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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Argentina	**Agency Name:** National Administration of Drugs, Foods and Medical Devices (ANMAT)	
Name of FRP: Fast Track Proceedings: 'Article 3'		
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	Applies to: - Drug products manufactured in Argentina or in an Annex II country, when there is a similar drug product already registered in Argentina. - Drug products manufactured in Argentina, with marketing authorization in any Annex I country, even if there are no similar products registered in Argentina.	
Must the product address an unmet medical need or serious condition?	No	
If a fee is required, what is the amount (in US$ equivalent)	The costs for obtaining the license to commercialize pharmaceutical products and medical devices in Argentina would mainly consist of the fees to be paid to ANMAT for requesting the authorization to act as a pharmaceutical or medical devices company and to obtain the marketing authorization certificates of the products. These fees vary depending on the type of product to be registered (i.e. synthetic, biological, orphan medicines, etc.). The fees are updated every year by ANMAT.	
Total target (agency) time for assessment (calendar days)	Timeline for approval: about 12 months	
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?**

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☐	☒	☐
If this is a reliance or recognition pathway, what are the accepted reference agencies?	- Argentina is a country that relies heavily on decisions made by countries that it considers of 'high sanitary surveillance'. Thus, the registration process will depend on in what countries a drug product is already being **marketed** in, regardless of the country of origin or countries where the pharmaceutical is registered but not marketed. - ANMAT made for this purpose two lists of countries, based on the level of sanitary surveillance, called Annex I and Annex II. (these lists are annexes to the drug registration decree) The lists have been created in 1992 and have not been updated ever since. Maybe for this reason, the EU is not considered as a block and some individual EU countries are listed in the two lists, while some others are just left out. <u>Annex I Countries:</u> - USA - France - Japan - United Kingdom - Sweden - Netherlands - Switzerland - Belgium - Israel - Denmark - Canada - Spain - Austria - Italy - Germany <u>Annex II Countries:</u> - Australia - China - Mexico - Luxembourg - Brazil - Norway - Cuba - New Zealand - Chile - Hungary - Finland - Ireland	

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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?	Summary of documents required for submission: - Product information: name, formula, pharmaceutical form, pharmacologic classification, marketing condition. - Technical information: testing standard, specifications, shelf life, manufacturing method, pharmaceutical equivalence evidence. - Labeling texts (packaging and leaflets) - If manufactured in an Annex II country: CPP of origin - GMP certificate from Annex I country or Argentina
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?	Argentina is a country that relies heavily on decisions made by countries that it considers of 'high sanitary surveillance'. Thus, the registration process will depend on in what countries a drug product is already being **marketed** in, regardless of the country of origin or countries where the pharmaceutical is registered but not marketed.
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?	- Drug registration in Argentina is regulated by Decree 150/1992 and posterior modifications. (link to Decree – Spanish) - Each pharmaceutical product (medicine) or medical device product requires being previously authorized by the health authority for manufacturing or import purposes and –as evidence of such authorization- a marketing authorization certificate ("MA") should be issued per product. MAs have a valid period of five (5) years, being able to be renewed for the same period. Registrations of orphan drugs have a

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	specific validity term that is defined on a case-by-case basis by ANMAT.
Date of this update	22 FEBRUARY 2020
References	1. Regulatory, Pricing and Reimbursement Overview. https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-overview-argentina/ Accessed on 22 February 2020. 2. Distribution and marketing of drugs in Argentina: overview. https://uk.practicallaw.thomsonreuters.com/w-014-7135?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1#co_anchor_a447637 Accessed on 22 February 2020. 3. Drug registration in Argentina. https://latampharmara.com/argentina/drug-registration-in-argentina/

*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.