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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: Article 170 Route		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 3/28/2019		
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	Medicines and Biological Products that have WHO prequalification.
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 decide on the application for a sanitary approval within a maximum period of **60 working days** counted from the day following that in which the applicant delivers the applicable documentation. After the aforementioned deadline, if COFEPRIS has not responded, it will be understood that it has reached a negative decision.
Total target (company) time for responses to agency questions (If stated)	In case the submitted documentation is not complete, COFEPRIS will inform the applicant within a period that will be equal to one third of the time granted to decide on the application, when it is of an administrative nature, and two thirds, when it is of a technical nature, under the terms of the provisions of Article 156 of the Regulation. The deadline for deciding on the application for a sanitary approval will be suspended when COFEPRIS requires the applicant to submit, expressly and in writing, documents, clarifications or missing information and will resume the business day following the one in which the applicant delivers said information, documents or makes the pertinent clarifications. In case the applicant does not provide the documents, clarifications or missing information within the timeframe established for this purpose, the application shall be regarded as not having been submitted.

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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?	A member of the ICH; or an observer from the ICH, among which include the World Health Organization, or a regulatory agency associated with an ICH member through mutual recognition.
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 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?	Choose an item.
Any other details you wish to provide?	- The holders of the sanitary approval granted under this Regulation (Regulation = Reference 1 in the next section), as well as the importers and vendors, shall inform COFEPRIS about the revocation, cancellation, or suspension of WHO prequalification, about which they have or should have knowledge; they must also notify COFEPRIS when there is any change in the safety profile or the risk-benefit of the medicines and vaccines that are registered under this Regulation, that occur during their commercialization or use, in terms of the provisions

	of Articles 38 and 81 Bis of the Regulation and the Official Mexican Standard NOM-220-SSA1-2016. Installation and operation of pharmacovigilance, as well as any other circumstance that must be reported to the competent authorities, in accordance with applicable legal provisions. - COFEPRIS shall revoke the sanitary approval granted under this Regulation (Regulation = Reference 1 in the next section) resulting from the loss of the prequalification granted by the WHO. - The documents accompanying the applications must be written in Spanish and, if not, they must have attached their respective translation to Spanish, endorsed with the signature of the responsible health manager. Documents issued by authorities of other countries must be apostilled or certified and translated by a certified translator.
Date of this update	4 APRIL 2020
References	1. DOF [Official Gazette of the Federation by its Spanish acronym]: 03/29/2019. 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.