FRPath.org
Where the Roads to Accelerated Assessments Converge

FRP Summary		
Country: European Union	**Agency Name:** EMA	
Name of FRP: PRIME (PRIority MEdicines)		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: March 2016		
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?	Submission dates set by the agency
Does the agency provide assistance/advice to the sponsor?	Yes- for selected submissions
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	Innovative medicines; regenerative medicines
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	None
Total target (agency) time for assessment (calendar days)	60 days
Total target (company) time for responses to agency questions (If stated)	Not applicable

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?	Not applicable
How many reference agency decisions are required?	Not applicable
Does this FRP require submission of Assessment Reports from prior decisions?	Not applicable
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Not applicable

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Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Not applicable
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	Through the EU Centralised procedure
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	No
How are queries to the companies sent?	At specified times during the assessment
Are external reviewers (e.g. non-agency) involved in the assessment?	No-all done internally
Post-authorization study commitments	Negotiable
For how long is the initial approval or designation valid?	See details Section below
Any other details you wish to provide?	Can also be used for products for a disease with an existing therapy. Other stakeholders such as health technology assessment bodies may be included in consultations. A voluntary submission through the centralized procedure. Promotes the use of early access pathways. Designation may be rescinded
Date of this update	28 August 2019
References	Guidance: https://www.ema.europa.eu/en/documents/other/european-medicines-agency-guidance-applicants-seeking-access-prime-scheme_en.pdf Kondo H et al: The current status of Sakigake designation in Japan, PRIME in the European Union, and Breakthrough Therapy Designation in the United States. TIRS 2017;51(1):51-54 Deuchar GA et al: Real world experience of PRIME and PIM applications. Reg Rapporteur 2017;14(10):4-7.

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.