Frequently Asked Questions

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Frequently Asked Questions (FAQ) on the ASEAN Joint Assessment (JA) Procedure

1	What is the objective of the Joint Assessment Coordinating Group (JACG)? The JACG shall function under the guidance of Pharmaceutical Product Working Group (PPWG) to facilitate the development and implementation of activities leading to further cooperation among National Regulatory Authorities (NRAs), such as joint assessment of applications for marketing authorization and other similar activities where staff of different NRAs can work together, respecting national decision-making processes.
2	What is an ASEAN Joint Assessment (JA) Procedure? ▪ Joint assessment is a formal procedure in which the same application is simultaneously submitted to all participating ASEAN National Medicines Regulatory Authorities (NMRAs). ▪ Applications can be submitted via three (3) different routes: - the responsive application route: applications concerning products that are included in the priority lists published by ASEAN NRAs; - the proposed application route: applicants propose products that are not included in the priority lists published by ASEAN NRAs; - the invited application route: applicants are approached by ASEAN NRAs or WHO and invited to submit an application for a product of important public health value. The full application dossier is uploaded by the applicant to the dedicated IT platform developed by WHO. The applicant also provides all participating NRAs with access to detailed assessment reports of the product (scientific evaluation and inspections reports)[1] generated by a reference NRA[2] or WHO. Abbreviated JA procedure: In this pathway, all participating NRAs access the full product dossier and the assessment reports, and conduct the joint assessment of the entire dossier through appropriate collaboration mechanisms. During the product assessment, the ASEAN NRAs take into account and give significant weight to the assessment performed by the reference NRA or WHO to reach their joint regulatory decision. After completing the joint review, if the outcome of the product benefit-risk evaluation is positive, recommendation to grant national authorizations to the product will be provided. ▪ An abbreviated JA procedure can only be initiated with a minimum participation of three (3) NRAs using the dedicated IT platform developed by WHO enabling applicants

[1] Assessment reports may be provided directly by the applicant or by the concerned reference NRA based on applicant's consent

[2] Reference NRAs are drawn from those defined by WHO as 'stringent' NRAs (*https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs*) or NRAs at 'maturity level' 3 or 4 following WHO benchmarking (*https://www.who.int/initiatives/who-listed-authority-reg-authorities/MLA4).* As of January 2022, for the purpose of Joint Assessments, reference NRAs are those that normally generate unedited assessment reports in English – which is necessary to enable ASEAN NRA to make effective use of report contents.

	to submit a dossier only once for all participating authorities. ▪ Assessment work is then carried out together by all participating NRAs and a joint assessment report is prepared. ▪ At the end of the process, the final decision on the application is then taken, within established timelines, by each individual NRA through their normal decision-making process based on the joint report and, where applicable, nationally-relevant considerations.
3	Which NRAs can participate in JA procedure? ▪ Participation in JA's procedure is open to all ASEAN Member States (AMS) on a voluntary basis. ▪ Participation is related to each product to be assessed. Therefore, each AMS will be able to participate for certain products and decline to participate for other products.
4	Which products are eligible for the JA procedure? NRAs websites will post and periodically update priority therapeutic groups or indications to guide applicants. However, applicants may propose products outside the scope mentioned in the posted priority lists (see point 2 above).
5	When to submit application for JA Procedure? At any time, applicants may express their interest to submit an application by approaching Chair and Co-Chair of the JA Coordinating Group. Nevertheless, applicants can still approach any AMS to express their interest to submit application.
6	How many applications can be submitted for JA Procedure? There are no formal limitations to the number of applications that can be submitted, as long as it is pragmatic and reasonable considering additional workload at NRAs.
7	How to submit application for JA Procedure? Applicants express their interest in participating by approaching Chair and Co-Chair of the JA Coordinating Group, copying WHO relevant contact (cabacom@who.int). After receiving confirmation that their Expression of Interest is accepted, applicants will submit documentation as instructed in due course.
8	When does the review of application for JA Procedure start? Review will start as soon as a complete and valid application has been uploaded to the IT platform, Joint Assessments Information Management System – JAIMS, by the applicant or provided by the applicant to WHO or a selected ASEAN NRA, as applicable case by case.

9	What does Lead NRA mean? ▪ Participating NRAs will designate a Lead NRA and a single point of contact (SPOC) between each NRA and the Lead NRA for the JA procedure for each specific product dossier. ▪ The same NRA can be designated as Lead NRA in more than one JA projects. ▪ The same SPOC can be designated for more than one JA projects. ▪ The role of the Lead NRA is to monitor the implementation of the JA procedure, to ensure that all participating NRAs have received the necessary documentation, to ensure that all participating NRAs have had the opportunity to provide comments and to prepare the consolidated List of Questions (LoQ) and the first draft of the assessment report.
10	How will information be shared among the JA countries? Information will be shared among the JA countries via an IT platform (Joint Assessments Information Management System – JAIMS) supported by WHO and the information will be only made accessible to the countries who agree to join the JA procedure and have signed a declaration of confidentiality.
11	Which reference NRA will be used for JA Procedure? ▪ Reference NRAs are drawn from those defined by WHO as 'stringent' NRAs (https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs) or NRAs at 'maturity level' 3 or 4 following WHO benchmarking (https://www.who.int/initiatives/who-listed-authority-reg-authorities/MLA4). ▪ As of January 2022, for the purpose of Joint Assessments, reference NRAs are those that normally generate unedited assessment reports in English – which is necessary to enable ASEAN NRA to make effective use of report contents. ▪ In addition, WHO will be the institution of reference for products approved via the WHO prequalification processes.
12	Can the JA use reliance mechanisms to assess applications? Yes, see point 2 above. It should be noted that the JACG has not yet developed a common set of eligibility criteria and implementation procedures for the use of reliance in the context of joint assessments. For the time being, the use of reliance mechanisms will be decided on a case by case.
13	How will product assessment queries be raised and responded to? ▪ Additional documentation or explanations will be in the form of a single consolidated List of Questions (LoQs) transmitted on behalf of all participating NRAs by the Lead NRA. ▪ The correspondence between applicant and Lead NRA will take place via the JAIMS platform.

14	Can GMP compliance also refer to Joint Sectoral Committee (JSC) compliance in addition to PIC/S compliance? This questioned can be considered at individual NRA level based on its own standard of GMP compliance. According to ASEAN Sectoral Mutual Recognition Arrangement for GMP Inspection of Manufacturers of Medicinal Products, the JSC on GMP MRA recognizes and benchmarks with PIC/S Guide to GMP for Medicinal Products.
15	What is the timeline for JA Procedure? A JA procedure should be completed within 150 days from the availability of the application dossier to the finalization of the JA report
16	Who will finalise the assessment reports? At the end of a JA project, Lead NRA and assessors from all participating NRAs will finalise the technical part of the assessment and issue a joint assessment report.
17	Who will grant the approval of the product? Product registration approval is a national decision issued by individual NRAs.
18	Will the Joint-Assessment report be shared among all ASEAN NRAs including those who did not participate in the JA Procedure? An ASEAN NRA who has not participated in a JA procedure may request another ASEAN NRA or WHO to share the relevant joint assessment report if they received an application for a product that has gone through the JA Procedure.
19	How will progressive updates on JA Procedure be shared? Is there a person to refer to for more information on JA Procedure? Updates on JA Procedure will be shared during ACCSQ-PPWG meetings. WHO can be contacted for matters related to ASEAN JA activities. Applicants may also submit proposals or enquiries through any ASEAN NRA.
20	Is the JA Procedure the same as Collaborative Registration Procedure (CRP)? No, they are different. A CRP is a procedure established between an individual NRA and the WHO in order to facilitate speedy registration of products prequalified by the WHO or approved by an SRA. Currently, only 4 ASEAN NRAs are making use of the CRP. For more details about the CRP: https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration

21	What is the Joint Assessments Information Management System (JAIMS)? JAIMS is an online platform, currently managed by WHO, that enables applicants to upload a dossier that can be accessed simultaneously by all participating NRAs for joint assessment, preparation of Lists of Questions, and finalization of JA reports. It also enables reference NRAs to upload assessment reports and any other relevant document aimed at facilitating the joint assessment process.