FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Tanzania	**Agency Name:** Tanzania Medicine & Medical Devices Authority	
Name of FRP: Fast track evaluation		
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?	FRPs are for Finished Pharmaceutical Products (FPP) that the applicant wishes to register; requested at the point of submitting the registration paperwork.	
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?	Negotiable	
If a fee is required, what is the amount (in US$ equivalent)	Fast Track Registration – Pharmaceuticals: USD 4000 Fast Track Registration – Biologicals: USD 7000	
Total target (agency) time for assessment (calendar days)	Products are evaluated on a First In First Out (FIFO) basis and the timeline for review and communication to applicant shall be within **3 months**.	
Total target (company) time for responses to agency questions (If stated)	6 months	
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 member of the International Conference on Harmonization (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	

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	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 by the East African Community (EAC) Partner States to have an effective and well-functioning medicines regulation system.
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: - Summary Product Characteristics (SmPC) and if it has not been approved from an SDRA at the time the application is submitted to TMDA, a draft document may be included. The approved SmPC from SDRA should then be supplied to TMDA as they become available; - Certificates of Suitability of monographs of the European Pharmacopoeia (CEP) or EAC-APIMF (East African Community – Active Pharmaceutical Ingredient Master File); - A WHO-type Certificate of GMP. - If available, evidence for Prequalification (PQ) of medicinal product by WHO should be submitted.
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, the product needs to have been marketed in another country. Provide registration status of the pharmaceutical product applied for registration in the countries with SDRAs and attach evidence(s) for the same; provide registration status of the pharmaceutical product applied for registration in countries in the EAC region and provide evidence(s) for the same.
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	- If applicant fails to submit additional samples, documents,

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provide?	information, data and clarification within the period of six months from the date of request letter, the application shall be rendered withdrawn. - There is a 5 year validity for a certificate of full registration unless earlier suspended or revoked, and subject to payment of prescribed annual retention fees. A certificate of provisional registration shall be valid for a period specified in the certificate and that period shall not extend three years. - Every Marketing Authorization Holder shall be duty bound to conduct periodic post-marketing surveillance (PMS) and safety studies. The PMS and adverse effects reports shall be submitted to the Authority after every two (2) years for evaluation and determination of risk-benefit profile of the registered products every two years. Failure to submit the reports shall render the registration of the medicinal product suspended.
Date of this update	17 November 2019
References	1. TFDA Fees and Charges. https://www.tmda.go.tz/uploads/publications/en1554370780-TFDA%20Fees%20and%20charges.pdf Accessed on 13 November 2019 2. TFDA Registration Medicines. https://www.tmda.go.tz/uploads/publications/en1573544130-GN%20314%20-%20Registration%20medicines.pdf Accessed on 13 November 2019 3. Guidelines of submission of documentation for registration of human pharmaceutical products. https://www.tmda.go.tz/uploads/publications/en1558078061-Guidelines%20on%20Submission%20of%20Documentation%20for%20Registration%20of%20Human%20Pharmaceutical%20Products_0.pdf Accessed on 13 November 2019. 4. Quality Assurance Tanzania. http://origin.who.int/hiv/amds/QualityAssuranceTanzania.ppt Accessed on 13 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.