Asia Partnership Conference of Pharmaceutical Associations

APAC Position Paper

Progress Report in 2017

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 (http://apac-asia.com/groups/ra/task_pp.html), 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	**KPMA** Korea Pharmaceutical 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**

** No progress report provided.*
*** KPMA's conclusion: No topic to be raised/tackled as an issue from the KPMA viewpoints.*
**** No update provided this time.*

PROGRESS REPORT ON FOCUSED TOPIC(S)

HKAPI (The Hong Kong Association of the Pharmaceutical Industry)

HKAPI's activities in 2016 for focused topic(s)

Topic #4: Collaborative training program

[Key activities]

Organized jointly with University of Hong Kong, the first "Regulatory Training Programme: Getting to be Competent Regulatory Affairs Professionals"

[Achievement]

In the program, we were able to engage different speakers, including regulators. Good Submission Practice is part of the course module.

[Next Plan]

Not applicable

[Remarks if applicable]

Not applicable

Related regulations/Regulatory authority's activities for focused topic(s)

Underline: Updates from last year

IPMG (International Pharmaceutical Manufacturers Group)

Activities in 2016 for focused topic(s)

Topic #4: Collaborative training program

[Key activities]

No collaborative training program, IPMG has discussed several times with Health Authority for update Criteria and Procedure of Drug Registration

[Achievement]

[Next Plan]

Continue corporate with Indonesian Health Authority for Training & Workshop

[Remarks if applicable]

Not applicable

Related regulations/Regulatory authority's activities for focused topic(s)

Not applicable.

Underline: Updates from last year

JPMA (Japan Pharmaceutical Manufacturers Association)

Activities in 2016 for focused topic(s)

Topic #5: Generation of review report in English

[Key activities]

JPMA had discussions with PMDA based on the internal survey results for English translation of the review reports.

[Achievement]

JPMA internally conducted survey research about the current activity of PMDA for English translation of the review reports (Dec 5th – 22nd, 2016).

JPMA and PMDA had a meeting for sharing the survey results on Jan 25th, 2017 and discussed next steps.

[Next Plan]

JPMA to survey products which have Review Report in English would align Industries' expectation.

[Remarks if applicable]

Not applicable.

Related regulations/Regulatory authority's activities for focused topic(s)

Totally, over 110 of the review reports were translated to English by PMDA and published at their web site. More than 30 of the translations are added since last year.

Underline: Updates from last year

KRPIA (Korean Research-based Pharmaceutical Industry Association)

Activities in 2016 for focused topic(s)

Topic #1: Structured framework of regulatory consultation system

[Key activities]

Kept raising 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.

[Achievement]

- MFDS added GMP site inspection of biologics into pre-review scope and will introduce pre-review system for biologics to improve review efficacy by checking requirement fulfillment on dossier submitted by a company prior to formal review.
- In addition, MFDS has plan to implement e-record system to align consultation result with formal review.

[Next Plan]

KRPIA will continuously listen to industry's' voice and suggest industry's opinion to MFDS for efficient review process.

[Remarks if applicable]

Not applicable.

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

MFDS has the process to increase transparency for revision of policy, standards, draft regulations, guidelines and new initiative from regulatory authority.

Prior to implementing final legislation, MFDS performs pre-announcement of legislation and listens to the variety opinions from civic group, relevant industry association and academia etc. Based on the opinion they got, they finally announce final legislation.

Even after announcement of final legislation, MFDS issues guideline or Q&A manual to increase the understanding of legislation, if necessary.

Thus, KRPIA is going to delete this Topic #2 from the topic list for the high level suggestions and proposals to the regulatory authorities

Related regulations/Regulatory authority's activities for focused topic(s)

Not applicable.

Underline: Updates from last year

PhAMA (Pharmaceutical Association of Malaysia)

Activities in 2016 for focused topic(s)

Topic #3: Review process tracking system

[Key activities]

PhAMA submitted this request to our regulatory authority (NPCB) on 18 June 2015, and was discussed in the PhAMA-NPCB Dialogue session on 30 June 2015 together with other issues.

[Achievement]

NPCB advised that registration milestones will be set into the new QUEST3+ system which was to be implemented in 2016. The QUEST3+ system was delayed and just implemented in January 2017.

[Next Plan]

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

[Remarks if applicable]

Review Timelines were already provided earlier for specified applications, e.g. New Drugs & Biologicals, Prescription Drugs & Non-Prescription Drugs, Licences & Certificates, Variation, etc.

Topic #4: Collaborative training program

[Key activities]

PhAMA submitted this request to our regulatory authority (NPCB) on 18 June 2015, and was discussed in the PhAMA-NPCB Dialogue session on 30 June 2015 together with other issues.

We formed a Joint Industry Working Group with related associations to discuss common issues including training proposal. Several meetings were held to finalize the proposal and organise the training program.

[Achievement]

Collaborative training was held on 09-10 March 2016 as a seminar on 'Collaborative Regulatory Training 2016: Challenges & Issues with Registration & Variation Applications'.

[Next Plan]

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

[Remarks if applicable]

Authority has been providing collaborative training and is agreeable to more training programs for industry with focus on new regulatory issues.

Related regulations/Regulatory authority's activities for focused topic(s):

Not Applicable

Underline: Updates from last year

SAPI (Singapore Association of Pharmaceutical Industries)

Activities in 2016 for focused topic(s)

Topic #4: Collaborative training program

[Key activities]

SAPI RAC discussed with Singapore HSA 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.

[Achievement]

Not applicable.

[Next Plan]

SAPI RAC has set up working group in 4th Quarter 2016 to plan for the training programme with Singapore HSA which is planned for 2nd Quarter of 2017. Good Submission Practice will be considered for the programme.

[Remarks if applicable]

Not applicable.

Related regulations/Regulatory authority's activities for focused topic(s)

Not applicable.

Underline: Updates from last year

IRPMA (International Research-Based Pharmaceutical Manufacturers Association)

Activities in 2016 for focused topic(s)

Topic 4: Collaborative training program

[Key activities]

1. GRM CoE Pilot Training Workshops on 6th -8th Nov.
2. 4th Joint Conference of TW/JP on Medical Products Regulation was conducted on 7th Dec in Tokyo.

[Achievement]

1. Successfully educating industries about "Good Submission Practice".
2. Cooperate with TFDA for conducting GRM CoE pilot program to introduce international regulations into Taiwan to better bridge Taiwanese regulation internationally.

[Next Plan]

1. IRPMA will cooperate with TFDA for the 2017 GRM Training Program, no matter as Pilot CoE only conducted by TFDA or implement as full CoE training program by TFDA and RAPS.
2. IRPMA will assist TFDA to educate participants from Taiwanese trainees to be qualified trainers for sharing Good Submission Practice concept and to have the concept implemented in Taiwan Pharma Industries.

[Remarks if applicable]

Not applicable

Related regulations/Regulatory authority's activities for focused topic(s)

TW-JP collaboration meeting and regular meeting with APAC.

Underline: Updates from last year

PReMA (The Pharmaceutical Research and Manufacturers Association)

Activities in 2016 for focused topic(s)

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

[Key activities]

Regulatory Reform

[Achievement]

As the government does not want to establish new public organization, the idea of having NIPA as independent agency to handle health product assessment cannot materialize.

The government issued Licensing Facilitation Act in 2015 to get commitment on timeline from all government agencies who have to provide service to private sector. However, drug registration delay cannot be resolved. Pharmaceutical industry has proactively engaged all parties concerned to find solution for this long-delayed timeline. Finally, our industry has been recognized as partner to make the regulatory reform work. We have been officially appointed by the Thai FDA to work with other stakeholders on fee and process we would like to see the reform.

[Next Plan]

PReMA will be actively working with alliances from other associations in the areas of regulatory reform that we agree together, particularly streamline process, use of e-submission (ICH e-CTD), committed timeline, tracking system and appropriate fee.

[Remarks if applicable]

Not applicable.

Topic #3: Review process tracking system

Review process tracking system is now in the regulatory reform process (as per details in Topic #2).

Topic #4: Collaborative training program

[Key activities]

Propose Good Registration Management training to FDA

[Achievement]

Both FDA and Chulalongkorn University recognized the importance of standard in registration management as they are now working on regulatory reform. PReMA has introduced the idea that Thailand (by FDA) should consider to apply for GRM COE, of

which the FDA does not show objection.

[Next Plan]

Continue to follow up on the actual training. PReMA will continue to follow up with FDA and Chulalongkorn to encourage them to apply for GRM COE. In the meantime, we will have brief introduction of the course to our member companies.

[Remarks if applicable]

Not applicable.

Related regulations/Regulatory authority's activities for focused topic(s)

Not applicable.

Underline: Updates from last year

End of text