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: Sakigake		
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?	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	Medical products for diseases in urgent need of innovative therapy which may satisfy the following two conditions: 1. Having firstly been developed in Japan and planned an application for approval (desired to have PMDA consultation from the beginning of R&D) 2. Prominent effectiveness (i.e. radical improvement compared to existing therapy), can be expected based on the data of mechanism of action, non-clinical study and early phase of clinical trials (phase I to II) Products unapproved in EU/US if they satisfy one of the following conditions: 1. Conducting/finalizing phase III study in Japan 2. Promising clinical data shown in public domain such as a paper in scientific journals 3. Achievement in Advanced Medical Care B	
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)	- Option 1: Application is to be submitted to Evaluation and Licensing Division (ELD) and to be reviewed by PMDA. The result of designation is to be notified within 60 days. - Option 2: ELD is to approach a potential applicant. The result of designation is to be notified within 30 days after the submission, if agreed by the applicant.	
Total target (company) time for	Click here to enter text.	

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responses to agency questions (If stated)		
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?		
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?	No, the product does not need to have been marketed in another country. The SAKIGAKE "scheme for rapid authorization of unapproved drugs" accelerates the practical application of unapproved/off-label use of drugs for serious and life-threatening diseases by expanding the scope of the Council on Unapproved Drugs/Off-label Use to include unapproved in Western countries if it satisfies certain conditions and by improving the environment for companies to undertake development of such drugs.	
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.	

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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.
Date of this update	24 JANUARY 2020
References	1. **Frequently Asked Questions (FAQ). https://www.pmda.go.jp/english/about-pmda/0004.html Accessed on 23 January 2020.** 2. **Strategy of SAKIGAKE by MHLW. https://www.pmda.go.jp/english/review-services/reviews/advanced-efforts/0001.html Accessed on 23 January 2020.** 3. **Drugs Reviews. https://www.pmda.go.jp/english/review-services/reviews/0001.html Accessed on 23 January 2020.** 4. **Outline of Reviews and Related Services. https://www.pmda.go.jp/english/review-services/outline/0001.html Accessed on 23 January 2020.** 5. PMDA's Consultation Service. https://www.pmda.go.jp/files/000219654.pdf Accessed on 23 January 2020.

6. Strategy of Sakigake. https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/dl/140729-01-01.pdf Accessed on 23 January 2020
7. Summary of the Strategy of SAKIGAKE. https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/dl/140729-01-02.pdf Accessed on 23 January 2020
8. 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
9. Annual Reports FY 2018. https://www.pmda.go.jp/files/000232603.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.