ASEAN Joint Assessment Procedure for Pharmaceutical Products Public Announcement

The National Medicines Regulatory Authorities (NRA) of ASEAN Member States have developed a new procedure for marketing authorizations: the ASEAN Joint Assessment Procedure. The pilot JA project supported and advised technically by the WHO which started in July 2017 has completed. This is a public announcement for a new JA candidate product.

Description and purpose of the procedure

A joint assessment is a formal procedure in which the same[1] marketing authorization application is simultaneously[2] submitted to all participating 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 taken by each individual NRA through their normal decision-making process based on the joint report and, where applicable, nationally-relevant considerations.

The primary purpose of joint assessments (JA) is to strengthen NRAs technical capacity and to foster mutual trust and reliance among ASEAN Member States (AMS) through a platform for communication and cooperation that supports the NRA of each AMS in ensuring that pharmaceutical products meet requirements of quality, safety and efficacy and that regulatory work is conducted in a timely and efficient manner. A second, important purpose of JA is to facilitate the review of priority medicines throughout ASEAN while respecting existing national decision-making processes.

Participation in JA by ASEAN NRAs

Participation in JA's is open to all ASEAN NRAs 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.
JAs will be implemented when a minimum of three AMS decide to participate.
Applicants are required to submit applications to all participating NRAs.

Overall description of the procedure

The JA procedure entails the following steps:

1. At appropriate intervals, 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 which products are eligible for the JA procedure within a specified time frame and any other relevant information.

2. In situations of high public health concern, as determined by the 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 forms provided in the procedure documentation. By submitting an expression of interest, applicants undertake to share with all participating NRAs the same information on all aspects of quality, safety and efficacy of the specified pharmaceutical products along with information on variations implemented and/or planned. After receiving confirmation that their Expression of Interest is

[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 applications are received in all participating NRAs.

accepted, applicants will submit a full application (see point 4 below) and a copy of a letter (templates provided in the procedure documentation) authorising a reference NRA (see below, eligibility criteria) or WHO to share confidential information on the product and its assessment and inspections' reports.

4. Applications must comply with the following aspects: a) application dossier including the same technical information as that submitted to reference NRA or WHO's Prequalification Programme (WHO-PQP); b) technical part of the dossier in ACTD or ICH-CTD format; c) administrative part of dossier specific to each participating NRA requirements; d) fees as required by each participating NRA.

5. Review of applications will start only after all participating NRAs have received the application(s) and related documentation and have considered it (them) accepted for assessment.

6. During the assessment additional documentation or explanations may be required from the applicant. Such requests will be in the form of a single consolidated request done on behalf of all participating NRAs. The time frame of the JA procedure is suspended until response is received from the applicant addressing the observations raised.

7. At an appropriate time, assessors from all participating NRAs will meet to finalize the technical part of the assessment and issue a joint assessment report. Experts provided by WHO and/or the reference NRA may be invited by participating NRAs to assist and provide technical advice.

8. 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.

Product eligibility criteria

The JA procedure will initially adopt the following eligibility criteria:

a) medicines for treatment of priority diseases in ASEAN region;
b) products already approved by a reference NRA*, prequalified by WHO-PQP, or assessed through special regulatory pathways such as EU Article 58 or US-FDA tentative approval;
c) products manufactured in a PIC/S-GMP compliant site (documentary verification only, no inspections foreseen).

Each Notice inviting expressions of interest will indicate which reference NRAs are accepted for each specific product.

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 the ASEAN Secretariat 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, applicants who have submitted applications for the JA procedure will be asked to sign a consent letter to permit such sharing of information.

*NRAs which are WHO maturity level 3 or 4, EMA, U.S. FDA