APAC Good Registration Practice (GRegiP) Policy Document

Appendix

APAC RA-EWG

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TOPIC #1: STRUCTURED FRAMEWORK OF REGULATORY CONSULTATION SYSTEM

Topic Description:	Establishing structured framework to support regulatory 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 development strategies.
Background:	Regulatory consultation is one of the most effective tools to enhance good communications between the review authorities and applicants during drug development and registration process, and to achieve high quality of application submission as well as its review. For applicants, having official consultations with the review authorities and obtaining their suggestions in drug development stage are helpful to understand product specific requirements and questions to be raised by reviewers in coming review stage. It enables the applicants to prepare high quality dossier by proactively covering the requirements and questions. Opportunity of consultation in actual review stage is also helpful not only to confirm status of review progress but also to have clear understanding about background of deficiencies and prepare quick and appropriate answers to them. For the review authorities, pre-submission consultation is beneficial for efficient review operation by having preliminary discussions on expected application contents before initiation of actual review and planning and scheduling for necessary review workload well in advance. In addition, it will help to avoid repeating unnecessary question-response cycles and reduce misunderstanding between reviewer and applicant about background of deficiencies. Most review authorities in APAC region already introduced various types of consultation mechanisms with applicants formally and/or informally. On the other hand, still there are some rooms to improve the existing system in order to enhance effectiveness and efficiency of consultations, e.g. introduction of formal consultation mechanism in multiple stages of drug development and registration process, release of official minutes, improvement of efficiency of administration procedure, introduction of joint consultation system with other authorities.
Proposed approach:	The followings are possible approach for this topic. ✓ Sharing existing consultation system and its problem in each APAC

	economy. ✓ Discuss any possibility of improvement and prepare proposal for each economy. ✓ Make proposals to the review authorities in each APAC economy and discuss for implementation..
Issues to be resolved:	It is necessary to establish practical consultation system for each economy considering differences in review system, number of review staff, review principle and procedure.

TOPIC #2: TRANSPARENCY TO REVIEW STANDARDS, DRAFT REGULATIONS, GUIDELINES, AGENCY POLICIES OR NEW INITIATIVES

Topic Description:	Improving and maintaining transparency to review standards, draft regulations, guidelines, agency policies or new initiatives.
Background:	While global and regional harmonization of technical guidelines has been progressed through the activities such as ICH and ASEAN harmonization, each regulatory authority has its own review principles, procedures, technical standards and economy specific regulations. Transparency to these review principle, standards and regulations is necessary to keep efficient communications between the review authorities and applicants, and for applicants to submit appropriate information to the review authorities. It is noted that applicants are responsible for proper use of the information/instructions released by the review authorities to prepare high quality of submission dossier as well as response to the queries from the authorities. From the viewpoint of the review authorities, keeping regulatory transparency will help to build mutual trust and confidence between or among the authorities on their review principle and systems. Also it will enhance future possibility of review work sharing among the authorities. In addition, transparent dialogue between the review authorities and applicants will ensure that queries that might arise during the course of the review can be addressed as in efficient manner as possible. Transparency to new initiatives and regulations by the review authorities, e.g. release of annual plan, public comment, will be also beneficial for both parties as they provide the industries with an opportunity of comments and proactive discussions. Many review authorities in APAC region have already initiated or conducted some activities for improvement of transparency. APAC RA-EWG will provide support to further expand these activities.
Proposed approach:	The following practical measures are proposed for further improvement of transparency and information sharing between the review authorities and applicants. ✓ Ensuring prior release of annual plan or midterm plan by the

	regulatory authorities so that industries can offer comments and have an opportunity to discuss, if necessary. ✓ Conducting public comment process for new draft regulations and guidelines before finalization. ✓ Convene public meetings that provide opportunity for industry and the entire public to have clear understanding about the topics on agenda and provide input.
Issues to be resolved:	It is necessary to take practical and feasible approach for each economy considering the current condition of regulatory system and environment. It is necessary to clarify and define what information should be confidential and what needs to be disclosed.

TOPIC #3: PROMOTING DOCUMENTATION AND PUBLICATION OF REVIEW POLICY, PROCEDURES, AND TEMPLATES.

Topic Description:	Promoting documentation and publication of review policy, procedures, and templates which enables applicant to prepare for application submission in compliance with these requirements.
Background:	This topic is a part of activities concerning transparency (Topic #2) but focusing on promotion of documentation and publication of review policy, procedures and templates. In drug registration application, applicants are required to prepare high quality of dossier which is in compliance with the requirements by the review authorities. This should be done based on good understanding of the review principle, standards and regulations adopted by each review authority. It is therefore necessary for an applicant to have proper access to the published documents concerning review policy, procedures and templates adopted by the review authorities. From the viewpoint of the review authorities, keeping regulatory transparency will help to build mutual trust and confidence between or among the authorities on their regulatory systems. Also it will enhance future possibility of review work sharing among the authorities.
Proposed approach:	✓ Conduct survey on the current status of documentation and publication of review policy, procedures, and templates in each APAC economy and those in reference countries/regions, e.g. US, EU. ✓ Discuss possibility of improvement and prepare proposal for each economy. ✓ Make proposal to the review authorities in each economy and discuss for implementation..
Issues to be resolved:	It is necessary to take practical and feasible approach for each economy considering the current condition of regulatory system and environment. It is necessary to clarify what information should be confidential and what needs to be disclosed.

TOPIC #4: REVIEW PROCESS TRACKING SYSTEM

Topic Description:	Having a review process tracking system so that applicants can track review progress and proactively plan for the next step.
Background:	Appropriate management of review timeline accompanied with highgood review quality is one of the goals of GRegiP activities. Most review authorities in APAC region have established target timeline or standard milestone in review process, e.g. screening period, time to complete initial round review, timing of issuance of deficiency, clock stop time for applicant's response, timing of advisory committee meeting. Introduction and/or improvement of review process tracking system will help reviewers to conduct efficient review management and ensure effective communications between the reviewer and applicant during review stage. Applicants can confirm the progress of review and proactively prepare for next coming requests and/or questions from reviewers. Though some review authorities in APAC region have introduced electronic system for review tracking, it is not yet a common throughout APAC economies.
Proposed approach:	✓ Conduct survey on current existing review process tracking system in each APAC economy and those in reference countries/regions, e.g. US, EU. ✓ Make proposal to the review authorities in each economy for introduction or improvement of the tracking system
Issues to be resolved:	It is necessary to take practical and feasible approach for each economy considering the current condition of regulatory system and environment. . Another option is to establish a robust review mechanism with strict timeline management and ensure adherence to pre-defined review timeline. This is more challenging approach.

TOPIC #5: COLLABORATIVE TRAINING PROGRAM

Topic Description:	Holding collaborative training program and workshop between the review authorities and industries on GRegiP.
Background:	Training is the essential platform for dissemination and implementation of GRegiP to all stakeholders in APAC region. Each review authority in APAC region has already established its own internal training program for reviewers as a part of GRevP activities. Also there are existing international training programs led by the regulatory authorities in Asia such as GRevP workshops by APEC RHSC, and international Training Seminar by PMDA. Training is also necessary for applicants so that they have good understanding on regulatory requirements for application and can achieve high quality of application as well as good and efficient communications with reviewers during review period. Considering that GRegiP shares its basic concept with GRevP, it seems that there exists good opportunities to have collaborative workshop and training program between the review authorities and industry to promote and disseminate both activities in APAC region. Such collaborative program between the review authorities and industry will prevent duplication of related activities and moreover may bring a synergy effect to accelerate dissemination and implementation of GRevP and GRegiP in Asia.
Proposed approach:	✓ Create a plan for joint workshop and training program between the review authorities and industry in APAC region for discussion with the review authorities. ✓ In parallel, seek for possible collaboration with existing international activities led by the review authorities. ✓ Hold a joint training program.
Issues to be resolved:	It is necessary to establish collaboration framework with the existing scheme of training programs in Asia, e.g. APEC RHSC, Local/international training program supporting the review authorities.

TOPIC #6: PUBLICATION AND SHARING OF REVIEW REPORT

Topic Description:	Facilitating publication and sharing of review report in English.
Background:	Discussions on this topic will cover the followings. A. Publication of summary review report or the report with masking of confidential information to public. B. Sharing full review report with other review authorities. A. A few authorities in APAC region have publicized summary of its review report or the report after masking of confidential information on their website. This activity is based on publication policy of each review authorities to keep their evaluation and decision making process transparent to public. APAC RA-EWG will support this publication activity as it enhances transparency to the authorities' decision making process and its rationale, and facilitate implementation of GRegiP in APAC. Publication of review report in English is encouraged. B. Sharing full review report between the review authorities will become possible basically only after agreement of MOU/MRA between the authorities. It will bring the following advantages to the review authorities. It will facilitate building mutual trust and confidence between the review authorities which may lead to future opportunity of collaboration in review, e.g. acceptance of review outcome by other authorities, review work sharing, and joint review. Such work sharing will enable the review authorities to use their review resources efficiently and make it possible for reviewers to focus on areas of major issues. It will also bring advantages to applicants such as reduced number of questions and answers already addressed by other review authorities
Proposed approach:	✓ Summarize benefit, risk and challenges of review report sharing and discuss with the review authorities in each APAC member economy. ✓ Support cooperative activities and discussions between the review

	authorities for MOU/MRA.
Issues to be resolved:	MOU/MRA between the regulatory authorities is essential precondition for review report sharing. It is necessary to support to build mutual trust and good relationship between the authorities. It is necessary to take practical and feasible approach for each economy considering the current condition of review management system by the authorities. It is also necessary to discuss resource and budget issues required for implementation, e.g. translation.

TOPIC #7: INTRODUCTION AND DISSEMINATION OF GOOD SUBMISSION PRACTICE

Topic Description:	Introducing and disseminating concept of Good Submission Practice (GSubP) to promote preparation of good quality of submission dossier by applicants.
Background:	In order to obtain early approval in drug registration process, it is important for applicants to prepare and submit application dossier with sufficient quality. Application with poor quality dossier will lead to rejection or a lot of deficiencies and result in delay of approval. For that purpose, applicants should have good and correct understanding of regulatory requirements and make proper use of information provided by the review authorities. As one of the essential parts of GRegiP activities, this topic aims to improve quality as well as efficiency of preparation of application dossier and deficiency response in review processes, and discuss how applicants can achieve it. The following points will be subject of discussions and/or clarifications in moving forward this topic. ➢ Defined structure of application dossier and contents of each document, its type and format. ➢ Clarification of scientific information and data to be described in technical part of application dossier ➢ Proper use of communication or consultation system managed by the review authorities ➢ Necessity of a general written guidance or a points to consider document for applicants
Proposed approach:	✓ RA-EWG to conduct a survey and prepare draft guidance or points to consider document of GSubP. ✓ Communicate with the review authorities to ask for their input and suggestions and make necessary adjustment. ✓ Optionally, hold collaborative workshops with the review authorities and concerned stakeholders to discuss key elements of GSubP. ✓ Endorse GSubP guidance by APAC and plan for implementation. ✓ Share the GSubP guidance with concerned stakeholders.

	✓ Conduct training in APAC region
Issues to be resolved:	It is necessary to take practical and feasible approach considering current condition of application process as well as regulatory requirements in each economy.

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