FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Caribbean Community and Common Market (CARICOM)	**Agency Name:** Caribbean Public Health Agency (CARPHA)	
Name of FRP: Caribbean Regulatory System		
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?	Choose an item.	
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	- Innovative medicines; - Generic medicines; and - Vaccines.	
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)	CARICOM Member States to grant approval/registration/marketing authorization/import permit within **60 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	A CRS-designated "reference authority" (national regulatory authority of Argentina, Brazil, Canada, Chile, Colombia, Cuba, European Union, Mexico, United Kingdom, United States or WHO	

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agencies?	prequalification).
How many reference agency decisions are required?	Click here to enter text.
Does this FRP require submission of Assessment Reports from prior decisions?	Publically available reports OK
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 Regulatory Initiative, which countries participate in this process?	CARICOM Member States: - Antigua and Barbuda - Bahamas - Barbados - Belize - Dominica - Grenada - Guyana - Haiti - Jamaica - Montserrat - Saint Lucia - St. Kitts and Nevis - St. Vincent and the Grenadines - Suriname - Trinidad and Tobago Associate Member States: - Anguilla - Bermuda - British Virgin Islands - Cayman Islands - Turks and Caicos Islands *Because these countries are diverse and have different regulatory requirements and timelines for processing, the CRS benefits companies by giving them one streamlined set of requirements and a known and accelerated timeline for processing compared to what currently exists.
Does the product have to have been marketed in another country? For a specific amount of time? If	Yes, the product has to have been marketed in another country. The product has to have a current approval/registration/marketing authorization from a CRS-designated "reference authority" (national regulatory authority of Argentina, Brazil, Canada, Chile, Colombia,

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so, for how long?	Cuba, European Union, Mexico, United Kingdom, United States or WHO prequalification).
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?	Choose an item.
Any other details you wish to provide?	- Very broadly, the CRS carries out the following regulatory focus activities: (i) Conducts abbreviated reviews of product dossiers for safety, quality, and efficacy of medicines and vaccines that meet the following CRS eligibility criteria, including: the product has a current approval/registration/marketing authorization from a CRS-designated "reference authority" (national regulatory authority of Argentina, Brazil, Canada, Chile, Colombia, Cuba, European Union, Mexico, United States or WHO prequalification); and the product is named on the most recent version of the WHO Essential Medicine List or PAHO Strategic Fund - this includes innovative and generic medicines, and vaccines; (ii) Recommends all favorably reviewed products to CARICOM Member States, and requests completion of in-country processes to grant approval/registration/marketing authorization/import permit within 60 calendar days, (iii) Carries out pharmacovigilance and post market surveillance of medicines and vaccines in the region. - The requirements are based on an abbreviated and accelerated procedure WHO uses for Prequalification when a product has already been registered by a reference authority. - If available, provide a public assessment report, such as the Scientific Discussion of the European Public Assessment Report, issued by the RA.
Date of this update	22 FEBRUARY 2020
References	1. The Caribbean Regulatory System. http://carpha.org/What-We-Do/Programmes-and-Projects/CRS/Caribbean-Regulatory-System Accessed on 22 February 2020. 2. Caribbean Public Health Agency / Caribbean Regulatory System (CARPHA/CRS). Guidance Document: Requirements for the Preparation of a Dossier for Medicines Recommendation for Marketing Authorization/Import

Permit in CARICOM States.
http://carpha.org/Portals/0/Documents/CRS_ReqsDS003.pdf
Accessed on 22 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.