AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

EVALUATION OF MEDICINAL PRODUCTS TECHNICAL COMMITTEE (EMP-TC)

Pilot of the Continental Listing of Medicinal Products

FACT SHEET

BACKGROUND

In accordance with the African Union (AU) Executive Council Decision, {EX.CL/Dec.857 (XXVI))} of January 2015, the African Medicines Regulatory Harmonisation (AMRH) initiative is a foundation for the African Medicines Agency (AMA). The pilot of the evaluation of medicinal products continental procedure is launched in support of the operationalization of AMA.

PURPOSE

The pilot is meant to pressure test the continental procedures and processes on evaluation of medicinal products developed and endorsed by the AMRH Steering Committee and the assembly of the 9th African Medicines Regulators Conference (AMRC) in support of AMA operationalisation.

Specifically, the pilot will:

a) Validate the proposed continental process and procedures by the Evaluation of Medicinal Products Technical Committee (EMP TC) and the Good Manufacturing Practice Technical Committee (GMP TC), including work-sharing and reliance models.
b) Inform the review and help to propose operational modalities for evaluation and approval of priority medicinal products through AMA.
c) Assist in identifying and proposing best operational models of the continental GMP inspection activities.
d) Assist in identification of best and practical working relationship between AMRH or AMA with the Regional Economic Committees (RECs) and National Regulatory Agencies (NRAs) and other international organisations such as the World Health Organisation (WHO), European Medicines Agency (EMA), Pharmaceutical Inspection Co-operation Scheme (PICS), etc.
e) Help to identify and address gaps in the proposed continental procedures and pathways.
f) Identify and propose any additional processes or procedures required as appropriate for the success of the continental pathways to strengthen the existing regulatory ecosystem on the continent.

CONTACT US

For all technical related matters contact: **amrh@nepad.org and copy to alexj@nepad.org**

For general enquiries and submissions communication: **AUDAPilot@sahpra.org.za**

Link to the Call for Industry Applications: Click here

TIMELINES

Activity	Timelines
Window open for industry to submit Expression of Interests (EOIs)	3rd November 2023
Window closed for industry to submit EOIs	28th February, 2024
Window opened for submission of dossiers	1st March 2024
Window closed for submission of product dossiers	30th April, 2024
Continental dossier reviews and inspections	Mid-March 2024
2nd Wider Stakeholders Engagement Meeting	9th February, 2024

GUIDELINES

Guidelines and links to a resource page to the continental pilot can be found on the AMRH website here:
- https://amrh.nepad.org/amrh-resources.
- https://amrh.nepad.org/publication/compendium-of-continental-guidelines-pilot-of-listing-of-human-medicinal-products.

FAQ

For access to the continental pilot frequently asked questions, please visit the published FAQs on the resource page (https://amrh.nepad.org/amrh-resources). [VG1] These FAQs will be updated as needed.