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: Equivalence Agreement		
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?	Before the marketing authorisation submission	
Does the agency provide assistance/advice to the sponsor?	Yes- for selected submissions	
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	New Molecules, Biologicals and Follow-On Products.	
Must the product address an unmet medical need or serious condition?	Choose an item.	
If a fee is required, what is the amount (in US$ equivalent)	Government fees for analyzing marketing authorization applications are as follows: - new molecules and biologicals: around US$8,600; and - generics and biosimilars: around US$4,800.	
Total target (agency) time for assessment (calendar days)	Requirements and time frames vary among new molecules, biologicals and follow-on products. Article 166 of the Health Law Regulations sets out the following approval time frames: - 180 calendar days for medicines that include an active pharmaceutical ingredient or therapeutic indication already approved in Mexico; - 240 calendar days for medicines approved abroad but not in Mexico; and	

	- 180 calendar days for new drugs (a meeting with the New Molecules Committee is required). - The approval time frame for biologicals and biosimilars is 180 calendar days (articles 177 and 177-bis 4 of the Health Law Regulations). *These time frames may vary in practice, but can be reduced if the application has been pre-examined by a third examiner (private company) approved by COFEPRIS to do so.
Total target (company) time for responses to agency questions (If stated)	COFEPRIS will address any question they might have about the data on the dossier in the form of a letter, commonly called deficiency letter, officially called *prevención* in Mexico.

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?	Relating to the special procedure for innovative biotech products: US FDA, the EMA, Health Canada, the Swiss Agency for Therapeutic Products (Swissmedic) or the Australian Therapeutic Goods Administration
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?	**For drug products manufactured outside of Mexico:** Certificate of Pharmaceutical Product (CPP) of origin, apostilled or legalized, with official translation (perito traductor). The CPP is a document that certifies that a pharmaceutical product is registered and/or commercialized in a country. Representation letter, assigning the legal representative of the foreign company in Mexico. It is advised to write a wide power of representation letter, with a minimum validity period of 5 years. In addition to CPP, If the manufacturing site is located outside of Mexico, provide license, certificate or other document authorizing the site to the activities related to manufacturing of pharmaceutical products of interest, issued by the competent authority of the country of origin, legalized or apostilled, translated to Spanish by an official translator (perito traductor) for **Sanitary authorization** (licencia sanitaria).

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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?	The product may have been marketed in another country.
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?	- If your product falls into the category of 'new molecule', you have to request a meeting with the New Molecule Committee before submitting the application. These are the cases in which your drug will be considered a "New Molecule": (i) New drug substances (new in the world or new for Mexico); (ii) New combinations of drug substances (for Mexico); (iii) New indications; and (iv) Other special cases (e.g. similar biotherapeutic products) - The marketing authorization is granted for a period of five years. Submission for registration renewal must be filed at least 6 months before expiry. - Legally, COFEPRIS should not grant marketing authorizations for generics that breach exclusivity rights. There is a linkage system between COFEPRIS and the Mexican Institute of Industrial Property (IMPI), which aims to prevent the granting of marketing authorizations in violation of patent rights. According to the IP Regulations, IMPI must publish every six months a gazette that includes patents covering allopathic medicines (Linkage Gazette). The initial IMPI position was that only patents relating to a compound were relevant to linkage review (excluding formulation and use patents). On 31 July 2012, for the first time the IMPI included formulation patents in the Linkage Gazette, in accordance with a 2010 ruling of the Mexican Supreme Court. (*Jurisprudence*

	No. 2a./J.7/2010, Federal Judicial Gazette, No. XXXI, page 135). - Orphan drugs were introduced into the General Health Law and the Mexican Pharmacopeia some years ago. In practice, they are approved by a particular procedure, following rules for new molecules when applicable and appropriate; however, specific rules would be welcomed. - The Mexican Official Norm for Pharmacovigilance, NOM-220, establishes mandatory provisions regarding pharmacovigilance that apply to all medicines. NOM-220 requires marketing authorization holders to have a pharmacovigilance plan, which must include provisions for monitoring adverse effects in patients caused by the product at every stage of treatment. - Foreign marketing authorizations are not valid in Mexico. However, COFEPRIS has developed a special procedure for drugs requiring first-time approval in Mexico, but that have been approved by equivalent regulatory authorities abroad. In this procedure, the approval requirements of the foreign agencies are recognized as equivalent to those in Mexico. - FDA approval may speed-up the Mexican approval process, but it does not exempt a product from Mexican sanitary registration requirements. Products not yet approved by FDA or other recognized agencies will undergo the standard process. For the registration of generic drugs, it is important to note that drugs are not covered by this streamlined process, and that there is a requirement to conduct the corresponding bioequivalence studies in Mexico. Only in some cases, such as personal use or research, are products exempted from being registered.
Date of this update	22 MARCH 2020
References	1. Drug registration in Mexico. https://latampharmara.com/mexico/drug-registration-in-mexico/ Accessed on 22 March 2020. 2. Pharma & Medical Device Regulation: Mexico. https://gettingthedealthrough.com/area/119/jurisdiction/16/pharma-medical-device-regulation-mexico/ Accessed on 22 March 2020. 3. Mexico - K. Healthcare Products & Services. https://www.export.gov/apex/article2?id=Mexico-Healthcare-Products-Services Accessed on 22 March 2020. 4. Mexico: Medicinal Product Regulation And Product Liability In Mexico: Overview. https://www.mondaq.com/mexico/Food-Drugs-Healthcare-Life-Sciences/842550/Medicinal-Product-Regulation-And-Product-Liability-In-Mexico-Overview Accessed on 22 March 2020. 5. Regulatory, Pricing & Reimbursement. https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-mexico/ Accessed on 22 March 2020. 6. Sanitary registry of allopathic medicines, vaccines and blood products of national manufacture, generic.

https://www.gob.mx/tramites/ficha/registro-sanitario-de-medicamentos-alopaticos-vacunas-y-hemoderivados-de-fabricacion-nacional-generico/COFEPRIS395 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.