FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Mexico	**Agency Name:** Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)	
Name of FRP: Recognition of MAs from Reference Authorities		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 1/28/2020		
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	Allopathic medicinal products, Biological medicinal products, Vaccines and Blood products. *The agreement is only applicable to drug products which are needed in the national territory AND are not available due to quality or shortage reasons. They will only be imported for distribution by public health entities.
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)	COFEPRIS must issue its opinion within **60 working days**, starting from the day following the registration request day. If there is no manifestation within this period, it must be understood that the opinion is negative. The requirements will be issued within 20 working days for administrative data and 40 working days for technical aspects. The revision period is suspended pending the response from the marketing authorization holder and if the marketing authorization used as a reference is canceled or suspended, the registration holder must notify COFEPRIS within 5 working days
Total target (company) time for responses to agency questions (If stated)	In the event that the documentation exhibited is not complete, COFEPRIS will inform the applicant within a period that will be equal to a third of the period granted to resolve the request, when it is administrative and two-thirds, when it is of a technical nature. The term to discharge the request for missing documentation will

	be established by COFEPRIS in accordance with the provisions of article 17-A of the Federal Law of Administrative Procedure. The term to resolve the origin of granting the sanitary registration, indicated in the sixth section of this Agreement, will be suspended when COFEPRIS requires from the applicant, expressly and in writing, documents, clarifications or missing information and will resume the next business day after the one in which the applicant delivers said information, documents or makes the pertinent clarifications. In the event that the applicant does not provide in the term granted for such effect, the documents, clarifications or missing information, the request will be considered as not submitted, rejecting the procedure.

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?	- Swiss Agency for Therapeutic Products – SWISSMED; - European Commission; - Food and Drug Administration of the United States of America; - Canadian Ministry of Health; - Australian Therapeutic Goods Administration; - PAHO / WHO reference regulatory agencies prequalified by the World Health Organization Prequalification Program for Drugs and Vaccines or regulatory agencies that are members of the Pharmaceutical Inspection Cooperation Scheme (PIC/S)
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?	Click here to enter text.
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	Yes, the product has to have been marketed in another country.

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have been marketed in another country? For a specific amount of time? If so, for how long?	Applicants are to submit a document that proves the reference marketing authorization, and in Spanish (always accompanied by the original documents in foreign language).
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	
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?	- The companies must request the marketing authorization through forms defined by the Department of Health. - If there is a need to import a product without marketing authorization, it must be authorized by the authorities mentioned in the Agreement, and the registration process must be initiated in Mexico within five business days after importation. Importation without marketing authorization can only be done once and all imported batches will be analyzed by COFEPRIS Analytical Control and Expansion Commission (Comisión de Control Analítica y Ampliación de Cobertura). - It should be noted that, among the authorities recognized by PAHO through the WHO program, is the Agência Nacional de Vigilância Sanitária - ANVISA in Brazil. - The documents that accompany the applications must be written in Spanish and, if not, they must attach their respective Spanish translation, endorsed with the signature of the health officer. Documents issued by authorities from other countries must be apostilled or legalized and translated by an expert translator.
Date of this update	4 APRIL 2020
References	1. COFEPRIS - Recognition of Marketing Authorizations from Reference Authorities - updated 18th March. https://www.vitaraconsulting.com/news/2020/2/4/cofepris-recognition-of-marketing-authorizations-from-reference-authorities Accessed on 4 April 2020. 2. AGREEMENT BY WHICH THE REQUIREMENTS ESTABLISHED IN ARTICLES 161 BIS, 167, 169, 170 AND 177 OF THE REGULATION OF HEALTH SUPPLIES AND THE TECHNICAL EVALUATION PROCEDURES CARRIED OUT BY THE FEDERAL COMMISSION FOR SANITARY PROTECTION AGAINST RACIAL PROTECTION GRANTING

	OF THE SANITARY REGISTRY OF HEALTH SUPPLIES REFERRED TO IN ARTICLES 2, SECTIONS XIV, XV, ITEMS BYCY 166, FRACTIONS I, II AND III OF THE REGULATION OF HEALTH SUPPLIES ; IN RELATION TO ARTICLES 222 AND 229 OF THE GENERAL HEALTH LAW, THE REQUIREMENTS REQUESTED AND EVALUATION PROCEDURES CARRIED OUT; AS WELL AS THE IMPORTATION OF MEDICINES WITH OR WITHOUT SANITARY REGISTRY IN MEXICO, DIRECTED TO ANY ILLNESS OR SUFFERING, WHICH ARE AUTHORIZED BY THE FOLLOWING REGULATORY AUTHORITIES: SWISS AGENCY FOR TERAP ÉU TICOS-SWISSMED PRODUCTS, EUROPEAN COMMISSION, FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES OF AMERICA, MINISTRY OF DETAILS, MINISTRY OF DEUTS AUSTRALIA, PAHO / WHO REFERENCE EGULATORY AGENCIES PREQUALIFIED BY THE PRE-QUALIFICATION PROGRAM FOR DRUGS AND VACCINES OF THE WORLD HEALTH ORGANIZATION OR REGULATORY AGENCIES MEMBERS OF THE PHARMACEUTICAL INSPECTION COOPERATION SCHEME. DOF: 01/28/2020. Accessed on 4 April 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.