ASEAN Joint Assessment Procedure for Pharmaceutical Products
Information for applicants

Revision 2

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Definition

Joint assessment is a formal procedure in which the same[1] application is simultaneously[2] submitted to all participating ASEAN National Medicines Regulatory Authorities (NRAs). 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 time lines, by each individual NRA through their normal decision-making process based on the joint assessment report and, where applicable, nationally-relevant considerations.

Product eligibility criteria

Notes announcing priority therapeutic areas and indications will be periodically posted on ASEAN NRAs websites inviting expressions of interest from applicants for the submission of applications for JA candidate product selection. Although there is preference for products within the priority areas, applicants can submit applications for other products - outside priority areas - for consideration by ASEAN NRAs as long as the products have already been approved by a reference NRA[3], prequalified by WHO, or assessed through special regulatory pathways such as EU Article 58 or US FDA tentative approval. In addition, products should be manufactured in a PIC/S-GMP compliant site (documentary verification only, no inspections foreseen.

Overall description of the procedure

Applications can be submitted via three (3) different routes:

1) the responsive application route: applications concerning products that are included in the priority lists published by ASEAN NRAs;
2) the proposed application route: applicants propose products that are not included in the priority lists published by ASEAN NRAs;
3) 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.

For each route, two (2) types of regulatory pathways are available, the **1) full JA procedure** and the **2) expedited JA procedure.** For both procedures 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)[4] generated by a reference NRA[3] or WHO.

1) **Full 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

[1] Same application refers to the technical content of the application; national administrative parts remain different.

[2] Simultaneously refers to the fact that JA procedure will not start until application documentation is available to all participating NRAs.

[3] 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.

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

benefit-risk evaluation is positive, recommendation to grant national authorizations to the product will be provided.

2) Expedited JA procedure: In this pathway, all participating NRAs access the full product dossier and the assessment reports, and apply verification of the sameness of the product information submitted by the applicant to the ASEAN JA procedure and to the reference NRA or WHO. This Regulatory pathway allows ASEAN NRAs to jointly relying on the assessments performed by reference NRAs or WHO, obviating additional regulatory assessment to reach their regulatory decision. It implies reduced timelines to complete the review of the application submitted. After completing the joint review, if the outcome of the verification is positive, recommendation to grant national authorizations to the product will be provided.

Preference is given to the expedited JA procedure. However, participating NRAs will decide on a case-by-case basis whether a full JA procedure must be applied.

The full JA procedure entails the following steps:

1. The first step is the publication of Notices of Invitation to Express Interest. At appropriate intervals, through internal JACG coordination mechanisms, participating ASEAN NRAs will post Notices of Invitation to Express Interest on their web sites inviting applicants to express their interest in submitting applications through the JA procedure. Notices will mention the following elements of information:
   a) which medicinal products are eligible for the JA procedure within a specified time frame;
   b) which ASEAN NRAs are tentatively participating for which products and which NRA is the Lead NRA for each product;
   c) time frame for submitting Expressions of Interest and any other relevant aspect of the procedure.

2. In situations of high public health concern, as determined by ASEAN NRAs, selected manufacturers may be directly invited to submit specified products for assessment under the JA procedure without publication of Notices for Expressions of Interest.

3. Applicants express their interest in participating using the standard form Applicant Expression of Interest - AEOI (Annex 1) and, when necessary, form Applicant Expression of Interest - AEOI1 (Annex 1a). By submitting an Expression of Interest, applicants undertake to share the same information with all participating NRAs on all aspects of quality, safety and efficacy of the specified medicinal products along with information on variations implemented and/or planned. Communication related the JA procedures should be addressed to JACG Chair and co-Chair with a copy to WHO.

4. Lead NRA seeks concurrence and confirmation from all participating NRAs to accept Expression of Interest. If at least three participating NRAs concur, Lead NRA requests applicant to submit a full application (see point 5 below) and a copy of a letter authorising reference NRA[3] (see model in Annex 2a) or WHO (see model in Annex 2b) to share confidential information on the product and its assessment and inspections' reports.

5. Applications must comply with the following aspects:
   d) the technical application dossier must include the same technical information as that submitted to reference NRA or WHO;

e) the technical part of the dossier in ACTD or ICH-CTD format shall be provided in electronic form to be uploaded to a dedicated, secure web site set up by WHO (Joint Assessments Information Management System (JAIMS – see below); only participating NRAs will be able to access the dossiers;
f) administrative part of dossier specific to each participating NRA requirements will be submitted directly to each participating authority;
g) fees as required by each participating NRA will be paid according to normal national procedures.

6. The administrative part of the dossier, including fees when applicable, shall be submitted individually to all participating NRAs following locally applicable procedures. The technical part of the dossier shall be uploaded to the JAIMS platform as mentioned above (uploading instructions will be provided). Review of applications will start as soon as the dossier is available on the platform and/ or specific national requirements, to be announced as applicable by concerned NRAs, have been met.

7. The Lead NRA coordinates and facilitates the implementation of the procedure and acts as 'rapporteur'. The Lead NRA will undertake the following steps (further addressed below and shown in flowchart):
   h) verify that all participating NRAs have appointed staff for the joint assessment and received credentials to access JAIMS;
   i) verify that applicant's submission is completed;
   j) ensure that exchange of letters for sharing documentation (see below) is completed;
   k) request reference NRA to share confidential information and assessment and inspections' reports in English;
   l) lead the assessment of application dossier, coordinate the preparation of List of Questions (LoQ) and draft assessment report and circulate to participating NRAs (work sharing among all participating NRAs is encouraged);
   m) receive comments by participating NRAs about draft assessment report and, if applicable, need to request additional information from applicant;
   n) coordinate the review of feedback from applicant, if applicable;
   o) set date for assessors from participating NRAs to participate in JA session;
   p) coordinate with WHO and/or expert(s) from reference NRA for participation in JA session.

8. An exchange of formal agreement letters takes place, facilitated by WHO, between participating NRAs and either reference NRA or WHO (in the case of products prequalified by WHO). The exchange of letters addresses the following matters:
   q) participating NRAs convey to reference NRA/WHO their willingness to implement JA for a specific product;
   r) participating NRAs request access to information and commit to comply with confidentiality requirements;
   s) If part of the information contained in the application dossier or in the reference NRA/WHO documentation to be shared does not belong to the applicant or to reference NRA/WHO, separate confidentiality commitments will have to be signed.

9. There could be situations in which a product proposed for JA is already authorized for marketing in one or more AMS. In these cases, the NRA that has already approved the product decides if it wishes to participate in the JA anyway. The applicant must act

according to the NRA decision and accept participation in the JA procedure. The outcome of the JA may result in no change, in a variation to the existing marketing authorization, or in a new marketing authorization.

10. Participating NRAs confirm their access to the application and reference documentation from reference NRA or WHO, assess the application and note their observations, if any, in the JAIMS platform. Observations may entail requesting additional documentation from the applicant. In this case, the Lead NRA will ensure that all observations have been received, consolidate them in a single document, and then notify the applicant as required. The time frame is suspended until response is received from the applicant addressing the observations raised.

11. After the feedback from the applicant has been received, the Lead NRA coordinates its review and the preparation of a draft joint assessment report. If all participating NRA concur with the conclusions stated in the draft report and deem unnecessary to raise further matters, then the report is formally transmitted to all participating NRAs for national decision-making. If one or more participating NRAs deem necessary a face-to-face discussion, the Lead NRA organizes a JA session with support from WHO.

12. At the request of participating NRAs through the Lead NRA, WHO will facilitate the participation of one or more senior assessors from a reference NRA or WHO in a JA session.

13. A face-to-face JA session is a technical meeting attended by two designated assessors (or more if funds permit) from each participating NRA. The session is assisted, when requested, by senior assessors provided by reference NRA and/or WHO. Purpose of the JA session is to review and discuss all aspects of the application, clarify technical issues, address diverging opinions, and prepare a joint assessment report. A full JA session is expected to last up to four working days. Alternatively, a JA session may be conducted via a web conference to reduce JA time. At the end of the JA session, participants take the joint assessment report to their own NRA for inclusion in the national decision-making process.

14. JA reports are confidential documents belonging to the participating NRAs. After receiving a JA report, each participating NRA is expected to take a decision on the application at their earliest decision-making meeting within the timelines provided at Step C.

A full JA procedure can only be initiated with a minimum participation of three NRAs, while two NRAs may decide to jointly review an application via the expedited JA procedure or the invited application route using the dedicated IT platform developed by WHO enabling applicants to submit a dossier only once for all participating authorities.

The expedited JA procedure: is an accelerated procedure which can be applied to products approved by reference NRAs or WHO. The expedited JA procedure will follow the same process and steps as for the full JA procedure. However, it will only be applied verification of the sameness of the product information submitted by the applicant to the ASEAN JA procedure and to the reference NRA or WHO, obviating additional regulatory assessment to reach the regulatory decision. The procedure will be expedited and timelines to complete the review are expected to be significantly reduced.

The invited applications route: is a faster procedure that can be proposed by any ASEAN NRA when a particular product is deemed to be of high public health interest for several ASEAN member countries and suitable for the JA process. The proposing NRA will prepare and circulate a short note describing the product and seek other NRAs endorsement of the proposal to conduct a JA. The product concerned may belong to any therapeutic group and does not need to match the criteria already published by ASEAN NRAs. Applicants or WHO may approach any ASEAN NRA to propose a product to be jointly assessed. The NRA receiving the proposal will decide whether this merit being shared for consideration by the other ASEAN NRAs.

The invited application route can be used to conduct the full assessment of a complete dossier (as in the full JA procedure) or to the expedited JA procedure.

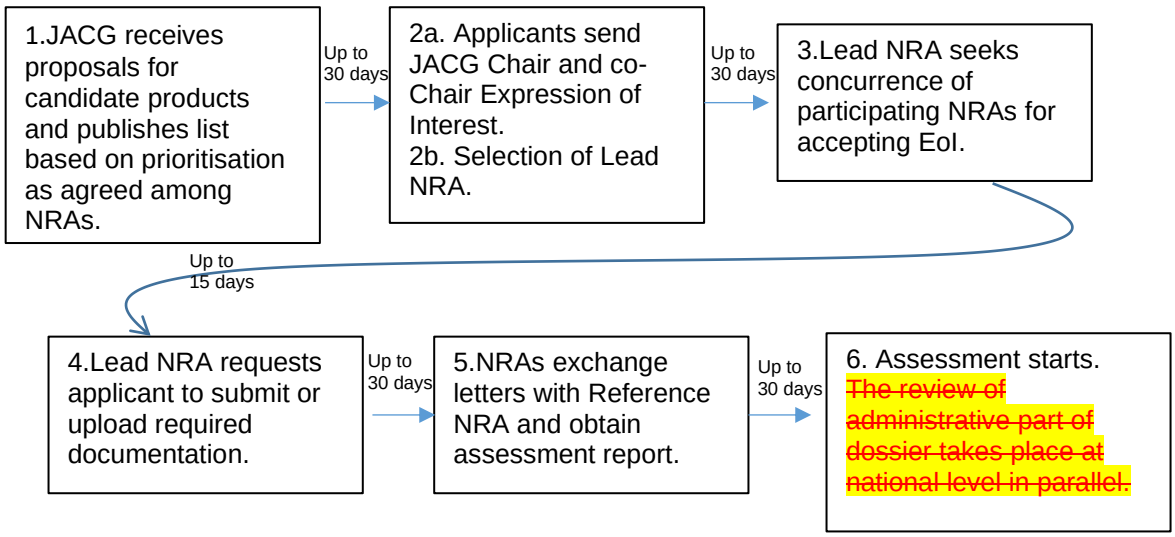
Sharing of JA documentation among AMS

An ASEAN NRA who has not participated in a JA procedure may receive an application for a product that has gone through a JA procedure after this has been finalized. This NRA may request another ASEAN NRA or WHO to share the relevant joint assessment report and may decide to rely on such report for its own national decision, if applicable legislation permits. When such situations arise, concerned applicants will be asked to sign a consent letter to permit such sharing of information.

Steps of full JA procedure

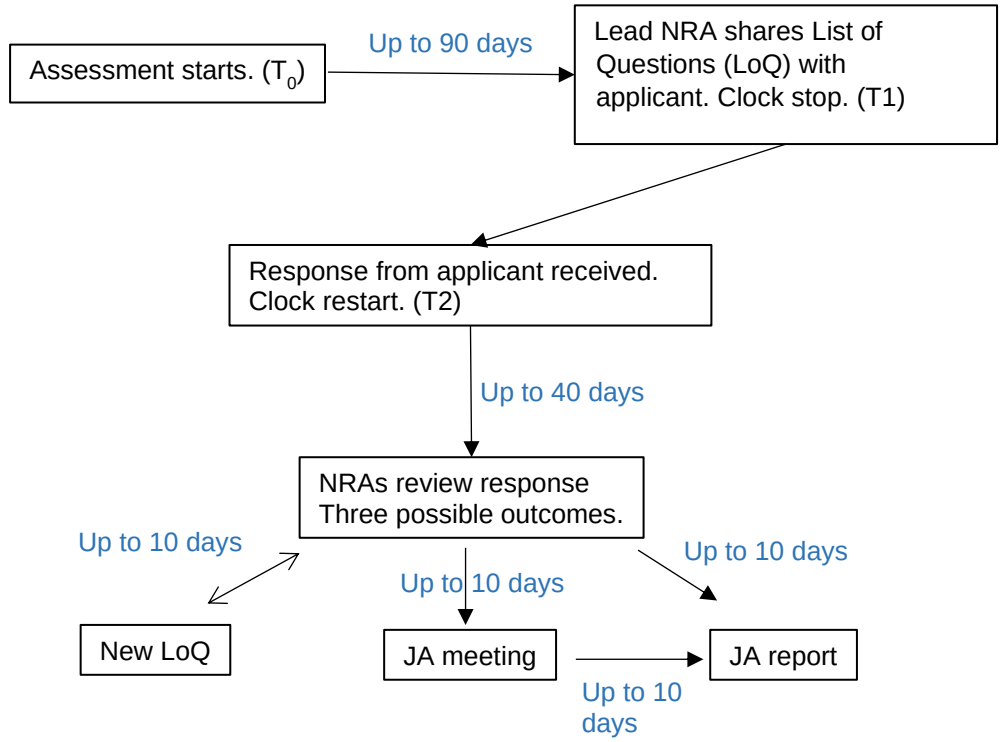
A. ASEAN JA candidate product selection (total up to 135 calendar days)

Proposed revision



B. ASEAN Joint assessment process (total up to 150 calendar days; 135 calendar days if JA meeting unnecessary)

Proposed revision



C. Regulatory decision-making process at country level

Timeline at individual National Medicines Regulatory Agencies (NRAs):

ASEAN Member State	Timeline (working days)
Brunei Darussalam	60
Cambodia	90
Indonesia	45
Lao PDR	45
Malaysia	30
Myanmar	-90 for normal situation -60 for urgent public health needs situation
Philippines	30
Singapore	30
Thailand	30
Viet Nam	60

Annex 1

Expression of applicant's interest for the submission of an application for the ASEAN Joint Assessment Procedure

The undersigned Applicant expresses its interest to submit an application in the framework of the ASEAN Joint Assessment Procedure to all participating[5] ASEAN NRAs based on the following details:
Applicant details:

Name: _____ ("the Applicant")

Address: _____

_____

E-mail: _____

Phone: _____

Product details:

INN(s): _____

Dosage form and strength: _____

Packaging: _____

Detailed[6] address of manufacturing site(s): _____

Brand name, if applicable: _____

Reference approval[7] details:

Reference NRA: _____

Marketing authorization number: _____

Date of approval (dd/mm/yyyy): _____

Date of latest revision[8], if applicable (dd/mm/yyyy): _____

Marketing authorization holder: _____

WHO prequalification reference number: _____

Date of prequalification (dd/mm/yyyy): _____

WHO prequalification holder: _____

[5] Names of participating NRAs for each specific eligible product(s) are mentioned in the Notice of Invitation to Express Interest.
[6] Address of manufacturing sites must be detailed enough to identify the exact site. If more than one site is referred to, there should be brief mention of manufacturing phase(s) conducted at each site.
[7] Accepted reference approvals are mentioned in the Notice of Invitation to Express Interest.
[8] Revision refers to renewal, major variation, or other relevant regulatory decision.

The Applicant confirms that the information and documentation provided in conjunction with the present Expression of Interest is true and correct, that the pharmaceutical product submitted for JA assessment is the same[9] as the reference approval product and that the technical part of the information is the same[10] as that submitted to reference approval NRA or WHO Prequalification Programme (WHO-PQP). Non-essential differences[11] from the information submitted to WHO-PQP, are the following:

_____

_____

_____

The Applicant:

1. undertakes to adhere to, and collaborate with the participating ASEAN NRAs, reference NRA/ WHO-PQP in line with the JA Procedure; and
2. authorizes the reference NRA/WHO-PQP[12] to provide participating ASEAN NRAs confidential access to the following information and documentation and to freely discuss the same with participating ASEAN NRAs: a) the full assessment and inspection outcomes (reports); b) information and documentation on subsequent variations as well as information and documentation on any actions taken by the reference NRA/WHO-PQP after approval of the Product. To this end, the Applicant submits copy of the consent letter sent to the reference NRA or WHO-PQP.

   As regards sharing the outcomes of assessments and inspections, only data owned by the applicant are shared. Sharing of any other data is subject to a separate additional agreement by the respective data owners.

3. authorizes the participating ASEAN NRAs to freely share and discuss all registration and product related information provided by the Applicant with the reference NRA or WHO-PQP, subject to the obligations of confidentiality and restrictions on use as contained in the relevant agreements and undertakings.

☐ The applicant is not the reference NRA marketing authorization or WHO prequalification holder.

An authorization letter from relevant holder is attached.

For the Applicant

Signature: _____

Name: _____

Title: _____

Place: _____

Date (dd/mm/yyyy): _____

[9] Same pharmaceutical product means: same product dossier, same manufacturing chain, processes and control of materials, same API and FPP specifications and same essential elements of product information.

[10] Technical data included in the dossier must be the same. There may be country-specific differences in administrative data. Additional technical data can be provided (e.g. bioequivalence with a country-specific comparator).

[11] Non-essential differences include differences in administrative information, brand name, name of applicant, format of product information, level of detail of product information, labelling of internal and external packaging, and language of product information.

[12] If the applicant for national registration is not the same as the WHO prequalification holder, then the authorization to WHO-PQP must be provided by the WHO prequalification holder or their legal representative.

Annex 1a

Model authorization letter to be used if the applicant is not the holder of the reference NRA marketing authorization or WHO prequalification.

A separate letter for each participating ASEAN NRA should be provided along with the Expression of Interest. A copy should be provided to the reference NRA or to WHO-PQP, as applicable.

This is to confirm that_____ (*applicant name*) submitting application for the ASEAN Joint Assessment Procedure for product _____ approved by _____ with authorization number _____, is acting for, or pursuant to rights derived from _____ (*name of reference NRA marketing authorization holder or WHO prequalification holder*) and that _____ (*name of reference NRA marketing authorization holder or WHO prequalification holder*) agrees with the application for the Joint Assessment procedure in the concerned ASEAN countries.

For_____ (*name of reference NRA marketing authorization holder or WHO prequalification holder*):

Signature: _____
Name: _____
Title: _____
Place: _____

Date (dd/mm/yyyy): _____

Annex 2a

Marketing authorization holder gives consent to reference NRA to share confidential information with ASEAN NRA for Joint Assessment Procedure

The marketing authorization holder hereby consents to _____ (*name of reference NRA*) providing the following information and documentation to _____(*name and address of ASEAN NRA*) to be used in conjunction with the ASEAN Joint Assessment Procedure applied to the product described below, and to freely discuss product-related matters with the aforesaid ASEAN NRA:

- the full assessment and inspections' reports;
- information and documentation on subsequent variations (as defined in the *WHO guidelines on variations to a prequalified product*, WHO Technical Report Series, No. 981, and any updates thereto), as well as information and documentation on any actions taken by _____ (*reference NRA*) after product approval;
- all other data, reports, information and documentation that are in possession of by _____ (*reference NRA*) and are necessary for the ASEAN Joint Assessment Procedure.

As regards sharing the outcomes of assessments and inspections, only data owned by the marketing authorization holder are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.[13]

Product details:

INN(s): _____

Dosage form and strength: _____

Packaging: _____

Detailed[14] address of manufacturing site(s): _____

Brand name, if applicable: _____

Reference approval details:

Reference NRA: _____

Marketing authorization number: _____

Date of approval (dd/mm/yyyy): _____

Date of latest revision[15], if applicable (dd/mm/yyyy): _____

[13] If certain data do not belong to the WHO prequalification holder, the WHO prequalification holder specifies such data in an annex to this declaration of consent. If applicable, the WHO Prequalification holder will submit letters issued by data owns authorizing the use of the data in the ASEAN Joint Assessment Procedure.

[14] Address of manufacturing sites must be detailed enough to identify the exact site. If more than one site is referred to, there should be brief mention of manufacturing phase(s) conducted at each site.

[15] Revision refers to renewal, major variation, or other relevant regulatory decision.

Marketing authorization holder:

Applicant details:

Applicant: _____

Address: _____

_____

Email: _____

Phone: _____

For the marketing authorization holder

Signature: _____

Name: _____

Title: _____

Place: _____

Date (dd/mm/yyyy): _____

Annex 2b

WHO prequalification holder gives consent to WHO-PQP to share confidential information with ASEAN NRA for Joint Assessment Procedure

The WHO prequalification holder hereby consents to WHO-PQP providing the following information and documentation to _____(*name and address of ASEAN NRA*) to be used in conjunction with the ASEAN Joint Assessment Procedure applied to the product described below, and to freely discuss product-related matters with the aforesaid ASEAN NRA:

- the full WHO-PQP assessment and inspections' reports;
- information and documentation on subsequent variations (as defined in the *WHO guidelines on variations to a prequalified product*, WHO Technical Report Series, No. 981, and any updates thereto), as well as information and documentation on any actions taken by WHO-PQP post prequalification of the Product.
- all such data, reports, information and documentation that are necessary for the ASEAN Joint Assessment Procedure.

As regards sharing the outcomes of assessments and inspections, only data owned by the WHO prequalification holder are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.[16]

Product details:

INN(s): _____

Dosage form and strength: _____

Packaging: _____

Detailed[17] address of manufacturing site(s): _____

Brand name, if applicable: _____

WHO prequalification details:

WHO prequalification reference number: _____

Date of prequalification (dd/mm/yyyy): _____

Date of requalification (if applicable): _____

WHO prequalification holder: _____

Applicant details:

[16] If certain data do not belong to the WHO prequalification holder, the WHO prequalification holder specifies such data in an annex to this declaration of consent. If applicable, the WHO prequalification holder will submit letters issued by data owns authorizing the use of the data in the ASEAN Joint Assessment Procedure.

[17] Address of manufacturing sites must be detailed enough to identify the exact site. If more than one site is referred to, there should be brief mention of manufacturing phase(s) conducted at each site.

Applicant: _____

Address: _____

_____

Email: _____

Phone: _____

For the WHO prequalification holder

Signature: _____

Name: _____

Title: _____

Place: _____

Date (dd/mm/yyyy): _____