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 FPPs Approved by SRAs		
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	Participation is open to any interested NMRA or pharmaceutical company, and the procedure is designed to be applicable to any SRA-approved Finished Pharmaceutical Product (FPP) (innovator or generic) that is relevant to public health needs.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	This procedure does not interfere with national regulatory decision-making processes, or with national legislation, or with levying of regulatory fees. 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)	Participating NMRAs will use the data submitted to support their decision-making regarding registration. If the NMRA of the country in which the registration of the SRA-approved 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 90 days
Total target (company) time for	Variable.

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responses to agency questions (If stated)		
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?	1 Reference Agency's decision: the respective SRA.	
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?	No alternate forms of reference documentation; a CPP is required. The product dossier should be organized in the common technical document format (CTD) that was approved by the SRA and adapted for the purpose of the procedure. In the case of innovator medicines, applicants will be advised to also provide a "bridging report" that contains additional discussion of data relevant to the countries to which the application is being submitted, if the SRA assessment report does not cover these elements sufficiently. The applicant — with the agreement of the relevant SRA — will share the full assessment and inspection reports for the FPP with the participating NMRAs, as well as additional data documenting potential deviations from the FPP approved by the SRA.	
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	Botswana Burkina Faso Burundi Cameroon Caribbean Community (CARICOM)	

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	Côte d'Ivoire Democratic Republic of the Congo Ethiopia Georgia Ghana Kenya Malawi Mali Mozambique Namibia Nigeria Senegal Sierra Leone Tanzania Uganda Zambia 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	
For how long is the initial approval or designation valid?	See details Section below
Any other details you wish to provide?	- This procedure aims to facilitate and accelerate national regulatory approvals by providing access to data that documents the relevant SRA decisions, and evidence that either the same FPP, as approved by the SRA, or an FPP whose differences from the SRA-approved product are well-defined and understood, is the FPP that is now being submitted for registration. As with the procedure for prequalified products, this procedure incorporates a mechanism

	for confidential sharing of the relevant information. - The role of the SRA will be limited to data authentication, and, when specifically agreed with individual SRAs, provision of additional explanation of their decisions, should either or both be requested by the NMRAs. - It is the NMRAs' responsibility to reach agreement with applicants regarding specific risk-management plans and pharmacovigilance follow-up. - 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. - Regarding validity of the initial designation or approval, national rules will apply. The validity is the prerogative of the respective NMRA. - How queries are sent to the company and post authorization commitments depend on the country whose NMRA is evaluating an applicant's request for product registration.
Date of this update	1 JANUARY 2020
References	1. Accelerated Registration of FPPs Approved by SRAs. https://extranet.who.int/prequal/content/faster-registration-fpps-approved-sras Accessed on 1 January 2020. 2. Annex 11: Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities. https://extranet.who.int/prequal/sites/default/files/documents/TRS_1010-2018_Annex11.pdf 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.