FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Kuwait	**Agency Name:** Kuwait Ministry of Health (MoH)	
Name of FRP: Biological Product/Biosimilars Registration		
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?	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	Biological products and biosimilars, which must satisfy the technical and product class specific provisions set out in the Gulf Health Council ("GHC") guidelines.
Must the product address an unmet medical need or serious condition?	Choose an item.
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)	Click here to enter text.
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 European Medicines Agency OR the US Food and Drug Administration.
How many reference agency decisions are required?	1: The European Medicines Agency OR the US Food and Drug Administration.
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Choose an item.
Can an alternate form of reference documentation to the CPP be used? If	Click here to enter text.

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so, what types of documents?	
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, this 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 must have been marketed in another country. Registration is required in one of the reference authorities, such as the European Medicines Agency or the US Food and Drug Administration.
How are queries to the companies sent?	Choose an item.
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?	4-5 years
Any other details you wish to provide?	- In January 2020, Kuwait's Ministry of Health ("MOH") issued Ministerial Decree No. 361 of 2019 ("Decree") regarding the registration of pharmaceuticals. The Decree supplements the pharmacy laws and provides an update to the various MOH decrees regarding the registration of pharmaceutical products. - In line with the local laws, a foreign pharmaceutical product may only be imported into the market (i) following appointment of a local agent who is duly authorised and licensed by the Ministry of Commerce and MOH to import and distribute such products in Kuwait, and (ii) registration of the pharmaceutical product with the MOH. - The Decree sets forth the requirements of the local agent, who is responsible for carrying out the pharmaceutical product and foreign manufacturer registration and obtaining the necessary importation approvals. It continues to be a requirement that a foreign marketing authorisation holder ("MAH") produces a legalised letter of appointment detailing that the appointed local agent is the sole and/or exclusive agent in Kuwait; however, the Decree does still provide a pathway for the MAH to transfer the product registrations to a new local agent. - Product registration files continue to be required to conform to the common technical document ("CTD") structure adopted by the GHC. - Further, registration certifications are valid for five years from the date of issuance and renewal files

	must be submitted six months prior to pharmaceutical registration certificate expiry. - The Decree also addresses, among others, the requirements for: registration of locally manufactured pharmaceutical products; registration of marketing authorization holders with the MOH; and bi-lingual (Arabic and English) product labelling.
Date of this update	31 May 2020
References	1. Kuwait's New Pharmaceutical Registration Guidelines. https://www.tamimi.com/news/kuwaits-new-pharmaceutical-registration-guidelines/ Accessed on 31 May 2020. 2. KUWAIT: NEW GUIDELINES FOR PHARMACEUTICAL REGISTRATION. https://www.sabaip.com/news/kuwait-new-regulations-for-pharmaceutical-registration/ Accessed on 31 May 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.