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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Uganda	**Agency Name:** Uganda National Drug Authority (NDA)	
Name of FRP: NDA Abridged Evaluation Process		
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?	At the time of submitting an application	
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	All products	
Must the product address an unmet medical need or serious condition?	No	
If a fee is required, what is the amount (in US$ equivalent)	- Registration of imported human and veterinary drugs and preparations = USD1250 - Registration of locally manufactured drugs by a large scale manufacturer = USD200	
Total target (agency) time for assessment (calendar days)	- Regulatory decision on products already authorized for marketing by SRA and those approved under Article 58 of EU Regulations = 120 days - Regulatory decision on MA for WHO Prequalified products = 90 days	
Total target (company) time for responses to agency questions (If stated)	Not 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?	- A member of the International Conference on Harmonisation (ICH) - 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 - A regulatory authority associated with an ICH member through a legally-binding, mutual	

FRPath.org Country and FRP Information Input Form	
	recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time) - Article 58 of EU Regulations - EAC-NMRA in which a similar application has been submitted
How many reference agency decisions are required?	1+
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?	Submit CPP in format recommended by WHO together with a valid MA for pharmaceutical production. If available, evidence for PQ of Finished Pharmaceutical Product (FPP) by WHO should be submitted. A copy of the current WHO-type CPP issued and fully completed, including answers to each question.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	Process is not part of RRI.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Yes, marketing in another country is required. Specific amount of time not stated.
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?	- Complete application (dossier) in CTD format, as per National Drug Authority Guidelines on Submission of Documentation for Marketing Authorization of a Pharmaceutical Product for Human Use, Doc. No.: DAR/GDL/004. - Evaluation reports from EAC-NMRA in which a similar application has been submitted. - At least 1 independent evaluation report from an SRA, where the product is already approved at the time of application should be provided.
Date of this update	13 November 2019

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References	- National Drug Authority Policy Act https://www.nda.or.ug/?ddownload=2214 - Drug Registration Regulation https://www.nda.or.ug/?ddownload=2215 - Drug Fees Regulation https://www.nda.or.ug/?ddownload=2220 - Guidelines Marketing Authorisation of SRO Approved Medicinal Products https://www.nda.or.ug/?ddownload=1575 - Guidelines on Submission of documentation for marketing authorization of a pharmaceutical product for human use https://www.nda.or.ug/?ddownload=1622

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.