FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: World Health Organization	**Agency Name:** World Health Organization	
Name of FRP: WHO Collaborative Registration Process: Accelerated Registration of Prequalified FPPs		
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 any product type
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	The procedure can be used to support applications for national registration of any Finished Pharmaceutical Product (FPP) that has been assessed for WHO prequalification and prequalified.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	WHO does not charge for collaborative registration. WHO Prequalification Team: medicines (PQTm) support for collaborative registration is free of charge for all applicants and NMRAs. Within countries, NMRAs' usual registration fees will normally apply to products registered under the collaborative procedure, although some NMRAs may waive these and others may apply additional fees for an accelerated process. Ultimately, national rules for submission of applications and regulatory fees will apply.
Total target (agency) time for assessment (calendar days)	If the NMRA of the country in which registration of the prequalified FPP is sought agrees to apply the procedure to the product concerned, it commits to reaching its decision within 90 days of receiving access to the assessment and inspection information, as to whether it will register the FPP, and to communicate its decision to WHO and the applicant within a further 30 days. Regulatory time starts after a valid application for the registration according to the procedure has been received and access to the confidential information has been granted (whichever is the later) and continues until the date of decision on registration. The regulatory time does not include the time

	granted to the applicant to complete missing parts of documentation, provide additional data or respond on queries raised by NMRAs. It may not be possible for the NMRA to issue its decision regarding registration within 90 days. If this is the case, the NMRA must communicate to PQTm its justification for its delayed decision. If the NMRA fails to do so, PQTm will follow up with the NMRA, to investigate the situation and to agree on remedial actions.
Total target (company) time for responses to agency questions (If stated)	Variable.

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?	The WHO PQP is the Reference Agency as the NMRAs rely on prequalification reports (dossier evaluation, inspection reports and test results) from WHO PQTm.
How many reference agency decisions are required?	1 Reference Agency's decision: WHO's PQTm.
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?	Participating NMRAs largely accept submissions already approved by WHO, that is, in the same CTD format as requested by WHO.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	Armenia Azerbaijan Belarus Bhutan Botswana Burkina Faso Burundi Cameroon Caribbean Community (CARICOM) Comores Côte d'Ivoire Democratic Republic of the Congo Eritrea Ethiopia

FRPath.org Country and FRP Information Input Form	
	Georgia Ghana Kazakhstan Kenya Kyrgyzstan Lao People's Democratic Republic Madagascar Malawi Mali Mozambique Namibia Nigeria Pakistan Philippines Senegal Sierra Leone South Africa Sri Lanka Sudan Tanzania Thailand Uganda Ukraine Uzbekistan Zambia Zanzibar Zimbabwe *CARICOM Member states: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Yes, the product has to have been marketed in another country.
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

FRPath.org Country and FRP Information Input Form	
For how long is the initial approval or designation valid?	See details Section below
Any other details you wish to provide?	- Additional NMRAs may be invited to participate by WHO if applicants express interest in registering their FPPs in countries the NMRAs of which are not yet participating in the procedure. - Applicants authorize WHO to share its assessment and inspection outcomes for the specific product(s), with the NMRA(s), of the country in which accelerated registration is sought. An applicant must submit the same dossier as the one approved by WHO for prequalification, although individual NMRAs may agree to submission of simplified dossiers and minor administrative differences are permitted, to reflect local labelling and other regulatory requirements. - The technical part of the dossier should be updated to reflect the data as approved by WHO during prequalification, any WHO-approved variations and requalification (where applicable). If, at the time of submission, any variations await WHO prequalification approval, the applicant should inform the NMRA accordingly. (National rules for submission of applications and regulatory fees will apply.) - It is the prerogative of any NMRA to decide whether or not the procedure can be applied to an application. Reasons for declining to apply the procedure include non-compliance of the FPP with specific national treatment recommendations, or that the FPP was submitted for registration some time ago, its evaluation is already well advanced, and the NMRA prefers to complete registration through the normal route. It is rare, however, for an NMRA to decline to apply the procedure. - Regarding validity of the initial designation or approval, national rules will apply. The validity is the prerogative of the respective NMRA.
Date of this update	1 JANUARY 2020
References	1. Accelerated Registration of Prequalified FPPs. https://extranet.who.int/prequal/content/collaborative-registration-faster-registration Accessed on 1 January 2020. 2. WHO Collaborative Procedure between WHO and National Medicines Regulatory Authorities in Assessment and Accelerated National Registration. https://extranet.who.int/prequal/key-resources/documents/faq-who-collaborative-procedure-

between-who-and-national-medicines Accessed on 1 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.