FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Pakistan	**Agency Name:** Drug Regulatory Authority of Pakistan	
Name of FRP: Conditional Marketing Authorization		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 11/15/2019		
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 any product type
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	No restrictions stated. The product has to meet the eligibility criteria for priority review of submission pathways.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	
Total target (agency) time for assessment (calendar days)	150 working days. The timeframe is calculated after a priority determination process, from acceptance of application dossier for evaluation through to the decision of the Registration Board.
Total target (company) time for responses to agency questions (If stated)	14 working days for the applicant to submit responses.

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?	- USFDA, Health Canada, EMA, TGA Australia and PMDA Japan, United Kingdom, Germany, France, Switzerland, Netherlands, Austria, Denmark, Sweden and Norway, or at least three (3) European Union countries will be taken as reference for consideration of Registration Board.
How many reference agency decisions are required?	Click here to enter text.
Does this FRP require	Not applicable

FRPath.org Country and FRP Information Input Form	
submission of Assessment Reports from prior decisions?	
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Negotiable
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	For products intended for use in emergency situations, less comprehensive pharmaceutical and non-clinical data may also be accepted in special situations of public health urgency e.g. legalized copy of administrative documents (e.g. CPP, etc.) may be accepted later.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, this process is not through an RRI
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Yes, the drug product needs to have been marketed in another country, preferably in a reference agency country. Drug products/formula which are not yet registered can only be applied for conditional marketing authorization while fulfilling the following criteria: (1) Drug product is aimed at treating, preventing or diagnosing seriously debilitating or life threatening diseases and not registered previously (2) Drug product required in public health emergency and not registered previously.
How are queries to the companies sent?	As they arise
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 approval or designation valid?	Choose an item.
Any other details you wish to provide?	- Request FRP prior to submission of application dossier. Address a "Letter of Intent" to Secretary, Registration Board in order to determine the eligibility of application for relevant expedited pathway. - Applicants for conditional MA are advised to engage in early dialogue with DRAP to discuss their product development plan well in advance of the submission of a registration/MA application. - The applicant will be required to complete specific obligations (e.g. ongoing or new studies, and in some cases additional activities) with a view to providing comprehensive data confirming that the benefit-risk balance is positive. - If a conditional MA is granted, the specific obligations and

	deadlines for their completion will be specified in the MA. DRAP may also make these conditions publicly available for information of healthcare professionals.
Date of this update	18 December 2019
References	1. Fee Submission Procedure. http://www.dra.gov.pk/Home/Download?ImageName=Fee%20Submission%20Procedure.pdf Accessed on 18 December 2019 2. Procedure for Registration of Drugs. http://www.dra.gov.pk/Home/Download?ImageName=Procedure%20of%20Registration.pdf Accessed on 18 December 2019 3. Policy Guidelines regarding Reference Regulatory Authorities for Registration of Drugs. http://www.dra.gov.pk/Home/Download?ImageName=Policy%20Guidelines%20Regarding%20Reference%20Regulatory%20Authorities%20for%20Registration%20of%20Drugs%20Dt_Up_05-01-2017.pdf Accessed on 18 December 2019 4. Draft Guideline for Priority Review and Accelerated Approval of Registration / Market Authorization. http://www.dra.gov.pk/Home/Download?ImageName=MA%2001.12%20DRAFT%20Guideline%20on%20Non%20Rutine%20MA.pdf Accessed on 18 December 2019

*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.

©2019 FRPath.org and the Erudee Foundation.