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 Prequalification of Medicines Programme (PQP) – Abridged Assessments		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 1/1/2001		
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?	When reqquested by the agency	
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	A finished pharmaceutical product (FPP) or an active pharmaceutical ingredient (API) included in an Invitation to Manufacturers to Submit an Expression of Interest for Product Evaluation (EOI). EOIs are issued by WHO, by therapeutic area, following consultation with WHO disease programmes and/or clinical specialists. Current EOIs relate to FPPs for treating HIV/AIDS, TB, malaria, neglected tropical diseases, diarrhoea, influenza or for reproductive health, and APIs used in the production of these FPPs. FPPs eligible for evaluation include both generic and innovator FPPs, and FPPs that contain just one active ingredient or that combine several. Applications for products that are not on the released EOI will not be accepted.	
Must the product address an unmet medical need or serious condition?	Yes	
If a fee is required, what is the amount (in US$ equivalent)	Single registration fee per product – Application fee: (1) FPP Abridged Assessment = $6,000 (2) API Abridged Assessment = $10,000 Annual fee per product – Annual fee: (1) FPP Abridged Assessment = $5,000 (2) API Abridged Assessment = $4,000	
Total target (agency) time for assessment (calendar days)	Variable - It is dependent on how much time the applicant needs to provide responses to comments and questions from WHO.	
Total target (company) time for responses to agency questions (If stated)	Variable - Following the assessment of each part of the dossier, a report will be provided to the applicant. Applicants are expected to submit responses to comments and any additional information that may be requested as soon as possible. Within one month, the	

	applicant should inform WHO of the estimated time frame required to address and respond to all queries. The procedure is usually suspended (i.e. WHO will not undertake any further action) until all required responses and any additional information is received by WHO.

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?	Stringent regulatory authority (SRA): a regulatory authority which is: (a) a member of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (as specified on www.ich.org); or (b) an ICH observer, being the European Free Trade Association (EFTA), as represented by Swissmedic and Health Canada (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time).
How many reference agency decisions are required?	Click here to enter text.
Does this FRP require submission of Assessment Reports from prior decisions?	Publically available reports OK
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?	No, the CPP must be provided, including answers to each question asked by the reference SRA. In addition, supply the latest SRA-approved product information (summary of product characteristics (SmPC), or an equivalent thereof, the patient information leaflet (PIL), or equivalent thereof, and the labelling). Provide a web link to the SRA-approved product information, preferably on the website of the SRA itself, if available. The quality information summary (QIS-SRA) template, available on the WHO Prequalification Programme website, should be fully completed and submitted with the application. The QIS-SRA provides a condensed summary of key information on the FPP as approved by reference SRA at the time of application for the prequalification of the FPP.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	This process is an open process. Any manufacturer of active pharmaceutical ingredients (APIs) and/or finished pharmaceutical products (FPPs) can express an interest in having its API or FPP products evaluated by WHO, provided those products are eligible for assessment.

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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 needs to have been marketed in another country. Submit a copy of the MA, or the equivalent thereof, issued by the reference SRA to demonstrate that the product is registered or licensed in accordance with the reference SRA requirements. If applicable, a copy of the latest renewal of the MA should be provided.
How are queries to the companies sent?	At specified times during the assessment
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- always
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?	- Exact date for when FRP was officially enacted not found. "The WHO Prequalification Team: medicines (PQTm) was first established — as the then Prequalification of Medicines Programme — in 2001, in response to the HIV/AIDS pandemic." - WHO recommends that applicants expressing interest in participation in the prequalification procedure inform the NMRAs in the country of manufacture of their intention and request them to collaborate with WHO in the quality assessment process. It is recommended that applicants provide the NMRAs with the necessary authorization to discuss the relevant product files with WHO representatives during dossier assessments and site inspections (subject to appropriate confidentiality provisions, if necessary). - In situations of high public health concern as determined by WHO, the Organization may also directly invite relevant parties to submit specified product dossiers for evaluation by WHO under this procedure without publication of an invitation for Expression of Interest (EOI) - If considered necessary or desirable by either party, and before the actual evaluation process starts, a discussion may be held as early as possible with a predefined agenda to address questions sent in advance to WHO by the manufacturer. - If available, a public assessment report, such as the Scientific Discussion of the European Public Assessment Report (EPAR), issued by the reference SRA. Assessment report(s) issued by the reference SRA that are not publicly available may be requested. - PQ Designation is valid for five (5) years.

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Date of this update	1 JANUARY 2020
References	1. Fee Schedule. http://who.int/medicines/news/finance-arrangements-prequal-med/en/ Accessed on 18 December 2019 2. WHO Prequalification Fees. http://who.int/medicines/news/finance-arrangements-prequal-med/en/ Accessed on 18 December 2019 3. Overview: History & Mission. https://extranet.who.int/prequal/content/overview-history-mission Accessed on 18 December 2019. 4. Technical Report Series (TRS) documents approved by the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) Accessed on 19 December 2019 5. guidance documents drafted by the WHO Prequalification Team Accessed on 19 December 2019 6. Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities (2014) Accessed on 19 December 2019 7. Procedure for Prequalification of Pharmaceutical Products (2011) http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf Accessed on 19 December 2019 8. Guidelines on APIMF Submission Procedure http://www.who.int/entity/medicines/areas/quality_safety/quality_assurance/GuidelinesActivePharmaceuticalIngredientTRS948Annex4.pdf?ua=1 Accessed on 29 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.