FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Egypt	**Agency Name:** Egyptian Drug Authority	
Name of FRP: Fast track procedure		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 1/1/2013		
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?	TBD
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	TBD
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	TBD
Total target (agency) time for assessment (calendar days)	HUMAN DRUG REGISTRATION WORKFLOW OVERVIEW: 1. Front Office: Applications; Checklists = 15 Working Days 2. Receiving the hard file = 30 Working Days 3. Pricing = 60 Working Days
Total target (company) time for responses to agency questions (If stated)	TBD

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?	TBD
How many reference agency decisions are required?	TBD
Does this FRP require submission of Assessment Reports from prior decisions?	Choose an item.

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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 so, what types of documents?	TBD
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, it 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?	TBD
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	Choose an item.
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	FAST TRACK 1. Intended for treatment of a serious life threatening condition 2. Demonstrates the potential to address unmet medical and patient needs 3. Fast track classification does not apply to a product alone/for specific indication or intended to treat a serious aspect of the condition 4. Number and availability of similar products should be taken in consideration 5. Products submitted for purposes of exportation only Fast Track procedure in Egypt was launched in 2013, exact date is not stated. The date stated under "Date when FRP was officially enacted" as 1/1/2013 is not accurate – only the year is correct. ***Documents (Guidelines and Ministerial Decisions) are available in Arabic only. They are in the References Box below.
Date of this update	13 November 2019
References	1. Draft for the ministerial decree for the new registration process for human pharmaceutical products.

	http://www.eda.mohp.gov.eg/Files/86_website_draft3.pdf Accessed on 13 November 2019 2. Biologicals: Fast Track Guidelines. http://www.eda.mohp.gov.eg/images/News/F_39.pdf Accessed on 13 November 2019. 3. Fast Track Announcement. http://www.eda.mohp.gov.eg/images/News/F_138.pdf Accessed on 13 November 2019. 4. Ministerial Decree 425/2015 Registration of Human Pharmaceuticals http://www.eda.mohp.gov.eg/Files/766_425_2015.pdf 5. Human Drug Registration http://www.eda.mohp.gov.eg/Files/190_HumanRegWFlow.gif 6. Technical Committee Decisions for 2013. http://www.eda.mohp.gov.eg/Files/197_MinisterDec296.pdf AND http://www.eda.mohp.gov.eg/Files/154_Technical_Committee_Decisions_2013.pdf

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.