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 Conditional Marketing Authorisation		
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	The European Medicines Agency (EMA) supports the development of medicines that address unmet medical needs of patients. In the interest of public health, applicants may be granted a conditional marketing authorisation for such medicines where the benefit of immediate availability outweighs the risk of less comprehensive data than normally required, based on the scope and criteria defined in legislation and guidelines. Medicines for human use are eligible if they are aimed at treating, preventing or diagnosing seriously debilitating or life-threatening diseases. This includes orphan medicines. For products intended for use in emergency situations, less comprehensive pharmaceutical and non-clinical data may also be accepted. Conditional marketing authorisations may be granted if the CHMP finds that all the following requirements are met: (i) the benefit-risk balance of the product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data; (iii) unmet medical needs will be fulfilled; (iv) the benefit to public health of the medicinal product's immediate availability on the market outweighs the risks due to need for further data.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	Marketing-authorisation application (single strength, one pharmaceutical form, one presentation): From €296,500. Fee reductions and incentives are available for micro, small and medium-sized enterprises (SMEs), designated orphan medicines, multiple applications on usage patent grounds and other classes of application. Full details on all fees and fee reductions are available in the explanatory note: https://www.ema.europa.eu/documents/regulatory-

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	procedural-guideline/explanatory-note-general-fees-payable-european-medicines-agency-1-april-2020_en.pdf
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?	Not applicable
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?	See details Section below
Any other details you wish to provide?	- Conditional marketing authorisations are valid for one year and can be renewed annually. The holder will be required to complete specific obligations (ongoing or new studies, and in some cases additional activities) with a view to providing

	comprehensive data confirming that the benefit-risk balance is positive. Once comprehensive data on the product have been obtained, the marketing authorisation may be converted into a standard marketing authorisation (not subject to specific obligations). Initially, this is valid for 5 years, but can be renewed for unlimited validity. - Applicants for a conditional marketing authorisation are advised to engage in early dialogue with EMA through scientific advice or protocol assistance and discuss their development plan well in advance of the submission of a marketing-authorisation application. Other stakeholders (e.g. health-technology-assessment bodies) can be included. Six to seven months before submission, when applicants notify the Agency of their intention to submit an application for a marketing authorisation they should indicate also their intention to request a conditional authorisation. Applicants are encouraged to discuss their plans in a pre-submission meeting. For products deemed suitable for a conditional marketing authorisation, applicants are also encouraged to consider requesting accelerated assessment. The applicant should present the formal request for a conditional marketing authorisation at the time of the application for marketing authorisation. The CHMP will assess the request as part of the assessment of the marketing-authorisation application. If a conditional marketing authorisation is granted, the specific obligations and deadlines for their completion will be specified in the marketing authorisation. EMA will also make these conditions publicly available as part of the European public assessment report.
Date of this update	30 May 2020
References	1. Conditional Marketing Authorisation. https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation Accessed on 30 May 2020. 2. Guideline on the scientific application and the practical arrangements necessary to implement Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No ... https://www.ema.europa.eu/en/guideline-scientific-

application-practical-arrangements-necessary-implement-regulation-ec-no-5072006 Accessed on 30 May 2020.

3. Fees payable to the European Medicines Agency. https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency 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.