FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Saudi Arabia	**Agency Name:** Saudi Food and Drug Authority (SFDA)	
Name of FRP: Abridged Procedure		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 10/2/2006		
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	New Products (New Chemical Entities); Biological Products (excluding biosimilar, blood products, vaccines and advanced therapy medicinal products)
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	Click here to enter text.
Total target (agency) time for assessment (calendar days)	60 day review procedure NB: The review clock will not begin until the product has been accepted to be priority reviewed.
Total target (company) time for responses to agency questions (If stated)	Click here to enter text.

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?	European Medicines Agency (EMA) **or** US Food and Drug Administration (FDA). NB: EMA registration means centralized procedure.
How many reference agency decisions are required?	1 Reference Agency Decision - European Medicines Agency (EMA) **or** US Food and Drug Administration (FDA)

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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?	Click here to enter text.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, this procedure 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 has to have been marketed in another country. ELIGIBILITY CRITERIA FOR THIS PROCEDURE: - The application must be submitted to the SFDA within two (2) years from the date of approval of the reference agency. - The product does not need a more stringent assessment as a result of different local disease patterns and/or medical practices. - The product and its intended use (indications, dosage information, and patient groups (for human product) has not been rejected, withdrawn, suspended by any drug regulatory agency for safety or efficacy reasons. - The manufacturer should be located in one of the following countries: USA, UK, Canada, Australia, Japan, Switzerland, Germany, France, Ireland, Italy, Spain, Portugal, Finland, Sweden, Norway, Denmark, Belgium, Netherlands or Austria.
How are queries to the companies sent?	At specified times during the assessment
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
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?	- The priority review process is intended for: the treatment of a serious or life threatening condition and/or demonstrates the potential to address unmet medical needs; products under SFDA's exempted list; or to product considered as first or second generic for

	innovated product. - The request of priority review is sent to the Drug Sector prior to submission. - The average review timeline in both procedures (Abridged or Verification) was six to seven months. The aspirational goal of 30/60 days review procedures is not yet achieved. - There is a mandatory pre-designation meeting with the Executive Directorate of Regulatory Affairs to check the eligibility of the request and to ensure the product file fulfills the requirements. The applicant will receive the Drug Sector decision within five (5) working days. In case of rejection, the application will be transferred to the regular pathway (note: registration fee is non-refundable).
Date of this update	19 November 2019
References	1. The Regulatory Reliance Review Model: Adoption in the Middle East. https://globalforum.diaglobal.org/issue/july-2019/the-regulatory-reliance-review-model-adoption-in-the-middle-east/ Accessed on 12 December 2019 2. Registration according to Verification and Abridged Process. https://www.sfda.gov.sa/en/drug/drug_reg/Regulations/VerificationAbridgedProcess.pdf Accessed on 12 December 2019 3. Guidance for Priority Review of Product Registration. https://www.sfda.gov.sa/en/drug/drug_reg/Regulations/PriorityReviewProductRegistration.pdf Accessed on 12 December 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. This may form part of a reliance or recognition pathway.