Good Registration Management

APAC
POSITION PAPER 2022

APAC
Regulations and Approvals Expert Working Group

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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.

The first position paper was published in 2015 (APAC Position Paper 2015) 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 was 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 2015 covered 5 topics: (1) consultation, (2) transparency, (3) tracking system, (4) collaborative training, and (5) review report in English, which were selected as important area for refining existing drug registration process throughout the APAC region. Industry could pick up topics to be focused on in their region for discussion with their respective regulatory authorities.

It has been several years since APAC Position Paper 2015 was released, and the environment surrounding pharmaceutical industry has been constantly changing. Therefore, the position paper has been revised as APAC Position Paper 2022 to provide updated suggestions and proposals that reflect current circumstances.

APAC Position Paper 2022 is covering 6 topics: (1) consultation, (2) transparency, (3) tracking system, (4) collaborative training, (5) digital tools/platform, and (6) reliance. The 5 topics in the first position paper have been reorganized into 4 topics with improvements ((1), (2), (3), and (4)). In addition, 2 topics are added as emerging important areas ((5) and (6)). It is expected that this new position paper will help industry to discuss with their relevant regulatory authorities for further improvement of the regulatory environment for Good Registration Management.

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. **1. Formal Consultation:** **Purpose & topic:** Discussions on study design/protocol, clinical development plan, submission planning & strategy including advisory for special projects (e.g., unmet medical needs, orphan drugs, new delivery systems). **Initiation:** Can be requested either by the regulatory authority or applicant **Method:** Face-to-face meeting or virtual meeting, basically. **Timing:** Any or pre-defined timing in development, pre-submission, or review stage, e.g., pre-IND meeting, pre-NDA meeting. **2. Informal Consultation/inquiry communication:** **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 or virtual meeting after an appointment **Timing:** Whenever necessary (or, e.g., designated date in a week) The following written documents need to be prepared and issued. ✧ A guidance on detailed procedural steps for each consultation mechanism ✧ Frequently Asked Questions from applicants 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. In addition, the outcome or agreement should be recorded clearly in the meeting minutes. 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:	✓ 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. ✓ To facilitate provision of regulatory information including review report in English even for non-English speaking economies to encourage international cooperation among the regulatory authorities and for overseas applicants. ✓ 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. In addition, the regulatory authorities should give appropriate feedback on comments from stakeholders. ✓ To provide annual and medium- to long-term policy, which the regulatory authorities plan to implement in future. Planned updates of current regulatory environment or system must be shared with stakeholders.
Expected Effect:	✓ Significant improvement for the efficiency of information sharing by the regulatory authority with effective use of IT tools such as Internet website, mail delivery and alert system. ✓ Facilitation of mutual understanding among the regulatory authorities and industry, which must practically lead international cooperation in the future, with information provision in English. In particular, review reports in English will help toward building mutual confidence across the regulatory authorities and may lead to future work sharing in drug review. ✓ 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. ✓ 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:	✓ To set and publish standard timelines for each review milestone so that applicant can foresee the events during whole review process in advance. ✓ 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. To ensure regular updating of application status on the system, especially when applications have remained idle for a certain period of time. 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.
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, Real-World Data/Evidence (RWD/E). ✓ To utilize the existing capacity building/training platforms. **Potential platforms:** ARC (Asia Regulatory Conference), APEC workshops, ASEAN meetings, WHO CPP training 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 the new development of pharmaceutical technology, it is also expected the regulatory 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 facilitates dialog between the two parties for better understanding and transparency of regulation. ✓ Industry's contribution supports to reduce the regulatory authorities' burden for rolling out new regulation. **Whole APAC Region** ✓ 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: UTILIZATION OF DIGITAL TOOLS/PLATFORM FOR DRUG REGISTRATION

Goal:	To facilitate utilization of digital tools/platform for drug registration
Proposed Option:	✓ Digitization of documents and materials required for drug registration (e.g., eCTD, eCPP, eGMP certificate). The regulatory authorities need to accept digitization both as issuing agencies and recipient agencies. ✓ To provide online platform where all the documents/materials for drug registration can be exchanged between the regulatory authority and applicant. In addition, all the correspondences are tracked there so that both parties can see them easily at any time. ✓ To invest in an online platform that is more flexible and does not limit the number or type of regulatory applications, e.g., parallel/bundling of new indications, parallel submission of variations, and submission of multi-site registration in one product license. ✓ Integration of multiple systems utilized by different functions within the regulatory authority, which facilitate information-sharing and collaboration between the departments involved in drug registration (e.g., drug review, GMP clearance, administrative affairs, laboratory testing and other PMS activities).
Expected Effect:	✓ Provide a more complete and better-quality information and greater availability, allowing responses to need and requirements faster and more efficiently. ✓ Reduce administrative burden caused by paper-based documentation, which enables both parties to allocate more resources to other processes necessary for drug registration. ✓ Allow both parties to send/receive information instantly anytime and anywhere, which speeds up each required process and may shorten the entire period of drug registration. Furthermore, a mutual online platform that can be available across the regulatory authorities in APAC region will facilitate information exchange between them and may accelerate work sharing in drug review. ✓ Enhanced information-sharing and collaboration within the regulatory authority through systems integration enable each department to access the most up-to-date information on the application and to avoid miscommunication and confusion caused by outdated information.

TOPIC #6: REGULATORY RELIANCE THROUGHOUT THE PRODUCT LIFE CYCLE

Goal:	To implement effective regulatory reliance throughout the product life cycle
Proposed Option:	✓ To reinforce implementation of reliance-based approach in various stages in the product life cycle (including but not limited to new submissions, new indications, post-approval changes, secondary testing and on-site inspections). ✓ To provide clear and transparent guidance on what documents are required and how they are used for the assessments. ✓ To facilitate mutual understanding among the regulatory authorities, which potentially could lead to international cooperation, work sharing initiatives, and/or collaborative decision-making. ✓ To utilize existing platforms for collaborative workshops of sharing and technical training between the regulatory authorities. **Potential platforms:** ARC (Asia Regulatory Conference), APEC, and ASEAN meetings; WHO; IFPMA; DIA.
Expected Effect:	✓ Reduce regulatory burden and offer an opportunity for faster, more predictable approvals and access to the patients compared to standard pathways. ✓ Utilize available capacity efficiently and allow the allocation of resources to other functions within the regulatory authority. ✓ Strengthen trust between participating regulatory authorities as the foundation of regulatory reliance. ✓ Foster aligned regulatory decision-making between the regulatory authorities to lay the groundwork for a fully harmonized global regulatory environment. ✓ May lead to a consideration of changes to the regulatory and legal frameworks to leverage of the benefits of regulatory reliance in the longer term.