FRPath.org
Where the Roads to Accelerated Assessments Converge

| *FRPath.org Country and FRP Information Input Form* | |
|---|---|
| **Country:** South Korea | **Agency Name:** Ministry of Food and Drug Safety (MFDS) |
| **Name of FRP:** Prior 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 |
|---|---|---|
| ☐ | ☒ | ☒ |

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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?** | At the time of the 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** | New drug, Incrementally Modified Drug (IMD), pharmaceutical drug, biological product, herbal medicinal product, or quasi-drug. |
| **Must the product address an unmet medical need or serious condition?** | No |
| **If a fee is required, what is the amount (in US$ equivalent)** | ONLINE/IN PERSON OR MAILING<br>UNIT = KRW [1 USD = 1,157.38 KRW on 15 Jan 2020]<br><br>**Prior review of medicinal products**<br>1) New drug (incl. new biologics) 2,317,050 [USD2,002]/ 2,650,950 [USD2,290]<br>2) Other pharmaceuticals (incl. orphan drug) 772,350 [USD668]/ 853,650 [USD738]<br>3) New material quasi-drugs 1,588,000 [USD1373]/ 1,755,000 [USD1517]<br>4) Other quasi-drugs 385,700 [USD334]/ 426,300 [USD369] |
| **Total target (agency) time for assessment (calendar days)** | 20 days (working day) after the date of application. |
| **Total target (company) time for responses to agency questions (If stated)** | - If the applicant has any opinion on the primary review result notified or the face-to-face meeting, such applicant shall submit a written opinion to the responsible department within 14 days from the date of notification.<br>- The applicant may submit additional data during the submission period of written opinion. If preparation of additional data is not possible within the period, the applicant may request an extension of data submission period for such preparation. In this case, such requested |

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| | extension shall not be more than 60 days.<br>- The submission period of either written opinion or additional data shall not be counted in the process period. | |
| **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 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 prior to final decision | |
| **Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?** | - The relevant certificate of pharmaceutical product (CPP) shall be submitted. However, if it is impossible to submit it at the moment of application, the deadline as to submission within the processing timeline of the relevant applied civil petition shall be described and it shall then be submitted within the designated deadline submission. Each CPP shall be issued within 2 years from the application date (the period in cases where the certificate issue period of the relevant government or public agency of the country of origin or registration is more than 2 years).<br>- However, drugs used in other countries than the country of origin and listed in foreign national drug formularies, "PDR (USA), Japanese Pharmacopoeia, ABPI DATA SHEET COMPENDIUM (UK), ROTE LISTE (German), VIDAL (France), L`iniformatore Farmaceutico (Italia), Arzneimittel Kompendium der Schweiz (Swiss), and Compendium Pharmaceuticals and Specialties (Canada)" published within the last 3 years, the certificate, which is signed by the person charged with the country of manufacturing and notarized by a public agency, is admissible as the CPP. | |
| **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. | |

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| **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 has to have been marketed in another country. Submit a certificate of marketing issued by the government or public agencies of the economy that granted approval or registration of such product, indicating that such product is legitimately marketed in accordance with the laws and regulations of the economy. |
| **How are queries to the companies sent?** | At specified times during the assessment |
| **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?** | - In the whole process of drug review and approval, consult with Central Pharmaceutical Affairs Advisory Committee (CPAC), if necessary.<br>- A person who wishes to submit application for prior review of medicinal products to the Minister of Food and Drug Safety (hereinafter referred to as "applicant") shall submit the application form and required dossiers via e-government drug service (ezdrug.mfds.go.kr), operated by the Minister. |
| **Date of this update** | 15 JANUARY 2020 |
| **References** | 1. Approval Process. https://www.mfds.go.kr/eng/wpge/m_17/de011008l001.do Accessed on 15 January 2020.<br>2. Regulation on Fees for Pharmaceutical Approval, etc. https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=71456&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1 Accessed on 15 January 2020<br>3. Regulation for Pharmaceutical Approvals, Notifications and Reviews. https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=71448&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=2 Accessed on 15 January 2020.<br>4. Regulation on Prior Review of Pharmaceuticals. https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=70099&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=3 Accessed on 15 January 2020.<br>5. Guide to Drug Approval System in Korea. https://www.mfds.go.kr/eng/brd/m_52/down.do?brd_id=e |

ng0013&seq=71608&data_tp=A&file_seq=1 Accessed on 15 January 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.