FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: East African Community (EAC)	**Agency Name:** East African Community (EAC)	
Name of FRP: EAC Medicines Regulatory Harmonization Program		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 3/30/2012		
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	All pharmaceutical products
Must the product address an unmet medical need or serious condition?	Negotiable
If a fee is required, what is the amount (in US$ equivalent)	The processing fee as prescribed in the respective NMRA's fees and charges schedule must be paid to the NMRA at the point of submission of the application.
Total target (agency) time for assessment (calendar days)	- The submitted application will be screened for completeness within **30 working days**. In the event that the dossier is incomplete, it will be rejected. The applicant will be notified of the rejection and asked to come and collect the dossier. - In case of a positive outcome during screening, the NMRA shall notify the MAH in writing that the screening has been successfully completed and place the dossier in the evaluation queue. - Review of application for marketing authorization of a product will follow the appropriate evaluation queue. Priority review may be granted where the product is intended for treatment of a serious or life threatening disease. Evaluation of priority product shall be carried out within 6 months from receiving the application. - Products shall be evaluated on a First in First out (FIFO) basis and the timeline for review and approval should be within **12 months**. - Abridged evaluation will be carried out on pharmaceutical products that are registered in any of the agreed benchmark regulatory agencies.
Total target (company) time for	- During product evaluation, the NMRA may request

responses to agency questions (If stated)	for further information and additional supporting documents from the applicant. Applicant should make available such information or documentation required for each correspondence within 180 days from the date of the request. - If no response is received from the applicant after the **180 days**, the clock stops and the application will be rejected/closed. A new application will have to be submitted if the MAH wishes to pursue marketing authorization of the product. - Evaluation of the additional information shall be carried out within 3 months from receiving such information. - The MAH will be informed of the decision of the NMRA in writing as to whether the application has been approved or rejected.

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?	**Stringent Drug Regulatory Authority (SDRA):** A National Medicines Regulatory Authority which is strict, precise, exact with effective and well-functioning systems. Among others, it includes a regulatory authority which is: - A member of the International Conference on Harmonisation (ICH) (as specified on www.ich.org); or an ICH observer, being the European Free Trade Association (EFTA), as represented by SwissMedic, and Health Canada (as may be updated from time to time); or - A regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time); or - A regulatory Authority that has been agreed on by the EAC Partner States to have an effective and well- functioning medicines regulation system.
How many reference agency decisions are required?	Click here to enter text.
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted
Is a CPP (Certificate of Pharmaceutical Product) required for	Yes at time of submission

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approval?	
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	NB: Certificate of Pharmaceutical Product must be original and specific to EAC Partner States where the product is intended to be marketed. It must be accompanied by full qualitative and quantitative formula of the product showing the names of all active and inactive ingredients, function, quantity per dosage unit e.g. mg/tablet, mg/5ml, etc. and percentage by w/w, v/v, etc and approved SPC.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	The East African Community (EAC) is a regional intergovernmental organization comprising six Partner States: - The community was first established in 2000 by Kenya, Tanzania, and Uganda while Rwanda and Burundi joined in 2007. The Republic of South Sudan joined the organization in 2016.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	- Provide registration status of the medicinal product applied for registration in the countries with SDRAs and attach evidence(s) for the same. - Provide registration status of the medicinal product applied for registration in the EAC region and attach evidence(s) for the same. - The applicant should provide, in Module 1.9.1 of the dossier, a list of countries in which a similar application has been submitted, dates of submission (if available) and the status of these applications. This should detail approvals (with indications) and deferrals, withdrawals and rejections with reasons in each case.
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?	4-5 years
Any other details you wish to provide?	- MAH shall be required to pay retention fees as specified by the respective NMRA. The registration of a product shall be valid for 5 years or such period as specified in the registration certificate (unless sooner suspended or cancelled by the NMRA). The renewal of product registration should be done not later than three months prior to expiry.
Date of this update	19 February 2020
References	1. **Compendium of Medicines Evaluation and**

*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.