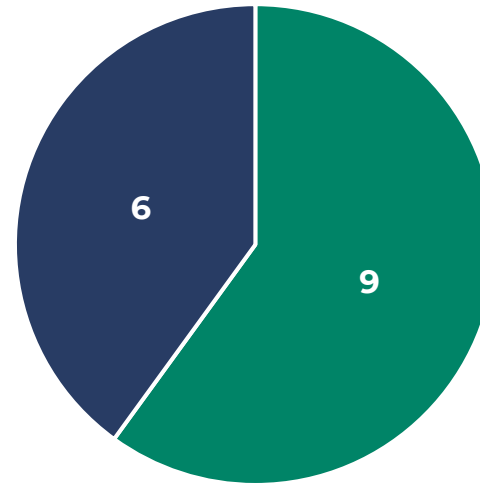
Why this topic matters?



Insufficient Transition Periods

- Transition periods for implementing changes are inconsistent across markets, with some regulators allowing concurrent supply of old and new versions, while others provide limited or no transition periods.
- Manufacturers are often given insufficient transition periods to implement changes, impacting supply chain continuity and patient access.

Can the previous version of a device still be imported after the change is approved by the NRA?



■ Yes ■ No

Insufficient Transition Periods

This creates uncertainty and disrupts supply chains, delaying patient access to essential devices.



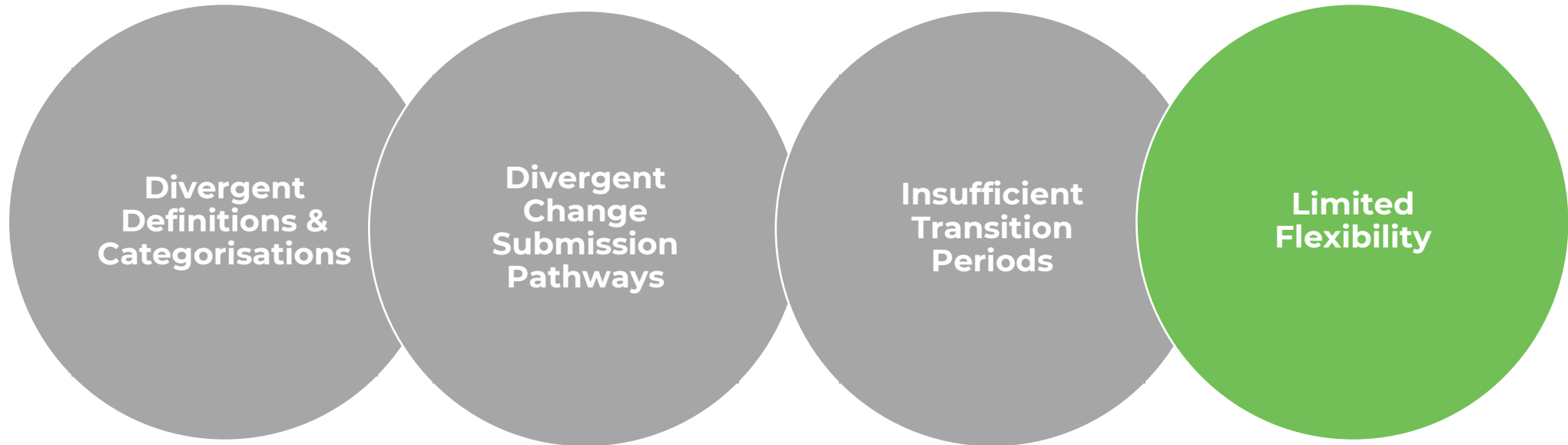
Provide a transition period of at least six months to ensure uninterrupted supply and smoother adaptation to regulatory changes.



Best practice

Singapore HSA allows a concurrent supply of both the original registered medical device and the changed medical device upon approval of Change Notification if both versions of the medical device conform to the Essential Requirements for safety and performance for medical devices as stipulated in the Regulations.

Why this topic matters?



Limited Flexibility

Rigid frameworks require extensive review even for low-risk changes, stifling innovation and delaying market access for updated devices.



Adopt risk-based pathways:

- Focus regulatory scrutiny on significant changes
- Allow low-risk modifications to proceed without NRA review



Best practice

South Korea streamlines changes for SaMD by restricting reviews to major functional updates only.

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		
Moderate-high 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

→ 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.

Change Management in Malaysia: Insights and Best Practices

February 2024

Training Session on
Change Management



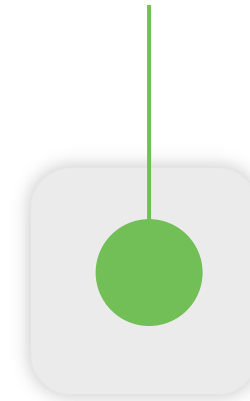
Q1 Q2 2025

Revision of the guidelines



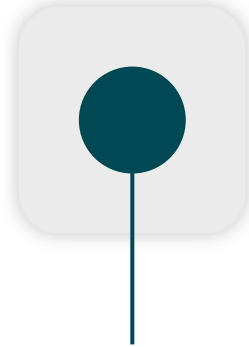
August 2025 onwards

Adoption of the
guidelines by MDA



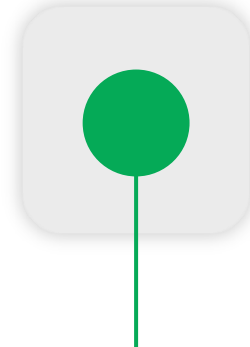
July-December 2024

Change Management
Workshop Series



Q3 2025

Public Consultation of
the New Guidelines



Next Steps

Share best practices and
learning with other regulators
in ASEAN markets





Scan the QR Code to Access
our paper



Thank you!

For any query feel free to contact me at cpelou@apacmed.org