Good Registration Management
APAC Position Paper

Progress Report in 2024

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	**EUROCHAM** European Chamber of Commerce in 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 2023 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.

- Regulatory affairs representative from IPMG conducted a workshop discussing on Drug Quality Standards and Pharmacopeia Supplements with BPOM in offline manner. The workshop was in relation with BPOM regulation No.23/2022 regarding Indonesia Pharmacopeia standard implementation, and conducted on 10th of July 2023.
  - Key activities and achievement
    - In the discussion, IPMG members addressed the issue on the hurdles in the implementation of BPOM regulations 23/2022, e.g impede of renewal authorization process.
    - IPMG also emphasized its recommendation to revise BPOM regulations 23/2022 whereby to keep all pharmacopeia standard equal.
    - Regarding the pharmacopeia supplements, IPMG raised a concern of lengthy renewal process due to additional request of EG/DEG testing.
    - IPMG also underlined the issue in the EG/DEG testing due to lack of external lab capacity for the testing and the debate on the preferable method for ED/DEG testing.
    - For the second supplement of Indonesian Pharmacopeia, the Ministry of Health will provide a grace period of one year under the draft of ministerial regulations that was being formulated at the time.
- IPMG Regulatory Affairs Taskforce has launched a pilot project for e-labelling. The pilot project made a proposal approved by BPOM on the 1st of September 2023.
  - Key activities and achievement
    - Currently, IPMG is formulating the e-labelling team with the participation from several companies.
- IPMG participated in a workshop by BPOM regarding Risk Study Analysis of Elemental Impurities and Residual Solvents to Ensure the Quality of Drug Substances and Products on 14th September 2023. Furthermore, one of IPMG members also send its expert as a speaker on this workshop (Andrew Teasdale – Astrazeneca).

[Next plan]

- IPMG will conduct a training plan for e-labelling by the end of February 2024.
- IPMG will seek an opportunity to discuss further with Directorate General of Pharmaceutical and Medical Devices about the issue of prioritization of Indonesia Pharmacopeia and emphasize more on the interchangeability between Indonesian Pharmacopeia and other prominent and recognized pharmacopeia.
- Furthermore, IPMG will monitor the update on government regulations on health, particularly on the issue of Indonesian Pharmacopeia.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

1. Prioritization of Indonesian Pharmacopeia in the new Health Law 2023.

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 2023 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 2023)

  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 (May 2023)
  - ✧ The result of the annual survey on the use of review reports was shared.
  - ✧ 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 Abbreviated Review Pathway using the PMDA review report became available for new drug registration on November 16, 2023 (see Guideline for Facilitated Registration Pathway).
- As of 31 December 2023, over 360 English-translated review reports are available on the PMDA website. Approximately 30 new reports were published in 2023.

PhAMA (Pharmaceutical Association of Malaysia)

Topic #4: Collaborative Training Program

PhAMA's activities and achievements in 2023 for the focused topic

[Key Activities and Achievements]

- Activities and achievements in 2023 included the following:
  - Collaboration with NPRA on the 2023 National Regulatory Conference (NRC); PhAMA supported NPRA in organising the conference as members of the Scientific sub-committee for proposed topics and coordination of speakers.
  - A Post-NRC Sharing Session on E-labeling Interoperability was organized for the e-Labelling Committee on 19 August.

[Next plan]

a) To arrange knowledge exchange between NPRA & our SMEs on Comparability Assessment with case studies pertaining to Site specific stability requirements.
b) To arrange knowledge sharing for NPRA by our SMEs on alternatives to animal DNA testing with reference to requirements for confirmatory testing of animal DNA in biological products.
c) To collaborate with NPRA for a Workshop on Screening Rejections for industry

[Remarks (if any)]: -

n/a

Recent regulation changes related to the focused topic

#b) 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 (which has been added to the DRGD Third Edition, 5th Revision, July 2023).

Keperluan Ujian *Deoxyribonucleic Acid* (DNA) Ke Atas Produk Akhir Bagi Produk Biologik Yang Menggunakan Bahan Bersumberkan Haiwan Dalam Proses Pengilangan Produk

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

PhAMA's activities and achievements in 2023 for the focused topic

[Key Activities and Achievements]

- E-Labelling:
  - PhAMA had continued to drive the e-labelling initiative. The DCA announced the implementation of e-labelling in Malaysia in April 2023, and issued the Guideline on Electronic Labelling (e-Labelling) for Pharmaceutical Products in Malaysia. A proposed study on the effectiveness of e-Labelling implementation in Malaysia was explored, but a decision on the study is however pending.
  - PhAMA supported members participating in the Voluntary Phase which is from 01 May 2023 to 31 December 2026.
  - PhAMA collaborated with the Ministry of Health (MOH) for their active participation at the APAC e-labeling Regulators' Workshop on 20 October 2023.
- QUEST 5:
  - PhAMA pursued further with NPRA on the status of the QUEST 5 system development for improved online registration at the NPRA-PhAMA Dialogue held on 09 October. PhAMA had also highlighted on the need for NPRA to implement workaround solutions pertaining to limitations with the current Quest 3+ system until Quest 5 is launched.

[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.

  PhAMA will collaborate with MOH and Universiti Teknologi Mara (UiTM) for a study on the effectiveness of e-Labelling implementation in Malaysia.
- QUEST 5:
  With the QUEST5 project approved under the Malaysian 2024 budget recently, PhAMA will pursue further discussions with the NPRA's ICT team on the Q5 specifications etc and collaborate on its development until the system goes live in 2026-2027.
- Serialization/Track & Trace:
  PhAMA will continue to collaborate with the Ministry of Health on their implementation plan for Serialization/Track & Trace of pharmaceuticals and to provide consultation on the development of the national serialization database and other associated systems.

[Remarks (if any)]

Serialization/Track & Trace: MOH had earlier planned to hold engagements with stakeholders including the pharmaceutical industry by year end of 2023, however this was postponed.

Recent regulation changes related to the focused topic

E-Labelling: Directive regarding the implementation of Electronic Labeling (e-Labelling) on pharmaceutical products in Malaysia was issued, with the 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 2023 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
- PFDA attended and presented during the 12th 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 2022 for the focused topic

[Key Activities and Achievements]

- Identification of partner associations to conduct GRM Training
- Continuously participating in GRM trainings
- Identification of potential topics for discussion
- Initial discussion with a partner association
- Initial discussion with FDA on proposed GRM Training

[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 2023 for the focused topic

[Key Activities and Achievements]

1. APEC GRM workshop preparation.
   - Invited the facilitators and proposed the topics of Session 4 to APEC GRM WG.
   - Conducted pre-meeting with all facilitators of Sessions 4, 5-2, 6 and 7 to rehearse the meeting workflow on August 30.
2. APEC GRM workshop on September 7-8.
   - Moderated and facilitated Session 4 group discussion –Planning of application (IRPMA host).
   - Facilitated Session 5-2 group discussion – Preparation of application dossier/practice (JPMA host).
   - Facilitated Session 6 group discussion – Communications (TFDA host).
   - Facilitated Session 7 case studies – Critical thinking and regulatory decision making (CDE host).
3. TFDA/CDE co-hosted GRM workshop on November 17 in Taipei City (domestic workshop).
   - Assisted and collaborated with TFDA/CDE to carry out GRM workshop on November 17.
     - Recommended the topics for Session 2 – Good Submission Practice to CDE.
     - Invited the speakers for Session 2 to CDE on October 19.
   - Moderated the Good Submission Practice and provided 3 lectures.
     - NDA management of application and case sharing.
     - Application management of Generics and case sharing.
     - NDA application preparation and skill.
   - There were in total of 120 attendees.
   - The satisfaction survey score is 4.5 – 4.6 out of 5.

[Next plan]

1. Continue to collaborate with TFDA/CDE/ JPMA to carry out GRM workshops.
2. Continue to promote GRM and Regulatory Convergence in Asia region.

[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 2023 for the focused topic

[Reasons for Topic Selection]

Electronic submission has been mandatory for new drug , biologic product and generic drug registration in June 23, 2023. All applications must be in eCTD or NeeS format. Tracking system is initiated by having email acknowledgement receipt for submission and progress to each step by Thai FDA.

[Key Activities and Achievements]

- Work with Thai FDA as a task force on e-submission and harmonize regulation and process /operation between Division of Innovative Health Products and Services and Medicines Regulation Division.

[Next plan]

- Continue working with Thai FDA as task force on e-submission.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

Notification of Thai FDA : June 23, 2023 – Consideration Guidelines for Modern Drug Registratted Submission Electronically.

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

PReMA's activities and achievements in 2023 for the focused topic

[Reasons for Topic Selection]

Medicines Regulation Division, Thai FDA has streamlined registration processes includes transitioning to 100% electronic submission and incorporating the Thai Rims (NeeS) platform which is make collaboration between regulatory authorities and industry more efficiency.

[Key Activities and Achievements]

- Assist Thai FDA in training the digital tools/platform for other entrepreneurs in the industry.
- Give feedbacks/recommendations to develop the system for the smooth transition from paper-based to electronic system.

[Next plan]

- Continues in working on eCTD manual update and giving feedback

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic:

Notification of Thai FDA : June 23, 2023 – Consideration Guidelines for Modern Drug Registratted Submission Electronically.

Topic #6: Regulatory reliance throughout the product life cycle

PReMA's activities and achievements in 2023 for the focused topic

[Reasons for Topic Selection]

Medicines Regulation Division, 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).

[Key Activities and Achievements]

- Work with Thai FDA as a task force on Collaraborative Registration Procedure (CRP).

[Next plan]

- Working with Thai FDA to issue the guideline/manual on WHO-PQ and WHO SRA CRP .
- Working with Thai FDA on the abbreviated review (abridged assessment) to expedite the review timeline and gather feedback from the industries.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

Notification of Thai FDA : February 3, 2023 – Guideline for Application of Registration and Amendment of Modern Medicines for Human through the Referred Evaluation Results from the Collaborative Registration Procedure (CRP).

Notification of Thai FDA : September 28, 2023 – Guidelines for Drug Registration Amendment (Grouping of variations).

EUROCHAM (European Chamber of Commerce in Vietnam)

Topic #3: Review process tracking system

EUROCHAM 's activities and achievements in 2023 for the focused topic

[Reasons for Topic Selection]

- **Continued collaboration with the DAV and review centres**

[Key Activities and Achievements]

- Seek to increase the capacity of review centers: completed MOUs and sponsorship commitments (2022-2023 period) with dossier appraisals centers: in-kind sponsors of IT equipment and pharmacopeia access.

[Next plan]

- Continues to monitor and support the smooth implementation of new legislations and operation of the submission system.
- Engage with the DAV-MOH in implementing online registration phase by phase.
- Organize training sessions/system showcases with advanced Health Authorities on request.
- Explore future collaboration opportunities with other agencies, such as the ADR centres

[Remarks (if any)] [Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

n/a

Topic #4: Collaborative training program

EUROCHAM's activities and achievements in 2023 for the focused topic

[Reasons for Topic Selection]

- **New legislation workshops conducted by authorities for industries**
- **Many cross-ministerial forums organised**

[Key Activities and Achievements]

- Sponsored and attended multiple MOH's workshops on health financing, patient support programs, tech transfers, new Labeling circular, new Decree guiding the current Pharma Law as well as Pharma Law revision, etc.
- Attended and sponsored university-led and research-led scientific workshops, such as the AFPS Conference.
- Delivered an industry-centered presentation at the MOH's Pharma Law revision workshop and Industry Dialogue forum, which proved PG's position as a trusted partner and reliable industry representative.
- Organised the E-labeling and Serialisation Workshop(hybrid), which attracted participation of the MOH, MOST and over 200 participants from both local companies and MNCs.

[Next plan]

- Continue to monitor and support the revision of multiple key legislations in the 2024-2025 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

EUROCHAM's activities and achievements in 2023 for the focused topic

[Key Activities and Achievements]

-

[Next plan]

-

[Remarks (if any)]

Online registration systems are under construction right now

Recent regulation changes related to the focused topic

n/a

Topic # 6: Regulatory reliance throughout the product life cycle

EUROCHAM's activities and achievements in 2023 for the focused topic

[Reasons for Topic Selection]

- Advocacy for reliance becomes a priority during the course of the Pharma Law

[Key Activities and Achievements]

- Organised the Reliance and Recognition in Drug Registration in November, which attracts high-level participation from the National Assembly, Office of Government, MOST, MOJ and MOH as well as WHO, review centres and universities. Many NRAs in the world also participated: TGA, NPRA, ANVISA, EMA. More than 600 pariticipants joined the workshop on-site and online.
- An independent study from CIRS on reliance (supported by Pharma Group), focusing on Approaches to implementing reliance to support the implementation of reliance by the DAV-MOH, has been completed and will be launched in early 2024.
- Sent multiple letters to policy makers on the innovative industry's proposal on reliance in the Pharma Law revision.
- Attended the WHO ASEAN CRP Workshop in Manilla
- Collaborated 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 legislation revision.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

n/a

End of text