APAC Position Paper

Progress Report in 2016

APAC RA-EWG

Table of Contents

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	*Not selected yet**
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.*

PROGRESS REPORT ON FOCUSED TOPIC(S)

IPMG (International Pharmaceutical Manufacturers Group)

Activities in 2015 toward focused topic(s)

Topic #4: Collaborative training program

[Key activities]

Introduction of Good Submission Practice in Workshop of Drug Registration on Dec 14, 2015

[Achievement]

There are 248 participants from 29 Foreign Pharmaceutical Company with 54 participants & 114 Local Pharmaceutical Company with 194 participants

Indonesian Health Authority respect and support for having Guideline Good Submission Practice in Indonesia

[Next Plan]

Continue corporate with Indonesian Health Authority for Training & Workshop

[Remarks if applicable]

Not applicable

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

Not applicable.

JPMA (Japan Pharmaceutical Manufacturers Association)

Activities in 2015 toward focused topic(s)

Topic #5: Generation of review report in English

[Key activities]

JPMA established a task force (TF) in order to review issues associated with generation of review report in English.

The TF finally completed identifying the issues by the end of 2015.

Using the review issues, JPMA discussed with PMDA on 28th Jan and 17th Mar 2016.

[Achievement]

The TF focused on major issues listed as following:
- Rationale of generating document in English
- Types of NDA requiring English version
- Timeline
- Operations in practice, etc.

JPMA explained the issue for “review report in English” clear to PMDA.

The criterion of selection for translation by PMDA became clear.

[Next Plan]

JPMA will negotiate with PMDA regarding appropriate timing of translation and the criterion of selection to recognize the products which the industries request.

The schedule of next meeting is being adjusted.

[Remarks if applicable]

Not applicable

Related regulations/Regulatory authority’s activities to focused topic(s)

Over 80 of the review reports were translated to English by PMDA and published at their web site.

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KRPIA (Korean Research-based Pharmaceutical Industry Association)

Activities in 2015 toward focused topic(s)

Topic #1: Structured framework of regulatory consultation system

[Key activities]

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.

[Achievement]

- MFDS has recognized that regulatory consultation is not legally binding and the review results are sometimes too different from pre-review or consultation.
- One of main reason occurring this issue is consultants differ from real reviewer caused by a lot of turn-over due to lack of resource.

[Next Plan]

KRPIA will continuously suggest MFDS to increase reviewer resources for efficient review process and will raise issue on the discussion table.

[Remarks if applicable]

Not applicable.

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

[Key activities]

MFDS announced the draft on orphan drug related regulations on Feb 5, 2016. However, draft regulations does 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.

[Achievement]

Correct and submit the various comments to make up lack of draft regulations.

[Next Plan]

Visit MFDS with industry and discuss draft regulations with MFDS based on the opinions from industry in order to make the regulations to reflect robust and transparent requirements and procedures on orphan drug registration.

[Remarks if applicable] Not applicable.
Related regulations/Regulatory authority's activities to focused topic(s) Not applicable.

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PhAMA (Pharmaceutical Association of Malaysia)

Activities in 2015 toward 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 will be implemented in 2016.

[Next Plan]

Waiting for registration milestones to be implemented in new QUEST3+ system.

[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.

Formed a Joint Industry Working Group (with related associations) to discuss common issues including training proposal. 1st meeting held on 27 July 2015 to get consensus on training proposal. Subsequent meetings held to finalize the proposal and coordinate 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 to focused topic(s):

For Topic #3, the Malaysian regulatory authority (NPCB) had embarked on a major revamp of the QUEST online registration system. Registration milestones for review process tracking will be incorporated during this revamp project i.e. QUEST 3+.

PHAP (The Pharmaceutical and Healthcare Association of the Philippines)

Activities in 2015 toward focused topic(s)

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

[Key activities]

Upon request, FDA has recognized the various industry associations for regular consultations on various regulatory matters.

Majority of new regulatory initiatives, policies, standards, and guidelines have been presented thru public hearings and consultations coordinated through the recognized industry associations. Should there be important initiatives and policies missed out for public consultations, the industry associations are quick to call FDA's attention.

[Achievement]

A TWG (composed of DOH, FDA, and Industry representatives) is now in place holding monthly meetings on various issues and concerns.

Draft policies and guidelines presented through public hearings accommodate registered representatives from various member companies of recognized industry associations.

[Next Plan]

Improvement of conduct and dissemination of results of TWGs and public consultations towards fairness and equity in the healthcare industry in general.

[Remarks if applicable]

Not applicable.

Topic #3: Review process tracking system

[Key activities]

FDA has initiated the Doc Track System as a means of communicating the status of applications to the respective applicant companies. FDA updates on the decking schedule may be considered as another venue to track the review process. However, the Industry noted that the review process per se has posted a significant backlog in the evaluation of registration applications and there was a need to identify the possible causes for the delays, and that the decking schedule is inadequate as to provide the real-time status of the review process.

[Achievement]

CDRR-Kapihan with the DOH Secretary Garin held last July 2015 brought about the need to create a Technical Working Group (TWG) composed of FDA personnel and representatives from the Industry Association to discuss the current process flow and present a proposal to improve the process starting from the receiving of applications by FDA. The Industry representatives have presented to FDA last Oct 2015 an output of initial discussion/deliberation including some proposals.

[Next Plan]

Industry to follow-up with FDA for their feedback/comments and action plans.

[Remarks if applicable]

Not applicable.

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

Not applicable.

SAPI (Singapore Association of Pharmaceutical Industries)

Activities in 2015 toward focused topic(s)

Topic #4: Collaborative training program

[Key activities]

SAPI RAC members discussed and agreed to raise discussion on the collaborative training with Singapore HSA if they would be willing to collaborate at the next F2F meeting.

[Achievement]

Not applicable.

[Next Plan]

SAPI will be meeting Singapore HSA on 1st April 2016 to discuss on the possibility of collaboration.

[Remarks if applicable]

Not applicable.

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

Not applicable.

IRPMA (International Research-Based Pharmaceutical Manufacturers Association)

Activities in 2015 toward focused topic(s)

Topic 4: Collaborative training program

[Key activities]

1. Internal training to IRPMA member companies on 13th Apr 2015.
2. International Good Submission Practice Workshop on Pharmaceuticals on 17th-18th Sep 2015.
3. Two Good Submission Practice Training & Experience Sharing Workshops on 20th and 24th Nov respectively.
4. 3rd Joint Conference of TW/JP on Medical Products Regulation on 26th Nov 2015.

[Achievement]

1. Successfully educating industries about "Good Submission Practice".
2. Introduced international regulations into Taiwan to better bridge Taiwanese regulation internationally.

[Next Plan]

1. Collaborating with TFDA and RAPS Taiwan to train industries more about Good Submission Practice to have a smooth implementation in Taiwan Pharma Industry.
2. "Good Distribution Practice" training.

[Remarks if applicable]

Not applicable

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

TW-JP collaboration meeting and regular meeting with APAC.

PReMA (The Pharmaceutical Research and Manufacturers Association)

Activities in 2015 toward focused topic(s)

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

[Key activities]

- NIPA – National institute for Health Product Assessment
- E-submission

[Achievement]

NIPA:

Current status: The new public organization act has recently been published and thus there is possibility that the new organization establishment be considered, however, this needs to depend on the decision of the government.

PReMA continues our engagement with OPDC, Japan Embassy, and FDA for clear understanding of private sector's need for change.

E-Submission:

Proposed to FDA to not expand the implementation of ICH eCTD from NCE, new biologics and vaccine to other process until the assessment of the first year result. In addition to sue the application version 0.92 until Dec. 2016 for the sake of preparedness of member companies.

[Next Plan]

NIPA:

Coordinate with Thai FDA and Chulalongkorn University including PMDA and EU to invite for dialogue on capacity building for Thai FDA's reviewers.

E-Submission:

To propose eCTD public manual in English based on ICH for Thai FDA to use.

To coordinate with industry experts to share best practice on life cycle management of e-submission to both Thai FDA and industry.

To coordinate with EU to provide speaker to provide training on how to review eCTD files.

[Remarks if applicable]

Not applicable.

Topic #3: Review process tracking system

[Key activities]

- Licensing Facilitation Act
- Abridged Review

[Achievement]

Licensing Facilitation Act:

Shared comments with Thai FDA to improve the public manual. Some have already been accepted and amended.

Selected some public manual to make English translation so all members can have as reference.

Abridged Review:

One member tried the system and got good feedback.

[Next Plan]

Licensing Facilitation Act:

Closely work with Thai FDA to improve work process based on the public manual issued.

Follow up to have public manual in areas not yet available, e.g., biologics.

Abridged Registration:

Will observe future implementation as there was only one example implemented.

[Remarks if applicable]

Not applicable.

Topic #4: Collaborative training program

[Key activities]

Propose Good Submission Practice in official training program

[Achievement]

Faculty of Pharmaceutical Science, Chulalongkorn University, accepted the idea to incorporate Good Submission Practice (actually the whole concept of Good Registration Management), to be part of their training outline.

[Next Plan]

Continue to follow up on the actual training.

[Remarks if applicable]

Not applicable.

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

Not applicable.

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