Asia Partnership Conference of Pharmaceutical Associations

Good Registration Management

APAC POSITION PAPER

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 Good Submission Practice (GSubP) guideline is a document for best practices by APAC RA-EWG under the concept of Good Registration Management. It is aimed to enhance the quality and efficiency of the drug registration process by improving the quality of submission as well as its management. Promotion of GSubP by the industry has been recognized as important in facilitating Good Review Practice (GRevP) by the regulatory authorities.

Objective of this APAC Position Paper is to provide 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 this document, it is expected to improve regulatory environment for Good Registration Management and achieve regulatory standardization which can facilitate future regulatory convergency 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. Industry can pick up topics of focus in their region and generate more detailed addendum document which would include concrete proposal or economy's specific issue, etc., for discussion with their respective regulatory authorities.

TOPIC #1: STRUCTURED FRAMEWORK OF REGULATORY CONSULTATION SYSTEM

Goal:	**To establish structured framework to support regulatory consultation**
Proposed Option:	To establish the following consultation mechanisms as an effective communication platform between the regulatory authorities and applicants. **<u>1. Formal Consultation</u>:** **Purpose & topic:** Discussions on study design/protocol, clinical development plan, submission planning & strategy including advisory for special projects (e.g. unmet medical needs, orphans drugs, new delivery systems). **Initiation:** Can be requested either by the regulatory authority or applicant **Method:** Face to face meeting, basically. **Timing:** Any or pre-defined timing in development, pre-submission, or review stage, e.g. pre-IND meeting, pre-NDA meeting. **<u>2. Informal Consultation/inquiry communication :</u>** **Purpose & topic:** Confirmation of review requirements, potential concern raised in review, clarification of deficiency etc. **Initiation:** Can be contacted either by reviewer or applicant **Method:** Phone call / e-mail / Face to face after an appointment **Timing:** Whenever necessary (or e.g. designated date in a week) A written guidance on detailed procedural steps for each consultation mechanism needs to be prepared and issued. For the formal consultation, it is necessary to clarify if outcome of or agreement in the consultation meeting has legal binding on the future NDA review by the regulatory authority. A practical and workable meeting process need to be established considering differences in review system and work burden in each economy.
Expected Effect:	✓ Improve effectiveness and efficiency of drug development, submission, and review process by enhancing communications between the regulatory authorities and applicants. ✓ Enables applicants to prepare good quality of application dossier dealing with potential concerns in advance. ✓ Reduce repetition of unnecessary question-response cycles and minimize misunderstandings between reviewer and applicant.

TOPIC #2: TRANSPARENCY TO REVIEW POLICY, STANDARDS, DRAFT REGULATIONS, GUIDELINES AND NEW INITIATIVE FROM REGULATORY AUTHORITY

Goal:	**To facilitate transparency to review policy, standards, draft regulations, guidelines, and new initiative from regulatory authority**
Proposed Option:	1. To encourage effective use of IT tools such as internet website, mail delivery and alert system for sharing information not only nationally but also internationally. 2. To facilitate provision of regulatory information in English even for non-English speaking economies to encourage international cooperation among the regulatory authorities and for overseas applicants. 3. To conduct public comment procedures during the process of drafting a new guideline or regulation. Sufficient comment period must be considered for comments from stakeholders. 4. To provide annual and medium- to long-term policy which the authorities plan to implement in future. Planned updates of current regulatory environment or system must be shared with stakeholders.
Expected Effect:	1. Significant improvement for the efficiency of information sharing by the authority with effective use of IT tools such as internet website, mail delivery and alert system. 2. Facilitation of mutual understanding among the authorities and industry which must practically lead international cooperation in the future, with information provision in English. 3. Valuable opportunity for industry to provide their comments and questions on the draft before finalization and implementation and enhancing a sense of participation by industry in building the regulation, followed by smooth implementation of regulations. 4. A good opportunity for industry to prepare for future changes in regulatory environment well in advance, and contribution to smooth implementation of new regulations.

TOPIC #3: REVIEW PROCESS TRACKING SYSTEM

Goal:	**To facilitate transparency to review process and status**
Proposed Option:	1. To set and publish standard timelines for each review milestone so that applicant can foresee the events during whole review process in advance. 2. To implement either of the following options. 1) To conduct review in accordance with the pre-defined standard milestones and timeline. 2) To establish a review process tracking system which applicants can access to confirm the review progress. Note) The system should be able to keep sufficient confidentiality of application, e.g. protected with ID and password specific to each applicant, or each application to be identified by application number, etc. which is informed to the applicant only.
Expected Effect:	✓ Enables applicants to confirm the progress of review, allocate sufficient resources to address review queries, and proactively prepare for next requests and/or questions from reviewers. ✓ Enables regulatory authorities to keep track of the review progress easily and manage review timeline effectively. ✓ Help both parties to have necessary communications in a timely manner. ✓ Increase transparency of review system.

TOPIC #4: COLLABORATIVE TRAINING PROGRAM

Goal:	**To facilitate collaborative training program and workshop between the regulatory authorities and industry**
Proposed Option:	**Each Economy** ✓ To reinforce existing training platform in terms of frequency, agenda item, etc, including Industry's commitment and initiative. **Candidate topics:** New regulatory guidance, enforced regulations, annual and/or mid- to long-term plan of the regulatory authorities, sharing of reviewer's perspectives and requirements. **Whole APAC Region** ✓ To hold collaborative workshops for common technical training of international standards, guidelines and policy. **Candidate topics:** ICH Q/S/E/M, PIC/S GMP, Good Review Practice and Good Submission Practice, etc. ✓ To utilize the existing capacity building/training platforms. **Potential platforms:** ARC (Asia Regulatory Conference), APEC workshops, ASEAN meetings, and/or professional group events like DIA, RAPS (Regulatory Affairs Professionals Society).
Expected Effect:	**Overall** ✓ Industry will have deep understanding of the contents of regulations including the regulatory authorities' position. ✓ Applicants to prepare application submissions fully complying with concerned regulatory requirements. ✓ By learning from the industry about new development of pharmaceutical technology, it is also expected the authorities may facilitate revision of regulations established long time ago to be made up to date in line with recent advancements in Pharmaceutical technology. **Each Economy** ✓ Collaborative program facilitate dialog between the two parties for better understanding and transparency of regulation. ✓ Industry's contribution supports to reduce the authorities' burden for rolling out new regulation.

	<u>Whole APAC Region</u> ✓ Common technical training program is beneficial and practical for early standardization with defined quality in APAC region. ✓ Through discussions for international standard, guideline and policy, harmonization in APAC region to be facilitated.

TOPIC #5: GENERATION OF REVIEW REPORT IN ENGLISH

Topic Title:	**To facilitate generation of review report in English.** - **It will help towards building mutual confidence across the regulatory authorities and may lead to future work sharing in drug review.**
Proposed Option:	To facilitate preparation of review reports for new drugs in English or make English translation of original review reports. - This proposal is for the regulatory authorities in APAC region which have not adopted English as official language. It is also proposed that the regulatory authorities in APAC region enhance communications to build mutual trust and share review reports under MOU/Confidentiality Agreement in order to facilitate future work sharing in drug review.
Expected Effect:	✓ Improve transparency of review and decision making process. ✓ Help towards building mutual confidence across the regulatory authorities and increase opportunities to cooperate with other regulatory authorities in drug review.

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