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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: West African Health Organization (WAHO)	**Agency Name:** WAHO	
Name of FRP: WA-MRH Joint Assessment Procedure.		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 7/20/2017		
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?	Choose an item.
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 scope of medicinal products covered in the joint assessment procedure includes the following:- a) WAHO's assessment of the priority health needs in the region; b) WHO's evidenced-based treatment guidelines (WHO Essential Medicine List); c) Programme Medicines: (HIV/AIDS, Malaria, Tuberculosis, Reproductive Health, Neglected Tropical Diseases, Vaccines); d) Medicines used in Public Health Emergencies; e) Products registered by Stringent Regulatory Authorities, prequalified by WHO, registered under Swissmedic MAGHP Procedure or EMA Article 58 (Positive Scientific opinion); f) Life Saving Commodities (LSC) by the UN Commission on Life Serving Medicines for Women and Children. NB: Invitation of Expression of Interest (EOI): At least twice a year and/or as needed, EWG on MPED under WA-MRH will review the scope and list of products invited under expression of interest. The updated invitation of expression of interest will be published on the WA-MRH Web-portal of WAHO websites. WA-MRH secretariat launches EOI for eligible medical products for a period of 1 month. Product Dossiers are submitted to the Lead Coordinating NMRA.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	- Payment is made to the Lead Coordinating NMRA (country specific) and the WA-MRH Secretariat. - Fees to be paid by the applicants to the WA-MRH Secretariat will continue as by regional registration

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	fees regulations.
Total target (agency) time for assessment (calendar days)	- This is a procedure for joint assessment by the Expert Working Group on Medical Products Dossier Assessment of the selected medicinal products, inspection of their respective manufacturing site(s) followed by Steering Committee approval of jointly accepted medicinal products. - If the assessment of medicinal products dossier is successfully completed and jointly accepted, the ECOWAS Member Sates NMRAs will grant marketing authorization within a **maximum of three (3) months** from the date of joint acceptance. - The Marketing Authorization Holder (MAH) can begin to make the medicine available to patients and healthcare professionals in ECOWAS Member States where marketing authorization has been granted.
Total target (company) time for responses to agency questions (If stated)	If any additional information is required, applicants will be required to provide such additional information to the WA-MRH Secretariat within **60 days**, and any extension beyond the specified period should be justified. If no written responses are received within 60 days from the date indicated on the letter, it will be deemed that the applicants have withdrawn the application.

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?	Click here to enter text.
How many reference agency decisions are required?	Click here to enter text.
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?	Click here to enter text.
If this process is through a Regional	The 15 members of the Economic Community of West

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Regulatory Initiative, which countries participate in this process?	African States (ECOWAS): 1. Benin, 2. Burkina Faso, 3. Cabo Verde, 4. Cote d'Ivoire, 5. The Gambia, 6. Ghana, 7. Guinea, 8. Guinea-Bissau, 9. Liberia, 10. Mali, 11. Niger, 12. Nigeria, 13. Senegal, 14. Sierra Leone, and 15. Togo.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Click here to enter text.
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
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- Currently, West Africa has no Regional Medicines Regulatory Agency, which has legal mandate for marketing authorization of medicinal products. In view of this, and within the framework of the West African Medicines Regulatory Harmonization (WA-MRH) Initiative, selected medicines in the regional basket will be authorized through the national authorization procedure, after the joint assessment procedure. - WA-MRH Project Development Objective (PDO): To Improve the availability of quality, safe and effective medicines and vaccines in the ECOWAS region. - PDO Results Indicators: (1) IR1: At least 7 NMRAs participating in a joint assessment of submitted application(s) for registration of medicines/vaccines and taking the outcome as a basis for their regulatory decision; (2) IR2: 4 or

	more NMRAs in the ECOWAS region have applied for International Standards Organization (ISO 9001-2015) certification on quality management system. - Components: (1) C1 - Regional Coordination and Capacity Building for Medicines and Vaccines Registration Harmonization; (2) C2 - Institutional Development and Strengthening of National Medicines Regulatory Authorities. - Technical support and expertise from WHO, Stringent Regulatory Authorities, any other technical experts in the area, may be sought in the process of dossier assessment. - National approval: After the applicant has submitted the file in the country, the final report is presented for consideration by the internal committee or the National Commission for a final decision. The National Commission shall meet within a maximum period of 30 days after the applicant has submitted the file in the country. A copy of the decision is sent to the MRH Secretariat for information. The market authorization (MA) notification must be made within 30 days of notification of the final decision. TOTAL DAYS = 171 Calendar days (Worst case: 261 days).
Date of this update	20 February 2020
References	1. West Africa MRH Project Summary. https://www.wahooas.org/web-ooas-prod/en/projets/wa-mrh-west-africa-medicines-regulatory-harmonization-project Accessed on 20 February 2020. 2. WEST AFRICAN HEALTH ORGANIZATION (WAHO). REGIONAL JOINT ASSESSMENT PROCEDURE FOR MEDICINE REGISTRATION AND MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS. https://www.wahooas.org/web-ooas/sites/default/files/publications/1993/wa-mrh-regional-joint-medicines-assessment-procedure.pdf Accessed on 20 February 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.