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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Kuwait	**Agency Name:** Kuwait Food and Drug Authority (KuFDA)	
Name of FRP: Reliance pathway		
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?	Choose an item.	
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	Lifesaving products or products with U.S., EU, or Japanese approval.	
Must the product address an unmet medical need or serious condition?	Yes	
If a fee is required, what is the amount (in US$ equivalent)	Prices are reviewed every six months.	
Total target (agency) time for assessment (calendar days)	The review process begins with the local agent (or sponsor) sending the registration dossier together with a covering letter to the **Kuwait Drug and Food Control Manager (KDFC)** formally demanding the pharmaceutical material registration. Manufacturers submit their drug application to Kuwaiti MoH for market authorization; approvals take 30-60 days.	
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?	U.S., EU, or Japan.	

FRPath.org Country and FRP Information Input Form	
How many reference agency decisions are required?	Click here to enter text.
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?	In addition to the CPP, applicant must submit the following documents: 1. Legalized certificate of free sale issued by health authorities to COO, showing the brand register & sell with the same name & composition; i. Legalized price certificate issued by COO authority, including ex-factory price, COO wholesale price; and ii. Name of developed countries where the commodity is licensed, the foreign company's license and the foreign company's business establishment.
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 has to have been marketed in another country. The pharmaceutical sector of Kuwait entertains various multi-source products which are imported from multiple countries and regions. The regulatory framework set in place attempts to ensure the following objectives: 1. **The product has been licensed and sold for at least twelve months in countries with recognized and competent regulatory authorities** 2. That the product follows the desired quality standards, globally accepted, to ensure that the product is manufactured for its intended use 3. That the product remains stable throughout the projected shelf life 4. For local patients, the price of the product must be reasonable and affordable.
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- as needed
Post-authorization study	Always required

FRPath.org Country and FRP Information Input Form	
commitments	
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- The Kuwait Food and Drug Authority (KuFDA) is the head regulatory agency, which follows the ministerial decree 302/80 to register pharmaceutical products. - Regulation of medicines in Kuwait is done on the basis of quality, safety and efficacy standards, price control, and patent protection. The country has 40 years of experience of a regulatory system and plays a prominent role in the GCC‟s regulatory environment. - The Kuwaiti review process ensures that (a) the product is registered and marketed in countries with recognized and competent regulatory authorities for at least 12 months, (b) that the product meets the desired, internationally recognized, quality standards to ensure that the product was manufactured for its intended use, (c) that the product is stable for the entire proposed shelf life and for six months under the stressed conditions of 40°C/75% relative humidity, and (d) the product price must be reasonable and affordable for local patients. - The regulatory process has three phases (a) the submission phase: the local agent (or the sponsor) submits the registration dossier along with a covering letter to the director of Kuwait Drug and Food Control (KDFC) officially requesting the registration of the pharmaceutical product (b) the evaluation phase: the reviewer evaluates the Chemical and Manufacturing Control (CMC) data focusing on data related to product safety and quality (c) the authorization phase: after the successful completion of full assessment, the final approval decision is made by the Drug Registration and Release Superintendent (DRRS) which is officially endorsed by the director of the authority.
Date of this update	21 February 2020.
References	1. Kuwait: A Guide To Distribution Of Pharmaceutical Products In Kuwait. https://www.mondaq.com/Food-Drugs-Healthcare-Life-Sciences/873342/A-Guide-To-Distribution-Of-Pharmaceutical-Products-In-Kuwait Accessed on 20 February 2020. 2. Market Overview 2016 Kuwait. https://www.tfhc.nl/wp-content/uploads/2017/08/KLSC-IMS-Kuwait-Health-Industry-Report-2016-vF2.pdf Accessed on 21 February 2020. 3. Guideline for Registration of Products. *According to Ministerial Decree 302/80.*

https://www.yumpu.com/en/document/read/34914634/guidelines-for-registration-of-pharmaceutical-products-according-to- Accessed on 21 February 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.