FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: European Medicines Agency	**Agency Name:** European Medicines Agency	
Name of FRP: EMA Article 58		
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
7For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	The Article 58 procedure is open to innovative new therapies, new chemical and biological medicines, including biosimilars, vaccines and generic medicines. *The goal is to facilitate the granting of a national marketing authorisation or the registration of a medicine at national or regional level.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	EMA applies the same fees as for the centralised marketing authorisation procedure. In exceptional cases, applicants can request a **total or partial fee waiver** from EMA's Executive Director. They should submit a request as early as possible, and not later than 3 months before applying for scientific advice or submitting an application.
Total target (agency) time for assessment (calendar days)	**Scientific evaluation:** Up to 210 active days of assessment; The CHMP evaluates the application with input from WHO experts and observers from target countries, as needed. The PRAC provides input on aspects related to risk management. The CHMP may also request inspections of sites used for clinical trials and manufacturing or of pharmacovigilance systems. NB: The pre-submission requirements and evaluation procedure are similar to the centralised marketing authorisation procedure.
Total target (company) time for responses to agency questions (If stated)	NB: The pre-submission requirements and evaluation procedure are similar to the centralised marketing authorisation procedure.

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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?	This is not a reliance or recognition pathway. EMA evaluates the medicine in collaboration with the World Health Organization (WHO) and the relevant non-EU authorities, in the context of its use in the target population. Experts carry out a robust scientific evaluation and the medicines are required to meet the same high standards as medicines marketed in the EU. National regulators take the decision on whether or not to use the medicine or vaccine in their country.
How many reference agency decisions are required?	EMA evaluates the medicine in collaboration with the World Health Organization (WHO) and the relevant non-EU authorities, in the context of its use in the target population. Experts carry out a robust scientific evaluation and the medicines are required to meet the same high standards as medicines marketed in the EU. National regulators take the decision on whether or not to use the medicine or vaccine in their country. Article 58 combines EMA's scientific review capabilities with the epidemiology and disease expertise of WHO, experts and national regulators in the target countries, to promote the development of high-priority medicines.
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?	Click here to enter text.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	EMA evaluates the medicine in collaboration with the World Health Organization (WHO) and the relevant non-EU authorities, in the context of its use in the target population. Experts carry out a robust scientific evaluation and the medicines are required to meet the same high standards as medicines marketed in the EU. National regulators take the decision on whether or not to use the medicine or vaccine in their country.
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.

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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?	Choose an item.
Any other details you wish to provide?	- Article 58 promotes the development of medicines and vaccines for patients in low- and middle-income countries outside the European Union (EU). - Article 58 medicines benefit from the full EMA regulatory toolkit including scientific advice, EMA's PRIME (PRIority MEdicines) scheme and accelerated review. - Regulators, experts and observers from low- and middle-income countries are invited to participate in the scientific review. This helps to ensure that specific disease expertise and local knowledge are taken into account. - Regulators from target countries can decide on the use of the medicines based on EMA's scientific assessment. - **The procedure:** The sponsor (a pharmaceutical company, a non-governmental organisation (NGO) or academia) should engage with EMA early for scientific advice (with the involvement of WHO and national regulators). The sponsor requests eligibility for Article 58. The sponsor submits an application for scientific review to EMA. The assessment is carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), in collaboration with WHO, experts and national regulators. EMA adopts a scientific opinion, which is published on its website. After the opinion, sponsors are required to implement risk management plans, just as for medicines approved for marketing in the EU. EMA can perform a benefit-risk review at any time if new safety data becomes available.
Date of this update	25 APRIL 2020.
References	1. EMA Article 58*— EU Medicines for All. 2. Medicines for use outside the European Union. https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/medicines-use-outside-european-union#fees-section Accessed on 25 April 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.