Good Registration Management
APAC Position Paper

Progress Report in 2025

APAC
Regulations and Approvals Expert Working Group

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INTRODUCTION

Asia Partnership Conference of Pharmaceutical Associations (APAC) is a platform built by 12 Asian Pharmaceutical Industry's Associations to advocate industry proposals in order to expedite the launch of innovative medicines for the peoples in Asia. Regulations and Approvals Expert Working Group (RA-EWG), formed under APAC, has been working to support promotion of regulatory convergence in Asia.

APAC Position Paper was published by RA-EWG in 2015 to provide high-level suggestions and proposals to the regulatory authorities from the viewpoint of industry. In 2022, it was revised as APAC Position Paper 2022 to provide updated suggestions and proposals reflecting subsequent environmental changes (https://apac-asia.com/images/achievements/pdf/11th/APAC_RA-EWG_PositionPaper2022.pdf). It is expected the position papers will be used for facilitating close communication and collaboration between industry and the regulatory authorities to contribute to improving Good Registration Management and eventually lead to regulatory convergence and work sharing of drug review in Asia.

APAC Position Paper 2022 covers 6 topics, (1) consultation, (2) transparency, (3) tracking system, (4) collaborative training, (5) digital tools/platform, and (6) reliance, which have been identified as important areas for refining existing drug registration processes across the APAC region.

Topic #1: Structured framework of regulatory consultation system
Topic #2: Transparency to review policy, standards, draft regulations, guidelines, and new initiative from regulatory authority
Topic #3: Review process tracking system
Topic #4: Collaborative training program
Topic #5: Utilization of digital tools/platform for drug registration
Topic #6: Regulatory reliance throughout the product life cycle

APAC member associations have selected topics to focus on in their economies for further discussion with their authorities (**Table**, *see next page*). This document shows the progress of APAC member associations' activities in 2023 on the focus topic(s) in the APAC Position Paper 2022.

Table Focused Topics by each association in their economy

China	**PhIRDA** China Pharmaceutical Innovation and Research Development Association	None
China	**RDPAC** R&D-based Pharmaceutical Association in China	None
Hong Kong	**HKAPI** The Hong Kong Association of the Pharmaceutical Industry	None
India	**OPPI** Organization of Pharmaceutical Producers of India	None
Indonesia	**IPMG** International Pharmaceutical Manufacturers Group	**#4**
Japan	**JPMA** Japan Pharmaceutical Manufacturers Association	**#2**
Korea	**KPBMA** Korea Pharmaceutical and Bio-Pharma Manufacturers Association	None
Korea	**KRPIA** Korean Research-based Pharmaceutical Industry Association	None
Malaysia	**PhAMA** Pharmaceutical Association of Malaysia	**#4, 5**
Philippines	**PHAP** The Pharmaceutical and Healthcare Association of the Philippines	**#2, 4**
Singapore	**SAPI** Singapore Association of Pharmaceutical Industries	None
Taiwan	**IRPMA** International Research-Based Pharmaceutical Manufacturers Association	**#4**
Thailand	**PReMA** The Pharmaceutical Research and Manufacturers Association	**#3, 5, 6**
Vietnam	**Pharma Group Vietnam**	**#3, 4, 5, 6**

PROGRESS REPORT ON FOCUSED TOPIC(S)
IPMG (International Pharmaceutical Manufacturers Group)

Topic #4: Collaborative Training Program

IPMG's activities and achievements in 2024 for the focused topics
[Key Activities and Achievements]
IPMG had several activities in scope of collaborative training program with BPOM (Indonesian HA), Ministry of Health and also local industry association.

- IPMG Regulatory Affairs Task Force met with the Secretary General of Pharmaceutical and Medical Devices Department from Ministry of Health to discuss several issues concerning Indonesian Pharmacopeia regulation:
  - Key activities and achievement
    - The task force advocated for pharmacopeia interchangeability between Indonesia and other international standards (USP, EP, etc).
    - In more detail, IPMG conveyed two points to the Secretary General:
      1. First, to position the Indonesian Pharmacopeia in equal position with other international pharmacopeias as interchangeable.
      2. Second, the current hierarchy for Indonesian Pharmacopeia impose hurdle the registration or renewal of drugs.
    - Following several discussion and advocacy, the 3rd supplement of Indonesian Pharmacopeia has been issued by BPOM, outlining the following:
      - the standards and requirements outlined in the Indonesian Pharmacopoeia apply to finished drugs distributed in Indonesia and active drug ingredients and excipients used in the manufacture of drugs in Indonesia.
      - For finished drugs entering Indonesian territory, fulfillment of standards for active pharmaceutical ingredients and additional ingredients must be in accordance with the standards of the Indonesian Pharmacopeia or other Pharmacopeia.
- Following the formal approval from Head of BPOM concerning implementation of E-labelling Pilot Project, IPMG together with BPOM have launched the project followed by several socialization events held in four regions across Indonesia, which are Purwokerto (Central Java), Hulu Sungai Utara (Borneo), Lombok (West Nusa Tenggara) and Medan (North Sumatera).
  - Key activities and achievement
    - Four successful socializations across Indonesia.
      - In average, 100 participants participated actively in each event, represented by BPOM, local BPOM, District Health Office, Local Pharmacist, hospital, primary care facility representative, Community group, Students/Academia.

- Responding to the success of the first phase activities, BPOM has issued a letter to approve expansion of the pilot project participants due to the positive output and high enthusiasm from the stakeholders.

[Next plan]

- IPMG will continue to collaborate with BPOM to implement the rest of the E-labelling Pilot Project until completed in 2025 and we hope to see the positive outcome of the pilot, in the form of BPOM implementing regulation of the e-labeling in Indonesia.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

1. The issuance of the 3rd supplement of Indonesian Pharmacopeia that allows pharmacopeia interchangeability for imported finished drugs.

JPMA (Japan Pharmaceutical Manufacturers Association)

Topic #2: Transparency to review policy, standards, draft regulations, guidelines and new initiative from regulatory authority

JPMA's activities and achievements in 2024 for the focused topic

Background: Review reports are a tool to improve the transparency of regulator's assessment and decision making. They are also expected to increase mutual trust and understanding between regulators, leading to cooperation in the evaluation of new drugs. JPMA's activities focus on promoting the use of PMDA review reports for new drug registrations in Asia.

[Key Activities and Achievements]

- Annual survey on the use of review reports (January 2024)

  The purposes of the survey were
  - ✧ To understand how often English-translated PMDA review reports were used in new drug registrations in Asia during in 2023
  - ✧ To identify important factors that promote the use of English-translated PMDA review reports

  Responses were received from over 30 JPMA member companies. It was confirmed that English-translated PMDA review reports were used for new drug registrations in at least Korea, Taiwan and Thailand in 2023.

- Meeting with PMDA (Oct 2024)
  - ✧ The result of the annual survey on the use of review reports was shared.
  - ✧ Request from PMDA was incorporated into the questionnaire for the next annual survey.
  - ✧ The further use of review reports for new drug registrations in Asia was discussed. In particular, possible measures to increase the number of English-translated review reports prepared by PMDA was discussed.

[Next plan]

- Continue to conduct an annual survey on the use of review reports.
- Continue discussions with PMDA on how to promote the use of review reports for new drug registrations in Asia.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

- In Malaysia, the NPRA announced "Revision of Categories and Criteria for New/Additional Indication Application – A Pilot Study" on August 07, 2024 to expand the implementation of reliance to include new/additional indication applications beginning with a pilot project. The PMDA review report can be used for this reliance (see the NRPA website).

- As of 31 December 2024, over 390 English-translated review reports are available on the PMDA website. Approximately 30 new reports were published in 2024.

PhAMA (Pharmaceutical Association of Malaysia)

Topic #4: Collaborative Training Program

PhAMA's activities and achievements in 2024 for the focused topic
[Key Activities and Achievements]

- Activities and achievements in 2024 included the following:
  - Workshop on Screening Rejections: PhAMA had engaged with NPRA to work on this collaboration. An NPRA-Industry task force met to finalise the screening checklist and discuss the training workshop.
  - Knowledge sharing on animal DNA testing: A PhAMA task-force had worked with our subject matter experts to develop a program for a knowledge sharing session with NPRA on alternatives to animal DNA testing with reference to the requirement for confirmatory testing of animal DNA in biological products.

[Next plan]

- To organize the Workshop on Screening Rejections for industry in collaboration with NPRA, currently targeted for April 2025.
- To organize the knowledge sharing session on alternatives to animal DNA testing, as a workshop by our SMEs for NPRA, currently proposed for March 2025.

[Remarks (if any)]:
n/a

Recent regulation changes related to the focused topic
Requirement for Animal DNA testing: NPRA circular ref. 600-1/9/12 (20) dated 24 May 2023 for Update of Appendix 4: Guideline on Registration of Biologics, DRGD.

Topic #5: Utilization of Digital Tools/Platform for Drug Registration

PhAMA's activities and achievements in 2024 for the focused topic
[Key Activities and Achievements]

- E-Labelling:
  - A study on the effectiveness of e-Labelling implementation in Malaysia has been initiated in collaboration with the Ministry of Health with support from industry led by PhAMA. The study is being conducted by Universiti Teknologi MARA (UiTM) and the main objectives of this research project are:
    a. To assess the impact and benefits of e-labelling implementation on the public, healthcare professionals, and pharmaceutical industries.
    b. To provide recommendations for the way forward in e-labelling implementation.
    c. To gather evidence to support policy decision-making on e-labelling for the Drug Control Authority (DCA).
    d. To explore the feasibility and implications of both voluntary and mandatory e-labelling implementation.
    e. To investigate the potential for expanding the scope of e-labelling to cover other groups of products.
  - PhAMA supported members participating in the Voluntary Phase (01 May 2023 to 31 December 2026). 276 products have been enrolled through PhAMA in this Voluntary Phase to-date.
  - PhAMA collaborated with the Ministry of Health (MOH) for their active participation at the APAC e-labeling Regulators' Workshop on 21st October, 2024.
- QUEST 5:
  - PhAMA had actively engaged with NPRA and other government bodies on the QUEST 5 system development for improved online registration including
    - the NPRA-Joint Industry Engagement on QUEST5 on 21 June 2024
    - the PhAMA team's efforts at the New Deal for Business (NDFB) platform, including collaboration with PEMUDAH, Ministry of Economy and the Malaysian Productivity Corporation (MPC) to push on our QUEST5 needs and address key challenges, and presenting the QUEST5 proposal to the National Economic Action Council (MTEN) under the Prime Minister
    - high-level overview engagement with stakeholders (MPC, PEMUDAH, MOPI and MAPS) on alternative options such as eCTD.
  - the Additional Product Indication workflow was successfully included in the QUEST5 development plans. (The QUEST5 project will be implemented with 2 releases where release 1 is expected to go live in early 2027 and release 2 in early 2028.)

- Track & Trace:
  - PhAMA representatives have been nominated to the Ministry of Health's committee to support the Pharmaceutical Track & Trace System (PTTS) development.

[Next plan]

- E-Labelling:
  - PhAMA will continue to collaborate with the Ministry of Health and the pharmaceutical industry on the implementation of e-labelling in Malaysia, with focus on the Voluntary Phase until 31 December 2026 and for the plans beyond.
- QUEST 5:
  - PhAMA will continue to collaborate with the NPRA on the QUEST 5 development until the system goes live (currently planned for 2027).
- Serialization/Track & Trace:
  - PhAMA will continue to collaborate with the Ministry of Health on the Pharmaceutical Track & Trace System (PTTS) implementation.

[Remarks (if any)]

The Track & Trace implementation timelines have been delayed and is now targeted for implementation in 3 years' time when the Product Tracking and Tracing System (PTTS) and stakeholders are ready. Development of a Repository for the PTTS for Registered Pharmaceutical Products will be carried out in 2025. A Pilot is then planned for mid-2026 and the PTTS will then be rolled in phases from 2027 until full implementation by 2029.

Recent regulation changes related to the focused topic

E-Labeling: Directive regarding the implementation of Electronic Labeling (e-Labelling) on pharmaceutical products in Malaysia and Guideline on Electronic Labelling (e-labelling) for Pharmaceutical Products in Malaysia.
https://www.npra.gov.my/easyarticles/images/users/1047/Lampiran-A-Guideline-on-E-Labelling-for-Pharmaceutical-Products-in-Malaysia.pdf

PHAP (Pharmaceutical and Healthcare Association of the Philippines)

Topic #2: Transparency to review policy, standards, draft regulations, guidelines, and new initiative from regulatory authority

PHAP's activities and achievements in 2024 for the focused topic

[Key Activities and Achievements]

- Pursued continued dialogue with PFDA by presenting existing challenges with proposed solutions. These dialogues were done on different platforms: from our quarterly PFDA-Industry Meetings (Kapihan at Talakayan), to APAC, to APRIA, and ASEAN
- Public posting on the PFDA website and Facebook Page of draft policies for comments, giving stakeholders 2 to 3 weeks to review
- On occasion, PFDA specifically informs PHAP of draft policies and requests for comments. Major reform was initiated in 2024 on the drug registration framework, and PHAP was able to fully participate in all public consultations called by the agency
- PFDA attended and presented during the 13th APAC

[Next plan]

- Continue working with other associations for a stronger industry position on common interests
- Continue supporting PFDA by sharing best practices

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

n/a

Topic #4: Collaborative training program

PHAP's activities and achievements in 2024 for the focused topic

[Key Activities and Achievements]

- No major development for 2024

[Next plan]

- Continue the discussion with other identified partners
- Craft an initial program proposal to PFDA for the conduct of GRM training.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

n/a

IRPMA (International Research-Based Pharmaceutical Manufacturers Association)

Topic #4: Collaborative training program

IRPMA's activities and achievements in 2024 for the focused topic
[Key Activities and Achievements]

- Assisted and collaborated with TFDA/CDE to carry out the 2024 APEC Good Registration Management workshop on September 3-5.
  - With 10 facilitators', 1 speaker, and 1 moderator's support.
  - Satisfaction survey results showed good to excellent in session 4 (Planning of Application), and session 5 (Preparation of Application Dossier).
- TFDA/CDE co-hosted the GRM workshop on November 5 in Taipei City (domestic workshop).
- E-labeling workshop on November 28: "Taiwan e-labeling strategy for digital health ~What to do now and future~.
  - The agenda included an overview of FHIR education and case studies, along with a discussion on the need for user-friendly patient labeling.
  - 80 in-person participants from the industry, TFDA, hospital users, and pharmacists.
  - Overall satisfaction survey results showed a 4.73/5 score.

[Next plan]

- Continue to collaborate with TFDA/CDE/ JPMA to carry out GRM workshops.
- Continue to promote GRM and Regulatory Convergence in Asia region.
- Continue to collaborate with TFDA to promote the e-labeling cover all products and FHIR template.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

n/a

PReMA (Pharmaceutical Research & Manufacturers Association)

Topic #3: Review process tracking system

PReMA's activities and achievements in 2024 for the focused topic

[Reasons for Topic Selection]

The Thai FDA launched the e-Tracking system, effective in January 2025, allowing health product entrepreneurs to monitor application statuses in real-time and optimize service operations.

The system simplifies the application process by providing a single-page overview of all submissions and predicting approval times, enabling better business planning for entrepreneurs.

The e-Tracking system represents a key advancement in the Thai FDA's digital services, enhancing convenience, transparency, and efficiency while ensuring consumer protection standards are upheld.

[Key Activities and Achievements]

- Continued collaboration with Thai FDA to identify challenges and gather input for the system and proposed TH FDA an e-Tracking system to streamline health product registration and monitoring.

[Next plan]

- Monitoring and Feedback Mechanism:
  - To monitor the system's performance post-launch and gather user experiences for continuous improvement.
  - Set up a task force to analyze feedback and work on refinements or adjustments to the system based on user input.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

Thai FDA Press Release, dated 2024 Dec 27: Link
https://www.fda.moph.go.th/news/25671227 (cited 2025 Feb 12)

Topic #5: Utilization of digital tools/platform for drug registration

PReMA's activities and achievements in 2024 for the focused topic

[Reasons for Topic Selection]

The Thai FDA has successfully transitioned to a 100% e-submission system during 2023-2024, marking a significant advancement in the regulatory process for drug registration. However, the current eCTD guidance requires updates to ensure it meets the evolving needs of stakeholders. Furthermore, the establishment of additional eCTD guidelines that specifically address Life Cycle Management for electronic submissions, thereby facilitating a smoother regulatory process.

[Key Activities and Achievements]

- Collaborated with the Thai FDA as part of a task force dedicated to e-submission. This partnership focused on drafting and revising the eCTD guidelines to enhance clarity and usability for pharmaceutical companies during the registration process.

[Next plan]

- Continue engagement with the Thai FDA to monitor the progress of the eCTD guideline and manual updates. This will include providing feedback based on industry experiences and challenges encountered during the submission process.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic:

n/a

Topic #6: Regulatory reliance throughout the product life cycle

PReMA's activities and achievements in 2024 for the focused topic

[Reasons for Topic Selection]

Thai FDA has announced Guideline for Application of Registration and Amendment of Modern Medicines for Human through the Referred Evaluation Results from the Collaborative Registration Procedure (CRP) in 2023. This initiative signifies a pivotal shift in regulatory practices, as the Thai FDA has adopted an electronic submission process using a reliance pathway that references assessments and approvals from Stringent Regulatory Authorities (SRA). This development aims to streamline the regulatory process, reduce redundancies, and improve access to essential medicines.

[Key Activities and Achievements]

- Collaborated with the Thai FDA to draft guidelines and manuals on the WHO Prequalification (WHO-PQ) and CRP Reliance assessments by WHO-recognized Stringent Regulatory Authorities (SRA).

[Next plan]

- The task force will continue to work with the Thai FDA to finalize guidelines for the reliance pathway submission process.
- Collaborate with Thai FDA in implementing an abbreviated review process to expedite submission timelines, while collecting industry feedback to enhance reliance submissions.
- Promote knowledge sharing and best practices among stakeholders, including industry representatives and the Thai FDA, to improve the submission process using the reliance pathway.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

n/a

Pharma Group Vietnam

Topic #3: Review process tracking system

Pharma Group Vietnam's activities and achievements in 2024 for the focused topic
[Reasons for Topic Selection]

- Continued collaboration with the DAV and review centres
- Marketing Authorizations validity tracking system is live and public

[Key Activities and Achievements]

- Continue to support drug dossiers review centers (2024 period) with dossier appraisals centers: in-kind sponsors of IT equipment and pharmacopeia access
- Advocated for the publication of Marketing authorization status to be fully online and public on DAV's website
- Provided information on public database/system showcases of advanced Health Authorities on request
- Conducted annual review timeline survey internally with members

[Next plan]

- Continue to monitor and support the smooth implementation of new legislations and operation of the submission system.
- Explore future collaboration opportunities with other agencies in and outside of Vietnam
- Look for opportunity to improve transparency of marketing authorizations via functional online registration system

[Remarks (if any)] [Remarks (if any)]
n/a

Recent regulation changes related to the focused topic

- Pharmaceutical Law No.44/2024/QH15
- Circular No. 55/2024/TT-BYT amending certain clauses in Circular 08/2022 on Drug registration

Topic #4: Collaborative training program

Pharma Group Vietnam's activities and achievements in 2024 for the focused topic

[Reasons for Topic Selection]

- Many legislation workshops conducted by authorities for industries on the new Pharmaceutical Law
- New legislations lead to training needs among industry and reviewers

[Key Activities and Achievements]

- Pharma Group is currently a standing member of 3 Circulars' Drafting Committee: Registration circular, Quality circular and Renewal circular.
- Delivered industry-centered messages at the MOH's Pharma Law revision consultation workshop, which proved PG's position as a trusted partner and reliable industry representative.
- Attended and delivered presentations on industry positions and international practice reference in 4 specialised workshops on Registration Circular amendment on CPP, Clinical data, Reliance and GMP
- Attended the 2024 WHO Asean Joint Assessment Workshop virtually
- Connect and introduce regulators to participate in international forums and workshops such as Reliance Toolkit Launch by EMA and EFPIA

[Next plan]

- Continue to monitor and support the revision of multiple key legislations in the 2025-2026 cycle to provide timely industry-centered viewpoints to the MOH and beyond.
- Strengthen existing relationships with research centers and universities
- Cultivate a new relationship with new stakeholders in other ministries

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

n/a

Topic #5: Utilization of digital tools/platform for drug registration

Pharma Group Vietnam's activities and achievements in 2024 for the focused topic
[Key Activities and Achievements]

- Online registration systems are fully functional. Companies can now submit their registration and post-marketing changes dossiers online
- Marketing authorization validity status is published online and public on DAV's website

[Next plan]

- Explore further collaboration to improve the online registration system

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

Circular No. 55/2024/TT-BYT amending certain clauses in Circular 08/2022 on Drug registration

Topic # 6: Regulatory reliance throughout the product life cycle

Pharma Group Vietnam's activities and achievements in 2024 for the focused topic

[Reasons for Topic Selection]

- Achieved goals of enabling Reliance for new marketing approval in the Pharmaceutical Law

[Key Activities and Achievements]

- Co-organised a virtual Workshop to launch CIRS RD Briefing 91 – Approaches to Implementing Regulatory Reliance: Considerations for Agencies with CIRS. Many health authorities in ASEAN, including the Vietnam's DAV, as well as industry peers also attended.
- Sent multiple letters to policy makers on the innovative industry's proposal on reliance in the Registration Circular revision
- Attend the 2024 WHO Asean Joint Assessment Workshop virtually
- Published the research paper Advancements in regulatory agility, regional collaboration, and digital transformation: insights from the Asia Partnership Conference of Pharmaceutical Associations (APAC) with APAC RA WG on the Vietname case study on Reliance and E-labeling

[Next plan]

- Continue to inform and provide information on reliance through meetings, letters, and workshops.
- Advocate for an implementable form of reliance to be included in upcoming Registration Circular revision
- Continue collaboration with international regulatory agencies and industry peers.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

Pharmaceutical Law No.44/2024/QH15

End of text