APAC Good Registration Practice (GRegiP) Policy Document

APAC RA-EWG

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1 BACKGROUND

In the 1st Asia Partnership Conference of Pharmaceutical Associations (APAC) meeting in March 2012, the common mission of APAC was confirmed as follows:

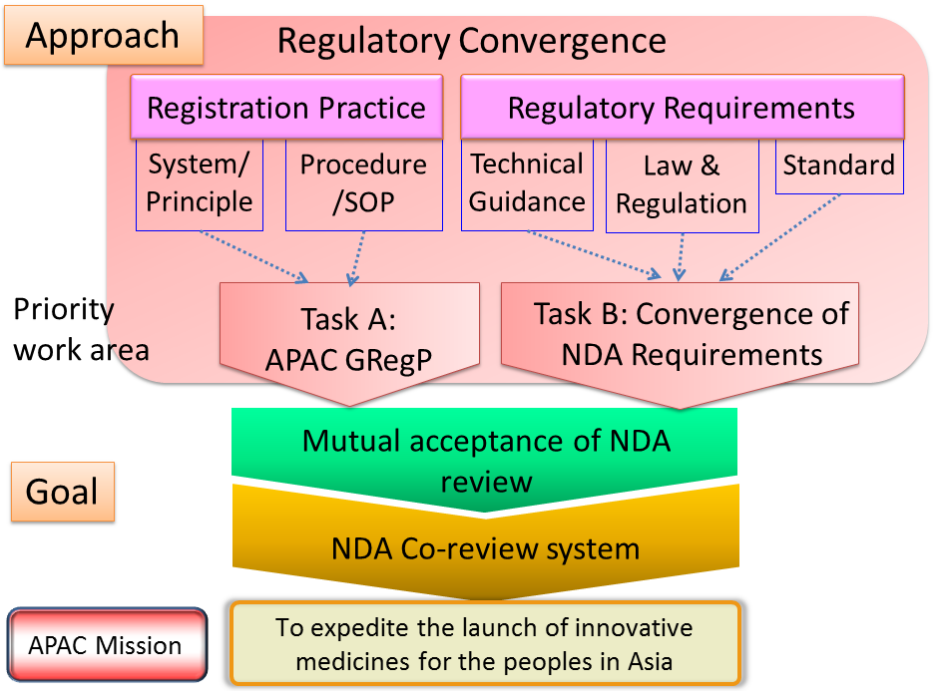
“To expedite the launch of innovative medicines for the peoples in Asia.”

Drug approval lag has been recognized as a major issue in Asia, with a large number of drugs having taken for 2 years or more before approval in Asia after first global approval, and that this limits early access to the innovative medicines in the region. In order to improve this condition and resolve the drug approval lag in Asia, it was agreed that APAC member organizations would offer recommendations from the industry viewpoints, to achieve early submission and approval of NDAs for prescription drugs in Asia and to provide a stable supply of quality drugs produced at global standards.

After the 1st APAC meeting, the Regulatory and Approval expert working group (RA-EWG) was established to discuss and resolve these two issues in regulatory field.

The working group generated the Concept Paper of APAC RA-EWG activities and set two stepwise goals to realize #1: mutual acceptance of NDA review and #2: NDA co-review system in APAC region. RA-EWG also developed a picture of roadmap describing possible approaches for promotion of regulatory convergence which may lead to the aforementioned goal.

Two main target areas have been identified for subject of regulatory convergence, i.e. Registration Practice and Regulatory Requirements. The former is intended to promote convergence of principle, system, timeline management as well as procedure to be applied in a new drug application and review, and thereby achieve good practice of drug registration process in APAC region.



Under the circumstances described above, RA-EWG decided to establish a Task of Good Registration Practice (GRegiP) which aims to promote Good Submission Practice (GSubP) in drug application process by applicants and also support to accelerate Good Review Practice (GRevP) by the review authorities. RA-EWG developed this policy document in order to share the basic concept of APAC GRegiP with concerned stakeholders.

2 PURPOSE & SCOPE

This document describes basic policy on APAC GRegiP which is proposed and agreed by all the APAC associations from the viewpoint of pharmaceutical industry in Asia.

It is intended for the APAC associations to be used for introduction, improvement and dissemination of GRegiP in the economy as well as for discussions with the regulatory authorities on the topic.

3 INTRODUCTION

In drug registration process, a common goal for both the review authorities and applicants is to achieve good quality of application and review with consistency, transparency, efficiency

and timeliness. Close and timely communications between both parties in any stage of drug registration process are essential to realize this goal.

For this purpose, it is important that applicants have good understanding on the basic principles of registration management, system and procedures which are executed by the review authorities in their responsible economy. This can be achieved by facilitating transparency and communications between the review authorities and applicants.

In general, Good Review Practice (GRevP) is defined and regarded as a code and concerned activities by the review authorities for standardization of quality control and documentation of the review system that aims to ensure quality, consistency, transparency, and timeliness of medicinal product assessment. The US FDA started GRevP activity from mid. 1990's and have been published a guidance document on review management principle and procedures, GRevP policy document and a series of review templates for reviewers and industries. Also in APAC region, many review authorities have been introducing basic concept of GRevP and established some form of concerned practice. However, status of implementation of GRevP and publication of GRevP policy and documents differ among the economies.

Considering that effective and efficient communications between the review authorities and applicants are the key to successful review management, promotion of GRevP is an important topic not only for the review authorities but also for applicants.

It should be also noted that applicants are required to contribute to the proper management of drug registration process by preparing high quality of application dossier and making prompt and good quality of responses to deficiencies from the review authorities. The activity to realize good quality of application submission by applicants will be defined in this document as Good Submission Practice (GSubP).

It is believed that collaborations between the review authorities and applicants in both GRevP and GSubP activities are essential to enhance quality and efficiency of the whole drug registration process management.

On the basis of these discussions, APAC RA-EWG proposes a new and comprehensive concept of Good Registration Practice (GRegiP) which covers GRevP and GSubP as collaborative activities between the review authorities and applicants to achieve good management throughout the drug application and its review process.

The RA-EWG prepared this policy document to facilitate introduction, improvement and dissemination of GRegiP in the APAC regions as a discussion material, to enhance good communications between the review authorities and applicants throughout the regulatory application and review process, and thereby achieve the aforementioned goal.

4 POLICY AND KEY ATTRIBUTES

The purpose of introduction and implementation of GRegiP is to improve the following key attributes in regulatory application and review process.

- ***Quality***: GRegiP will enhance quality of application preparation as well as its review process by establishing and providing basic review principles and review management process.
- ***Consistency & Clarity***: GRegiP will ensure clear and consistent review outcome by following well-defined review principles and management. Also, good communications between the review authorities and applicants will contribute to consistency in review process.
- ***Predictability & Transparency***: Appropriate information sharing on review principles and management by the review authorities will help applicants in generating well-prepared regulatory applications that satisfy the review authority. Further, transparent dialogue will ensure that queries that might arise during the course of the assessment can be addressed in as efficient a manner as possible..
- ***Timeliness & efficiency***: GRegiP will improve the timeliness and efficiency of application preparation/review by facilitating effective communications between the review authorities and applicants.

In order to improve these key attributes and realize good quality of drug registration management, it is essential to keep close and timely communications between the review authorities and applicants throughout the application and review process. The RA-EWG considers GRegiP as a platform to achieve effective communication and cooperation between the two key stakeholders.

Based on this premise, the RA-EWG defines GRegiP as follows;

"A code and concerned activities for establishing effective communication platform between the review authorities and applicants in order to improve quality, consistency, predictability, transparency and timeliness of drug registration process."

5 RESPONSIBILITY AND COMMITMENT

To facilitate early access to innovative medicines in Asia, the RA-EWG will facilitate implementation and dissemination of GRegiP in Asia by taking the following actions.

- Based on the policy described in this document, APAC RA-EWG will cooperate with the review authorities in each economy and any concerned stakeholders for introduction and/or improvement of GRegiP.

- APAC RA-EWG will make a proposal on practical measures for introduction and/or improvement of GRegiP to the review authorities in each APAC economy and concerned stakeholders.
- APAC RA-EWG will take necessary actions for implementation of the proposed and agreed measures in collaboration with the review authorities and other stakeholders.
- APAC RA-EWG will share experiences and expertise with each other, especially to help the economies who do not have an effective framework in place for early drug availability.

6 PROPOSED APPROACHES

APAC RA-EWG proposes the following practical measures to promote GRegiP in APAC region and thereby to facilitate effective communications between the review authorities and applicants throughout drug registration process.

- Establishing structured framework to support agency consultation - to provide a formalized mechanism for the review authorities and applicants to communicate openly prior to, during and post approval for product submissions and strategies.
- Improving and maintaining transparency to review standards, draft regulations, guidelines, agency policies or new initiatives so that industry is offered opportunity to comment.
- Promoting documentation and publication of review policy, procedures, and templates. This enables applicant to prepare for application submission in compliance with these requirements.
- Having a review process tracking system so that applicants can track review progress and proactively plan for the next step.
- Holding collaborative training program and workshop between the review authorities and industries.
- Facilitating publication and sharing of assessment report (in English). It will enhance mutual confidence between the review authorities and may lead to effective review by focusing on areas of major concern.
- Introducing and disseminating a concept of Good Submission Practice (GSubP) to promote preparation of good quality of submission dossier by applicants. It will contribute to enhance quality as well as efficiency of drug registration process.

These measures need to be adapted and implemented considering the actual circumstances of each economy.

Details of each measure are to be descried in Appendix of this policy document.

7 REEFERENCES

1. The 1st APAC meeting minutes, March, 2012
2. Concept Paper for APAC RA EWG Activities, April, 2013

8 APPENDIX

- Proposed approach for promotion of GRegiP

Endorsed at the third APAC meeting on Apr.10, 2014
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End of text