FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Ethiopia	**Agency Name:** Ethiopian Food and Drug Authority	
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?	Not stipulated.
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	New Chemical Entities, locally produced medicines, WHO Prequalified 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)	- Rate of service fee for the registration of agent = USD50.00 - Rate of service fee for the registration, pre-screening of the dossier, 2nd & 3rd Round pre-screening of the dossier = 400 Birr [USD 14] - Rate of service fee for registration, dossier evaluation, re-registration, major and minor variation – Generic Medicine = 1500 Birr [USD 50] - Rate of service fee for registration, dossier evaluation, re-registration, major and minor variation – New Medicine = 2100 Birr [USD 71]
Total target (agency) time for assessment (calendar days)	The applicant will be notified of the results of its evaluation within **30 days** of its submission
Total target (company) time for responses to agency questions (If stated)	The applicant should respond to the requested query within **six months** of notification about the missing elements and/or clarification. If a supplemental submission is not executed within the specified period, urge to be supplemented within 15 days shall follow.

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	Stringent Regulatory Authorities; Regulatory authority of a

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pathway, what are the accepted reference agencies?	member of the International Conference on Harmonization (ICH); or an ICH observer, being the European Free Trade Association, 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 statement, including Australia, Iceland, Liechtenstein, and Norway (as may be updated from time to time), or the WHO Prequalification Programme are considered to be products registered with a Stringent Regulatory Authority (SRA)
How many reference agency decisions are required?	Not stated
Does this FRP require submission of Assessment Reports from prior decisions?	Publically available reports OK
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?	GMP Certificate & CPP issued by a competent authority in the exporting country should be provided in Module 1 of CTD. Certificate of Suitability (CEP) also required. In case of a WHO Prequalified Product, the final acceptance letter and a copy of the WHO Public Assessment Report (WHOPAR).
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; regulatory situation in another country is required (provide a list of countries in which this product has been granted a Marketing Authorization (MA) and the restrictions on sale or distribution e.g. withdrawn from market). Specific amount of time/how long not stated.
How are queries to the companies sent?	As they arise
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?	- Fast Track Registration: Antimalarial, antiretroviral, anti-tuberculosis medicines; reproductive health care products; anti-cancer drugs; vaccines; drugs for "orphan diseases"; and drugs for emergent humanitarian aid shall have priority for evaluation

	and registration. - FULL Assessment of dossiers of the Innovators (Module 1 – 5 submitted). - Public Assessment Reports (SmPC & CPP). SmPC = Summary of Product Characteristics. - In Ethiopia, requirements for all applications is the same except the time prioritization in case of fast track registration.
Date of this update	12 November 2019
References	1. Medicines Market Authorization Strategy 2017. http://www.fmhaca.gov.et/wp-content/plugins/download-attachments/includes/download.php?id=3010 Accessed on 10 November 2019 2. Guideline for registration of medicines 2014. http://www.fmhaca.gov.et/publication/guideline-for-registration-of-medicines-2014/ Accessed on 10 November 2019. 3. Rate of service fees regulation #370 of 2015. http://www.fmhaca.gov.et/wp-content/plugins/download-attachments/includes/download.php?id=3008 Accessed on 10 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.