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: Conditional Early Approval		
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	Meet all the requirements from 1 to 4 listed below: 1. Seriousness of indications: Diseases which have significant impact on lives (life-threatening diseases); Progress of disease is irreversible and the disease has a significant impact on daily lives; Others 2. Medical usefulness: No existing remedies, preventive therapies or diagnostics; Medical usefulness is better than that of existing remedies, preventive therapies or diagnostics in terms of efficacy, safety, and patient's physical and mental burden 3. Being difficult to conduct confirmatory clinical trials or considered to take considerable time to complete trials because of a limited number of patients 4. Considered to have a certain degree of efficacy and safety through clinical trials other than confirmatory clinical trials.
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?**

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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?	Yes- always	
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?	- 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. - 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. - To ensure that application materials are submitted promptly after the completion of the clinical studies required for marketing approval, PMDA consultations should take place immediately after the applicant learns that the results of nonconfirmatory clinical studies can assure certain level of efficacy and safety. - PMDA will prepare an assessment report regarding System Eligibility based on the result of nonconfirmatory clinical studies even if the expected application data package includes the results of ongoing or future studies. Both PMDA and the applicant should agree on the content of the assessment report.
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. 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.

*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.

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