FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: United Arab Emirates (UAE)	**Agency Name:** Ministry of Health and Prevention of the United Arab Emirates (MOHAP)	
Name of FRP: Fast-track registration		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 1/1/2018		
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	Innovative and orphan drugs. - Innovative drugs are defined as 'drugs that contain an entirely or partially new active ingredient and whose owner holds a patent' - Orphan drugs are defined as 'drugs that are used for treatment, diagnosis or prevention of rare diseases.'
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)	The Drug Registration Committee evaluates an application for a new drug within 15 working days of submission and makes the decision to approve or reject the application within 10 working days from the date of evaluation.
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?	US FDA, EMA.
How many reference agency decisions are required?	Click here to enter text.
Does this FRP require submission of	Unredacted

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Assessment Reports from prior decisions?	
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Yes prior to final decision
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 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?	The product may be marketed in another country. Ultimately, registration in the UAE will be dependent on the product having approval from the majority of the members of the Drug Registration Committee.
How are queries to the companies sent?	As they arise
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?	- The application can be fast-tracked if it is submitted through electronic channels where the registration file is accepted as e-CTD. The registration files (safety + quality + pricing) submitted to the Ministry are evaluated by the Medical Registration Committee by e-mail within a period not exceeding 15 working days. - The registration and pricing certificate for the pharmaceutical product is issued within 48 hours from the date of the ministerial decision on the price. - The price of the product shall be based on the price proposed by the marketing authorization holder or importer if the price in the country of origin is temporarily unavailable. For the product to be registered, it should have the approval from the majority of the members of the Drug Registration Committee. - In case of declined application, the registration may be presented again to the members of the Drug Registration Committee once more information about the product is provided or after approval by one of the accredited international bodies. The product is then re-priced in reference to the price in the country of origin

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	or the prices in the GCC countries during the first year of registration. The marketing authorization holder has to submit the pricing documents within three months from the issuance of the price in the country of origin or the GCC.
Date of this update	19 JANUARY 2020
References	1. UAE: A World Leader for Early Access to Innovation. https://pharmaboardroom.com/articles/uae-a-world-leader-for-early-access-to-innovation/ Accessed on 19 January 2020. 2. Minister of Health and Prevention issues ministerial decree for the registration of innovative medicines and rare drugs. https://www.mohap.gov.ae/en/MediaCenter/News/Pages/1950.aspx Accessed on 19 January 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.