FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Ecuador	**Agency Name:** Agencia Nacional de Regulación, Control y Vigilancia Sanitaria	
Name of FRP: Health Drug Registration for Homologation		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 12/7/2010		
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	All drugs registered by the countries mentioned as reference agencies on the next page; and biological drugs (Among them: vaccines, blood products, biotechnologicals and biosimilars), where they have been recorded by these countries, provided they have specific regulations for the purpose.
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)	Click here to enter text.
Total target (agency) time for assessment (calendar days)	- The user must enter into the electronically automated system for granting the Health Registration Certificate, and once they have obtained their password, fill in the relevant application, and will enter the required information in the application form for registration of health registration medicines for homologation. - The user must scan and enter into the system all the documents required. - The National Agency for Regulation, Control and Health Surveillance -ARCSA, or the agency performing its duties, in the term of one day, shall verify whether the documentation is complete and if the information entered in the application is correct. - Once the documentation is complete and correct, payment of health registration is allowed. The system will notify the user the amount payable and the deadline for such payment, and the forms provided.

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	- Once the user makes the payment and is verified by the National Agency for Regulation, Control and Health Surveillance, an electronic invoice is created in the system and automatically sent to the user for printing. - After this process, the documents will be distributed to the departments responsible for the evaluation thereof, and within five (5) days the Health Registration Certificate shall be issued. - The Health Registration Certificate will be published in the system and available for the user to have access to it.
Total target (company) time for responses to agency questions (If stated)	If the documentation is not complete and correct, the system shall electronically notify the user, indicating the drawbacks found in the application. The user shall mend the application according to comments received and will have a term of eight (8) days for this activity, before it changes the status of the process. Should the user re-enter the application erroneously, or not enter before the deadline, the process will be cancelled and the system will notify the applicant all the reasons for the cancellation.

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?	Health authorities of countries whose drug regulatory agencies have been qualified by the Pan American Health Organization (PAHO) / World Health Organization (WHO) as Regional Reference Authorities, as well as those Health Registrations issued by the Health authorities of the United States, Canada, Australia, Japan, by the European Agency of Medicines (EMA) and the Ministry of Food and Drug Safety of the Republic of Korea.
How many reference agency decisions are required?	Minimum of 1 reference agency decision. If the product is marketed in more than one country listed above, submit all proof as applicable.
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 following documents are required: 1. Application Form, which must contain the information set out; 2. Notarized copy of the valid appointment of the legal

	representative or power of attorney registered in the Mercantile Register and copy of the RUC (Tax Registration Number), in case of legal persons; and, for individuals, a copy of identity or citizenship card and the RUC, if they had not submitted previous processes; 3. Duly authenticated authorization form of the product holder to request the Health Registration by Homologation; 4. Notarized copy of Health Registration Certificate issued by any reference country mentioned on Page 2 of this FRPath form; 5. Receipt of payment for the amount of Health Registration, according to valid regulations; 6. Notarized copy of the **"Certificate of Pharmaceutical Product currently traded internationally"** according to the WHO model or the" Free Sale Certificate " (counter drug) issued by the competent authority of health of the country of origin of the product, stating: product name, concentration and dosage form of the drug, complete quantitative and qualitative formula, name, city and country of the manufacturer.
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 must be marketed in another country. As part of the application, the applicant must submit inter alia: • Notarized copy of Health Registration Certificate issued by any country mentioned on Page 2 as a reference.
How are queries to the companies sent?	As they arise
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
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?	- REGULATION FOR HEALTH REGISTRATION OF DRUGS IN GENERAL Ministerial Agreement 586 is the official gazette 335 of 7 Dec 2010. - The applicant must also submit the following as part of their application: o A copy of the draft of internal and external tags that will be used for marketing in the

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	country, written in Spanish, in clearly legible and indelible characters pursuant to the provisions of Article 31 of the Regulations.; and, ○ The prospect led the user, written in Castilian language with characters clearly legible and indelible, to be included in the medicine container.
Date of this update	25 APRIL 2020.
References	1. REGULATION FOR HEALTH REGISTRATION OF DRUGS IN GENERAL. Ministerial Agreement 586: Official Gazette 335 of Dec 07th 2010.

*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.