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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: South Africa	**Agency Name:** South African Health Products Regulatory Authority (SAHPRA)	
Name of FRP: Reliance-based Evaluation Pathways – ABRIDGED REVIEW		
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 stated	
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?	No	
If a fee is required, what is the amount (in US$ equivalent)	ZAR 53,900 / USD 3,690	
Total target (agency) time for assessment (calendar days)	250 Calendar Days	
Total target (company) time for responses to agency questions (If stated)	180 Calendar Days	
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?	SAHPRA's Recognised Regulatory Authorities - European Medicines Agency Centralised Procedure (EMA CP) - European Medicines Agency Decentralised Procedure (EMA DCP) - Health Canada - Medicines and Health Products Regulatory Agency (MHRA),	

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	UK - Ministry of Health, Labour and Welfare (MHLW), Japan - Swiss Agency for Therapeutic Products (Swissmedic) - Therapeutic Goods Administration (TGA), Australia - US Food and Drug Administration (US FDA) - *World Health Organization Prequalification (WHO PQ) - *Zazibona Collaborative Procedure
How many reference agency decisions are required?	1+
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	No
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	CPP is not essential for registration but a copy of the authorization letter should be provided. Evidence of GMP status of manufacturer and copies of labeling, for products authorized in the reference countries, are also required. Full quality data (Module 3), full non-clinical data (Module 4), and full clinical data (Module 5) are required.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	This process is not through a RRI. However, SAHPRA is part of the ZAZIBONA Collaborative/Work-sharing procedure.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Yes, marketing in another country is required. Amount of time not specified. For how long? Not specified.
How are queries to the companies sent?	As they arise
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- always
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?	- The title of "Abbreviated Medicines Review Process" has been changed to "Reliance-based Evaluation Pathways" - Medicines applications for new registrations and variations in South Africa will follow one of four evaluation/review pathways: (a) Full Review (b) Abridged Review (c) Verified Review (d) Recognition. Review pathways (b), (c) and (d) represent reliance-based evaluations. - Abridged and verified review processes do NOT involve an abbreviated application. All data and information required

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	for a full review should be submitted i.e. full CTD module structure, as well as the SCoRE document. Evaluators may still need to review data in the dossier as required (even when presented with unredacted reports)
Date of this update	13 November 2019
References	1. Fees https://www.sahpra.org.za/documents/992cfdc6SAHPRA_Fees_24.05.2019(ExtractfromGovernmentGazette42474-5).pdf 2. General Information https://www.sahpra.org.za/documents/1d9c57df2.01_General_information_Jul12_v8_showing_changes.pdf 3. The Regulatory Review Process in South Africa. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6047299/ 4. Updated – General Information. https://sahivsoc.org/Files/2.01_general%20information_%20jul19_v10%20(1).pdf

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.