FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Zimbabwe	**Agency Name:** Medicines Control Authority of Zimbabwe	
Name of FRP: Expedited or "Fast-track" Registration Procedure		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 1/2/2018		
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?	Prior to the submission of the required evaluation documentation for already existent products (generics & innovator products)	
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	Generics, Biosimilars, Innovator medicines	
Must the product address an unmet medical need or serious condition?	No	
If a fee is required, what is the amount (in US$ equivalent)	The following fees are applicable for applications using this pathway: $4 500 excl. VAT per product for New Chemical Entities $4 000 excl. VAT per product for generic products $3 000 excl. VAT per product for line extensions *VAT = 15% in Zimbabwe	
Total target (agency) time for assessment (calendar days)	Finalization of the application within 6 months of MCAZ time is guaranteed with this pathway.	
Total target (company) time for responses to agency questions (If stated)	60 days given to respond to queries after an evaluation cycle.	
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	Stringent Regulatory Authorities (SRAs) = Members, associates and	

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recognition pathway, what are the accepted reference agencies?	observers of ICH e.g. USFDA, EMA, etc.
How many reference agency decisions are required?	1 regulatory authority of the ICH region or associated countries.
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?	CPP must be submitted as part of the requirements of CTD format. In addition, a complete copy of certificate(s) of suitability of the European Pharmacopoeia (CEP) (including any annexes) should be provided in Module 1 and proof of compliance with current Good Manufacturing Practices (cGMP)
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No
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 be marketed in another country. Specific amount of time is not stated by the Authority.
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
Post-authorization study commitments	Choose an item.
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- For Generic Medicines, the channel for expedited review of applications for registration of medicines is done in cycles and calls are sent out. In each cycle, 10 applications are accepted of which 1 of them may be for a biosimilar. Once the 10th application is received, no more applications are accepted until the next call. - For Innovator medicines, since 2 January 2018, there has and continues to be an expedited review pathway for SRA-approved innovator products registered in their country of

	origin. This pathway is open throughout the year. - Only products manufactured at plants (unit and block level) deemed GMP-compliant by MCAZ or in SRA-regulated countries with SRA-issued GMP certification are eligible for expedited review. - Authority requires FULL dossiers for evaluation regardless of it being a reliance pathway.
Date of this update	12 November 2019
References	1. Alternative submission pathways https://www.mcaz.co.zw/index.php/alternative-submission-pathways Accessed on 10 November 2019 2. How to Register Conventional Medicines https://www.mcaz.co.zw/index.php/how-to-register Accessed on 10 November 2019 3. Expedited/Fast-track application process Circular 08/2019 https://www.mcaz.co.zw/images/evr/Circula-8-of-2019-Opening-of-Expedited-Review-Channel-for-Assessment-of-Applications-for-Registration-of-Human-Allopathic-Medicines-in-2019.pdf 4. MCAZ Quotation Form https://www.mcaz.co.zw/images/evr/Quotation_confirmation_form.doc Accessed on 10 November 2019 5. MCAZ CTD Guidelines http://www.mcaz.co.zw/index.php/downloads/category/11-guidelines?download=74:mcaz-ctd-guidelines Accessed on 10 November 2019 6. MCAZ Guideline Complementary Medicines – Approved by Registration Committee http://www.mcaz.co.zw/index.php/downloads/category/11-guidelines?download=127:guideline-complementary-medicines-approved-by-registration-committee 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.