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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	An abridged review is a reliance-based review comprising: • Validation by SAHPRA to ensure that the product application submitted for registration by SAHPRA is the same as the product registered by the specified RRA • Evaluation of Module 1: Regional administrative information (as required) • Evaluation of specific aspects of the dossier, depending on the type of application submitted The abridged review process does not involve an abbreviated application – all data and information required for a full review should be submitted, i.e. the full CTD module structure, as well as the SCoRE document. Evaluators may still wish to review data in the dossier as required. An abridged review is applicable to the following types of applications: i. For a new registration application for a generic medicine already registered by an RRA ii. For a new registration for a WHO PQ product: Applicants are required to follow SAHPRA's process for the WHO Collaborative Registration Procedure NB: Reliance-based evaluation will be based on the following principles: • Reliance is applicable for both new registration and variation applications (Type IB and Type II). • Reliance for Clinical and ME&R is applied independently, i.e. the review types selected by the units could differ based on	

	unit-specific document requirements and the availability thereof. • The application submitted for registration by SAHPRA should be the same as the most updated product on record at the RRA, i.e. all approved variations for the RRA's registered product should be incorporated in the application submitted for registration by SAHPRA. Pending variations with the RRA should not be included in the application submitted to SAHPRA in order for the application to qualify for reliance. • All decisions regarding final evaluation pathway (i.e. full review or reliance-based review) as well as the extent of reliance on the RRA's evaluation of the product being applied for are at the discretion of SAHPRA, based on the documents (and quality thereof) available for reliance based evaluation. • Any and all decisions regarding approval and final registration will be made by SAHPRA, in consideration of multiple factors including an RRA registration.
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?	To qualify for a reliance evaluation pathway, a product being applied for must be registered by one or more of the recognised regulatory authorities (RRAs) with which SAHPRA aligns itself. SAHPRA will leverage evaluation efforts done by RRAs in order to make its evaluation process more efficient and enhance market access. SAHPRA's current RRAs include: • European Medicines Agency Centralised Procedure (EMA CP) • European Medicines Agency Decentralised Procedure (EMA DCP) (no restrictions on which member state acts as the reference member state)

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	• Health Canada • Medicines and Health Products Regulatory Agency, UK (MHRA) • Ministry of Health, Labour and Welfare (MHLW), Japan • Swiss Agency for Therapeutic Products (Swissmedic) • Therapeutic Goods Administration, Australia (TGA) • US Food and Drug Administration (US FDA) Two additional procedures can be used for reliance / collaborative review, which are not strictly regulatory authorities: • World Health Organisation 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

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	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 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	10 MAY 2020
References	1. Fees https://www.sahpra.org.za/documents/992cfdc6SAHPRA_Fees_24.05.2019(ExtractfromGovernmentGazette42474-5).pdf 2. QUALITY AND BIOEQUIVALENCE GUIDELINE. https://www.sahpra.org.za/wp-content/uploads/2020/02/2.02_Quality-and-Bioequivalence-Guideline_Jul19_v7-1.pdf Accessed on 10 May 2020. 3. CLINICAL GUIDELINE. https://www.sahpra.org.za/wp-content/uploads/2020/02/2.09_Clinical-Guideline_Jul19_v2-1.pdf Accessed on 10 May 2020. 4. GUIDANCE FOR THE SUBMISSION OF THE SOUTH AFRICAN CTD /eCTD - GENERAL & MODULE. https://www.sahpra.org.za/wp-content/uploads/2020/02/2.01-Guidance_General_Module_1_May19_v6-1.pdf Accessed on 10 May 2020. 5. The Regulatory Review Process in South Africa. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6047299/ 6. 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.