Asia Partnership Conference of Pharmaceutical Associations

APAC Position Paper

Progress Report in 2020

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*). This document provides progress of APAC member associations' activities based on focused topic(s) in APAC Position Paper.

Table Focused Topics by each association in their economy

China	**RDPAC** R&D-based Pharmaceutical Association in China	*Not selected yet**
Hong Kong	**HKAPI** The Hong Kong Association of the Pharmaceutical Industry	**#4****
India	**OPPI** Organization of Pharmaceutical Producers of India	*Not selected yet**
Indonesia	**IPMG** International Pharmaceutical Manufacturers Group	**#4**
Japan	**JPMA** Japan Pharmaceutical Manufacturers Association	**#5**
Korea	**KPBMA** Korea Pharmaceutical and Bio-Pharma Manufacturers Association	*None****
Korea	**KRPIA** Korean Research-based Pharmaceutical Industry Association	**#1**, #2****
Malaysia	**PhAMA** Pharmaceutical Association of Malaysia	**#3**, #4****
Philippines	**PHAP** The Pharmaceutical and Healthcare Association of the Philippines	**#2**, #3****
Singapore	**SAPI** Singapore Association of Pharmaceutical Industries	**#4****
Taiwan	**IRPMA** International Research-Based Pharmaceutical Manufacturers Association	**#4**
Thailand	**PReMA** The Pharmaceutical Research and Manufacturers Association	**#2, #3, #4**
Vietnam	**EUROCHAM** European Chamber of Commerce in Vietnam	*Not selected yet**

** No progress report provided*
*** Completed topic*
**** KPBMA's conclusion: No topic to be raised/tackled as an issue from the KPBMA viewpoints.*

PROGRESS REPORT ON FOCUSED TOPIC(S)

IPMG (International Pharmaceutical Manufacturers Group)

IPMG's activities in 2019 toward to focused topic(s)

Topic #4: Collaborative Training Program

[Key activities]

IPMG in collaboration with The National Agency of Drug and Food Control of Republic of Indonesia (BPOM) has conducted *Good Registration Management* (GRM) Workshop on August 28-29th, 2019. Some key speakers from the local Agency, experts from local University, JPMA (Kazuo Ushio) and SAPI (Thean So Lo) were participating in the Workshop. There were about 20 local Agency officials and 150 Regulatory Officers from MNC & local companies joined in the event.

[Achievement]

Outcome from the event was quite satisfactory according to the participants inputs.

[Next Plan]

IPMG planned to arrange the second *Good Registration Management* (GRM) Workshop in 2020 with more advanced topics and invite more international speakers to participate in the event. Date is still yet to be determined.

[Remarks if applicable]

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Recent regulations changes related to focused topic(s)

N/A

JPMA (Japan Pharmaceutical Manufacturers Association)

JPMA's activities in 2019 toward to focused topic(s)
Topic #5: Generation of review report in English

[Key activities]

- Meeting with PMDA (October, 2019)
  - To share the last year's survey result from JPMA companies regarding the use of English-translated PMDA's review report.
  - To exchange thoughts on how to promote the use of English-translated review report and what the challenges are.
- Annual questionnaire survey regarding the use of review report (January, 2020)
  The purposes of the survey are;
  - To know how many times English-translated PMDA's review report were submitted to Asian regulatory authorities for drug review in 2019.
  - To identify important factors in promoting the use of English-translated review report from viewpoint of industry

[Achievement]

- Meeting with PMDA (October, 2019))
  - Confirmed the PMDA's position on the use of English-translated PMDA's review report.
  - Obtained advices from PMDA on annual questionnaire survey, and those were reflected to the survey conducted in January 2020.
- Annual questionnaire survey regarding the use of review report (January, 2020)
  - Over 30 JPMA member companies responded.
  - The survey result showed an increase in the use of English-translated review report at new drug registration application in Asia when compared to the last year.

[Next Plan]
JPMA to continue the annual questionnaire survey and to share the survey result with PMDA to discuss how to promote the use of English-translated review report for accelerating review process in other regulatory authorities.

[Remarks if applicable]
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Recent regulations changes related to focused topic(s)

- The position paper regarding new drug review cooperation between MHLW/PMDA and TFDA/CDE was released in October 2019. Under the scheme, the English-version review report made by one side will be used by the other side for NDA review.
- Over 220 of review reports have been translated into English by PMDA and posted on web site. Approx. 40 reports were newly translated to English in 2019.

IRPMA (International Research-Based Pharmaceutical Manufacturers Association)

IRPMA's activities in 2019 toward to focused topic(s)

Topic #4: Collaborative training program

[Key activities]

- 2 IRPMA internal GRM training workshop on Jun 12 and Jul 18, 2019.
- Assisted and collaborated with TFDA/ RAPs Taiwan/ JPMA to carry out GRM CoE workshop from Sep 17 to 19, 2019.

[Achievement]

- For domestic workshop training workshops, there were more than 100 participants in total and with 1/4 from the regulatory.
- In 2019 GRM CoE workshop, 67 trainees from 12 APEC countries participated the workshop.

[Next Plan]

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

[Remarks if applicable]

- Not applicable

Recent regulations changes related to focused topic(s)

- Refuse to File (RTF) checklist for generic drug registration (MOHW official letter no.1081406427; Jul 19, 2019)
- Refuse to File (RTF) checklist for new drugs and bio-pharmaceutical products registration (MOHW official letter no.1081408580; Aug 20, 2019)
- Refuse to File (RTF) checklist for indication, administration and dosage changes of post-marketing drugs (MOHW official letter no.1081408585; Aug 20, 2019)
- "Designation of Medications for Pediatric Population or the Minority Patients with Serious Diseases","Abbreviated Review, Accelerated Approval, and Priority Review for New Drug Registration", and"Designation of Breakthrough Therapy" (MOHW official letter no.1081410835; Nov 18, 2019)

PReMA (Pharmaceutical Research & Manufacturers Association)

Activities in 2019 toward to focused topic(s)

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

[Key activities]

Ministerial Regulations for new Drug Act

[Achievement]

Further to new Drug Act (No. 6) B.E. 2562 published in the Government Gazette on April 16, 2019. The key changes are:

- New Drug Registration to provide "Documents that show the number of patent or petty patent application which went through the publication process according to patent law" (Section 9).
- The certificate of drug formula registration shall be valid for seven years from the date it was issued and need renewal. (Section 11).
- New section added on procedure, regulations and conditions of drug research (Section 8) and the penalty fee (Section 12).
- All fees in Drug Act 1967 has been replaced (Section 14).

Ministerial Regulations for Drug Act has been discussed with Thai FDA on 3 important points:

- Section 9: documents that show the number of patent or petty patent application
- Section 11, section 16: renewal of the certificate of drug formula registration
- Section 14: All fees

RASC will work further with Thai FDA on section 11, 16 when it comes to the first renewal time in 2024.

[Next Plan]

Work with FDA on Ministerial Regulations on renewal.

[Remarks if applicable]

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Recent regulations changes related to focused topic(s)

New Ministerial Regulations

Activities in 2019 toward to focused topic(s)

Topic #3: Review process tracking system

[Key activities]

Registration Timeframe and Public Manual

[Achievement]

Timeframe for approval of new drug (NCE) and biologics is 220 working days*
Vaccine 280 working days*
* *Referred to FDA notification on May 2018*
Biosimilar: 230 working days
Generic: 135 working days

Public manual has been developed by FDA but has not been officially announced.

[Next Plan]

Follow up on official public manual with process and registration timeline

[Remarks if applicable]

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Recent regulations changes related to focused topic(s)

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Activities in 2019 toward to focused topic(s)

Topic #4: Collaborative training program

[Key activities]

APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop

[Achievement]

Further to the success of the first Good Registration Management (GRM) Conference in Thailand on June 26-28 last year at the Faculty of Pharmacy Chulalongkorn University, the Thai FDA has applied to be an APEC LSIF RHSC Training Centers of Excellence on Good Registration Management.

With Public-Private Collaboration between the Pharmacy Faculty, Chulalongkorn University and five Industry Associations (PReMA, TPMA, RAPAT, TIPA and TSMIA) the 2019 APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop was held on October 28-30 at the Ambassador Hotel.

Deputy Prime Minister and Minister of Public Health, H.E. Anutin Charnvirakul gave the opening remarks and took group photo with representatives from APEC, AHC, Thai FDA, Academia and the 5 industry associations who support this CoE Pilot Workshop.

There are almost 300 participants from various segments in Thailand and ASEAN countries registered in common session in day-1 and 63 participants on day 2 and day 3 sessions for applicant (industry) and 40 participants for reviewer (government).

From this pilot workshop, the Thai FDA will pursue a formalized GRM Center of Excellence of APEC with the aim to Improve GRM session to be more relevant to ASEAN economies and conduct domestic GRM workshop to cascade down to the operational level through partnerships among academia, regulators, industry and science organizations to deliver and maintain topic-focused program, yield sufficient benefit to all partners to ensure long-term support and sustainability

[Next Plan]

Continue supporting Thai FDA for ongoing GRM workshop in Thailand in 2020.

[Remarks if applicable]

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Recent regulations changes related to focused topic(s)

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