FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Indonesia	**Agency Name:** National Agency of Drug And Food Control (NADFC)	
Name of FRP: Path II (Two)		
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?	Before the marketing authorisation submission	
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	Drugs that will be evaluated through Path II (two) are: 1. New drug which has been approved in the group of countries that applied harmonization of evaluation system and 1 (one) county that has applied established evaluation system which is supported by an independent assessment report; 2. New Drug which has been approved in 3 (three) countries that applied established evaluation system supported with independent assessment report. 3. Copy drug without STINEL (Electronic Information Standard) and blood products.	
Must the product address an unmet medical need or serious condition?	Choose an item.	
If a fee is required, what is the amount (in US$ equivalent)	Click here to enter text.	
Total target (agency) time for assessment (calendar days)	New registration Path II (two): 150 working days.	
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?**
☐	☒	☐

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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 for approval?	Yes at time of submission
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?	This process is not through a Regional Regulatory Initiative.
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	Always required
For how long is the initial approval or designation valid?	4-5 years
Any other details you wish to provide?	- Drug registration shall be submitted by the applicant to the Head of the National Agency. Drug registration consists of 2 (two) stages, that is pre-registration and submission of the registration dossier. Pre-registration is a registration procedure that is conducted to decide the evaluation Path and the completeness of drug registration documents.
Date of this update	6 February 2020
References	1. DECREE OF THE HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL REPUBLIC OF INDONESIA NUMBER : HK.00.05.3.1950 ON CRITERIA AND PROCEDURE OF DRUG REGISTRATION - THE HEAD OF NATIONAL AGENCY OF DUG AND FOOD CONTROL REPUBLIC OF INDONESIA.

http://apps.who.int/medicinedocs/documents/s18009en/s18009en.pdf Accessed on 6 February 2020.

2. AN OVERVIEW OF THE DRUG REGULATORY SYSTEM IN INDONESIA. https://www.indianembassyjakarta.gov.in/pdf/AN_OVERVIEW_OF_THE_DRUG_REGULATORY_SYSTEM_IN_INDONESIA_jan31-19.pdf Accessed on 6 February 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.