FRPath.org
Where the Roads to Accelerated Assessments Converge

| *FRPath.org Country and FRP Information Input Form* | | |
|---|---|---|
| **Country:** Peru | **Agency Name:** Dirección General de Medicamentos, Insumos y Drogas (DIGEMID) | |
| **Name of FRP:** Click here to enter text. | | |
| **Is this FRP Proposed or Active?** Choose an item. | | |
| **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** |
| ☐ | ☐ | ☐ |

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| **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** | Click here to enter text. |
| **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)** | The fees will depend on the product whose Sanitary Registration is being requested and range from $400 to $1,200. |
| **Total target (agency) time for assessment (calendar days)** | - Category 1 (medicines in the essential medicines list): 45 to 60 days;<br>- Category 2 (medicines not in the essential medicines list but registered in countries of high regulatory surveillance (US, selected European countries, Japan, and Korea)): 45 to 90 days; and,<br>- Category 3 (other medicines): up to 12 months [13]. |
| **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?** | Click here to enter text. |
| **How many reference agency decisions are required?** | Click here to enter text. |

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| **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?** | Click here to enter text. |
| **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** | Choose an item. |
| **For how long is the initial approval or designation valid?** | 4-5 years |
| **Any other details you wish to provide?** | - For the fabrication of pharmaceutical products local laboratories must have certificates of Good Practices, the Sanitary Authorization issued by DIGEMID and the Operating License issued by the local government.<br>- Sanitary Registrations are valid for 5 years and they can be renewed starting one year before their expiration date. For the renewal the owner of the registration must present all the requirements for registration except for studies supporting the efficacy and safety of the product.<br>- The authorization process is the same for both type of products. No distinction is made between a local manufacturer and a foreign manufacturer.<br>- There is no expedited pathway for Orphan Drugs. Foreign marketing authorizations are not recognized for Orphan Drugs.<br>- There is a specific regulatory framework for the marketing authorization of biosimilar medicines in Peru, Supreme Decree N° 013-2016-SA, Regulation for the Filing and Content of the Required Documents in the Registration of Biologic Products that Opt for the Similar Way. |

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| **Date of this update** | 22 MARCH 2020 |
| **References** | 1. Regulatory, Pricing and Reimbursement Overview. https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-peru/ Accessed on 22 March 2020.<br>2. Orphan Drugs & Rare Diseases: Peru. https://pharmaboardroom.com/legal-articles/orphan-drugs-rare-diseases-peru/ Accessed on 22 March 2020.<br>3. Biosimilars & Biologics: Peru. https://pharmaboardroom.com/legal-articles/biosimilars-biologics-peru/ Accessed on 22 March 2020.<br>4. Trade agreements and drug access: assessment of the impact of the 2009 Peruvian new drug policy on anti-infectives registration and availability. https://link.springer.com/article/10.1186/s40545-018-0151-0 Accessed on 22 March 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.