FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Haiti	**Agency Name:** National Drugs Regulatory Authority (DPM / MT) National Drugs Regulatory Authority (DPM / MT)	
Name of FRP: Click here to enter text.		
Is this FRP Proposed or Active? Choose an item.		
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?	Choose an item.
When should the FRP be requested?	Choose an item.
Does the agency provide assistance/advice to the sponsor?	Choose an item.
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	Click here to enter text.
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	Click here to enter text.

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(calendar 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?**	
☐	☐	☐	
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?	Choose an item.		
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Choose an item.		
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	Click here to enter text.		

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Regulatory Initiative, which countries participate in this process?	
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Click here to enter text.
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?	- Health registration is compulsory for any product to be distributed on the Haitian market. Consequently, all pharmaceutical products must be regularly registered by the manufacturer and receive a Marketing Authorization Certificate (AMM), issued by the DPM / MT-MSPP. This service is therefore responsible for: (i) Guarantee the quality, safety and efficacy of drugs placed on the market; (ii) Analyze the technical MA application files; (iii) Prepare MA certificates; (iv) Renew marketing authorization certificates every five years; and (v) Analyze the technical files for Customs Clearance Authorization. Head of Department: Othniel Eugène: othniel.eugene@mspp.gouv.ht
Date of this update	22 MARCH 2020
References	1. Procedure for obtaining authorization from the Ministry of Health. https://www.paho.org/hai/index.php?option=com_content&view=article&id=7008:promess-procedures-afin-d-obtenir-une-autorisation-au-ministere-de-la-sante&Itemid=237&lang=en Accessed on 22 March 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.