FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Japan	**Agency Name:** Pharmaceuticals and Medical Devices Agency (PMDA)	
Name of FRP: 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	Priority review products refer to orphan drugs (expected to be used by less than 50,000 patients) and products designated for priority review by the Ministry of Health, Labour and Welfare in consideration of their clinical usefulness and the seriousness of the diseases for which they are indicated.	
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)	9 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?**
☐	☐	☒
If this is a reliance or recognition pathway, what are the accepted reference agencies?	The EC/EMA and MHLW/PMDA has implemented various measures to promote orphan medicines development. Under the confidentiality arrangements between the EC/EMA and MHLW/PMDA in the field of pharmaceutical affairs, exchanging experience and information would lead to improvement of measures taken by each authority in a timely manner, as well as accumulation of supplement data, which would enable the balance between the risk and benefit of orphan medicines to be evaluated in a comprehensive way.	

FRPath.org Country and FRP Information Input Form	
	The principle here is to exchange information on discussion of MHLW/PMDA and or COMP summaries following evaluation under the confidential arrangements. - The name of the product, orphan condition, status of a submission in Europe, Japan or both. EMA to submit list of products processed and completed through the COMP (Committee on Orphan Medical Products) on a monthly basis. MHLW/PMDA to submit list of products processed and completed through the PAFSC (Pharmaceutical Affaires and Food Sanitation Council) on a quarterly basis. - Exchange of reports or its outline in cases where there has been a divergence of opinion between Agencies/Ministry (conclusions by COMP and PAFSC) dependent on the interest of the topic and its implications for Orphan Designation. One of the key aims is to identify areas of overlap and differences in the process of generating an opinion. - Information exchange of situations regarding the research and development stage where necessary. Membership under this operation should be four parties, i.e., EMA, MHLW, PMDA and the European Commission (DG SANCO).
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?	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?	Yes, submit a summary of current regulatory or development status, and marketing history, out of Japan.
How are queries to the	Choose an item.

FRPath.org Country and FRP Information Input Form	
companies sent?	
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- always
Post-authorization study commitments	Always required
For how long is the initial approval or designation valid?	Longer than 5 years
Any other details you wish to provide?	- Japan's Pharmaceutical Affairs Law requires all forms related to the marketing application to be submitted in Japanese. - During the review process, the reviewers exchange opinions with external experts (Expert Discussions) to ensure that more effective reviews are conducted by making use of their advanced expertise. - Priority review products refer to orphan drugs (expected to be used by less than 50,000 patients) and products designated for priority review by the Ministry of Health, Labour and Welfare in consideration of their clinical usefulness and the seriousness of the diseases for which they are indicated. - PMDA's reviews and related services consist of various activities, such as "consultations" providing advice in relation to regulatory submission, GLP/GCP/GPSP inspections to ensure the submitted data are in compliance with the ethical and scientific standards, and GMP/QMS/GCTP inspections to ensure quality management of the manufacturing facility for the product submitted for approval. Consultation service on R&D or regulatory submission involves consultation fee, while topics to be discussed in such consultations may be clarified free of charge in a pre-consultation meeting. Since required procedures, communication and forms with PMDA are all processed in Japanese, we strongly recommend you to appoint a Japanese Marketing Authorization Holder (MAH) if you intend to enter into the Japanese market. Accordingly, it is also recommended to request for PMDA's consultation service through the intermediary of such MAH. When you are requesting the free pre-consultation meeting only, an accompanying interpreter instead of the appointed Japanese MAH may be acceptable. - After orphan drug/medical device designation and approval, the re-examination period for the drugs will be extended up to 10 years for drugs and up to 7 years for medical devices.

FRPath.org Country and FRP Information Input Form	
Date of this update	23 JANUARY 2020
References	1. **Frequently Asked Questions (FAQ). https://www.pmda.go.jp/english/about-pmda/0004.html Accessed on 23 January 2020.** 2. **Drugs Reviews. https://www.pmda.go.jp/english/review-services/reviews/0001.html Accessed on 23 January 2020.** 3. **Outline of Reviews and Related Services. https://www.pmda.go.jp/english/review-services/outline/0001.html Accessed on 23 January 2020.** 4. PMDA's Consultation Service. https://www.pmda.go.jp/files/000219654.pdf Accessed on 23 January 2020. 5. **Overview of Orphan Drug/Medical Device Designation System. https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/orphan_drug.html Accessed on 24 January 2020.** 6. Orphan Products Development Support Program. https://www.nibiohn.go.jp/en/activities/orphan-support.html Accessed on 24 January 2020. 7. Global Development and Approval by Cooperation of Key Regulatory Agencies. https://www.pmda.go.jp/files/000226656.pdf Accessed on 24 January 2020. 8. Outlook of Orphan and Pediatric Drug Development from Regulatory Perspectives. https://www.pmda.go.jp/files/000226869.pdf Accessed on 24 January 2020. 9. Implementation of a Conditional Early Approval System for Pharmaceutical Products. https://www.pmda.go.jp/files/000227089.pdf Accessed on 24 January 2020. 10. Format for Preparing the Common Technical Document for Submission of New Drug Applications to Reduce Total Review Time. https://www.pmda.go.jp/files/000153518.pdf Accessed on 24 January 2020. 11. European Union - Japan orphan medicines cooperation. https://www.ema.europa.eu/en/documents/other/european-union-japan-orphan-medicines-cooperation_en.pdf Accessed on 24 January 2020. 12. Annual Report FY 2018.

*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.