IMDRF International Medical Device Regulators Forum

RHI Update

APEC Regulatory Harmonization Steering Committee (RHSC) – Medical Device PWA

Post-March 2025 Updates for 28th IMDRF Stakeholder Forum

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Goal & Strategic Focus of RHSC

- The RHSC promotes a strategic and coordinated approach to regulatory harmonization and capacity building efforts within the APEC region.

- A “Medical Product” is meant to include pharmaceuticals, biologics, medical devices, and any other product the SCSC deems appropriate.

Vision & Mission of RHSC

- **Vision**: to accelerate regulatory convergence for medical products in the APEC region as much as possible by 2030

- **Mission**: to facilitate regulatory cooperation among medical product regulatory authorities, build human capacity in regulatory science among medical product regulatory staff, and promote political will for convergence and reliance among regulatory policymakers in APEC

- RHSC will adopt a strategic, coordinated approach to regulatory convergence and reliance, and does not seek to develop new guidance or standards.

APEC SOM3 RHSC Plenary Meeting 2025

14 economies attended in-person: Australia, Canada, Chile, China, Japan, Republic of Korea, Malaysia, Philippines, Peru, Russian Federation, Singapore, Chinese Taipei, Thailand, United States

Relaunching the APEC RHSC KPIs
: Measuring Progress on Regulatory Convergence

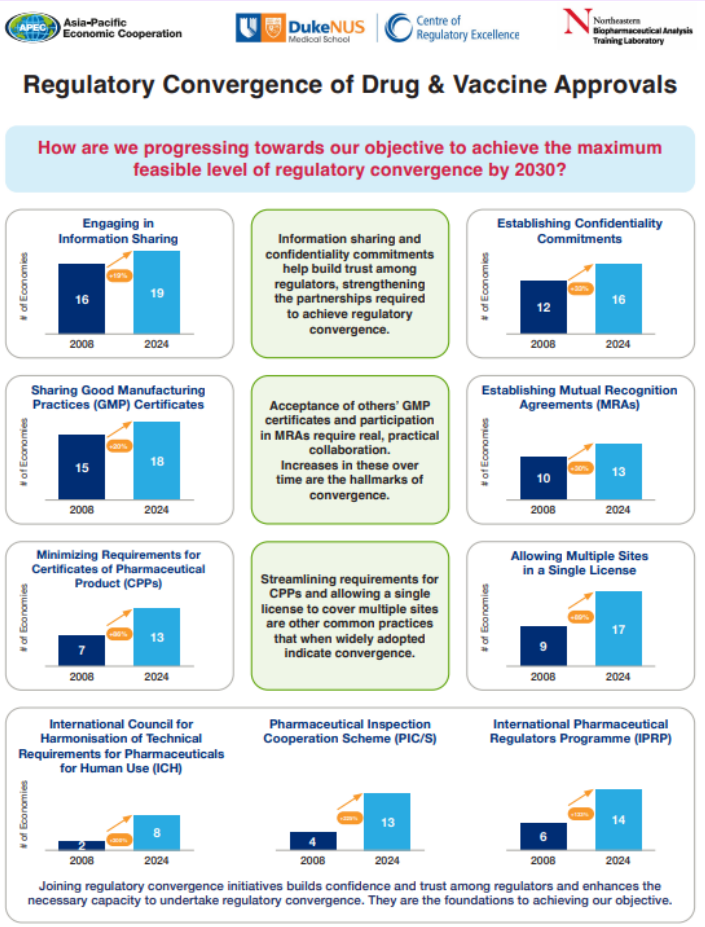
- Self-funded project to understand RHSC progress towards achieving its vision to “accelerate regulatory convergence for medical products in the APEC region as much as possible by 2030”
- Key Performance Indicators (KPIs) in two phases:

  Phase 1: Update KPIs last reviewed in 2020, using survey completed in 2025

  - *Status: RHSC endorsed updated KPIs*

  Phase 2: Expand KPIs and survey economies in 2026

  - *Status: RHSC provided feedback on expanded KPIs. Self funded project proposal to be submitted to SCSC.*



Policy Dialogues

Implementation of ICH E17 Guideline on General Principles for Planning and Design of Multi-Regional Clinical Trials (MRCT)

- ICH E17 provides a harmonized framework for conducting trials in multiple regions under a single protocol
- The guideline aims to facilitate simultaneous global drug development, enable earlier patient access to new therapies, and reduce the duplication of clinical studies across jurisdictions
- Uptake of its principles remains uneven. For instance, divergent approaches to sample size allocation and patient pooling strategies lead to duplication of clinical studies across jurisdictions
- Panelists conveyed the need for political will and capacity building to reduce instances where regulatory authorities unnecessarily insist on local population data. Panelists also raised opportunities for regional cooperation, for example by facilitating the ability of regulatory authorities to mutually recognize certifications of clinical research organization.

Policy Dialogues

Rare Disease Therapies & Orphan Medical Products

- Patients living with a rare disease face unique and persistent barriers to timely diagnosis, treatment, and care, often amplified by regulatory fragmentation and capacity constraints
- To increase access to orphan drugs (treatments for rare diseases), economies have taken steps to introduce facilitated regulatory pathways and incentives for manufacturers
- There are still opportunities for improvement in convergence, agility, and collaboration to support timely access to rare disease therapies
- Panelists discussed challenges and opportunities to address definitional inconsistencies between economies. Economies, such as Malaysia, Japan, and Chinese Taipei shared updates on domestic efforts to facilitate access to orphan drugs

Policy Dialogues

Building Regulatory Trust: Conversation Between RHSC and the Access Consortium

- Access Consortium is a working-sharing coalition of regulatory authorities that formally rely on each other's assessments and approvals.
- Economies can reduce duplicative efforts, accelerate regulatory review timelines, and ensure timely patient access to high-quality therapies.
- Experts provided perspectives on the benefits in participating in work-sharing, as well as the pivotal role in building and maintaining trust among regulatory authorities.

Update on Priority Work Areas (PWAs) for Medical Products

- RHSC Chair will circulate a discussion paper to the RHSC, outlining the proposed life cycle of PWAs and Centers of Excellence (CoEs), including: criteria, metrics, and processes for sunsetting inactive or completed initiatives

- CoE Coalition Co-Chairs will develop a best practices document providing guidance to CoEs

Multi-regional Clinical Trials (MRCT) & Good Clinical Practices Inspection (GCP)

Global Supply Chain Integrity

Biotherapeutic Products and Advanced Therapies

Good Registration Management

Pharmacovigilance

Medical Devices

Pharmaceutical Quality

Electronic Data Standards

Current Champions and CoEs for Medical Device PWA (MD PWA)

CO-CHAMPIONS

- Japan (MHLW / PMDA)
- Korea (MFDS)
- United States (US FDA)

SUB-CHAMPIONS

Japan (JIRA)

United States (AdvaMed)

CENTERS OF EXCELLENCE (CoE)

- Sichuan University (SCU), China
- Pharmaceuticals and Medical Devices Agency (PMDA), Japan
- Soonchunhyang University (SCH), Korea
- Taiwan Food and Drug Administration (TFDA), Chinese Taipei
- University of Southern California (USC), United States

Updates on MD PWA Activities

- Decided which SC member participates in each CoE program committee
  - to make the communication with the CoEs much better
  - to supervise them effectively

Name of institution	US FDA	MHLW /PMDA	MFDS	AdvaMed	JIRA
Sichuan University (SCU), China		✓			✓
Pharmaceuticals and Medical Devices Agency (PMDA), Japan		✓			✓
Taiwan Food and Drug Administration (TFDA), Chinese Taipei		✓		✓	✓
University of Southern California (USC), United States	✓		✓	✓	
Soonchunhyang University (SCH), Korea			✓		✓

Summary and Outlook of CoE Activities for MD PWA

Name of institution	2025	2026
Sichuan University (SCU), China	October 21–23 (Hybrid: Online & In-person)	Training planned (Details TBC)
Pharmaceuticals and Medical Devices Agency (PMDA), Japan	-	Training planned (Dates TBC)
Soonchunhyang University (SCH), Korea	September 4–October 31 (Online)	Training planned (Details TBC)
Taiwan Food and Drug Administration (TFDA), Chinese Taipei	August 26–28 (Hybrid: In-person & Virtual)	(TBD)
University of Southern California (USC), United States	November 3–4 (US) / November 4–5 (Asia) (Online)	Training planned in the 4th quarter

MD PWA Plans for 2025-2026

- Consider possible alignment with the IMDRF foundational documents
- Consider how to align to the IMDRF strategic plan
- Discuss the scope of the MD PWA Core Curriculum
- Proceed with CoE assessment and new application
- Continue to conduct CoE workshops
- Discuss the reliance on MDSAP in APEC region (as suggested at the 2025 SOM3 RHSC)

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Thank you

For any questions, please send an email to

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Ministry of Food and Drug Safety