Good Registration Management
APAC Position Paper

Progress Report in 2023

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 based 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

[Reasons for Topic Selection]

Similar perception between applicant and health authority in the drug registration evaluation referring to the drug registration guideline is important in order registration process for the product. Therefore, the collaborative training in the Good Registration Management (GRM) is one of the key activities to obtain smooth approval of the product registration, and accelerate patients access to the product.

IPMG's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

- Members of IPMG and representatives from Indonesia FDA (BPOM) joined Good Registration Management Training conducted by CoE in Taipei via online due to COVID pandemic. The training was conducted on September 13th 2022.
- Key activities and achievement
    - The members of IPMG who join the GRM training in Taipei has shared the training experiences to 100 IPRG members. This was enriching the capability of IPMG members on the Good Registration Management to maintain right first time for the registration submission. The meeting was held in December 2022.
    - IPMG contributed to the review process by submitting input and comments to the several regulations issued by BPOM, eg. 2D Barcode /Serialization regulation revision, Bioequivalence regulation, etc.
    - IPMG initiated e-labelling, orphan drug, real world evidence (RWE) to be regulated in Indonesia. Sharing information with SME for e-labelling has been conducted for e-labelling task force in IPMG.

[Next plan]

- IPMG contributed in the review process by submitting input and comments to the drug registration guideline revision No, 24/2017
- Continuing Good Registration Management training for IPMG members in collaboration with APAC, HA, others stakeholders by Q4 2023
- E-labelling training for IPMG, HA and others stakeholders by Q3 2023

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

1. Emergency Use Authorization (EUA) year 2022
2. 2D Barcode / serialization guideline revision no. 33 year 2018
3. Input & Draft revision on Indonesia Drug Registration Guideline No 24 year 2017

JPMA (Japan Pharmaceutical Manufacturers Association)

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

[Reasons for Topic Selection]

Review reports are an important tool for improving the transparency of regulator's assessment and decision-making. It is expected that the publication of review reports will help to improve mutual trust and understanding between regulators and increase opportunities for collaboration with other regulators in the review of new drugs. JPMA has therefore decided to focus on this topic to promote the use of PMDA review reports for new drug registrations in Asia.

JPMA's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

- Annual survey on the use of review reports (April 2022)
  - The purposes of the survey were
    - To know how many times English translations of PMDA review reports were used for new drug registrations in Asia in 2021.
    - To identify important factors in promoting the use of PMDA review reports in new drug registrations in Asia from an industry perspective.
  - Over 30 JPMA member companies responded. The number of times review report were used was similar to previous years.
- Meetings with PMDA (July and September 2022)
  - The result of the annual survey on the use of review reports was shared.
  - The further use of review reports was discussed. In particular, discussions were held on how PMDA confirms English translations of masked portions of a review report.

[Next plan]

- To conduct an annual survey on the use of review reports.
- To have meetings with PMDA to discuss how to promote the use of PMDA review reports for new drug registrations in Asia.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

- Food and Drug Administration Philippines announced in June 2022 that the Abridged and Verification Review Pathway using the PMDA review report can be applied in the registration of a new drug (https://www.fda.gov.ph/wp-content/uploads/2022/06/FDA-Circular-No.2022-004.pdf).
- As of 31 December 2022, over 330 English-translated review reports are available on the PMDA website (https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html). Approximately 30 new reports were published in 2022.

PhAMA (Pharmaceutical Association of Malaysia)

Topic #4: Collaborative Training Program

[Reasons for Topic Selection]

To facilitate collaborative training program and workshop between the Malaysian regulatory authority and industry. There is a need to continue this collaborative training program as part of shaping new policies, new innovations coming our way including RWE/RWD etc.

PhAMA's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

- Collaborative training programs held in 2022 included the following:
  - Real World Evidence/Data Webinar, 21-22 Feb 2022
  - Seminar on Regulatory Control of API (Active Pharmaceutical Ingredients), 24 May 2022
  - Sharing session on 'Optimizing Usage of Comparability Assessment' with NPRA, 13 Sept 2022
  - Webinar on ICH Q12 – PACMP: Way Forward for Post-Approval Change Management Optimization, 21-22 Sept 2022
  - Webinar on Impurities in Pharmaceutical Products, 4-5 Oct 2022

[Next plan]

- Collaboration with NPRA on the 2023 National Regulatory Conference.
- The NPRA-PhAMA Dialogue held on 25th November included discussions on topics for future collaborative training programs. The proposed training/sharing activities include the following:
  - RWE/D focused topics
  - Comparability Assessment topics: CQA (Critical Quality Attributes), CPP (Critical Process Parameters)
  - Conditional Registration Pathway using Reliance (experience sharing from other countries in evaluating CR)

[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

[Reasons for Topic Selection]

To facilitate utilization of digital tools/platform for drug registration. E-labelling, Serialization/Track & Trace and the improved QUEST 5 online registration system are important topics in Malaysia currently.

PhAMA's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

- E-Labelling: PhAMA had initiated a proposal for implementation of e-labelling in Malaysia through discussions with a Joint industry group and obtained consensus from the Ministry of Health to work with the industry for its implementation with a pilot project planned for 2023.
  Collaborated with NPRA for active participation at the APAC Regulators Workshop (29 Nov 2022).
- Serialization/Track & Trace: We have followed up with the Ministry of Health in their development of the implementation plan for Serialization/Track & Trace of pharmaceuticals. A circular was issued in July 2022 with details on the MOH implementation of a pilot project for Pharmaceutical Track & Trace. A webinar on serialization was hosted by the APEC Centre of Excellence for Supply Chain (Taylor's University) involving members from all industries in August 2022.
- QUEST 5: Followed up with NPRA on the developments of the QUEST 5 system for improved online registration. At the NPRA-PhAMA Dialogue held on 25th November PhAMA had highlighted on the need to invest in an online platform that is more flexible and does not limit the number or type of regulatory applications e.g., parallel/bundling of new indications, parallel submission of variations and submission of multi-site registration in one product license.

[Next plan]

- PhAMA will continue to collaborate with the Ministry of Health and the pharmaceutical industry to conduct the e-labelling pilot project in 2023 and pursue further on its implementation in Malaysia.
- 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.
- PhAMA will compile our Quest 5 wish list and submit to NPRA for reference /cross-checking, and will pursue further with NPRA on its development until the system goes live in 2026-2027.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

n/a

PHAP (Pharmaceutical and Healthcare Association of the Philippines)

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

[Reasons for Topic Selection]

Philippine FDA is in the midst of instituting major regulatory reforms for drug registration. Ensuring transparency will ensure that the process take into consideration the inputs from all sectors, including the pharmaceutical industry.

PHAP's activities and achievements in 2022 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
- PFDA presentation of target policies/ reforms
- 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

[Next plan]

- Closer collaboration/alignment with other associations for a stronger position
- Continue supporting PFDA on their current practices
- Ask for PFDA's feedback on PHAP's comments/ suggestions

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

n/a

Topic #4: Collaborative training program

[Reasons for Topic Selection]

One of PHAP's intended activities is the conduct of joint Good Review Management Training with PFDA. PHAP also intends to provide additional training programs for PFDA on relatively new regulatory topics.

PHAP's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

- Identification of partner associations to conduct GRM Training
- Identification of potential topics for discussion
- Initial discussion with a partner association

[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

[Reasons for Topic Selection]

Taiwan FDA has conducts GRM training for improving good registration management, enhancing regulatory cooperation, capacity building, and regulatory harmonization among APEC economies for years. IRPMA co-organized the events and would to share the outcome for this topic.

IRPMA's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

IRPMA assisted Taiwan FDA/ CDE/ Academia Sinica/ RAPs Taiwan to hold two GRM Workshops on August 29th and November 29th.

「2022 APEC GRM CoE Workshop 」invited 19 experts and scholars to serve as keynote speakers or topic moderators, recruiting a total of 104 trainees from 12 different countries.

Another domestic GRM workshop invited 9 experts and scholars to serve as keynote speakers or topic moderators, recruiting a total of 454 trainees.

[Next plan]

Continue to hold GRM training, so that Taiwan can contribute to the promotion of good registration management and the promotion of international legal harmonization in the Asia-Pacific region. The Taiwan Food and Drug Administration will design the 2023 GRM training course based on the satisfaction survey results after the 2022 course and the topics that participants may be interested in.

[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

[Reasons for Topic Selection]

E-submission (ICH eCTD format) has been mandatory for new drug and biologic product registration since 2016 but has not been implemented for generic drug registration under Medicines Regulation Division (MRD)

PReMA's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

Work with Medicines Regulation Division as a task force on e-submission

[Next plan]

Harmonize the regulations between Division of Innovative Health Products and Services and Medicines Regulation Division

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic:

Starting on Feb 15, 2023 all submissions will be Non eCTD electronic Submission (NeeS) or eCTD

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

[Reasons for Topic Selection]

MRD acknowledged the important of digital technology. A secure shared solution could facilitate valuable collaboration between regulatory authorities and industry to maximize their resources and enhance efficiency.

PReMA's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

- Work with Medicines Regulation Division as a task force.
- Work with IT Department of Thai FDA to help understand pain points and find solutions/recommendations.

[Next plan]

- 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.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic:

Starting on Feb 15, 2023 the following application will be online

- Advertising to HCP
- Sample import permit

Topic #6: Regulatory reliance throughout the product life cycle

[Reasons for Topic Selection]

MRD has abridged assessment but the conditions for this route must be identical with SRA which industry cannot apply abridged assessment**.**

PReMA's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

- Sent official letter to MRD on suggestion using reliance pathway.
- Arranged workshop/meeting with Thai FDA on sharing knowledge on reliance pathway.

[Next plan]

Explore the abbreviated review and expedite the review and gather feedback from the industries.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic:

MRD aligned with HPI announced the regulatory reliance pathway.

Abbreviated review

Abridged assessment
- Need unredacted assessment report from SRA
- May be changed to full assessment
- Collaboration with Pharmaceuticals and Medical Devices Agency (PMDA)

Reliance assessment
- WHO Pre-Qualification program (PQ)
- Collaborative Registration Procedure with Stringent Regulatory Authorities (SRA CRP)

Expedited review

Accelerated review
- Health needs & urgent
- Serious disease
- Appropriate surrogate marker

Fast track review
- Health needs & urgent
- Consultation program

Priority review
- Health needs & urgent
- Serious disease
- Thai FDA Priority list
- Orphan
- Shortage

EUROCHAM (European Chamber of Commerce in Vietnam)

Topic #3: Review process tracking system

[Reasons for Topic Selection]

- New projects initiated between regulators and local tech companies
- New dialogue channel established between authorities

EUROCHAM's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

- Coordinated IT workshops and communications between MOH-DAV and PMDA Japan.
- Coordinated between Viettel (local tech companies) and the MOH-DAV in designing and building the infrastructure for the online review system.
- Seek to increase the capacity of review centers: signed MOUs with dossier appraisals centers: in-kind sponsors of IT equipment and pharmacopeia access.
- PG Regulatory WG proposed an alert system for overdue dossiers

[Next plan]

- Continues to monitor and support the smooth implementation of new legislations
- Engage with the DAV-MOH in implementing online registration phase by phase
- Organize training sessions/system showcases with advanced Health Authorities on request.

[Remarks (if any)]

n/a

Recent regulation changes related to the focused topic

n/a

Topic #4: Collaborative training program

[Reasons for Topic Selection]

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

EUROCHAM's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

- Sponsored and attended MOH's workshops on the new registration circular 08/2022, health financing, e-registration, price control, patient support programs, tech transfers, etc.
- Attended and sponsored university-led and research-led workshops on e-registration, drug naming, health insurance, drug shortage, IPP listing, etc.
- Delivered an industry-centered presentation at the MOH's 5-year of implementation of Pharma Law conference, which proved PG's position as a trusted partner and reliable industry representative

[Next plan]

- Continue to monitor and support the revision of multiple key legislations in the 2023-2024 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

[Reasons for Topic Selection]

n/a

EUROCHAM's activities and achievements in 2022 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

[Reasons for Topic Selection]

- Advocacy for reliance gaining momentum

EUROCHAM's activities and achievements in 2022 for the focused topic

[Key Activities and Achievements]

- An independent study from CIRS on reliance (commissioned by Pharma Group), focusing on Approaches to implementing reliance to support the implementation of reliance by the DAV-MOH, is currently underway.
- Sent a letter briefing the National Assembly on reliance
- DAV-MOH attended the 10th WHO meeting on CRP
- Initiated a preliminary meeting with the TGA on reliance implementation in developing economies

[Next plan]

- Continue to brief key stakeholders on reliance through meetings, letters, and workshops
- Organise reliance-centered workshops led by independent experts or advanced health authorities
- Advocate for a preliminary 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