FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Jordan	**Agency Name:** Jordan Food and Drug Administration (JFDA)	
Name of FRP: JFDA Abridged Procedure		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 2/1/2017		
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?	At the time of the 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 molecule registration, new indications, and to lifecycle maintenance activities (e.g., variations and renewals).
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)	90-day review procedure conditional on approval issued either by either EMA or FDA as main eligibility criteria.
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?	The EMA or FDA.
How many reference agency decisions are required?	1 reference agency decisions: the EMA or FDA
Does this FRP require submission of Assessment Reports from prior decisions?	Publically available reports OK
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Yes at time of submission
Can an alternate form of reference	Click here to enter text.

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documentation to the CPP be used? If so, what types of documents?	
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, the process is not through a Regional Regulatory Initiative
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.
How are queries to the companies sent?	In batches
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?	- In February 2017, the JFDA published in their official Journal a brief note about the verification/abridged procedure (90-day review process), followed by the detailed final guideline published in July 2017. - There is also a clause related to the retroactive effect of the guideline through which a product fulfilling fast track review criteria and submitted via the normal pathway can be switched to the Abridged or Verification procedure. - The public assessment report from EMA or FDA is the reference review document of JFDA, and its submittal with the marketing authorization application is mandatory. - It has been noted that the average review timeline in both procedures (Verification or Abridged) was three to five months. For the JFDA, this is a significant milestone compared to the standard procedure where the average review timeline was 18 months for small molecules and 24 months for biological products.
Date of this update	4 JANUARY 2020
References	1. Jordan FDA Adopts Reliance Review Model. https://globalforum.diaglobal.org/issue/october-2019/jordan-fda-adopts-reliance-review-model/ Accessed on 4 January 2020 2. Haqaish WSA, Obeidat H, Patel P, Walker S. The Jordan Food and Drug Administration: Comparison of its Registration Process with Australia, Canada, Saudi Arabia and Singapore. *Pharmaceut Med.*

2017;31(1):21–30. doi:10.1007/s40290-016-0172-4

*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.