FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: ASEAN	**Agency Name:** SIAHR- ASEAN	
Name of FRP: Supporting implementation of ASEAN harmonized requirements for drug registration (SIAHR)		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: Click here to enter a date.		
1. Facilitates activities during development	**2. Accelerates the regulatory review process**	**3. Relies on or recognizes a prior regulatory decision**
☐	☒	☒

Is a Guidance or SOP describing how to apply this FRP publicly available?	Yes- see reference below
When should the FRP be requested?	When reqquested by the agency
Does the agency provide assistance/advice to the sponsor?	Yes- For any product type
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	New Chemical Entities (NCE), Biotechnological Products (Biotech), Major Variations Products (MaV), Minor Variations Products (MiV), and Generics (G).
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	Fees as required by each participating NRA will be paid according to normal national procedures.
Total target (agency) time for assessment (calendar days)	Review of applications will start only after all participating NRAs have received the application(s) and related documentation and have considered it accepted for assessment.
Total target (company) time for responses to agency questions (If stated)	Click here to enter text.

Select one of the following (* see definitions at end of document)

Is this a verification review (a recognition pathway)?*	**Is this an abridged* review (selected dossier portions)? (a reliance pathway)?***	**Is this a full* review of all parts of the dossier?**
☐	☒	☒

If this is a reliance or recognition pathway, what are the accepted reference agencies?	Click here to enter text.
How many reference agency decisions are required?	Click here to enter text.
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted
Is a CPP (Certificate of Pharmaceutical Product) required	Choose an item.

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for approval?	
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Click here to enter text.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	Brunei; Cambodia; Indonesia; Lao PDR; Malaysia; Myanmar; Philippines; Singapore; Thailand; Vietnam;
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Yes, the product has to have been marketed in another country.
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
Post-authorization study commitments	Choose an item.
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- The first step is the publication of Notices of Invitation to Express Interest. At appropriate intervals, and on the basis of the agreement reached by the JACG, 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. - Lead NRA requests applicant to submit a full application and a copy of a letter authorising reference NRA or WHO-PQP to share confidential information on the product and its assessment and inspections' reports. Applicants must submit applications to all participating NRAs as announced in the Lead NRA request.
Date of this update	6 JANUARY 2020
References	1. ASEAN JOINT ASSESSMENT PROCEDURE. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=9&ved=2ahUKEwi1kqXo_O7mAhUZTxUIHeYxCnkQFjAIegQICBAH&url=https%3A%2F%2F

www.npra.gov.my%2Fimages%2FAnnouncement%2F2016%2FASEAN-WHO-SIAHR_Joint%2520Assessments-information_for_applicants-Dec_2016_rev2.docx&usg=AOvVaw1DHh6Z2W7_-pN9NFFz3R72 Accessed on 6 January 2020

*Definitions:

Verification review: A checklist review based on recognition of a prior regulatory decision. Recognition is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of economy A is sufficient to meet the regulatory requirements of economy B.

Abridged review: An abbreviated review of selected portions of the dossier and the reliance on prior assessment decisions. Reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Full review: A comprehensive review of all components of the dossier. This may or may not be CPP-dependent. This may form part of a reliance or recognition pathway.