Concept Paper for APAC RA EWG Activities

to promote the access/availability of innovative medicines for the people in Asia

Proposal

The agreement on the Regulations and Approvals reached in 2012 by the first Asia Partnership Conference of Pharmaceutical Associations (APAC) in Tokyo provided the basic proposal and rationale for offering recommendations to realize early submission and approval of New Drug Applications (NDAs) for innovative medicinal products, and stable supply of medicinal products with global quality standards in Asia. The purpose of this document is to provide stakeholders with the fundamental framework of APAC Regulations and Approvals expert working group (RA EWG) activities and to outline a strategic multi-year approach for meeting this objective in support of the broad objectives of improved public health and economic development. While the RA EWG established for this work may adopt roadmaps on their own timeframe, the ultimate aim would be to help engage Asian regulatory agencies towards a common goal of achieving regulatory convergence for innovative medicinal products.

Background & Challenges

In the session of the "Roundtable Discussion" of the first APAC held in March 16, 2012, it was highlighted that drug approval lag is a major issue in Asia with a large number of medicines having taken up to two years before being approved in Asia after being approved elsewhere, and that this restricts early access to the innovative medicines. It would be ideal in the future of Asia to be built on a common application dossier and co-review system of drug application, but there are many challenges to achieve this. Creating additional working groups to assist with collaborations and policies could be difficult in the resource-limited environment of many economies. It may be a better way, therefore, to make use of existing groups and resource efficiently. In addition, some economies have very little manpower or resources to support collaborative efforts even if they support the idea and it may be necessary for more developed Asian economies to take the lead to develop ideas on possible ways forward to address the issues.
APAC member associations, working in concert with regulatory agencies, academia and others as appropriate, will develop specific strategies to promote regulatory convergences. It is important for APAC member associations to persuade Asian regulatory agencies to support goal of achieving regulatory convergence for innovative medicinal products; by such as having interest in industry involvement in the development of regulations through public-private consultation processes, having close collaborations with the regulators concerned, having an opportunity to exchange the thoughts and others as appropriate. Collaborative partnership between regulators and industry in the APAC region is crucial, whereby we work together to have faster/accelerated approvals with rolling submissions, which are balanced by industry's commitment to keep regulators apprised of comprehensive post-market surveillance monitoring and risk management program instead. The APAC could then only indirectly influence the regulatory policies and requirements of economies. To influence regulators, member associations may be asked to clarify the situation from their points of view, to identify priority areas which have significant impact to their business and development, and to attempt to help them achieve their common goals.

Regulatory convergence lowers market barriers for medicinal products by making it easier to satisfy regulatory requirements in multiple economies without jeopardizing safety, quality and efficacy standards. This helps pharmaceutical industries get approvals faster,

which enable them to provide patients with innovative medicinal products faster while they still have a patent. It is believed that it also lowers overall regulatory costs. Regulatory convergence should also come hand in hand with standardized marketing authorization procedures, and the first step towards this can be achieved through by leveraging existing public or private forums and frameworks sharing common goal with the APAC.

The public perception of clinical testing and medicinal products is very important, and it is considered crucial to support the effort of capacity-building in economies which are interested in to provide better understanding for the public on the benefits of clinical testing and innovative medicines.

To achieve the mission, establishment of two expert working groups, (1) Regulations and approvals and (2) Drug Discovery Alliance was endorsed by the first APAC. The working group would have to be very precise in its goals and timeframes, and would also have to ensure that nothing is duplicated or redundant within the limited resources that we have. It was suggested that the JPMA could take a leading role in creating proposals and gathering feedback on the best way to strengthen this approach.

Mission

To promote the access/availability of innovative medicines for the people in Asia

Topics of consensus reached at the 1st APAC conference in March, 2012

Regulations and approvals working group:

- Offer recommendations to realize early submission and approval of NDAs for innovative medicinal products in Asia
- Stable supply of innovative medicinal products with global quality standards in Asia

Areas identified in the topics of consensus reached, which have significant impact on business in the APAC member economies

- Identified priority areas: IND, NDA, Clinical trials and GMP evaluation system
  Further priority areas will be included if any requested from the APAC member associations.
- To identify and clarify the differences in regulatory requirements between Asian economies, the survey regarding the areas identified was developed at starting of April, 2012 and its results and outcomes were included in the report entitled "Analysis Report" (which will be available for the public in 2nd APAC meeting). Of the differences identified, some of them have been incorporated based on mutual recognition and listed in the categories of "Issues to be resolved".

Issues to be resolved:

- The issues to be resolved need to meet the scope of the topics described above.
- The following issues have been identified as common issues over the Asian economies or issues in the specific legions of economies as to be resolved and evaluated relative to international practices/standards, and then common understanding is established.
- The issues to be resolved will be prioritized by a consensus-driven approach in the RA EWG when developing roadmaps.
  - IND: regulatory acceptance for an early initiation of multi-national clinical trials in Asia (review time of IND application, acceptance of application documents written in foreign languages)
  - NDA: regulatory acceptance of NDA documents in the form of ICH CTD, acceptance of NDA technical documents written in foreign languages, review time,

small number of reviewers, regulatory acceptance and interchangeability/utilization of the review outcomes from other Asian economies
- Clinical trials: acceleration of simultaneous NDA in all Asian countries (countries to be involved, number of subjects required in individual countries and mutual use of the clinical trial results)
- GMP evaluation system: acceleration of mutual recognition of GMP inspection/evaluation with an increased number of PIC/S member economies in Asia (number of GMP inspections, heavy workload for GMP inspection, training and capacity building of inspectors).

- Further priority issues will be included if any requested from the APAC member associations.
- The following aspects will be taken into considerations when prioritizing the issues to be resolved or developing the roadmap for the prioritized issues to be resolved:
  - Pathways for priority/accelerated review for drugs for selected category of diseases
  - Exemptions or fast-track development pathways for drugs of rare diseases, diseases endemic or neglected tropical diseases to the APAC region.

Goal:

In order to realize the mission, we will share information regarding the challenges faced in each economy and build a platform to transmit all necessary proposals of the APAC as necessary. Furthermore, the pharmaceutical associations of each economy will propose solutions to their governments and other stakeholders regarding the pharmaceutical-related challenges of each Asian economy. All the activities to reach the goal are to be undertaken by the strategic approach including a step-by-step approach stated in the following section "Roadmap overview".

Roadmap overview:

Strategic approach

Overview:

- Roadmaps should be prioritized from the view of maximizing the effectiveness and resources in APAC economy associations.
- Roadmap for the prioritized "Issues to be resolved" needs to be developed based on the following multi-phase approach.
- Goals would be achieved through individual and collective actions by APAC member associations.
- Each member association may proceed at its own pace, but the goals and objectives are asked to be aligned from the start of each year with each member association, with the objectives of arriving at a common destination of medicinal product regulatory convergence by the targeted years agreed.
- Associations would always retain the right, authority and responsibility to make their own decisions in the context of their public health systems.

Multi-phase activities by a step-by-step approach:

The steps described below are intended as guides for APAC economies to move forward each activity/task toward a goal.

- Step 1: Setting foundation:
  Assessment, Gap analysis, Common understanding,
  Workshop, Training and education activity, Evaluation of current practice,
  Formation of technical working group
- Step 2: Advancing the process: Workshop, Consultation with stakeholders and

regulators
- Step 3: Assessing readiness

Principle and Objectives:
- Activities should be under the umbrella of the APAC.
- Activities should be open to all APAC member associations.
- Participation should be open to industry, academia and regulators.
- Any activities/agreements will be flexible and should take account of societal and cultural needs.
- Participation in topic/project discussion should be voluntary.
- Participation and activities are encouraged and contingent on resources in each economy association.
- Any association can propose an area, issues and roadmaps for focused convergence/recommendations efforts and become its champion, leading efforts within the RA EWG.
- Meeting should leverage other international forums and frameworks sharing common goal with the APAC to use resources most efficiently.

Background/references:

1) 1st APAC meeting minutes, March 16, 2012
2) Analysis Report to be published in April, 2013

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End of text