

FRPath.org Country and FRP Information Input Form				
Country: Malaysia Agency Name: National Pharmaceutical Regulatory Agency (NPRA)				
Name of FRP: Verification Review				
Is this FRP Proposed or Active? Active				
Date FRP was officially enacted	Date FRP was officially enacted: Click here to enter a date.			
1. Facilitates activities	2. Accelerates the regulatory 3. Relies on or recognizes a			
during development	review process prior regulatory decision			
	\boxtimes			
Is a Guidance or SOP	Yes- see reference below			
describing how to apply this FRP publicly available?				
When should the FRP be requested?	Before the marketing authorisation submission			
Does the agency provide assistance/advice to the	Yes- For any product type			
sponsor? For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	 New product applications (in the category of New Drug Products, Biologics including biosimilars and Generics) which fulfils either one of the following conditions; a) Product which is intended for: Unmet medical needs (e.g. medicines for rare diseases, new vaccines, etc.), Life-saving such as for treatment/ prevention of serious medical conditions (e.g. anticancer, antiretroviral, etc.), Treatment/ prevention in pandemic/endemic situations, for the interest of public health, Emergency supply/crucial for treatment purposes according to the current needs in the country, Supply to the Ministry of Health Malaysia under circumstances where alternative product with the same active ingredient is unavailable, b) Product which involves a change in the formulation due to the decision/instruction by the Drug Control Authority (DCA), for the purpose of formulation improvement with appropriate scientific justification(s), C) Product which is the first generic product, or the first locally manufactured generic product. 			
Must the product address an unmet medical need or serious condition?	Yes			
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 Drug Products = 90 working days. Total target (company) time for responses to agency questions (if stated) - The applicant is allowed to correspond with a maximum of 3 times correspondence within 60 working days in to the standard timeline if applicant failed to correspond within the standard timeline if applicant failed to correspond within the standard timeline if applicant failed to correspond within the standard timeline if applicant failed to correspondence from NPRA to submit the required supplementary data/information or documentation within six (6) months from the first correspondence date. 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? - European Medicines Agency (EMA) - United States Food and Drug Administration (US FDA) - United States Food and Drug Administration (US FDA) - WHO Prequalified Medicinal Products (specifically new drug products and biologics including biosmillars) covered by the alternative listing procedure (evaluated by US FDA and EMA) may be accepted under this pathway. How many reference agency decisions are required? Verification Review applies to a product that has been evaluated and approved by two (2) reference drug regulatory agencies must be declared as the primary reference agency. The chosen primary reference agency is defined as the reference drug regulatory agencies must be declared as the primary reference agency. The chosen primary reference agency is d	FRPath.org Country and FRP II	nformation Input Form		
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Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?The CPP is required PLUS the Summary of Product Characteristics (SPC), PI and/or PIL approved by the reference drug regulatory agency that issued the approval letter. *NPRA reserves the right to request additional supporting documents where it is deemed appropriate.If this process is through aNo, this process is not through a Regional Regulatory Initiative.	Pharmaceutical Product)			
reference documentation to the CPP be used? If so, what types of documents?(SPC), PI and/or PIL approved by the reference drug regulatory agency that issued the approval letter. *NPRA reserves the right to request additional supporting documents where it is deemed appropriate.If this process is through aNo, this process is not through a Regional Regulatory Initiative.	required for approval?			
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where it is deemed appropriate.If this process is through aNo, this process is not through a Regional Regulatory Initiative.	the CPP be used? If so, what			
If this process is through a No, this process is not through a Regional Regulatory Initiative.	types of documents?	*NPRA reserves the right to request additional supporting documents		
	Regional Regulatory			
Initiative, which countries	Initiative, which countries			
participate in this process?	participate in this process?			

EDDath and Country and EDD information langet Form		
FRPath.org Country and FRP Information Input Form		
Does the product have to	Yes, the product has to have been marketed in another country. The	
have been marketed in	application must be submitted to the National Pharmaceutical	
another country? For a	Regulatory Division (NPRA, which acts as the Secretariat to the DCA)	
specific amount of time? If	within two (2) years from the date of approval by the chosen primary	
so, for how long?	reference drug regulatory agency.	
How are queries to the	As they arise	
companies sent?		
Are external reviewers (e.g.	Choose an item.	
non-agency) involved in the		
assessment?		
Post-authorization study	Always required	
commitments		
For how long is the initial	Choose an item.	
approval or designation		
valid?		
Any other details you wish	- Upon confirmation of payment, the application with the	
to provide?	submitted data shall be evaluated. Review of applications shall	
to provide?		
	follow a queue system. There shall be separate queues for the	
	different categories of products and/or according to level of	
	claims (e.g. general, medium or high claim for health	
	supplements).	
	- Correspondence via the system shall be sent to the applicant if	
	there is any clarification and further supplementary data/	
	information or documentation pertaining to the application, if	
	deemed necessary by the Authority.	
	 The complete assessment report and other relevant 	
	supporting documents must be submitted from the primary	
	reference agency only.	
Date of this update	15 JANUARY 2020	
References	1. Evaluation of Application.	
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	3. Direktif untuk melaksanakan Guidelines on facilitated	
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	2020.	
4.	FAQs: NCE.	
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	<u>225-english/1527044-faq-</u>	
	nce.html?highlight=WyJ2ZXJpZmljYXRpb24iLCJyZXZpZXciLC	
	J2ZXJpZmljYXRpb24gcmV2aWV3llo=&Itemid=1391 Accessed	
	on 15 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.

By submitting this form, I agree that the information is true to the best of my knowledge and I consent that it can be used without restriction by FRPath.

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