APAC Position Paper

Interim Report
(April 2015 – March 2018)

APAC RA-EWG

Asia Partnership Conference of Pharmaceutical Associations

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INTRODUCTION

Asia Partnership Conference of Pharmaceutical Associations (APAC) is a platform 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 and built by 13 Asian Pharmaceutical Industry's Associations, has been working to support promotion of regulatory convergence in Asia.

APAC Position Paper (http://apac-asia.com/groups/ra/task_a.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 supporting improvement of 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: Facilitating 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 interim report provides progress of improvement on the focused topic(s) since April 2015 from APAC member associations' perspective.

Table Focused Topics by each association in their economy

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

** Please provide interim report for focused topic(s) if possible*
*** KPMA's conclusion: No topic to be raised/tackled as an issue from the KPMA viewpoints.*

INTERIM REPORT FOR FOCUSED TOPIC(S)

IPMG (International Pharmaceutical Manufacturers Group)

Focused topic(s)

Topic #4: Collaborative training program

Status as of April 2015

Introduction of Good Submission Practices on Dec 15, 2015.

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

Status as of March 2018

No further steps taken re-Collaborative Program between NAFDC & IPMG, as NAFDC was busy revising the Regulation Criteria and Procedure of Drug Registration in the period Jan 2016 until October 2017.

IPMG contributed in the review process by submitting input and comments to the draft, also actively involved in Public Consultations taken place on March 17, 2016, March 30, 2017, Aug 23, 2017 before NAFDC launched the revised Regulation Criteria and Procedure of Drug Registration on Nov 29, 2017.

Also in Nov 29, 2017, BPOM arranged presented Good Submission Practice with the focus on Quality of Clinical Documentation, which presented by a very well-known lecturer from Gajah Mada University Prof Iwan DwiPrahasto.

Key Progress from April 2015 to March 2018

Actively involved by giving inputs and comments in the revision of the Guidelines for Drug Registration

Remaining issue to be solved

Continue collaborate with Indonesia Health Authority, NAFDC, in capacity building through Training and Workshop to help ensure the implementation of GRM in Indonesia

Visual scale for progress as of March 2018

START — GOAL

Apr 2015

JPMA (Japan Pharmaceutical Manufacturers Association)

Focused topic(s)

Topic #5: Facilitating generation of review report in English

Status as of April 2015

PMDA published around 80 review reports in English at their Website.

Status as of March 2018

PMDA published around 150 review reports in English at their Website.

Key Progress from April 2015 to March 2018

- Twice questionnaires within JPMA for gap analysis on this topic
- Multiple dialogues with PMDA to understand their policy and quantity target of translation (1st Goal)
- Continuous discussion with PMDA not only facilitating generation of review reports in English but also how to utilize them

Remaining issue to be solved

How to utilize review report in English and its actual achievement of utilization (2nd Goal).

Visual scale for progress as of March 2018

START | 1st GOAL | 2nd GOAL

Apr 2015

KRPIA (Korean Research-based Pharmaceutical Industry Association)

Focused topic(s)

Topic #1: Structured framework of regulatory consultation system

Status as of April 2015

KRPIA 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.

It was recognized that regulatory consultation was not legally binding and the review results were sometimes different from pre-review or consultation.

One of main reasons occurring this issue was that consultants differ from real reviewer caused by a lot of turn-over and lack of resource.

Status as of March 2018

Not applicable

Key Progress from April 2015 to March 2018

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.

Thus, the main issue has been resolved through the implementation of the above system.

Remaining issue to be solved

Based on the progress on this topic, KRPIA deletes this Topic #1 from the topic list for the high level suggestions and proposals to the regulatory authorities

Visual scale for progress as of March 2018

START

Apr 2015

GOAL

Focused topic(s)

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

Status as of April 2015

Not applicable

Status as of March 2018

Not applicable

Key Progress from April 2015 to March 2018

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.

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

Remaining issue to be solved

As there are opportunities industry provide their comments on new initiative or regulations and industry can discuss it with MFDS, KRPIA deletes this Topic #2 from the topic list for the high level suggestions and proposals to the regulatory authorities

Visual scale for progress as of March 2018

START

Apr 2015

GOAL

PhAMA (Pharmaceutical Association of Malaysia)

Focused topic(s)

Topic #3: Review process tracking system

Status as of April 2015

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

Status as of March 2018

The QUEST3+ system has been implemented in January 2017, and a timeline function has been built into the system. The timeline for responding to correspondence will be finalized after further considerations. There are registration milestones in the system (eg for screening, query and approval steps).

Key Progress from April 2015 to March 2018

PhAMA submitted this request 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, which was implemented in January 2017.

Remaining issue to be solved

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

Visual scale for progress as of March 2018

START GOAL

Apr 2015

Focused topic(s)

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 2018

Several collaborative training programs were held including;

- CGTP and Biotherapeutics Talk, 01 April 2015
- Collaborative Regulatory Training 2016: Challenges & Issues with Registration & Variation Applications, 09-10 March 2016.
- Introduction to Regulation of Pharmaceuticals, 31 October – 01 November 2016
- Introduction and Best Practices on Pharmacovigilance and eCTD, 18 September, 2017
- QUEST3+, 03 October, 2017
- API Requirements, 04 October, 2017
- Regulatory Training Course on ASEAN Common Technical Document (ACTD), 15-17 November 2017

Key Progress from April 2015 to March 2018

PhAMA submitted this request 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. 13 training modules have been identified for this program, and 2 modules have been conducted to date. Certification programs for different levels of regulatory professionals are also being explored.

Remaining issue to be solved

No issue remains to be solved. Nevertheless we will work on other future training programs in collaboration with regulators and other stakeholders as the need arise.

Visual scale for progress as of March 2018

START GOAL

Apr 2015

PHAP (The Pharmaceutical and Healthcare Association of the Philippines)

Focused topic(s)

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

Status as of April 2015

Status as of March 2018

The last FDA CDRR-Industry meeting was held on 24 January 2018 but the pharma industries associations were not invited since agenda covered that for the hospital and community pharmacies. PHAP to check for the availability of the minutes of the meeting and proposed next schedule.

Key Progress from April 2015 to March 2018

The Food and Drug Regulations had the 1st meeting of the Technical Working Group (TWG) for Drug Regulation last 22 September 2015 where PHAP representatives were participants to this activity. The agenda included the following topics: Processing of LTO and CPR, Receiving Process at PAIR, Foreign GMP Inspection, Medical Oxygen Manufacturer, CSP/Special Permit for Hospitals, Inspection Issues, BE Requirement, and Proposed Fees. Subsequent meetings were held by FDA scheduled on a quarterly basis although there were instances of some changes in schedule, as needed. The last TWG meeting was held on Feb 2016, and succeeding meetings were no longer regular. The FDA Kapihan at Talakayan (referring to FDA Forum) was re-introduced in 27 June 2017 to replace the TWG meetings. However, PHAP was not included in the first meeting and that they have noted that invitation to attendees will be limited to relevant groups within the proposed agenda. These sessions were supported our focus topic on transparency on planned and draft policies and guidelines, as well as it serves as venue for discussion of industry and FDA concerns.

Remaining issue to be solved

There is a need to request for FDA consideration to invite all association representatives in every meeting regardless of the proposed agenda in view of transparency and in order to ensure that updates from previous meetings may be discussed and followed-through.

Visual scale for progress as of March 2018

START GOAL

Apr 2015 

Focused topic(s)

Topic #3: Review process tracking system

Status as of April 2015

Status as of March 2018

The latest decking schedule was issued on 22 January 2018 following an issuance last 29 Dec 2017 and it was understandable to see no change in the applications handled. The FDA-CDRR started to addressed the concern of long pending applications vs the new submissions where it seems that there is now simultaneous decking of new applications of variations with that of the 'old' submissions and this poses confusion on the list of decking schedule that were issued last Dec 2017 and Jan 2018.

Key Progress from April 2015 to March 2018

The FDA Center for Drug Regulation and Research (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. However, there were still some concerns on these issuances since the decking may not automatically refer to the actual evaluation of the applications by the assigned reviewers. 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).

Remaining issue to be solved

There is a need to request for FDA clarification or improvement on the list of decking schedule issued for industry reference. Moreover, the DocTrack System as a review process tracking system may still be improved in terms of access control, etc.

Visual scale for progress as of March 2018

START — GOAL

Apr 2015

SAPI (Singapore Association of Pharmaceutical Industries)

Focused topic(s)

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 2018

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

Key Progress from April 2015 to March 2018

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.

Remaining issue to be solved

None.

Visual scale for progress as of March 2018

START GOAL

Apr 2015

IRPMA (International Research-Based Pharmaceutical Manufacturers Association)

Focused topic(s)

Topic #4: Collaborative training program

Status as of April 2015

Good Submission Practice concept communicate to the industry.

Status as of March 2018

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. As of now, IRPMA has 10 experienced trainees/trainers.

Key Progress from April 2015 to March 2018

- 2015-2017:
  - 2016: TFDA announced "Good Submission Practice" and became Champion of GRM pilot CoE.
  - International Conferences: 3 conferences
    (2015 Good Submission Practice, 2016 pilot COE and 2017 COE)
  - Seminar & workshops: **3 training & workshops** in 2015, **20 seminars** in 2016.
- Dec. 2017: IRPMA has 10 experienced trainees/trainers.
- 2018 plans:
  - 3 Train the Trainer (TTT) GRM workshops, first targeting in Mar.
  - 3 Good Submission related courses in Feb & Mar, cooperated with TsRAP.
  - International GRM Conference: work with TFDA, PMDA and JPMA to conduct the conference.

Remaining issue to be solved

IRPMA experts are not familiar with document requirements of generic drugs. While the concept of good submission should be the same, differences in document requirements between originators and generics makes a communication gap.

Visual scale for progress as of March 2018

START — GOAL

Apr 2015

PReMA (The Pharmaceutical Research and Manufacturers Association)

Focused topic(s)

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 2018

However, 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.

Key Progress from April 2015 to March 2018

Industry, including PReMA involved in the planning from end 2016 to mid-2017. The new timeline of new drug/biologic registration has been agreed to be less than one year, after the new process has been in place starting August 2017. At the time of this report, at least 75% of all pending registration has already been completed.

Remaining issue to be solved

How to ensure that the promised timeline can be delivered.

Visual scale for progress as of March 2018

START GOAL

Apr 2015

Focused topic(s)

Topic #3: Review process tracking system

Status as of April 2015

E-submission was introduced.

Status as of March 2018

E-submission (ICH e-CTD format) has been mandatory for new drug and biologic

product registration since 2016. This has been handled by newly established division – Division of Health Product Innovation. As of now the timeline of electronic submission is still on time. Besides e-submission, this new division also starts to explore possibility for submission in CD-ROM, called i-submission, for variation registration.

Key Progress from April 2015 to March 2018

e-CTD has been adopted and fully implemented for new and biologic products.

Remaining issue to be solved

Ensure that the system is sustainable and official track change report available.

Expansion of the e-submission process to all kinds of submission.

Have sustainable IT system supporting overall digital system of FDA.

Visual scale for progress as of March 2018

START GOAL

Apr 2015 

Focused topic(s)

Topic #4: Collaborative training program

Status as of April 2015

Information sharing on Good Submission Practice Concept.

Status as of March 2018

Chulalongkorn University and industry (PReMA, TPMA, RAPAT, TSMIA, TIPA) agree to promote Good Registration Management (both GRevP and GSubP) for the Country. Thai FDA accepts the concept and agrees to collaborate. Even though Thai FDA has interest in becoming CoE for GRM, they have to consider internally whether they would be ready. Therefore, they decide not to proceed for CoE status at the moment.

Key Progress from April 2015 to March 2018

All agree to try with the first training on GRM in June 2018.

Remaining issue to be solved

Make GRM as capacity building standard for the country.

Visual scale for progress as of March 2018

START GOAL

Apr 2015 

End of text