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: The time-limited conditional approval system for regenerative medicines		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 11/27/2013		
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	Cellular and tissue-based products refer to: 1. Products derived from human or animal cells/tissues processed by methods such as cell culture, and are those used for the purposes of: • reconstruction, restoration or formation of structures and functions of the human body; and • prevention or treatment of diseases 2. Products transfected into human cells/tissues for the purpose of gene therapy. *Since these products are all derived from processed living cells/tissues, the products are characterized by their varied quality and in that their efficacy is difficult to be confirmed in some cases.
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)	Click here to enter text.
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	Click here to enter text.

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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?	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?	See details Section below
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. - Cellular and tissue-based products have been newly defined by the Pharmaceuticals and Medical Devices Act that was promulgated on November 27, 2013 - The drawbacks of the conditional approval system for cellular and tissue-based products is that long-term collection and evaluation of data that support the efficacy of a product derived from processed human cells and tissues are necessary because there is heterogeneity in product quality due to individual variation.

	- With the regulatory system that facilitates early practical application of cellular or tissue-based products: 1. faster access of patients to new products is expected; 2. clinical trials are for the prediction of efficacy and assurance of safety, whereas clinical trials with the conventional regulatory approval process are for evaluation of efficacy and safety; 3. conditional approval is for a limited time period; 4. confirmation of efficacy and safety is in the post-marketing stage, followed by the filing of re-application within the limited time period. There will then be either approval or revocation of the conditional approval. If approved, there will be continued marketing. - 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	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.
6. 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.

Regulatory System That Facilitates Practical Application of Cellular and Tissue-based Products
(Time-limited Conditional Approval)

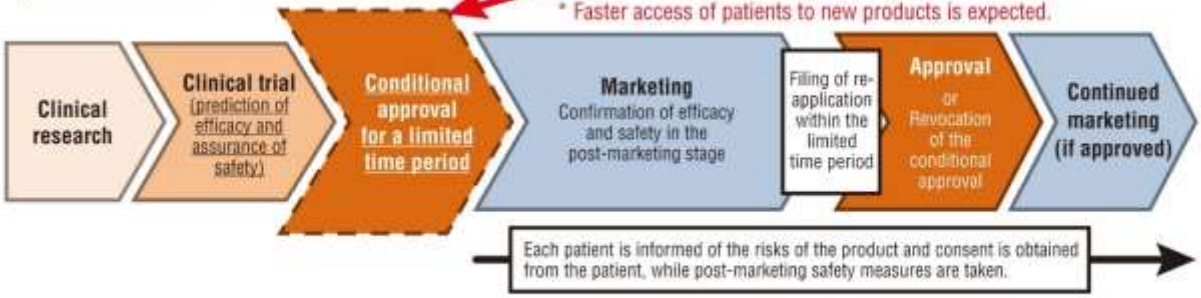
"Drawbacks of the conventional approval system for cellular and tissue-based products"

Long-term collection and evaluation of data that support the efficacy of a product derived from processed human cells and tissues are necessary because there is **heterogeneity in product quality** due to individual variation.

Conventional Regulatory Approval Process

Regulatory System That Facilitates Early Practical Application of Cellular or Tissue-based Products

* Faster access of patients to new products is expected.



- Based on the clinical data from a limited number of patients, efficacy **is predicted in a shorter time** compared with the conventional process.
- Acute-phase adverse reactions etc., can be evaluated for safety in a short period of time.