FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Europe	**Agency Name:** European Medicines Agency (EMA)	
Name of FRP: EMA Adaptive Pathways		
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?	Before the marketing authorisation 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	The adaptive pathways approach is part of the European Medicines Agency's (EMA) efforts to improve timely access for patients to new medicines. Adaptive pathways is a scientific concept for medicine development and data generation which allows for early and progressive patient access to a medicine. The approach makes use of the existing European Union (EU) regulatory framework for medicines. Adaptive pathways is based on three principles: (i) iterative development, which either means: (a) approval in stages, beginning with a restricted patient population then expanding to wider patient populations; (b) confirming the benefit-risk balance of a product, following a conditional approval based on early data (using surrogate endpoints) considered predictive of important clinical outcomes; (ii) gathering evidence through real-life use to supplement clinical trial data; (iii) early involvement of patients and health-technology-assessment bodies in discussions on a medicine's development. This concept applies primarily to treatments in areas of high medical need where it is difficult to collect data via traditional routes and where large clinical trials would unnecessarily expose patients who are unlikely to benefit from the medicine. The approach builds on regulatory processes already in place within the existing EU legal framework. These include: (i) scientific advice; (ii) compassionate use; (iii) the conditional approval mechanism (for medicines addressing life-threatening conditions); (iv) patient registries and other pharmacovigilance tools that allow collection of real-life data and development of the risk-management plan for each medicine. Adaptive pathways does not change the standards for the evaluation of benefits and risks or the requirement to demonstrate a

	positive benefit-risk balance to obtain marketing authorisation.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	A fee is not required. The payment of a fee will be needed with the submission of the SA HTA request, according to the guidance
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 reference agencies?	No, this process is not a reliance or recognition pathway.
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
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?	Member States of the European Union (EU) and the European Economic Area (EEA).
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- as needed
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?	- EMA ran a pilot project between March 2014 and August 2016 to explore the practical implications of the adaptive pathways concept with medicines under development. - This pilot provided a framework for informal dialogue between stakeholders, including patients and health technology assessment bodies, to explore different options in a 'safe harbour' environment and consider detailed technical and scientific questions based on concrete examples. EMA received 62 applications and selected 18 proposals for face-to-face meetings. At the end of the pilot, 6 of the applicants had received parallel advice from EMA and HTA bodies and 1 benefited from EMA scientific advice. - EMA is exploring the adaptive pathways concept further in the context of parallel scientific advice with HTA bodies, with the inclusion of additional stakeholders, such as patients and payer organisations. Additional support is available to eligible development programmes in an additional pre-submission meeting prior to the one foreseen by the parallel scientific advice procedure, allowing companies to discuss their options and ideas before drafting the protocols that will be the subject of scientific advice. Micro, small and medium-sized enterprises may have two additional pre-submission meetings.
Date of this update	31 MAY 2020
References	1. Adaptive Pathways. https://www.ema.europa.eu/en/human-regulatory/research-development/adaptive-pathways Accessed on 31 May 2020. 2. Guidance for companies considering the adaptive pathways approach. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-companies-considering-adaptive-pathways-approach_en.pdf Accessed on 31 May 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.