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: INVIMA Exceptional Circumstances		
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	'Vital unavailable' medicines (VUMs) can be imported or manufactured without a license (MA issued by the healthcare authority). These are mostly prescribed to patients suffering from an orphan disease recognized in Colombia (which are listed within Resolution No. 5265 of 2018), or correspond to medicines not commercialized in the country. Decree 481 of 2008 allows the importation and manufacture of VUMs for an individual patient, a specific group of patients or a clinical emergency without the need for a prior MA, thus allowing for faster market entry, provided that the following conditions are met: - the API has already proven its safety and efficacy in other countries and is not under clinical research; - the drug is not being marketed or is in insufficient supply in the country; and - there is no therapeutic substitute for the drug. * Medicines under clinical research cannot be used to treat patients in Colombia (unless they are employed within an approved clinical trial in the territory).	
Must the product address an unmet medical need or serious condition?	Yes	
If a fee is required, what is the amount (in US$ equivalent)		
Total target (agency) time for assessment (calendar days)	Authorisation may take from 15 days to two months to be issued. However, during the VUM import application assessment, the MRC may require the applicant to submit an application for	

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<tr><th colspan="3">FRPath.org Country and FRP Information Input Form</th></tr>
<tr><td></td><td colspan="2">pharmacological evaluation first, which may take up to four months.</td></tr>
<tr><td>Total target (company) time for responses to agency questions (If stated)</td><td colspan="2">Click here to enter text.</td></tr>
<tr><td colspan="3">Select one of the following (* see definitions at end of document)</td></tr>
<tr><td>Is this a verification review (a recognition pathway)?*</td><td>Is this an abridged* review (selected dossier portions)? (a reliance pathway)?*</td><td>Is this a full* review of all parts of the dossier?</td></tr>
<tr><td>☐</td><td>☒</td><td>☐</td></tr>
<tr><td>If this is a reliance or recognition pathway, what are the accepted reference agencies?</td><td colspan="2">Canada, Denmark, France, Germany, Japan, the Netherlands, Norway, Sweden, Switzerland, the United Kingdom and the United States, or from countries that have signed mutual recognition agreements with these countries.</td></tr>
<tr><td>How many reference agency decisions are required?</td><td colspan="2">Click here to enter text.</td></tr>
<tr><td>Does this FRP require submission of Assessment Reports from prior decisions?</td><td colspan="2">Choose an item.</td></tr>
<tr><td>Is a CPP (Certificate of Pharmaceutical Product) required for approval?</td><td colspan="2">Yes at time of submission</td></tr>
<tr><td>Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?</td><td colspan="2">According to Decree 481, the Medicines Review Commission (MRC) at the INVIMA may authorise the import of VUMs for groups of patients. The application must contain:
justification of the quantities of the VUM needed. This import will be authorised for a maximum of three to six months of treatment. Documentation supporting the number of patients is helpful;
certificate of incorporation of the entity requesting the import authorisation;
WHO certificate for the pharmaceutical product; and
Certificate of analysis.</td></tr>
<tr><td>If this process is through a Regional Regulatory Initiative, which countries participate in this process?</td><td colspan="2">No, this process is not through a Regional Regulatory Initiative.</td></tr>
<tr><td>Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?</td><td colspan="2">Yes, the product has to have been marketed in another country.</td></tr>
<tr><td>How are queries to the companies sent?</td><td colspan="2">Choose an item.</td></tr>
<tr><td>Are external reviewers (e.g.</td><td colspan="2">Yes- as needed</td></tr>
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non-agency) involved in the assessment?	
Post-authorization study commitments	Always required
For how long is the initial approval or designation valid?	
Any other details you wish to provide?	- Decree 481 of 2004 states that 'vital unavailable' medicines (VUMs) (eg, named-patient supply) do not require an MA. However, their safety and efficacy must be proved through other special requirements. - 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. - 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.