FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Tunisia	**Agency Name:** DPM Tunisie	
Name of FRP: Prioritization Request		
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?	Before the marketing authorisation submission
Does the agency provide assistance/advice to the sponsor?	Yes- for selected submissions
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	- Products requiring call for tender - New product of major public health benefit / orphan medicinal product - First generic of a reference product - Transfer to local manufacturing - Launching of a new local manufacturer (during its first year) - Justified major variations (Send the application directly to the LNCM) *The number of the prioritized files cannot exceed 4 molecules (4 INNs) per company and per year. It is applicable for any object of prioritization except for the launch of a new local manufacturer or the extension of a new unit of a manufacturer already in place where the request of prioritization may concern maximum 8 molecules. These 8 molecules must be submitted within the first year from the date of the submission of the first marketing authorization application.
Must the product address an unmet medical need or serious condition?	Negotiable
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	**Is this an abridged* review**	**Is this a full* review of all parts of**

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recognition pathway)?*	**(selected dossier portions)? (a reliance pathway)?***	**the dossier?**
☐	☐	☒

If this is a reliance or recognition pathway, what are the accepted reference agencies?	Click here to enter text.
How many reference agency decisions are required?	Click here to enter text.
Does this FRP require submission of Assessment Reports from prior decisions?	Choose an item.
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?	Click here to enter text.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	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 applicant has to submit the list of all the countries where the product is submitted, registered and marketed.
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?	- For any application for registration (new application, renewal, variation, transfer), the applicant has to book an appointment at the DPM via the website. - The marketing Authorization is issued by the CTSP for a period of 5 years. The Marketing Authorization applicant has to inform the Ministry of Health of the effective date of the marketing (date of first customer delivery) of the medicinal product by sending a notification letter to the DPM and by providing a mock-up. - The written requests of prioritization for the Marketing Authorization file shall be submitted to the DPM. They will be assessed jointly with the LNCM and with the Central Pharmacy of Tunisia, if required. An answer is sent to the applicant. The

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	requests of prioritization are applicable only for the eligible dossiers.
Date of this update	23 MARCH 2020
References	1. Medicinal Products Registration Guide in Tunisia. http://www.dpm.tn/images/pdf/guide_dpm_en.pdf Accessed on 23 March 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.