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 Accelerated Assessment		
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	Medicinal products of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Applicants requesting an accelerated assessment procedure should justify that the medicinal product is expected to be of major public health interest. Based on the request, the justifications presented, and the recommendations of the Rapporteurs, the CHMP will formulate a decision. Such a decision will be taken without prejudice to the CHMP opinion (positive or negative) on the granting of a marketing authorisation. Applicants are reminded that evidence requirements for applications to be assessed under accelerated assessment are the same as for other applications.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	Fees for obtaining and maintaining a Union authorisation to market medicinal products for human use are levied in accordance with Regulation (EC) No 297/95. The fee will become due on the date of the notification of the administrative validation to the applicant and fees will be payable within 45 calendar days of the date of the said notification. After approximately 15 days an invoice will be sent to the applicants billing address held on the Agency's file. The invoice will contain details of the product and type of procedure involved, the fee amount, the customer purchase order number associated with the procedures invoiced and financial information. Applicants requiring a purchase order number or similar references on the invoice are requested to clearly indicate it on the cover letter or

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	application form accompanying the dossier. The Agency does not accept stand-alone notifications of purchase order numbers that are not associated with a dossier. Applicants not requiring a purchase order number on the invoice should also clearly state this in the cover letter. Applicants are requested to provide this information in the eSubmission delivery file. Marketing-authorisation application (single strength, one pharmaceutical form, one presentation): From €296,500.
Total target (agency) time for assessment (calendar days)	Evaluating a marketing authorisation application under the centralised procedure can take up to 210 days, not counting clock stops when applicants have to provide additional information. On request, the CHMP can reduce the timeframe to 150 days if the applicant provides sufficient justification for an accelerated assessment. This time frame will be split into 3 phases of 90+30+30 days of assessment. The applicants will be allowed to have one month clock-stop by default for preparation of responses to Day 90 List of Questions and no clock stop by default after Day 120 List of Outstanding Issues. In case of advanced therapy medicinal products, due to the need to include more scientific committees in the review of the application, the 150-day timetable will be adapted differently and split into 2 phases of 120+30 days of assessment.
Total target (company) time for responses to agency questions (If stated)	The applicants will be allowed to have one month clock-stop by default for preparation of responses to Day 90 List of Questions and no clock stop by default after Day 120 List of Outstanding Issues.

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?	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.

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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?	At specified times during the assessment
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.
Any other details you wish to provide?	- Any request for accelerated assessment should be made at least two to three months before submitting the marketing-authorisation application. - Before submitting a request for accelerated assessment, applicants should seek guidance from the EMA procedure manager to ensure timely submission of their request. - EMA strongly recommends that applicants request a pre-submission meeting six to seven months before submission to prepare for evaluation under accelerated assessment. In this meeting, they can discuss their proposal for accelerated assessment with the Agency and rapporteurs from the CHMP and any other committees concerned, such as the Pharmacovigilance Risk Assessment Committee (PRAC) or the Committee for Advanced Therapies (CAT). They can present the data package and risk management plan they intend to include in their application. - The request for a pre-submission meeting should be sent electronically to EMA together with supporting documentation. - Under the PRIME scheme launched in March 2016, it is now possible for applicants to receive confirmation during the clinical development phase that their medicine might potentially be eligible for accelerated assessment. - Applicants should provide information concerning GMP and GCP aspects so that routine GCP and pre-approval GMP inspections can be integrated into the accelerated assessment procedure. If a need for an

	inspection is identified, it will be requested as early as possible in the evaluation procedure.
Date of this update	30 May 2020
References	1. Accelerated Assessment. https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/accelerated-assessment Accessed on 30 May 2020. 2. Pre-authorization guidance. https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/pre-authorisation-guidance Accessed on 30 May 2020. 3. Guideline on the scientific application and the practical arrangements necessary to implement the procedure for accelerated assessment pursuant to Article 14(9) of Regulation (EC) No 726/2004. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-scientific-application-practical-arrangements-necessary-implement-procedure-accelerated/2004_en.pdf Accessed on 30 May 2020. 4. Fees payable to the European Medicines Agency. https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency#fees-for-marketing-authorisations-section Accessed on 30 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.