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 V (Five)		
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	Path V: New drugs/biology product, major variations registration with new indication/posology which have already been approved in the harmonized country with good known evaluation system, and/or approved in at least 3 countries with good known evaluation system, and new copy drug.	
Must the product address an unmet medical need or serious condition?	Negotiable	
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)	• Review Path: V • Preregistration review: 1-12 months • Registration review: 150 working days • Clock stop: Maximum 120 working days • Administrative process (grant approval): 1-2 months • Maximum review time: 570 working day *Clock Stop will take place if the evaluators request any additional data or any clarification or information to applicant. The process will stop until the applicant submits the additional data or clarification. The applicant cannot delay the submission of the additional data requested for more than 120 working days. When there is a delay in submission of data requested, the registration process will be rejected by NADFC. However, the applicant has the option to resubmit the dossier as a new registration application.	
Total target (company) time	In some cases, the NADFC may request additional data in order to	

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for responses to agency questions (If stated)	determine the product approval/non-approval. In this situation, the applicant will have 120 days to submit this requested information. If the applicant is unable to provide the data within the given timeframe, the application will be rejected. However, the applicant has the option of resubmitting the dossier as a new Indonesia drug registration application.	
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?	The competent regulatory agencies with whom Indonesia has signed the mutual recognition agreement and other agreements (IDRAC 111270).	
How many reference agency decisions are required?	Approval in at least 3 countries with good known evaluation system.	
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 as this regulatory pathway is for products that have had prior approval.	
How are queries to the companies sent?	Choose an item.	
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- as needed	
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	- Drug registration shall be submitted by the applicant to the	

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provide?	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. - Marketing authorization licenses are valid for five years in Indonesia. The Indonesia drug registration forms and accompanying documents can be in Bahasa Indonesian or English. Drugs produced for export-only are not required to have labels in Bahasa Indonesian; only English labels are required. - If an application is reviewed by the NADFC and the NADFC decides that the product cannot be approved, the applicant has the option of submitting an appeal. The written appeal should be submitted within six months from the date of application rejection. The appeal should be accompanied by additional product data in order to better justify approval of the product. Applicants are allowed a maximum of two appeals.
Date of this update	20 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. 3. Indonesia Pharmaceutical Regulatory Update. https://www.pacificbridgemedical.com/publication/indonesia-pharmaceutical-regulatory-update/ Accessed on 20 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.