FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Uruguay	**Agency Name:** Ministerio de Salud Publica (MSP)	
Name of FRP: Expedited 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?	Choose an item.
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	Drugs.
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)	MSP fees for the company authorization (as manufacturer or importer) depend on the area of the premises and number of employees of the company. In case of an importer with an outsourced storage, fees amount to 1 Readjustable Unit (USD 35 approx.) MSP fees for product registration are: Drugs: Expedited: 50 Readjustable Units (USD 1,750 approx.) plus 5 Readjustable Units (USD 175 approx.) per active ingredient in the product.
Total target (agency) time for assessment (calendar days)	Expedited: 30 days approx.
Total target (company) time for responses to agency questions (If stated)	Click here to enter text.

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?	Click here to enter text.
How many reference agency decisions	Click here to enter text.

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are required?	
Does this FRP require submission of Assessment Reports from prior decisions?	Choose an item.
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Choose an item.
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?	**Biologicals and Biosimilars:** Decree 38/015 sets forth the requirements to grant the marketing authorization for biologics and biosimilars. Besides the information and documentation for drugs set forth by Decree 324/999, the following must be submitted, among others: Biologicals: evidence of marketing in other countries, in the case of imported products; **Biotechnological Similar Drugs:** evidence of marketing in other countries, in the case of imported products.
How are queries to the companies sent?	Choose an item.
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?	4-5 years
Any other details you wish to provide?	- The regulatory framework for the authorization of drugs, biologicals and medical devices is mainly comprised of Law 9,202 (MSP Organic Law), Law 15,443 (Drugs Law), Decree 521/984, Decree 324/999 and Decree 12/007 (Drugs), Decree 3/008 (Medical Devices) and Decree 38/015 (Biologicals). These regulations are supplemented by other decrees, resolutions and ordinances published by the MSP. Price control in the private sector is not regulated. - Marketing authorizations are valid for five years. Marketing authorizations must be renewed every five years. Non-compliance with filing the renewal request before the end of the five-year term will cancel the registration and a new registration process shall need to be followed. For renewal, applicants must provide evidence of compliance

	with good manufacturing practices, safety and efficacy standards, pharmacovigilance, labeling standards and all other applicable provisions.
Date of this update	26 APRIL 2020.
References	1. Regulatory, Pricing and Reimbursement. 06/11/2018. FERRERE / Uruguay. https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-uruguay/ Accessed on 26 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.