



APAC Position Paper

Progress Report in 2019

APAC RA-EWG



Table of Contents

INTRODUCTION	1
PROGRESS REPORT ON FOCUSED TOPIC(S)	3
IPMG (International Pharmaceutical Manufacturing Group)	3
JPMA (Japan Pharmaceutical Manufacturers Association)	4
PHAP (The Pharmaceutical and Healthcare Association of the Philippines)	5
IRPMA (International Research-Based Pharmaceutical Manufacturers Association)	7
PReMA (Pharmaceutical Research & Manufacturers Association)	8



INTRODUCTION

Asia Partnership Conference of Pharmaceutical Associations (APAC) is a platform built by 13 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 Committee	<i>Not selected yet</i>
Hong Kong	HKAPI The Hong Kong Association of the Pharmaceutical Industry	#4
India	OPPI Organization of Pharmaceutical Producers of India	<i>Not selected yet</i>
Indonesia	IPMG International Pharmaceutical Manufacturers Group	#4
Japan	JPMA Japan Pharmaceutical Manufacturers Association	#5
Korea	KPBMA Korea Pharmaceutical and Bio-Pharma Manufacturers Association	<i>None*</i>
Korea	KRPIA Korean Research-based Pharmaceutical Industry Association	#1, #2
Malaysia	PhAMA Pharmaceutical Association of Malaysia	#3, #4
Philippines	PHAP 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 Pharmaceutical Research & Manufacturers Association	#2, #3, #4
Vietnam	EUROCHAM European Chamber of Commerce in Vietnam	<i>Not selected yet</i>

* *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 Manufacturing Group)

IPMG's activities and achievements for the focused topic in 2018

Topic #4 Collaborative Training Program

[Key activities]

National Agency of Drug and Food Control Republic of Indonesia (BPOM) is having several new regulations and other projects such as 2D Barcode, OIC conference, Simplify Registration and Criteria and procedure of withdrawal which is not meeting the standard, so it keeps postponing our Collaborative Training Program project from December 2018 to February 2019 and now the latest suggestion by BPOM is July 2019

[Achievement]

-

[Next Plan]

In our last meeting with BPOM on 28 Feb 2019, they suggested to hold the Workshop Good Registration Management in Jul 2019 for 2 days. we will discuss further step in the next meeting in March-Apr 2019 for preparing it.

[Remarks if applicable]

-

Recent regulations changes related to focused topic(s)

-



PROGRESS REPORT ON FOCUSED TOPIC(S)

JPMA (Japan Pharmaceutical Manufacturers Association)

JPMA's activities and achievements for the focused topic in 2018

Topic #5: Generation of review report in English

[Key activities]

Conducted a questionnaire survey with around 30 JPMA member companies.

The purposes of the survey are;

- To know how many times English-translated PMDA's review report were submitted to foreign regulatory authorities for drug review in each year.
- To identify the important factors in promoting the use of English-translated review report from the viewpoint of industry

[Achievements]

We observed following results from the questionnaire survey.

- Observed several actual usage of English-translated review report at new drug registration application in Asia.
- Identified important factors that might influence the use of English-translated review report.

[Next plan]

JPMA to share the survey result with PMDA and to discuss how to promote the use of English-translated review report for accelerating review process in other regulatory authorities.

[Remarks if applicable]

-

Recent regulations changes related to focused topic(s)

Totally, over 180 of review reports have been translated into English by PMDA and published at its web site. Around 30 of them were newly translated to English in 2018.



PROGRESS REPORT ON FOCUSED TOPIC(S)

PHAP (The Pharmaceutical and Healthcare Association of the Philippines)

PHAP's activities and achievements for the focused topic in 2018

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

[Key activities/Achievements]

In 2018, the FDA Center for Drug Regulation and Research (FDA-CDRR) conducted four Industry consultative meetings:

- 1) Concerns of drug retailers, 24 January 2018
- 2) Introductory meeting with new management of CDRR, 20 June 2018
- 3) Proposed revised Fees and Charges, 29 June 2018
- 4) Pilot Project Review of OTC Applications (ROTCA), 5 October 2018

This is a sudden decrease in the frequency of consultations. In 2017, consultative meetings were conducted regularly on a monthly basis. This is compounded by (1) FDA's policy on industry interactions, wherein inquiries and follow-ups are limited to submission of forms, and (2) issues on the information-communication technology (ICT) system and making it challenging for both parties to communicate. These have effectively limited industry interactions.

FDA is currently working on to upgrade their ICT system. For, PHAP we have been seeking other avenues to engage the FDA. In partnership with other associations, we have sought audience with FDA through the Department of Health (DOH) and Congress Committee on Health. In these meetings, FDA committed to re-establish the FDA CDRR-Industry Technical Working Group that will tackle challenges in the regulatory system. PHAP has also participated in the Modernizing Government Regulations (MGR) Program of the Development Academy of the Philippines. MGR is a program that aims to review existing regulations through an industry regulatory review and recommend measures to streamline unnecessary rules and compliance costs. While the first run was on healthcare, we have recommended that a more focused approach on FDA regulatory processes be the next focus of the program.

[Next plan]

-

[Remarks if applicable]

-

Recent regulations changes related to focused topic(s)

-



PHAP's activities and achievements for the focused topic in 2018

Topic #3: Review process tracking system

[Key activities/Achievements]

The FDA-CDRR started to issue updates on 'Decking Schedules' for industry reference on Aug 2016 following request for status reports on pending applications. These updates would show the list of submitted application dates for the different types of applications that are being assigned to evaluators and may serve as guidance for applicant companies in tracking the status of their applications. Another venue for applicant companies to track their submitted applications was provided by FDA via a section on the FDA website named 'DocTrack Status'. This allows the applicant companies to check the status of their applications by encoding the reference application number and contact detail of their representative (as access control). Lastly, FDA also instituted the use of follow-up forms which the applicant company fills-out and submits to

The latest Decking Schedule was issued in January 2019. For the follow-up forms, the prescribed timeline to provide feedback is two weeks after submission; however, in practice it takes 2-4 months. Overall industry is able to track the review process. However, even with the Decking Schedule and DocTrack system, there are still challenges for applicant companies to rely on these for the tracking of their applications due to some inconsistencies on the record or updating may not be real-time.

[Next plan]

-

[Remarks if applicable]

-

Recent regulations changes related to focused topic(s)

FDA Memo entitled "Follow-ups, Inquiries and Face-to-Face Interaction issued last September 2018, limiting follow-ups to made via submission of forms instead of face to face interaction.



PROGRESS REPORT ON FOCUSED TOPIC(S)

IRPMA (International Research-Based Pharmaceutical Manufacturers Association)

IRPMA's activities and achievements for the focused topic in 2018

Topic # 4: Collaborative training program

[Key activities]

- Assisted and collaborated with TFDA/RAPs Taiwan/JPMA to carry out GRM CoE Workshop (Sep 26-28, 2018)
- 2 IRPMA internal GRM Training Workshop in 2018 (Mar 23 and Aug 24, 2018)

[Achievement]

- 68 participants from 15 APEC countries attended the GRM CoE Workshop, with 20 Taiwanese participants joined applicant-side. It showed increasing interests to GRM from the industry and health authorities.
- Total 90 trainees attended GRM Training Workshop with satisfaction rate of 93.8%.

[Next Plan]

- Collaborating with TFDA/RAPs Taiwan/JPMA to carry out GRM CoE Workshop
- IRPMA internal GRM training Workshop
- IRPMA lecturers/trainers to support local industry's GRM Workshop

[Remarks if applicable]

Not applicable

Recent regulations changes related to focused topic(s)

- "Refuse to File checklist" (FDA Drug No. 1071408056; Sep 20, 2018)
- "Data Sheet for Data Exclusivity and Clinical Trials" (FDA Drug No.1071408287; Sep 20, 2018)
- Checklist for "New Indication" and "New Administration Route" application (FDA Drug No. 1071408946; Nov 23, 2018)



PROGRESS REPORT ON FOCUSED TOPIC(S)

PReMA (Pharmaceutical Research & Manufacturers Association)

PReMA's activities and achievements for the focused topic in 2018

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

[Key activities]

e-CTD Expansion

[Achievement]

e-CTD has been adopted and fully implemented for new and biologic products. FDA planned to expand e-CTD to all submission with various IT platforms in 2019 and introduced new system in December 2018.

[Next Plan]

Work with FDA on e-CTD on all submission and evaluate/feedback to have sustainable IT system.

Initiate reliance pathway with FDA.

[Remarks if applicable]

-

Recent regulations changes related to focused topic(s)

Pre-submission planning form for electronic submission



PReMA's activities and achievements for the focused topic in 2018

Topic #3: Review process tracking system

[Key activities]

Registration Timeframe and Public Manual

[Achievement]

Even no official timeframe announced, however, agreed timeframe for approval of new drug (NCE) and biologics is 220 working days; Vaccine 280 working days; Biosimilar: 160 working days; Generic: 135 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]

-

Recent regulations changes related to focused topic(s)

New licensing process for drug submission



PReMA's activities and achievements for the focused topic in 2018

Topic #4: Collaborative training program

[Key activities]

The first GRM Workshop in Thailand

[Achievement]

Collaborated with Chulalongkorn University and industry (PReMA, TPMA, RAPAT, TSMIA, TIPA) on GRM Workshop on June 26-28, 2018. There were 241 participants in day 1 common session. In day 2 and day 3 separate sessions, there were 50 participants in Applicant session and 38 participants in Reviewer session.

Thai FDA agreed to apply GRM CoE of ASEAN and already submitted the draft application in August 2018. The application has been reviewed by Taiwan FDA and PMDA in December 2018. Thai FDA plans to submit the application to the RHSC in January 2019.

[Next Plan]

Support Thai FDA to be GRM CoE of ASEAN by arranging ASEAN GRM in Thailand in 2019.

[Remarks if applicable]

-

Recent regulations changes related to focused topic(s)

-