FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: ZAZIBONA	**Agency Name:** ZAZIBONA	
Name of FRP: ZAZIBONA Collaborative Medicines Registration Process.		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 1/1/2015		
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?	Before the marketing authorisation 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	- Any medicine meeting the criteria of being an essential medicine is eligible to be considered for registration via the Zazibona collaborative process. Special consideration may be given to medicines that are vital to effective treatment and to expanding treatment programmes, where there are currently limited options for health practitioners in the participating countries. Applicants or local representatives are encouraged to make pre-submission consultations on eligibility of their products. - The focus will however be on the 10 priority disease conditions identified by SADC (Annex 1) plus reproductive health products. Priority will be given to the products included in the List of UN Commission for Live-Saving Commodities for Women and Children. Any other medicines that are important from a public health perspective may be considered on a case-by-case basis. - In addition to be eligible for the Zazibona collaborative process an application should have been lodged with at least two (2) active Zazibona countries. - **Applications not eligible:** The invited generic products exclude those which have been prequalified by the World Health Organization (WHO), for which an accelerated registration mechanism (WHO PQ Collaborative Registration Process) can be applied.	
Must the product address an unmet medical need or serious condition?	Yes	
If a fee is required, what is the amount (in US$	Click here to enter text.	

equivalent)	
Total target (agency) time for assessment (calendar days)	The collaborative process is designed to achieve registration within a total time of **11 months**, during which the applicant will have two windows of opportunity to respond to consolidated lists of regulatory assessment questions within a period of 60 days. Total regulatory time for collaborative process is therefore 210 days, which corresponds to regulatory deadlines of established regulatory authorities. Timelines for the collaborative process start at the point of allocation of rapporteurship i.e. within 1 month of the submission, followed by 10 weeks for initial assessment, 2 weeks for sharing assessment report, 8 weeks for the manufacturer/supplier or applicant to respond, and 2 weeks to process the response. The specified timelines are only indicative and may vary depending on the specific dates of the assessment sessions. Products are only considered for 2 review cycles (for the responses) thereafter a final recommendation will be made. The target timelines may vary depending on the number of submissions relative to the available technical capacity of the participating NMRAs. A NMRA reserves the right to make a final determination on any application and may request further information. Each NMRA will be required to finalize the registration process within a reasonable timeframe after the final recommendation from the collaborative process depending on the schedules of the meetings for the Authorities/Boards/Committees responsible for final regulatory decision at national level.
Total target (company) time for responses to agency questions (If stated)	Please consult the section above.

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?	Products registered by stringent regulatory authorities (SRA) are eligible for an abridged review process provided there is access to the assessment reports for which the authorization was based on.
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 approval?	Yes at time of submission

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Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	ZAZIBONA Document Requirements: Product dossier, in English, organized in CTD format for submitting product data and information. For the purpose of generic medicine registration, data demonstrating quality of raw materials (Active Pharmaceutical Ingredients and Excipients) and FPP are necessary, as well as demonstration of bioequivalence with an acceptable comparator. Details are specified in the relevant guidelines that reflect the harmonized SADC position. Paper and electronic copies of the dossier should be submitted as per national requirements.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	7 Active Participating Member States: - Botswana - Democratic Republic of Congo (joined 2017) - Namibia - South Africa (joined June 2016) - Zambia - Zimbabwe - Mozambique 2 non-active participating Member State: - Swaziland (joined Nov 2016) - Seychelles (joined 2017) * This process may be extended to include participation by other interested SADC Member States.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Click here to enter text.
How are queries to the companies sent?	At specified times during the assessment
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?	Choose an item.
Any other details you wish to provide?	- Endorsed by SADC Ministers of Health & Ministers Responsible for HIV & AIDS in January 2015 - The vision of the ZAZIBONA process is: (i) a region in which good-quality medicines are available to all those who need them; (ii) significantly reduce time taken to grant marketing authorization (registration) in the individual countries; and (iii) efficient utilization of resources within regional national regulatory authorities through work sharing. - The process objective is to promote a collaboration model

	to facilitate access to good-quality medicines through worksharing in assessment of medicines and inspection of medicine manufacturing and testing facilities. Products that meet assessment criteria are then granted registration in the participating countries, in which CTD-format applications for registration would have been submitted. - Where countries agree that it is necessary, variations to the products which have been registered under this collaboration may be handled through the same process. - The ZAZIBONA collaboration does not represent the replacement of the need to submit applications for registration in participating countries in line with national requirements. However, in order to facilitate cooperation among ZAZIBONA authorities, certain modifications are expected. Although there is close collaboration on assessments and inspections, final national registration decisions are the responsibility of individual participating authorities.
Date of this update	19 FEBRUARY 2020
References	1. ZAZIBONA Collaborative Medicines Registration Process. https://www.mcaz.co.zw/index.php/latest-news/16-zazibona-collaborative-medicines-registration-process Accessed on 19 February 2020. 2. SADC Collaborative Medicines Registration Initiative (Zazibona). https://www.saapi.org.za/download/presentation/davis-mahlatji.pdf Accessed on 19 February 2020. 3. Zazibona Request Form. http://www.mcaz.co.zw/index.php/downloads/category/21-forms?download=231:zazibona-request-form Accessed on 19 February 2020. 4. Zazibona Registration Pathway. http://www.mcaz.co.zw/index.php/downloads/category/13-zazibona?download=1:zazibona-registration-pathway-v01-09062015 Accessed on 19 February 2020. 5. Annex I documents. http://www.mcaz.co.zw/index.php/downloads/category/13-zazibona?download=4:annex-i-documents Accessed on 19 February 2020.

*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.