AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

PILOT OF THE CONTINENTAL LISTING OF MEDICINAL PRODUCTS: CALL FOR INDUSTRY APPLICATIONS

African Medicines Regulatory Harmonisation (AMRH)

Evaluation of Medicinal Products Technical Committee

World Health Organization

SAHPRA
South African Health Products Regulatory Authority

1. Introduction

1.1. Summary

African Union Development Agency (AUDA NEPAD) through the African Medicines Regulatory Harmonisation (AMRH) initiative is announcing the launch of a phase 1 of the pilot of the continental procedure on evaluation of medicinal products through its Evaluation of Medicinal Products Technical Committee (EMP-TC) supported by the continental technical committee on Good Manufacturing Practices (GMP-TC).

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

1.2. Background

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). Recently these technical committees have been working to lay a foundation of continental regulatory processes and procedure in support of the operationalization of the African Medicines Agency (AMA) whose Treaty came into force in November 2021.

Specifically, the Evaluation of Medicinal Products Technical Committee (EMP-TC) was established by the AMRH Steering Committee to play a vital role in the scientific evaluation of human medicinal products at continental level and to coordinate and conduct the assessment of applications for the priority medicinal products as guided by its Guidance on Eligibility Criteria for Priority Medicinal Products and provide scientific recommendations to support product registration and marketing authorization at national levels.
The EMP TC's continental procedure for evaluation of medicinal products and guidance for priority products eligibility criteria were approved by the AMRH Steering Committee and adopted by the Assembly of the 9th African Medicines Regulators Conference in August 2023.

Therefore, other AMRH Technical Committees, such as the Good Manufacturing Practices Technical Committee (GMP-TC) will facilitate the work of the EMP TC through establishing compliance to GMP requirements. The African Medicines Quality Forum (AMQF) and the African Vaccines Regulatory Forum (AVAREF) where applicable will also be engaged to facilitate the work of the EMP TC in laboratory investigation and GCP inspections as appropriate.

1.3. What are the Objectives of the Pilot?

This pilot is meant to validate the continental evaluation of medicinal products procedures and processes developed, approved, and endorsed by the AMRH Continental Technical Committees, Steering Committee and the Assembly of the 9th African Medicines Regulators Conference (AMRC).

1.4. What are the Benefits of the Pilot?

The lessons which will be learnt from this pilot will inform improvements to the developed continental processes and procedures and expected to provide a foundation for the footing of a robust and well-founded AMA.

In addition, the pilot will facilitate national authorisation of the products recommended by the EMP-TC and strengthen a network of regulators at continental level who can share information and rely on each other's decisions and recommendation through work sharing.

1.5. How will the Process be like?

The EMP TC will undertake a comprehensive evaluation of the quality, safety, and efficacy of priority medicinal products, based on medicinal products dossiers submitted by the applicants and on an assessment of the GMP/GCP/GLP compliance through relevant continental technical committees under AMRH.
If evaluation demonstrates that a product and its corresponding manufacturing and clinical site(s) meet the continental standards acceptable by the Technical Committees (i.e., internationally acceptable standards), the medicinal product will be issued with an INDEPENDENT SCIENTIFIC OPINION or RECOMMENDATION which will then allow the product to be included in the continental list (listing) of medicinal products recommended by the EMP-TC (if positive).
The assessment as well as inspection reports will be shared with concerned National Regulatory Agencies (NRAs) in Africa to support and facilitate registration and marketing authorization of Africa's priority medicinal products.

The EMP TC may also publish negative opinion if deemed appropriate in the interest of public health.

2. Submission of EoI

2.1. Who can Apply?

Manufacturers or suppliers (Applicants) planning to file an application for a new product to multiple National Regulatory Agencies in Africa of priority medicinal products category 1 and or 2 eligible for continental evaluation route as per the Guidance on Eligibility Criteria for Priority Products.

• The submission should be intended to be submitted at the same time and should be provided to all targeted regulatory authorities.

Applicants intending to submit a proposal for the GMP inspection pilot ONLY maybe accepted and should confer with the facility and ensure that the facility will be inspection ready and can host a collaborative hybrid inspection. The facility should satisfy themselves that they have appropriate IT infrastructure, availability of necessary interpretation service and can co-ordinate with at least two inspectorates across different time-zones.

2.2. Which products are eligible for the call?

Priority Medicinal Products Category 1 and or 2 as per the Guidance on Eligibility Criteria for Priority Products.

Category 1 includes:

- 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.

Category 2 includes:
- Medicinal Products for addressing priority diseases identified in African populations, e.g., Noncommunicable Diseases (NCDs), Neglected Tropical Diseases (NTDs) and priority Communicable Diseases.
- Medicinal Products intended for use in rare or life-threatening, seriously debilitating, or chronic disease that affects very few people in Africa for which no satisfactory method of diagnosis, prevention or treatment has been authorized or, if such method exists, the medicinal product would be of significant benefit to those affected by the disease such as Orphan Medicines in other jurisdiction.
- Medicinal Products for Emergency Use.

2.3. What to submit for the EoI?

An Expression of Interest (EOI) letter for product evaluation at continental level to be submitted by the applicants (manufacturer or supplier duly authorized) along with the self-screening checklist on the eligibility of priority products (self-screening checklist can be accessed https://amrh.nepad.org/amrh-resources).

2.4. Where and when to submit the EoI?

Send the EOI to the following mailbox addresses:

AUDAPilot@sahpra.org.za
alexj@nepad.org
dube.mzimba@sahpra.org.za

The window for submissions of EOI is opened from the 1st of November 2023 and will be closed by 22nd December 2023.

3. Submission of Applications for Evaluation by the EMP TC

3.1. Where to submit the Application?

All applications and other supporting documents for the purpose of this pilot should be submitted to the South African Health Product Regulatory Authority (SAHPRA) which has been selected by the AUDA NEPAD to receive, process, and manage the application dossiers during the pilot phase.

3.2. What are the documents to be supplied and under which format for the application?

All Medicinal Product Dossiers should be submitted in electronic Common Technical Documentation (eCTD).

The electronic CTD should be prepared as per the SAHPRA' eCTD submission Guidelines (2.23_Submission in eCTD format_Jul19_v3). Link below:

https://www.sahpra.org.za/wp-content/uploads/2020/01/d85066dd2.24_Guidance_General_Module_1_May19_v6.pdf

The validation criteria for the submission can be accessed using the link provided below.

https://www.sahpra.org.za/wp-content/uploads/2022/12/SAHPGL-HPA-03_v4-Guideline-on-eCTD-Validation-Criteria.pdf

3.3. How to submit?

Medicinal Product Dossier should be submitted as per the current SAHPRA submission procedure and compiled in accordance with the EMP TC Guidelines on Submission of Application for Listing of Medicinal Products. The EMP TC specific guidelines for medicines, vaccines, biotherapeutic products and similar biotherapeutic products can be accessed https://amrh.nepad.org/amrh-resources.

For a more detailed submission guidance and application forms and letter template. Please refer to the EMP TC Procedural Aspect Guidelines During Pilot. The Guidelines can be accessed https://amrh.nepad.org/amrh-resources.

3.4. When to apply?

Following acceptance of the EoI, applicants can send applications beginning 1 January 2024. The EMP TC plans to conduct a rolling review of submitted applications, with the aim of starting the first evaluations and inspections in the mid-March 2024 timeframe. The submission window for Phase 1 will therefore be closed by 28 February 2024, 16:00hrs SAT.

Applicants intending to submit applicants for GMP inspections only not linking to medicinal product dossier should submit their applications before 31st November 2023 clearly indicating their requests in the EOI submitted.

3.5. What fee do I have to pay to participate in the pilot?

Please note that, No Fees will be charged to applicants fin this Phase 1 of the continental pilot by the AMRH EMP TC.

3.6. In which language should the EoI be submitted?

The EOI application and all supporting documents should be submitted in English.

4. Once the EMP TC recommendation has been adopted

4.1. Which NRA have agreed to accept EMPTC pilot recommendations?

The Pilot of the Continental Evaluation of Medicinal Products Procedure was approved by the AMRH Steering Committee and endorsed by the 9th Assembly of the African Medicines Regulators Conference (AMRC) in August 2023. These two structures have representatives of all African NRAs. The NRAs are currently engaged to formally recognize AMRH EMP TC as one of the facilitated registration pathways in Africa and to utilize recommendations as appropriate.

4.2. How will the EMP TC Recommendation translate into national authorizations?

The EMP TC is a continental Technical Committee whose members represent all African regions and therefore the assessment process by the EMP TC has the ownership of Africa's NRAs and therefore, these NRA will use EMP TC evaluations to make a final decision at national level to register the recommended or listed products.

entry level is expected to be specific for Module I.

4.3. What information will be exchanged between TCs and NRAs?

Dossier evaluation reports, GMP inspection reports and EMP TC sessions' reports on decision for listing medicinal products will be shared by the TCs with concerned or participating NRAs.

4.4. Will NRA submission requirements be aligned to the continental pilot requirements?

The EMP TC has adopted requirements on consultation with Africa's NRA and therefore these requirements are harmonized, however submission of country level is expected to be specific for Module I.

4.5. Which national requirements will be needed?

Applicants are encouraged to liaise with concerned NRAs for specific country NRAs.

4.6. Will there be additional fee for the granting of national authorisation?

YES, fees at country level should be paid as per the specific country rules and laws.

4.7. What will be the timelines for the adoption of the national authorisation?

Most countries in Africa, commits to 90 working days to process country level evaluation and decide on the product for products recommended through recognized regulatory and quality assurance mechanisms, however with the nature of the EMP TC where the process is fully inclusive and involves review some of the country-specific data (such as stability data etc.,), the adoption is expected to be within 60 days.

5. Supplementary Information

5.1. General principles for the Evaluation following submission of an EoI by applicants.

The assessment will be undertaken to assess whether the medicinal product being evaluated meets internationally acceptable requirements of safety, quality and efficacy and the site(s) is/are complying with Good Manufacturing Practices or Good Clinical Practices as applicable.

This procedure, established by the AMRH EMP TC, is based on the following principles:
a) Understanding of the production and quality control activities of the manufacturer
b) Assessment of medicinal product data (quality, efficacy, and safety data) received in a Common Technical Document (CTD) format.
c) Inspection of Finished Pharmaceutical Product (FPP)/Immunological Product (IP) and Active Pharmaceutical Ingredient (API)/ Immunogenic Substance (IS) manufacturing sites (GMP).
d) Inspection of clinical testing units or contract research organizations (CROs) with Good Clinical Practices (GCP) and Good Laboratory Practices (GLP).
e) Random sampling and testing of medicinal products supplied to countries.
f) Product lifecycle management with monitoring of changes in the product dossier and management of variations. ALTHOUGH during the phase 1 of the pilot, these will be handled at national level.

Once EMP-TC is satisfied that the procedure is complete for the relevant product, as manufactured at the specified manufacturing site(s), and that required standards are met, the product will be considered as recommended by the EMP-TC and will be included in the list of products recommended by the EMP-TC published on the AUDA NEPAD's AMRH website.
5.2. Terms and Conditions applicable to this Invitation

Applicants intending to submit EoIs to participate in this pilot, must meet the following criteria:
a) Provide a consent as part of the EoI letter to allow the AMRH TCs to share the assessment and inspection reports with NRAs in Africa
b) Submit a letter demonstrating how the product for which a product dossier is submitted meet criteria described in the Category 1 or 2 Priority Medicinal Products as stated in the section 2 of this invitation.
c) Provide a commitment letter of adhering to prescribed timelines for addressing queries and concerned country specific requirements.
d) To facilitate national level authorisation, Applicants should adhere to the reliance principles among African regulators which requires that the data for the same product, same facility(ies), and same change(s) be submitted in the same format [e.g., following harmonized standards specified in ICH M4Q, M8, etc.].

6. Contacts
6.1. AMRH Secretariat/EMP-TC Secretariat
For enquiries and all technical related matters contact: amrh@nepad.org and copy to alexj@nepad.org

6.2. SAHPRA for submission of product dossiers
For general enquiries and submissions communication: AUDAPilot@sahpra.org.za

Key Contacts: Project Manager – Dube Mzimba (dube.mzimba@sahpra.org.za)
Project Sponsor – Christelna Reynecke (christelna.reynecke@sahpra.org.za)

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