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Draft ☐ Final ✱

ASEAN Joint Assessment (AJA) for Pharmaceuticals – How should it evolve?

✱ **Date:** 28/05/2024 ✱ **Version:** 1




✱ Position Paper

Executive Summary

The AJA pathway can evolve to be the future regulatory path of choice, bringing lifesaving medicines to ASEAN patients faster along with convergence of requirements in the region, strengthening NRAs capability, and fostering mutual understanding and collaboration.

The learnings and experiences from the AJA procedure should be leveraged to improve the overall process. Below are the key recommendations from industry to refine and increase the efficiency and attractiveness of the AJA processes:

- Embedding AJA in the NRA's legal framework for registration procedures for new products and post-approval changes management is key to enable a transparent, efficient, and predictable regulatory environment, making the AJA a pathway of choice for industry in the future.
- Adopt a more competitive and predictable AJA assessment time for expedited (90 calendar days) and full AJA (120 calendar days) with a clearly defined product selection timeline (135 calendar days) compared to the national reliance pathway assessment timelines.
- Allow applicants to choose the participating AMS at the time of product selection.
- Issue a single consolidated list of questions during the AJA review to facilitate an efficient query procedure.
- Adopt the CTD format for all submissions and minimize additional national requirements. Submit CTD Modules 2-5 only to WHO JAIMS and NRA Module 1 to the NRAs directly.

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1. ASEAN Joint Assessment (AJA): developments to date

Industry welcomes the recent developments to the AJA process:

- Expansion of scope of products to include biologicals, vaccines and additional therapeutic areas.
- Australian Therapeutic Goods Administration (TGA) and World Health Organization (WHO) involved in 'retrospective' review of products with ASEAN regulators to gain first-hand experience of joint assessment.
- Additional option of expedited AJA procedure.

The industry believes that AJA can be a valuable product registration pathway for ASEAN region to facilitate patient access to innovative medicine. As AJA is based on reliance principles, it has potential to foster NRAs collaboration and harmonization, and streamline health agency and industry resources. Nonetheless, to further increase uptake so that the population in ASEAN can benefit from this innovative regulatory pathway, stakeholders should have a continuous improvement mindset and maintain strong collaboration with each other.

2. How should AJA evolve?

It is important to continue **creating awareness and understanding on AJA pathways and processes among AJA stakeholders**. WHO workshops (Bangkok in Oct 2022 and Manila in Aug 2023) helped to educate all AJA stakeholders with an aligned understanding of the procedures and requirements to enable an effective AJA review. Such workshops are greatly appreciated as they help in building trust among NRAs and industry through dialogue and collaboration.
The EFPIA ASEAN Regulatory Network are proposing the following recommendations for improvement for consideration to further enhance the AJA procedure.

1. <u>Further improve the Procedures and Timelines</u>

This is recognized by ASEAN Joint Assessment Coordinating Group (JACG) during the WHO workshops in Aug 2023 and industry is fully supportive of this.
Currently full AJA procedure (excluding invited route) comprises two steps: candidate product selection (up to 135 calendar days) and joint assessment (up to 150 calendar days) [1]. The total of 285 calendar days makes the procedure less attractive compared to existing national reliance pathways in ASEAN NRAs[1].
With the appeal from JACG for applicants to submit more applications via AJA, it is recommended to consider simplifying and accelerating the first step candidate product selection process.
In addition, for AJA to be more comparable with national reliance pathways, it is recommended to consider reducing the joint assessment timeline as follow since reference NRA's assessment is leveraged:

- **Expedited AJA - 90 calendar days**
- **Full AJA - 120 calendar days**

[1] For example, evaluation time by the Philippines FDA and Thailand FDA are stated to be ca. 30-45 working days [2] and ca. 200 days [3], respectively, representing the shortest and longest timelines of national reliance pathways in ASEAN.


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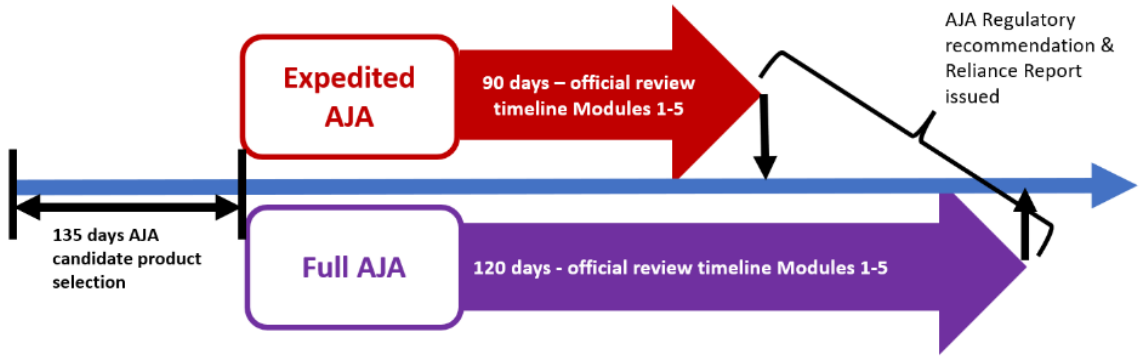
The joint assessment timelines are calculated from the submission of Modules 1-5 (Per ICH CTD), to the Joint Regulatory recommendation and issuance of joint assessment report. Below diagram shows the proposed timeline for both the expedited AJA (90 days) and full AJA (120 days). This duration excludes the time for NRA national regulatory decision making after the AJA regulatory recommendation.



2. Streamline Dossier Submission

To have a streamlined dossier submission, it is recommended for participating NRAs to adhere to AJA guideline [1] where the WHO Joint Assessment Information Management System (JAIMS) platform is fully utilized for single submission of the core technical part of the dossier Module 2-5 for the purpose of the ASEAN Joint Assessment. In parallel, only administrative part of dossier, Module 1, will be submitted locally to NRA through national system.
This will bring efficiency as there is no duplicate submission of M2-M5 onto each participating NRAs national system after uploading the same onto JAIMS, i.e., applicant would *only upload one core dossier (M2-M5) onto* WHO JAIMS.

3. Include Post Approval Changes in AJA scope

The concept of reliance for regulation of medical products should be applied throughout the life cycle of medical products, according to WHO [4]. Hence it is recommended to expand the AJA scope to include Post Approval Changes (PAC), e.g., line extensions, new indications, and CMC changes. Guidance on requirements, submissions, timelines, and evaluations of PAC via the AJA pathway should be published.

4. Issue Single List of Questions (LoQs)

A single list of questions (LoQ) issued by AJA to the applicant during the review would bring efficiency, clarity, predictability, and convergence in the AJA review process and it will help build confidence among all stakeholders. A single LoQs will help the applicant in managing limited resources to provide timely response to the questions. Multiple lists of questions, which at times are repeated questions issued by NRAs to applicant, will slow down the overall process.
It is recommended that the WHO JAIMS be a central platform with technical capacity for the collation and coordination of questions from the participating NRAs. It should be used by the lead and participating NRAs to facilitate discussion, review, and consolidation of all questions into 1 LoQs before sending to the applicant.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5. Inclusion of AJA Pathway in NRA Registration Procedure

It is welcoming that NRAs have begun to include AJA procedure as part of the reliance pathways under their national reliance or registration pathways. For instance, Malaysia's updated Guideline for Facilitated Registration Pathway now officially includes the AJA[2] [5]. It is highly encouraged for all the ASEAN NRAs to officially include AJA procedure into their national reliance pathways. This will confer status to the AJA procedure and gives the company additional choices in using reliance pathways.
In addition, publishing detailed guidance on the AJA procedure, timelines and submission requirements on respective NRA websites will provide transparency and predictability for applicant planning to submit under AJA procedure.

6. Selection of AMS

We recommend that the applicant is allowed to select the AMS (2 or more in line with the guidance) in an AJA filing. Such flexibility and autonomy are very valuable for applicants and medicinal products with diverse profiles.

7. Remove Country Specific Requirements (CSR)

We recommend aligning with international regulatory best practices of reference agencies, such as the:

- Acceptance of Multiple DS and/or DP manufacturing site under 1 product licence;
- Waiver/Flexibility about the need and timing to submit Certificate of Pharmaceutical Product (CPP) for AJA procedure [6].

In addition, we recommend adopting WHO and ICH guidelines related to the review of Quality, Efficacy, and Safety of the product. This includes alignment with ICH stability study data requirements.

3. Summary

The AJA pathway is a promising reliance pathway that brings convergence in the region, strengthens NRAs capability, and fosters mutual understanding. In the ASEAN spirit, such program if well executed, will help to bring lifesaving medicines to ASEAN patients expeditiously.

The experiences and challenges encountered during the AJA procedure shall be leveraged as valuable learnings to improve the overall process. The above recommendations from industry aim to refine and increase efficiency of the AJA processes.

To achieve this efficiency, we recommended for increased effectiveness training for all stakeholders involved, e.g., training on usage of WHO JAIMS platform.

We encourage participating NRAs to abide by the revised AJA guidelines, i.e., timelines, which will bring more confidence & a higher participation rate among companies.

[2] Malaysia NPRA GUIDELINE FOR FACILITATED REGISTRATION PATHWAY Revision 1 (November 2023) includes the ASEAN Joint Assessment (JA) procedure under the Verification Review Pathway.


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4. Reference

[1] AJA Procedure for Pharmaceutical Products Information for Applicants (link here)
[2] Philippines FDA Circular No. 2022-004
[3] Thai FDA Notification: Application for Drug Registration of New Drugs, New Biological Products and human vaccines, 31-Jul-2018
[4] Annex 10 Good reliance practices in the regulation of medical products: high level principles and considerations. WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth report.
[5] Malaysia NPRA GUIDELINE FOR FACILITATED REGISTRATION PATHWAY Revision 1 (November 2023) includes the ASEAN Joint Assessment (JA) procedure under the Verification Review Pathway. (link here)
[6] Asia Partnership Conference of Pharmaceutical Associations (APAC) Report on Regulatory Agility Implemented During the COVID-19 Pandemic: Inspiring Partnerships and Recommendations for the Way Forward, 29 September 2022, mentions country specific requirements (CSR) that could pose challenges (link here).

5. Appendix (Acronyms):

JACG – Joint Assessment Coordinating Group
WHO JAIMS – WHO Joint Assessment Information Management System
AMS – ASEAN Member State
ICH CTD – International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, Common Technical Document
CMC – Chemistry, manufacturing, and controls
NRA – National Regulatory Authority
PAC – Post Approval Changes


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