AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

Request for expression of interest for selection of medicinal products assessors and GMP Inspectors to support evaluation of medicinal products

African Medicines Regulatory Harmonisation (AMRH)

Evaluation of Medicinal Products Technical Committee

AMRH
African Medicines Regulatory Harmonisation Programme

Under the African Medicines Regulatory Harmonization (AMRH) Initiative, several Technical Committees (TCs) have been put in place to spearhead regulatory systems strengthening and harmonization in Africa working with Regional Economic Communities (RECs) medicines harmonization initiatives and National Regulatory Authorities (NRAs). These continental technical committees are working to support the AU in the operationalization of the African Medicines Agency (AMA) and among other, the TCs shall be responsible for conducting scientific assessments and to providing scientific opinions on the safety, efficacy, and quality of priority medical products.

Specifically, the Evaluation of Medicinal Products Technical Committee (EMP-TC) established by the AMRH Steering Committee plays a vital role in the scientific evaluation of human medicinal products at continental level and in harmonizing assessment, registration and marketing authorization activities at REC and NRA levels.

Among its specific objectives, this committee is tasked to develop continental medicinal product evaluation processes to support registration by countries and devise a mechanism for submission of applications for continental assessment for priority products. It is also expected to organize the assessment of applications for the list of priority medicinal products assessed at continental level and provide final scientific recommendations on medicinal products (positive or negative), based on assessment reports, and share them with African NRAs to support registration and marketing authorizations.

A Technical Committee for Good Manufacturing Practices (GMP-TC) was constituted to provide technical support to AU Member States to build their GMP inspectorate capabilities, provide technical advice on the development and implementation of sustainable GMP Standards. This is done in collaboration with NRAs, RECs, pharmaceutical industry, and partners in support of the AU Pharmaceutical Manufacturing Plan for Africa (PMPA) and the Partnership for African Vaccines Manufacturing (PAVM) initiative. The GMP-TC should also facilitate GMP inspections of manufacturing sites for priority products and support the EMP-TC in its mandate.
The EMP TC has developed and endorsed a continental procedure for evaluation of medicinal products and guidance for priority products eligibility criteria which have also been approved by the AMRH Steering Committee and adopted by the Assembly of the 9th African Medicines Regulators Conference. The EMP TC procedure describes the process proposed to undertake

a comprehensive evaluation of the quality, safety, and efficacy of priority medicinal products, based on information submitted (medicinal products dossiers and site master files) by the applicants of such products (manufacturers or suppliers) and on an assessment of the GMP/GCP/GLP compliance through inspection of the corresponding manufacturing facilities and clinical sites. This will be done through a standardized procedure based on quality standards applicable for continental evaluation. These standards will be mainly based on WHO standards, and if not existing, ICH standards or any other relevant standards until customized African standards are developed and adopted.

The continental procedure proposed by the EMP-TC will be piloted in collaboration with the Good Manufacturing Practices (GMP) TC using medicinal products dossier assessors and GMP inspectors from National Regulatory Authorities (NRAs) already active in Medicine Regulatory Harmonization projects under Regional Economic Communities (RECs) and other experts working in NRAs where MRH projects are not active. Priority products targeted under this pilot project will be New Chemical or New Biological Entities, complex generic products (i.e., products that have complex active ingredients, formulations, dosage forms, or routes of administration, or medicine-device combination products and liposomal forms) and vaccines and other biological products such as other Biotherapeutic and Similar Biotherapeutic Products (Biosimilar) including gene therapies and advanced gene therapies.

In this respect, the AMRH Secretariat invites Expression of Interests (EoIs) from qualified dossier assessors and GMP inspectors to be engaged in evaluation of medicinal products applications and sites inspections respectively that will be submitted by applicants as part of the continental pilot project.

The scope of assignment for assessors shall be the evaluation of medicinal product dossiers (chemical and biological) in a Common Technical Document (CTD) format.

- Administrative and Product Information including product labelling.
- Quality part (Active ingredients and Finished Products)
- Safety part (non-clinical data)
- Efficacy part (clinical studies or bioequivalence data)

The inspectors will be responsible to assess the manufacturing sites/clinical sites compliance to Good Manufacturing Practices and/or Good Clinical Practices respectively based on the information received as part of the CTD (Site Master File, GMP certificates, etc..). Inspectors are also expected to be involved in conducting on-site inspections as deemed appropriate by the GMP TC.

Assessors and inspectors selected through this process will work as independent experts. However, when selected, they will need to provide to the AMRH Secretariat a form signed by their head of NRAs endorsing their credentials and allowing them to contribute to this continental process before their candidature could be confirmed by the AMRH. The assessors and inspectors will receive an allowance or honoraria for the work performed for the AMRH Secretariat and will be expected to participate in assessments sessions convened by the AMRH from time to time as appropriate.

The desired qualification and experience for assessors are as follows:

Qualification:

- Preferably pharmacists or any other related qualification on human medicines (with know-how of drug discovery and development, pre-clinical and clinical development of medicinal products, chemistry, pharmaceutical manufacturing, legal aspects, information technology, analytical approaches, pharmacology and toxicology, molecular biology, biotechnology, and chemistry)
- A higher academic qualification such as master's degree in pharmaceutical sciences or biological sciences, regulation and regulatory affairs or related fields would be an added advantage.

Experience:

- A minimum of 5 years progressive experience as an assessor in a National Regulatory Authority in Africa (advanced level)
- With at least 3 years' experience participating in joint assessments under RECs MRH projects.
- An experience as assessor for the WHO Prequalification program for medicines or vaccines will be an added advantage.

Assessors and inspectors selected will work under the confidentiality undertaking and conflict of interest policies from AUDA NEPAD.

Interested assessors and inspectors with the required competencies should submit the following:

- A cover letter expressing interest addressed to the AMRH EMP TC Secretariat stating their areas of expertise and progressive experience (e.g., for assessors Quality, Clinical etc.) and types of products (e.g., medicines, vaccines, biological and or biotechnological medicinal products)
- A detailed CV indicating relevant experiences as described above. The CV should not be more than 5 pages long and should be reflective of area applied for.
- Certified copies of degree certificate(s)

Interested and potential candidates who wish to be provided with clarifications on this matter may contact the AMRH Secretariat (amrh@nepad.org).

Expression of interest documents should be submitted electronically through the e-mail address: **amrh@nepad.org** with the subject titled **"EXPRESSION OF INTEREST (EoI) AS ASSESSOR OR GMP INSPECTOR (As appropriate) FOR EVALUATION OF MEDICINAL PRODUCTS FOR EMP-TC".**

The deadline for submission is **10 November 2023** at 14:00 South-African time. Late submission of Expression of Interest shall not be accepted for evaluation irrespective of circumstances.

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