FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form	
Country: El Salvador	**Agency Name:** National Medicine Directorate (Dirección Nacional de Medicamentos- DNM)
Name of FRP: Mutual Recognition Registration Process.	
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?	Choose an item.
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	- **Pharmaceuticals (drugs)** that have a registration from a Sanitary Regulator that have a certification level IV from the Pan American Health Organization (PAHO), and from Regulators from the United States of America, Canada, Australia, Switzerland, Japan, and the Medicine European Agency (EMA). - For **biotechnological and biological products**, the mutual recognition is allowed only if the countries mentioned above have specific regulations for this type of pharmaceutical 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)	If all documentation is correct and complete, the National Medicine Directorate will issue a sanitary registration for the pharmaceutical product in 10 business 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?
☒	☐	☐

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If this is a reliance or recognition pathway, what are the accepted reference agencies?	The Pan American Health Organization (PAHO), the United States of America, Canada, Australia, Switzerland, Japan, and the Medicine European Agency (EMA).
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?	Certificate of the Pharmaceutical Products, determined by World Health Organization (WHO). In case the certificate is not available, the following documentation should be submitted: a. Certificate of Free Sale issued by the country of origin. In the case of a shared origin, the CFS will be admitted from the country of precedence as long as the product is commercialized in that country. b. Certificate of Good Manufacturing Practices of each of the establishments that have intervened in the manufacturing and packaging of the product, issued by the regulatory/authorized institution of the country or countries where the manufacturing process takes place.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, 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?	Choose an item.
Post-authorization study commitments	
For how long is the initial approval or designation valid?	4-5 years
Any other details you wish to provide?	- All documentation must be submitted in Spanish and be Apostille. - In February 2013, the Salvadoran government approved the decree "Special Regulation for the Mutual Recognition of Foreign Sanitary Registration". This mutual recognition only applies to pharmaceuticals

	(drugs) that have a registration from a Sanitary Regulator that have a certification level IV from the Pan American Health Organization (PAHO), and from Regulators from the United States of America, Canada, Australia, Switzerland, Japan, and the Medicine European Agency (EMA). - For biotechnological and biological products, the mutual recognition is allowed only if the countries mentioned above have specific regulations for this type of pharmaceutical products. To apply for a mutual recognition registration process, companies need to supply all documentation determine by Article 20 of the Salvadoran Medicine Law.
Date of this update	22 MARCH 2020
References	1. Requirements for Registering Pharmaceutical Products. EL SALVADOR 2014. http://files.export.gov/x_6879464.pdf Accessed on 22 March 2020. 2. GENERAL REGULATION OF THE MEDICINES ACT. https://www.medicamentos.gob.sv/index.php/es/normativa-m/reglamentosdnm-m/reglamento-ley-de-medicamentos Accessed on 22 March 2020. 3. SPECIAL REGULATIONS FOR THE RECOGNITION OF FOREIGN HEALTH RECORDS. https://www.medicamentos.gob.sv/index.php/es/normativa-m/reglamentosdnm-m/reglamento-especial-para-el-reconocimiento-de-registros-sanitarios-extranjeros-dnm 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.