FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Kenya	**Agency Name:** Pharmacy and Poisons Board	
Name of FRP: Fast track for locally manufactured and priority medicines		
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?	Click here to enter text.	
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 products	
Must the product address an unmet medical need or serious condition?	Yes	
If a fee is required, what is the amount (in US$ equivalent)	Application for registration of a pharmaceutical product: - Imported in to Kenya: US$ 1000 - Fully manufactured in Kenya: US$ 500	
Total target (agency) time for assessment (calendar days)	Fast-tracked registration (Locally manufactured and Priority Medicines only), Post Approval Variation and Renewal of registration: - Complete applications will be processed within 90 working days of receiving the application including evaluation of documentation and consideration by a committee on drug registration	
Total target (company) time for responses to agency questions (If stated)	During product evaluation, the NMRA may request 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 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 Marketing Authorization Holder (MAH) wishes to pursue marketing authorization of the product.	
Select one of the following (* see definitions at end of document)		
Is this a verification review (a	**Is this an abridged* review**	**Is this a full* review of all parts**

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recognition pathway)?*	**(selected dossier portions)? (a reliance pathway)?***	**of the dossier?**
☐	☒	☐
If this is a reliance or recognition pathway, what are the accepted reference agencies?	Regulatory authorities which are: - Members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). MEMBERS: European Union member States (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, and United Kingdom; Japan; United States OBSERVERS: European Free Trade Association (EFTA) represented by Swiss Medic of Switzerland, and Health Canada (as may be updated from time to time). ASSOCIATES through mutual recognition agreements: Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time). - For medicines used exclusively outside the ICH region, positive opinions or tentative approval under any of the following three special regulatory schemes are recognized as stringent approval: (1) Article 58 of European Union Regulation (EC) No. 726/2004 (2) Canada S.C. 2004, c. 23 (Bill C-9) procedure (3) United States FDA tentative approval (for antiretrovirals under the PEPFAR programme) - A regulatory Authority that has been agreed by the East African Community (EAC) Partner States to have an effective and well-functioning medicines regulation systems.	
How many reference agency decisions are required?	Not stated.	
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted	
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Yes at time of submission	
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	In addition to CPP, submit: - Certificates of approval of DMF (Drug Master File) by Stringent Regulatory Authority; - Pre-registration analysis of the finished pharmaceutical product: (Attach certificate of analysis from a recognized WHO Prequalified Quality Control Laboratory in Kenya and within the Region) - Summary of Product Characteristics (SPC)	

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	The API information can be submitted to EAC in the order of preference in one of the following four options: (a)Option 1: Certificate of suitability of European Pharmacopeia(CEP); (b)Option 2: Active pharmaceutical ingredient pre-qualified by WHO; (c)Option 3: EAC Active Pharmaceutical Ingredient Master File (EAC-APIMF); (d)Option 4: Full details in the Product Dossier (PD)
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, it is not through an RRI
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Yes, product needs to have been marketed in another country. Submit: - Registration status from countries with Stringent Regulatory Authorities (SRAs) where applicable; - List of countries in which a similar application has been submitted; - Statement on whether an application for the Marketing Authorization has been previously rejected, withdrawn or repeatedly deferred in the EAC Partner States.
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?	- An application may be fast tracked if the product is (i) locally manufactured in Kenya. Note that contract manufacturing outside Kenya by a Kenyan company will not render the product to be locally manufactured. (ii) a Priority Medicine i.e. the product is indicated for diseases which at the time of application have no registered alternative medicine or evidence has been submitted to show that the product has significant advantages in terms of safety and efficacy over existing products indicated for treatment or prevention of life threatening diseases. - 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 following conditions must be fulfilled for abbreviated evaluation: (i) The Finished Pharmaceutical Product (FPP) must be on the market in the country of origin; if not raise a query. (ii) The submitted FPP composition should be

	identical (qualitatively and quantitatively) with the approved product and the Summary of Product Characteristics (SPC) should be comparable to the approved SPC in the country of origin (iii) The submitted FPP must be manufactured in the same facilities as the approved product (iv) If conditions outlined above are fulfilled, continue with evaluation using abbreviated evaluation template. If conditions outlined above are not fulfilled, carry out full evaluation using full evaluation template.
Date of this update	18 November 2019
References	1. PPB Medicines Evaluation and Registration Guidelines version QMS. https://www.pharmacyboardkenya.org/files/?file=PPB_Medicines_Evaluation_and_Registration_Guidelines%20_version_QMS.pdf Accessed on 17 November 2019. 2. Draft Pharmacy and Poisons (Parallel Importation of Medicinal Substances) Rules 2018. https://www.pharmacyboardkenya.org/files/?file=Draft%20Pharmacy%20and%20Poisons%20Parallel%20Importation%20of%20Medicinal%20Substances%20Rules%202018.pdf Accessed on 17 November 2019. 3. Biotherapeutic Products Guidelines. https://www.pharmacyboardkenya.org/files/?file=Biotherapeutic_Products_Guidelines.pdf Accessed on 17 November 2019. 4. CAP 244 Laws of Kenya - Pharmacy and Poisons Board ACT. https://www.pharmacyboardkenya.org/files/?file=PharmacyandPoisonsAct17of1956.pdf Accessed on 17 November 2019. 5. Draft Importation of Orphan Medicinal Substances guideline. https://www.pharmacyboardkenya.org/files/?file=DraftImportation-of-OrphanMedicinalSubstancesGuideline.pdf Accessed on 17 November 2019. 6. PPB Drug Registration Guidelines. https://pharmacyboardkenya.org/files/?file=drug_reg_guidelines.pdf Accessed on 18 November 2019.

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.