FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Colombia	**Agency Name:** Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	
Name of FRP: Abbreviated Procedure		
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?	Yes- For any product type	
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	1. New medicines, including: - those with an active pharmaceutical ingredient (API), which has not been included in the Pharmacological Code (also known as 'new chemical entities'); or - those with an API which is included in the Pharmacological Code, but the product is related to new associations, fixed dosages, new indications or new pharmaceutical forms; and - medicines already included in the Pharmacological Code. 2. Biosimilars.	
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)	The Phase II fee for a chemical synthesis medicine ranges from approximately US$3,900 to US$4,800, and for biological medicines is US$3,900 (for vaccines, the fee is approximately US$4,680). *Generic versions of products included in the Code only need Phase II assessment.	
Total target (agency) time for assessment (calendar days)	The official timeline for approval is about 90 days. In practice, INVIMA takes more time than the legally established limits. The INVIMA takes approximately eight to 17 months to grant an MA for medicinal products already included in the Pharmacological Code.	
Total target (company) time for responses to agency questions (If stated)	60 working days.	
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)?**	**Is this a full* review of all parts of the dossier?**

FRPath.org Country and FRP Information Input Form		
	(a reliance pathway)?*	
☐	☒	☐
If this is a reliance or recognition pathway, what are the accepted reference agencies?	INVIMA accepts foreign marketing authorizations of drugs approved in a reference country (Japan, USA, Australia, Norway, Germany, Canada, France, Switzerland, Sweden, England, Denmark, and the Netherlands) to improve times and documents during the registration process.	
How many reference agency decisions are required?	Article 27, paragraph 1 of Decree 677 provides an abbreviated procedure for innovators by means of which INVIMA can forego conducting a pharmacological evaluation (safety and efficacy) of a product whenever such product is already approved in **at least two reference countries** and has not been rejected in any of the other reference countries.	
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?	The applicant is required to submit a CPP: Certificate of pharmaceutical product (CPP) of origin, compliant with the requirements of Decreto 426 de 2009. The validity of this document will be the one stated in it, otherwise it will be set at 1 year.	
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?	4-5 years	
Any other details you wish to provide?	- To obtain MAs for new medicines, the applicant must first submit a pharmacological evaluation application. The	

pharmacological evaluation studies the safety and efficacy of the drug and is performed by the Medicines Reviewing Committee, which takes into account the following features: efficacy, safety, dosage, indications, contraindications, warnings, toxicity, trading conditions and restrictions.

- Alternatively, article 27, paragraph 1 of Decree 677 provides an abbreviated procedure for innovators by means of which INVIMA can forego conducting a pharmacological evaluation (safety and efficacy) of a product whenever such product is already approved in at least two reference countries and has not been rejected in any of the other reference countries. Furthermore, article 72 of the National Development Plan (Law 1753 of 2015) now also requires an additional economic (cost/benefit) evaluation to be performed (by the IETS) in parallel to the pharmacological evaluation. However, regulations of article 72 are still under development, which is why this economic evaluation is not yet being applied.
- Regarding biological and biotechnological products, a pharmacological evaluation must be performed even if the active ingredient (drug substance) is already included in the Colombian Pharmacological Code. This evaluation assesses the efficacy (indications, contraindications, interactions, precautions, warnings, pharmacokinetics, pharmacodynamics, dose, risk-to-benefit ratio) and safety (adverse effects, immunogenicity, trading conditions, special restrictions and risk-to-benefit ratio). Specific requirements for the submission of information for pharmacological evaluation are detailed in Decree 1782. This Decree contains an abbreviated route, by means of which biosimilar products should not have to submit clinical trials, nor head-to-head comparability assays to demonstrate their safety and efficacy. This route has been questioned by biotech R&D manufacturers and sanitary authorities worldwide. Mandatory immunogenicity assays and a perfect characterization of the API and its manufacturing procedure will be required of applicants even if they choose the abbreviated route.
- The official timeline for approval is about 90 days, and the period of registration is 5 years. Application for renewal of the marketing authorization must be submitted at least 3 months before the expiration date of the registration.
- All documents must be translated to the "Colombian" Spanish dialect. The Spanish spoken in Latin America changes from country-to-country. Just like there are differences in English expressions, spelling, industry and business terminology among English-speaking countries (USA, UK, Australia, Canada, etc.) Spanish varies

	throughout Latin America. Colombian Spanish has its own peculiarities just like Mexican or Argentinian Spanish have. For Colombia's INVIMA purposes, this is important since the evaluation committee members should be able to easily understand the dossier file that is submitted for approval. - We recommend that sponsors translate their documents by Colombian Spanish-speaking translators certified by the Colombian Ministry of Foreign Affairs.
Date of this update	22 February 2020
References	1. INVIMA Requirements for Registration of a Pharmaceutical Drug in Colombia. https://www.bioaccessla.com/invima-requirements-for-registration-of-drugs-in-colombia Accessed on 22 February 2020. 2. Regulatory, Pricing and Reimbursement. https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-colombia/ Accessed on 22 February 2020. 3. Life Sciences: product regulation and liability in Colombia. https://www.lexology.com/library/detail.aspx?g=0f52bfa1-a19a-4565-aecc-ac00ae143f82 Accessed on 22 February 2020. 4. Pharma & Medical Device Regulation. https://gettingthedealthrough.com/area/119/jurisdiction/8/pharma-medical-device-regulation-colombia/ Accessed on 22 February 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.