FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Brazil	**Agency Name:** Agência Nacional de Vigilância Sanitária (ANVISA)	
Name of FRP: ANVISA Priority Review		
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	- Emergent or neglected disease –significant improvement in treatment - Vaccine for National Immunization Programme - New or innovative drug product, API manufactured in Brazil - Public Health Emergencies and shortages - First Generic	
Must the product address an unmet medical need or serious condition?	Yes	
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 maximum timeframes for ANVISA to make a final decision regarding pre-market approvals for drugs are set by Law 13.411/2016: 120 days from the submission date of the prioritization request, for drugs in the prioritized category; and 365 days from the submission date of the request, for drugs in the ordinary category. The aforementioned timeframes may be extended by a maximum of a third.	
Total target (company) time for responses to agency questions (If stated)	120 days for sponsor's response.	
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?	Click here to enter text.	
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?	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?	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?	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?	- Pre-market approvals are valid for five years from the date of their publication in the Brazilian Official Gazette, and may be renewed for equal and successive periods. - Please note that it is not possible for foreign companies to make administrative arrangements for issuing market authorizations directly with ANVISA. Foreign companies shall have partner companies legally constituted in Brazil that will be legally responsible for the products imported to and distributed in the Brazilian territory.	
Date of this update	22 February 2020	
References	1. Medicinal Products Regulation in Brazil.	

https://www.mhlw.go.jp/content/11123000/000451940.pdf Accessed on 22 February 2020.
2. Ministério da Saúde - MS Agência Nacional de Vigilância Sanitária – ANVISA. Este texto não substitui o(s) publicado(s) em Diário Oficial da União. RESOLUÇÃO DA DIRETORIA COLEGIADA - RDC Nº 204, DE 27 DE DEZEMBRO DE 2017. http://portal.anvisa.gov.br/documents/10181/2718376/RDC_204_2017_.pdf/b2d4ae64-2d91-44e9-ad67-b883c752c094 Accessed on 22 February 2020.
3. Drugs. http://portal.anvisa.gov.br/drugs 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.