APAC
Asia Partnership Conference of Pharmaceutical Associations

# APAC Position Paper

# Final Progress Report (April 2015 - March 2021)

APAC RA-EWG

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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 (https://apac-asia.com/images/ra/pdf/pillar4/apac_position_paper.pdf), which was generated by RA-EWG and endorsed at the 4th APAC convention in April 2015, provides the five high level suggestions and proposals to the regulatory authorities from the viewpoint of industry. By facilitating close communication and collaboration between industry and the regulatory authorities based on APAC Position Paper, it is expected to improve regulatory environment and facilitate the regulatory convergence and work sharing of drug review in Asia.

APAC Position Paper covers 5 topics, (1) consultation, (2) transparency, (3) tracking system, (4) collaborative training, and (5) review report in English, which are selected as important area for refining existing drug registration process throughout 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: Generation of review report in English**

APAC member associations have picked up topics of focus in their economy for further discussion with their authority (**Table**, *see next page*).

For the 10th APAC, this final progress report summarizes the improvement on the focused topic(s) since April 2015 from APAC member associations' perspective.

## Table Focused Topics by each association in their economy

| | | |
|---|---|---|
| China | **RDPAC**<br>R&D-based Pharmaceutical Association in China | *None* |
| Hong Kong | **HKAPI**<br>The Hong Kong Association of the Pharmaceutical Industry | **#4** |
| India | **OPPI**<br>Organization of Pharmaceutical Producers of India | *None* |
| Indonesia | **IPMG**<br>International Pharmaceutical Manufacturers Group | **#4** |
| Japan | **JPMA**<br>Japan Pharmaceutical Manufacturers Association | **#5** |
| Korea | **KPBMA**<br>Korea Pharmaceutical and Bio-Pharma Manufacturers Association | *None* |
| Korea | **KRPIA**<br>Korean Research-based Pharmaceutical Industry Association | **#1, #2** |
| Malaysia | **PhAMA**<br>Pharmaceutical Association of Malaysia | **#3, #4** |
| Philippines | **PHAP**<br>The Pharmaceutical and Healthcare Association of the Philippines | **#2, #3** |
| Singapore | **SAPI**<br>Singapore Association of Pharmaceutical Industries | **#4** |
| Taiwan | **IRPMA**<br>International Research-Based Pharmaceutical Manufacturers Association | **#4** |
| Thailand | **PReMA**<br>The Pharmaceutical Research and Manufacturers Association | **#2, #3, #4** |
| Vietnam | **EUROCHAM**<br>European Chamber of Commerce in Vietnam | *None* |

# FINAL PROGRESS REPORT ON FOCUSED TOPIC(S)

## HKAPI (The Hong Kong Association of the Pharmaceutical Industry)

**Focused topic**

Topic #4: Collaborative training program

**Status as of April 2015**

- A workshop for understanding the new regulatory changes – from Chapter 138 to Hong Kong guide of Secondary Package had been held on 13 February 2015.
- 109 participants from 38 pharmaceutical companies attended the workshop. They had a better understanding on the new regulatory framework launched in 2015.

**Status as of March 2021**

- Coordinating with Department of Health on the training programmes of new regulatory framework.

**Key activities and achievement**

- "Regulatory Training Programme: Getting to be Competent Regulatory Affairs Professionals" had been organized jointly with the University of Hong Kong from 2016 to 2018. A programme with 8 modules to holistically present the regulatory issues in Hong Kong from the perspective of product life cycle, with case study for workshop after lectures. Good submission practice is part of course module. Other pharmaceutical associations and pharmacy students were invited to join. Around 150 attendees for every lecture.
- Joint seminar with Department of Health on 14 December 2018. HKAPI engaged the Department of Health to expedite drug registration timeline within the system and providing training for good submission practice.
- Two workshops on "Product Life Cycle Management from Regulatory Perspective and Best Practice" and "New Product Submission & Best Practices" were held on 17 October and 18 December 2019 respectively. The officers from Department of Health briefed the updated Change of Registered Particulars guidelines, new product submission and the implementation.
- Seminar on newly enacted law on Advance Therapies Product was briefed by Department of Health to members to ensure they understand the law and the registration procedure.

**Future plan (if any)**

- Continue to collaborate with our regulatory authority on good submission practice.

# IPMG (International Pharmaceutical Manufacturers Group)

**Focused topic**

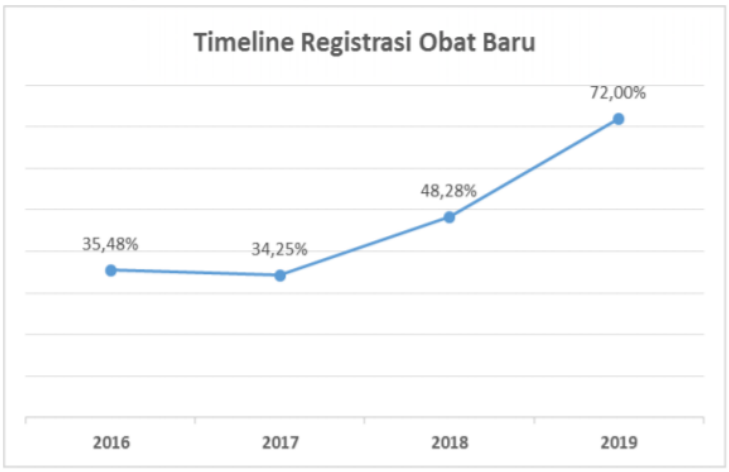
Topic #4: Collaborative Training Program

**Status as of April 2015**

- Introduction of Good Submission Practices on Dec 15th, 2015. Total participants were 248 participants. 29 foreign company with 54 participants, 114 local company with 194 participants.

**Status as of March 2021**

- Implementation of simplification registration, electronic system, Good Submission Practices and Good Review Practices seems becoming factors of improving fulfillment of on-time registration evaluation timeline for new drug by the National Agency of Drug and Food Control of the Republic of Indonesia (BPOM) from 2016-2019.




**Gambar 13. Trend pemenuhan timeline Registrasi Baru Obat Baru**

*Source: annual report, Directorate of Registration, BPOM 2019 (www.pom.go.id)*

- IPMG collaboration with the National Agency of Drug and Food Control of the Republic of Indonesia (BPOM) is ongoing by giving input on the development, revision of related regulations in Indonesia by public announcement/socialization, public consultation and email communication.

**Key activities and achievement**

- Collaborative Training Program on Good Submission Practices as well as Good Review Practices were held by the National Agency of Drug and Food Control of Republic of Indonesia (BPOM) and IPMG, for example:
    - Good Registration Management Workshop on August 28th -29th 2019 with 170 participants from local agency officials, multinational and also local companies

- Good Submission Practices with focus on Quality of Clinical Documentation training on Nov 29th, 2017 for local and pharmaceutical companies.

- IPMG contributed in the review process by submitting input and comments to the drug registration draft No, 24/2017 and also for the introduction and implementation of reliance registration pathway and reference countries in the Indonesia drug registration guideline No15/ 2019. Reference countries are EU, US, Australia, England and Japan.
- Members of IPMG joined APEC Good Registration Management Workshop conducted by CoE in Taipei since 2016-2019.

**Future plan (if any)**

- To continue conducting Good Registration Management Workshop to align with the development of drug registration guideline in Indonesia. Due to COVID pandemic situation, details are not determined yet.

## JPMA (Japan Pharmaceutical Manufacturers Association)

**Focused topic**

Topic #5: Facilitating generation of review report in English

**Status as of April 2015**

- About 80 review reports in English were available at PMDA Website.

**Status as of March 2021**

- Over 270 review reports in English are available at PMDA Website, totally.
- PMDA has released about 40 new review reports in English every year in past few years.

**Key activities and achievement**

- Twice questionnaires within JPMA for gap analysis on this topic (2016 and 2018).
- Annual survey within JPMA to know how many times English-translated PMDA review reports were utilized for Asian new drug registration (since 2019). These survey results confirm that English-translated PMDA review report, including applicant's translations, has been utilized for Asian new drug registration at least 26 times for 3 years.
- Multiple dialogues with PMDA to share the results of the questionnaires and the surveys and to let PMDA know industry's request regarding review report in English.

**Future plan (if any)**

- Continuous survey on the use of review report in English and continuous discussion with PMDA to promote the utilization of review report in English for accelerating review process in Asian regulatory authorities.

## KRPIA (Korean Research-based Pharmaceutical Industry Association)

**Focused topic**

Topic #1: **Structured framework of regulatory consultation system**

**Status as of April 2015**

- KRPIA has raised the issue to maximize of supporting regulatory consultation at the discussion table between MFDS and industry such as, MFDS-industry CEO meeting session, DG meeting, etc.

**Status as of March 2021**

- MFDS introduced pre-review system for biologics in Jun 2017 to improve review efficacy and consistency by checking requirement fulfillment on dossier submitted by a company prior to formal review.
- In addition, MFDS implemented e-record system to align the consultation result with formal review process.
- MFDS composed the dedicated department for implementation of pre-review system for pharmaceuticals in 2020.

**Key activities and achievement**

- Continuously delivered the industry position thru various communication channels. (e.g. MFDS-Industry TFs, submission of industry position paper, etc.)
- Based on the opinions they got from the above process, MFDS finally established the dedicated department for implementation of pre-review system.

**Future plan (if any)**

- N/A

## KRPIA (Korean Research-based Pharmaceutical Industry Association)

**Focused topic**

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

**Status as of April 2015**

- MFDS announced the draft on orphan drug related regulations on Feb 5, 2016. However, draft regulations do not reflect clear and robust procedures and requirements on fast track registration (or registration) of orphan drug. Thus, after KRPIA corrected the comments and suggestions from industry during the public period and submit the suggestions to MFDS.

**Status as of March 2021**

- MFDS has improved the process to increase transparency for revision of policy, standards, draft regulations, guidelines and new initiative from regulatory authority.
- MFDS develops the draft regulation or draft guidelines through active discussion in MFDS-industry TF team.
- Prior to implementing final legislation, MFDS performs pre-announcement of legislation and listens to the variety public opinions from civic group, relevant industry association and academia etc. In addition, they convene the public meetings that provide opportunity for industry and the entire public to have clear understanding about the topics on agenda and provide input.

**Key activities and achievement**

- Continuously delivered the industry position thru various communication channels. (e.g. MFDS-Industry TFs, submission of industry position paper, etc.)
- Based on the opinions they got from the above process, they finalize the regulations and guidelines. Even after announcement of final regulations, MFDS issues the detailed guideline or Q&A manual to increase the understanding on the relevant regulations.

**Future plan (if any)**

- N/A

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## PhAMA (Pharmaceutical Association of Malaysia)

**Focused topic**

Topic #3: Review process tracking system

**Status as of April 2015**

- There was no official review process tracking system. However, Review Timelines were provided for specified applications, e.g. New Drugs & Biologicals, Prescription Drugs & Non-Prescription Drugs, Licenses and Certificates, and for some Variations.

**Status as of March 2021**

- The QUEST3+ system has been implemented in January 2017, and a timeline function has been built into the system. There are registration milestones in the system (eg for screening, query and approval steps).
- The system is being reviewed for further improvement. (Options including eCTD are being explored.)

**Key activities and achievement**

- PhAMA submitted the request for an improved Review process tracking system to our regulatory authority (NPRA) on 18 June 2015, and at the Dialogue session on 30 June 2015, NPRA advised that registration milestones will be set into the new QUEST3+ system, and it was implemented in January 2017.
- PhAMA had proposed to the Ministry of Health in 2019 for further improvements and to explore eCTD as a potential innovative digital platform for local regulatory submissions, with follow-up discussions with NPRA in 2020.

**Future plan (if any)**

- Will continue to collaborate with our regulatory authority to facilitate on transparency where deemed necessary and appropriate.

  For example, continue provide feedback and suggestions for Quest system enhancement and seek educational platforms to share innovative systems to regulatory authority.

## PhAMA (Pharmaceutical Association of Malaysia)

**Focused topic**

Topic #4: Collaborative training program

**Status as of April 2015**

- Our regulatory authority (NPRA) has been providing collaborative training and agreeable to more training programs for industry with focus on new regulatory issues.

**Status as of March 2021**

- Several collaborative training programs were held including;
  - CGTP and Biotherapeutics Talk, 01 April 2015
  - Challenges & Issues with Registration & Variations, 09-10 March 2016
  - Introduction to Regulation of Pharmaceuticals, 31 Oct – 01 Nov 2016
  - Introduction & Best Practices on Pharmacovigilance and eCTD, 18 Sept, 2017
  - QUEST3+, 03 Oct, 2017
  - API Requirements, 04 Oct, 2017
  - Regulatory Training Course on ASEAN CTD (ACTD), 15-17 Nov 2017
  - Workshop on Good Submission Practice (GSubP), 04-05 July 2018
  - Biological Products and Their Regulatory Control, 12-13 Nov2018
  - Training Seminar on ICH Stability Guidelines (ICH-Q1) 6-8 August 2019
  - GRM Workshop for Industry 2019, 01-02 October 2019

**Key activities and achievement**

- PhAMA submitted the request for more collaborative training programs to NPRA on 18 June 2015, and at the Dialogue session on 30 June 2015, NPRA advised that they will continue training on new guidelines and policy prior to implementation.
- In 2015 PhAMA led a Joint Industry Working Group with related associations to discuss common issues including training proposals. Since then, PhAMA played an active role in driving a Regulatory Training Focus Group to develop a more structured training program for regulatory professionals in collaboration with Taylor's University and NPRA, as well as organizing collaborative programs to meet the training needs of PhAMA members and the pharmaceutical industry.

**Future plan (if any)**

- We will work on other future training programs in collaboration with regulators and other stakeholders as the need arise.

  For example, to consider clinical-related topics such as use of Real World Evidence for regulatory decision-making in additional to quality-related topics

## PHAP (The Pharmaceutical and Healthcare Association of the Philippines)

**Focused topic**

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

**Status as of April 2015**

- FDA launched a new website containing information on regulatory guidelines, draft policies, and portal for certain regulatory transactions and consumer reporting. Presentations and minutes of public consultations are also published in this website.
- Medium and long-term policy planning is operationally challenging for FDA due to the quick change in management (usually 1 to 2 years only).

**Status as of March 2021**

- FDA relaunched its FDA website, slowly transitioning from the old website.
- Notices for draft policies, comments and public consultation is released through FDA Facebook Page. The Facebook page is able to reach a wider audience.
- Public consultation is limited to online platforms and submission of comments.
- No concrete medium and long-term policy plan made public yet.

**Key activities and achievement**

- PHAP continues to advocate for good regulatory practice, especially on policy making/standards development. A number of position papers were communicated to the FDA on this. PHAP also asked for long-term plans of the FDA.
- FDA resumed the conduct of the FDA-Industry dialogue last September 2020. This dialogue aims to present policy proposals and solicit comments from industry.

**Future plan (if any)**

- PHAP will continue its advocacy for a regular FDA-Industry dialogue (quarterly). PHAP aim to re-establish the FDA-Industry Technical Working Group, a group that will tackle policy/regulatory reforms.

# PHAP (The Pharmaceutical and Healthcare Association of the Philippines)

**Focused topic**

**Topic #3: Review process tracking system**

**Status as of April 2015**

- FDA has a published processing timeline for all regulatory processes, identifying each step, person responsible, requirements, and processing time per step. However, FDA is not able to meet these timelines, resulting to delays.
- FDA launched its document tracking system (DTS) to allow clients to monitor the progress of applications.

**Status as of March 2021**

- FDA is reviewing its processing timelines to be more realistic and to comply with newly enacted laws that require facilitated processing for certain applications.
- ARTA, a government regulatory agency tasked with streamlining government processes, is working with FDA to ensure that its processes are transparent, streamlined, and consistent.
- FDA instituted changes in its electronic platform for certain regulatory transactions. It is expected that the registration platform, which is currently semi-online, will transition to full online. This will also result in changing the current tracking system.

**Key activities and achievement**

- PHAP continues to advocate for regulatory reforms, ensuring transparency of regulatory processes.
- FDA is slowly shifting to full-online submission, online payment, and online release of authorizations.

**Future plan (if any)**

- PHAP will continue its advocacy for a fully-online application platform, and the introduction of alternative registration schemes.

  PHAP will work with FDA and ARTA to ensure that innovative products are facilitated and reflected in a revised processing timeline.

## SAPI (Singapore Association of Pharmaceutical Industries)

**Focused topic**

Topic #4: Collaborative training program

**Status as of April 2015**

- SAPI RAC discussed with Singapore HSA in 2016 to collaborate in training for industry members. Singapore HSA agreed to have the join collaboration in the training and would target training in 2017 in 2nd Quarter.

**Status as of March 2021**

- SAPI will continue to collaborate with HSA on future collaborative training opportunities.

**Key activities and achievement**

- SAPI RAC has set up working group in 4th Quarter 2016 to plan for the training programme with Singapore HSA for the joint training. SAPI conducted the Good Submission Practice workshop with HSA participation on 12-13 April 2017.

**Future plan (if any)**

- N/A

## IRPMA (International Research-Based Pharmaceutical Manufacturers Association)

**Focused topic**

Topic #4: Collaborative training program

**Status as of April 2015**

- Good Submission Practice concept communicate to the industry.

**Status as of March 2021**

- In the past years, Health Authority and the industry has been putting more and more efforts into elevating GRM awareness and improving submission quality. Several international conference and internal training courses were taken place. IRPMA will co-work with TFDA to organize GRM workshop in the way of providing facilitators & lecturers.

**Key activities and achievement**

- Assisted and collaborated with TFDA/ CDE/ Academia Sinica/ RAPs Taiwan to carry out GRM workshop on Aug 29 & Nov 19, 2020.
- For domestic workshop training workshops, there were more than 360 participants in total.

**Future plan (if any)**

- Collaborate with TFDA/ RAPs Taiwan/ JPMA to carry out GRM CoE workshop
- IRPMA lectures/ trainers to support local industry's GRM workshop

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# PReMA (Pharmaceutical Research & Manufacturers Association)

**Focused topic**

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

**Status as of April 2015**

- The idea of National Institute for Health Product Assessment was proposed but finally flopped as the government did not want to create another public organization.

**Status as of March 2021**

- Due to the feedback through Public Facilitation Act, where the performance of all government agencies must be reported, the Government agreed to issue special law requiring FDA to reform for all their licensing service processes and also allow the FDA to collect fee for health product assessment.
- PReMA has worked with professional associations and Thai FDA to improve drug registration processes and review fees, according to the order of the Head of the National Council for Peace and Order No. 77/2559 regarding the enhancing of health products registration process. PReMA was appointed as a subcommittee to work in detail on the said process.

**Key activities and achievement**

- Participating in the meeting with Thai FDA as a member of subcommittee with the results of the Public Manual, related ministerial regulations and notifications.

**Future plan (if any)**

- Cooperate with Thai FDA on new regulations on Drug Act (no. 6) B.E. 2019: the certificate of drug formula registration shall be valid for seven years from the date it was issued. The certificate of drug formula registration issued under the Drug Act 1967 before this Act come into force shall be valid as follows:
  (1) The registration certificate registered before 1 January 1997 shall expire upon completion of 5 years from the date this Act come into force.
  (2) The registration certificate registered between 1 January 1997 to 31 December 2007 shall expire upon completion of 7 years from the date this Act come into force.
  (3) The registration certificate registered after 1 January 2008 shall expire upon completion of 9 years from the date this Act come into force.

## PReMA (Pharmaceutical Research & Manufacturers Association)

**Focused topic**

Topic #3: Review process tracking system

**Status as of April 2015**

- E-submission was introduced.

**Status as of March 2021**

- E-submission (ICH e-CTD format) has been mandatory for new drug and biologic product registration since 2016. Now Thai FDA would like to expand to all applications by the end of 2021.

**Key activities and achievement**

- Work with Medicines Regulation Division as a taskforce on e-submission.

**Future plan (if any)**

- Continue working with Thai FDA on e-submission to make sure that the e-submission of all applications implemented smoothly.

## PReMA (Pharmaceutical Research & Manufacturers Association)

**Focused topic**

Topic #4: Collaborative training program

**Status as of April 2015**

- Information sharing on Good Submission Practice Concept.

**Status as of March 2021**

- Thai FDA has been endorsed as a formal APEC GRM CoE by RHSC in June 2020.

**Key activities and achievement**

- The first Good Registration Management (GRM) Conference in Thailand align with APEC CoE for GRM TTT and APAC Regulatory Affairs Executive Working Group strategic plan was conducted on Public-Private Collaboration of Thai FDA, Faculty of Pharmacy Chulalongkorn University and five Industry Associations (PReMA, TPMA, RAPAT, TIPA and TSMIA) on 26-28 June 2018 at Faculty of Pharmacy Chulalongkorn University.
- The 2019 APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop was conducted on Public-Private Collaboration of Thai FDA, Faculty of Pharmacy Chulalongkorn University and five Industry Associations (PReMA, TPMA, RAPAT, TIPA and TSMIA) on 28-30 October 2019 at the Ambassador Hotel,

**Future plan (if any)**

- Continue to support Thai FDA on GRM Workshop

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