FRPath.org
Where the Roads to Accelerated Assessments Converge

| *FRPath.org Country and FRP Information Input Form* | | |
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| **Country:** Pakistan | **Agency Name:** Drug Regulatory Authority of Pakistan | |
| **Name of FRP:** Priority Review of Submission | | |
| **Is this FRP Proposed or Active?** Active | | |
| **Date FRP was officially enacted:** 11/15/2019 | | |
| **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?** | Before the marketing authorisation 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** | No restrictions stated. The product has to meet the eligibility criteria for priority review of submission pathways and they are as follows:<br>- Orphan medicines for the treatment of rare diseases<br>- New drug molecule/New indication drug<br>- Short availability<br>- Serious condition e.g. outbreak of a disease etc. |
| **Must the product address an unmet medical need or serious condition?** | Yes |
| **If a fee is required, what is the amount (in US$ equivalent)** | FEES:<br>1. New Drug or Molecule/drug not manufactured locally = Rs. 50,000/- [USD 325]; Renewal fee = 20,000/- [USD 130]<br>2. Any other drug for import = Rs. 100,000/- [USD 645], Renewal = Rs. 20,000/- [USD 130]<br>1 USD = 154.725 PKR as at 18 December 2019. |
| **Total target (agency) time for assessment (calendar days)** | 150 working days. The timeframe is calculated after a priority determination process, from acceptance of application dossier for evaluation through to the decision of the Registration Board. |
| **Total target (company) time for responses to agency questions (If stated)** | 14 working days for the applicant to submit responses. |

**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** | - USFDA, Health Canada, EMA, TGA Australia and PMDA |

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| **recognition pathway, what are the accepted reference agencies?** | Japan, United Kingdom, Germany, France, Switzerland, Netherlands, Austria, Denmark, Sweden and Norway, or at least three (3) European Union countries will be taken as reference for consideration of Registration Board. |
| **How many reference agency decisions are required?** | Click here to enter text. |
| **Does this FRP require submission of Assessment Reports from prior decisions?** | Unredacted |
| **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?** | No alternate forms of reference documentation can be used. |
| **If this process is through a Regional Regulatory Initiative, which countries participate in this process?** | No, this process is not through an RRI |
| **Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?** | Yes, the product needs to be marketed in another country. Regulatory status in the reference regulatory authorities is required. Specific amount of time is not stated. |
| **How are queries to the companies sent?** | As they arise |
| **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?** | Choose an item. |
| **Any other details you wish to provide?** | - Process is for an unmet medical need in special situations (i.e. public health emergencies), orphan medicinal products or innovative therapies.<br>- The Registration Board considers the application dossier for those drugs through priority review process, indicated for treatment of chronic ailments which are short in availability including drugs for the treatment of cancer, viral diseases, thalassemia, immunosuppressants, vaccines and sera, new molecules, formulation (therapies) and blood factors.<br>- The Drug Regulatory Authority of Pakistan requires the FULL dossier.<br>- Request FRP prior to submission of application dossier. |

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| | Address a "Letter of Intent" to Secretary, Registration Board in order to determine the eligibility of application for relevant expedited pathway. |
| **Date of this update** | 18 December 2019 |
| **References** | 1. Fee Submission Procedure. http://www.dra.gov.pk/Home/Download?ImageName=Fee%20Submission%20Procedure.pdf Accessed on 18 December 2019<br>2. Procedure for Registration of Drugs. http://www.dra.gov.pk/Home/Download?ImageName=Procedure%20of%20Registration.pdf Accessed on 18 December 2019<br>3. Policy Guidelines regarding Reference Regulatory Authorities for Registration of Drugs. http://www.dra.gov.pk/Home/Download?ImageName=Policy%20Guidelines%20Regarding%20Reference%20Regulatory%20Authorities%20for%20Registration%20of%20Drugs%20Dt_Up_05-01-2017.pdf Accessed on 18 December 2019<br>4. Draft Guideline for Priority Review and Accelerated Approval of Registration / Market Authorization. http://www.dra.gov.pk/Home/Download?ImageName=MA%2001.12%20DRAFT%20Guideline%20on%20Non%20Rutine%20MA.pdf Accessed on 18 December 2019 |

*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.