FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Gulf Health Council	**Agency Name:** Gulf Health Council	
Name of FRP: GHC Central 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	Pharmaceutical Products (Any Medicine Manufactured on Pharmaceutical Basis).	
Must the product address an unmet medical need or serious condition?		
If a fee is required, what is the amount (in US$ equivalent)	Total fees for central registration and GCC: 1. Evaluation of innovative and biological products for registration = SAR 204,000 [USD 54,400] 2. Evaluation of generic products file for registration = SAR 87,000 [USD 23,200] 3. Evaluation of generic products file for registration (Intravenous solutions that do not contain active substances) = SAR 57,000 [USD 15,200]	
Total target (agency) time for assessment (calendar days)	The council is targeting a one-year approval timeline; local pricing will be the only step to occur at the national level.	
Total target (company) time for responses to agency questions (If stated)	Corporate commitment to respond to the observations of the Committee within a period not exceeding (6) months from the proposal date, otherwise the Company Registration will be Considered Cancelled.	
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	Click here to enter text.	

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are the accepted reference agencies?	
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?	The CPP should be in accordance with WHO guidelines. However, if the CPP is not available, a marketing authorization from the country of origin (COO) should be submitted. Marketing authorization should include the following: 1. Product trade name in the COO. 2. Number and date of marketing authorization in the COO. 3. Name of active and inactive substances with their concentrations. 4. A statement that certifies the product is marketed in the COO. If not, please specify the reasons and provide a marketing authorization showing that the product is marketed in one of the countries approved by GCC (reference member state in EU, USA, Canada, Switzerland, Australia, and Japan). 5. Provide official document demonstrating that the product has been registered for no less than one year in the COO.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	Saudi Arabia, Kuwait, the United Arab Emirates, Qatar, Bahrain, Yemen and Oman.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	According to Page 9 of 23 of Reference 4: - The product submitted for central registration must be registered & marketed in the country of origin/Reference Country for at least one year before application for its central registration; - If the product is not marketed, the reasons must be clarified and the applicant is to submit a CPP from a country approved by the GCC Committee.
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 commitments	Always required
For how long is the initial	4-5 years

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approval or designation valid?	
Any other details you wish to provide?	- The Gulf Health Council was established in 1976 under the guidance of the Council of Ministers. It enjoys legal, financial and administrative independence, and the authority and capacity to achieve all of its objectives. Its membership is limited to GCC Member States, and also includes Yemen, which joined the Gulf Health Council in 2003. The Council works to consolidate relations between Member States, to strengthen integration and to promote the health of all citizens of Member States. - Registration validity: The Pharmaceutical Product that is Centrally Registered, is valid for Five years from the date of registration with the Central Gulf Committee for drug registration and registration can be renewed upon application, three months before the expiry date of the certificate and be accompanied by the requirements for re-registration.
Date of this update	19 February 2020
References	1. Steps taken to streamline regulatory processes in the Middle East. https://clarivate.com/cortellis/blog/steps-taken-streamline-regulatory-processes-middle-east/ Accessed on 19 February 2020. 2. GCC Data Requirements for Human Drugs Submission. *Content of the Dossier*. Version 1.1. http://ghc.sa/ar-sa/Documents/ا ست%20وأدلة%20مدونات/الـ مركزي%20الـ تسجيل شادية/updated%20file/GCC%20Data%20Requirements%20for%20Human%20Drugs%20Submission%20version%201.1.pdf Accessed on 19 February 2020. 3. Total fees for central registration and GCC. http://ghc.sa/en-us/Pages/crfees.aspx Accessed on 19 February 2020. 4. Executive Board of the Health Ministers' Council For GCC: Registration By-Laws of Pharmaceutical Companies and Their Products. http://ghc.sa/en-us/Documents/Central%20registration/Regulate%20and%20bylaws/Registration%20By-Laws%20of%20Pharmaceutical%20Companies%20and%20Their%20Products.pdf Accessed on 19 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.