FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Costa Rica	**Agency Name:** Ministerio de Salud (MdS)	
Name of FRP: Mutual Recognition of Sanitary Registration of Medicines for Human Use		
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?	At the time of the 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	The Regulatory Authority may authorize the import and use of medicines without sanitary registration in the following cases: - Donations - Officially declared national emergencies and public necessity. - Orphan drugs for States Parties. - Medicines used in clinical studies with approved protocols - In cases of medical justification. - Samples to carry out registration procedures. - Medicines purchased through the OPS Revolving Fund. - For products subject to test data protection, the current regulations of each country will apply. *Products that require bioequivalence studies are subject to the regulations in force in each country. *This procedure does not apply to biological and biotechnological products
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)	The Regulatory Authority resolves within 8 business days, issuing the respective document in accordance with the regulations.
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)

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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?	Yes at time of submission
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	WHO type pharmaceutical product certificate, which must be presented in original or authenticated photocopy of the legalized document. If this type of certificate is not issued, the presentation of: (i) Free Sale Certificate: In case of presenting a certificate that endorses two or more products, an authenticated and / or certified photocopy of the legalized document will be accepted; (ii) Certificate of Good Manufacturing Practices of each of the establishments involved in the manufacture of the product, for the pharmaceutical form and specific type of product to be registered, issued by the Regulatory Authority of the country or countries where the process of manufacture, legalized original or authenticated photocopy of it, it must indicate that it complies with the regulations of good manufacturing practices.
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?	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?	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 provide?	- The renewal of the registration of a medicine may be managed at least 3 months before its expiration.

	Once the health registration has expired, the renewal request will not be accepted and must be processed as a new registration. If during the 6 months after the expiration of the registration of a medicine the interested party requests that the assigned number be kept presenting the justified cause, the Regulatory Authority will keep the original number, however, during this period, it will not be able to market it. The renewal cannot be granted, until the requested post-registration changes have been approved. - The Sanitary Registry will have a validity period of 5 years from its granting, and may be renewed for similar periods. In cases of infractions of the sanitary or regulatory laws and regulations, the Regulatory Authority will proceed to cancel it. - In case of approval, the RM and initial code of the country that performs the recognition and that precedes the correlative number granted by the State Party will be assigned, which will be kept at the time of renewal. Said code must be included in the manner established for the health registration number in the current Drug Labeling RTCA. The validity of the recognition will be the same as the original registration. - For products subject to test data protection, the current regulations of each country will apply and products that require bioequivalence studies are subject to the regulations in force in each country. - This procedure does not apply to biological and biotechnological products.
Date of this update	23 MARCH 2020
References	1. Resolution No. 333-2013 (COMIECO-LXVI) of 12/12/2013 and annexes: Reg.RTCA 11.03.59: 11 Pharmaceutical Products, Medicines for human use. Req. Health Reg. Annex 1. Procedure for Mutual Recognition of Health Reg. Medicines annex 2. N ° 38414-COMEX-MEIC- S. 2. Regulation of Registration, Control, Import and Advertising of Medicines. No. 28466-S. 3. General law of health. No. 5395. 4. Costa Rica Ministry of Health Overview. https://www.emergobyul.com/resources/costa-rica/ministry-health Accessed on 22 March 2020. 5. Registration of Generic Drugs in Central America and Mexico. http://www.ijpacr.com/files/21-07-2017/29.pdf 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.