AFRICAN MEDICINES REGULATORY HARMONISATION (AMRH)

INVITATION OF EXPRESSION OF INTEREST TO MANUFACTURERS/DEVELOPERS OF MPOX DIAGNOTSIC TESTS TO A CONTINENTAL FACILIATED JOINT REVIEW AND EMERGENCY USE LISTING

1. INTRODUCTION

1.1. Invitation to Manufacturers, Developers or Duly Authorized Applicants

African Union Development Agency (AUDA NEPAD) through the African Medicines Regulatory Harmonisation (AMRH) initiative's African Medical Devices Forum invites manufacturers, developers or applicants of in vitro diagnostics for the detection and/or diagnosis of infection with the monkeypox (mpox) virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola Orthopoxvirus to submit their expression of intent for a continental facilitated Expedited Evaluation and Emergency Use Listing.

Manufacturers or developer are invited to a collaborative review process to be facilitated by the African Medical Devices Forum (AMDF). The AMDF-TC will facilitate a collaborative and expedited review process with experts from national regulatory authorities of countries currently affected by the Mpox outbreak.

1.2. Background

On Aug 13, 2024, the Africa Centres for Disease Control and Prevention (Africa CDC) declared mpox a public health emergency of continental security (PHECS) in Africa which was the followed by a declaration by the World Health Organization of Mpox as a Public Health Emergency of International Concern

The decision was driven by the worsening mpox situation on the continent: since 2022, 40 874 cases and 1512 deaths have been reported across 15 AU member states. In 2024 alone, 17 541 cases and 517 deaths have been reported from 13 AU member states. These figures represent a 160% and 19% increase in the number of cases and deaths, respectively, in 2024 compared with the same period in 2023. A 79% increase in the number of cases was observed in 2023 compared with 2022. The Democratic Republic of the Congo (DRC) accounts for 96% of all cases and 97% of all deaths reported in 2024.

1.3. The African Medical Devices Forum (AMDF)

The African Medicines Regulatory Harmonization (AMRH) Initiative, established in 2009 as an African Union (AU) Programme, aim to improve regulatory systems across the continent by working through regional economic communities (RECs). In 2012, the African Medical Devices Forum (AMDF), formerly the Pan Africa Harmonization Working Party (PAHWP), was created by medical device regulators in Africa to ensure the availability of high-quality, safe, and effective medical devices through harmonized regulations.

In June 2013, the AMDF was officially recognized as a Technical Committee under the AMRH Initiative, providing recommendations on medical device including in vitro diagnostics (IVDs) regulation harmonization to the AMRH Steering Committee (SC). This integration supports the broader harmonization efforts within the AU, aiming to provide technical and scientific guidance to all AU member states. With the establishment of the African Medicine Agency (AMA), a continental framework for the regulatory harmonization of medical products, the AMDF is expected to play a technical role in assessing priority medical devices, including in vitro diagnostics (IVDs), strengthening regulatory capacity, and fulfilling other objectives as outlined by the AMA.

1.4. How will the Emergency Evaluation and Listing Process be like?

The AMDF will use its platform and resources to bring together the 12 countries reported by the Africa CDC to have been affected and facilitate a collaborative rolling review of technical files for the candidate IVDs to establish their quality, safety and performance. The AMDF will collaborate with the Africa CDC Diagnostics Advisory Committee (DAC) network of laboratories to conduct laboratory performance evaluation of the IVDs before a listing decision is made.

Based on the AMDF Guidelines on Emergency Response and the WHO Guideline for Emergency Use Listing where evaluation demonstrates that a diagnostic tests meet the continental standards acceptable by the AMDF-TC under public health emergencies (i.e., internationally acceptable standards), the Tests will be issued with a POSITIVE RECOMMENDATION which will then allow the product to be included in the continental list (listing) of medical products recommended by the AMRH.

The assessment and any other scientific reports generated during this process will be shared with concerned 12 National Regulatory Agencies (NRAs) to support emergency marketing authorization at national level.

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

1.5. How is this process linked to Africa CDC Pooled Procurement

IVDs listed by the AMDF following this joint review will be published on the AUDA NEPAD website. The tests that are listed by the AMRH programme of AUDA NEPAD will be considered as continentally approved tests. Africa CDC will work with Ministries of Health to develop policies on the use of these tests, recommend them for use and procure through procurement mechanisms either within the African Union, Member States or in collaboration with other procurement agencies in the continent.

2. SUBMISSION OF EOI

2.1. Who can Apply?

Manufacturers, Developers or authorized suppliers (Applicants) capable of furnishing technical files to the AMDF.

2.2. What to submit for the EoI?

An Expression of Intent (EOI) letter for a Continental Facilitated Joint Evaluation to be submitted by the applicants (manufacturer or supplier duly authorized).

2.3. Where and when to submit the EoI?

Send the EOI to the following mailbox addresses: amrh@nepad.org cc alexj@nepad.org

The window for submissions of EOI is opened from the on 7th September 2024. The Window of submission of EOIs will be closed on 31st December 2024.

3. SUBMISSION OF TECHNICAL FILES (APPLICATION DOSSIER) FOR A COLLABORATIVE EVALUATION THROUGH AMDF-TC

3.1. Where to submit the Application?

After the EOI is accepted, all applications and other supporting documents for the purpose of this Emergency Use Listing will 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 on behalf of the AMRH in the interim period.

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

All Product Dossiers should be submitted in STED or ToC format.

3.3. Which Type of Products are Eligible.

Priority IVDs eligible for this call are the Mpox Molecular Diagnostic Tests (RT-PCR) listed by the Africa CDC' Diagnostics Advisory Committee. The list can be accessed here.

Using reliance practices to accelerate access to diagnostics, AMDF will rely on SRAs or WLAs to expedite the review process by engaging relevant Authorities from which the authorisation or listing was granted.

3.4. When to apply?

Applicants can send applications along with their EOIs or submit the EOI and later their application dossier (technical files). The AMDF is currently engaging countries to jointly plan and conduct an expedited review of submitted applications, with the aim of starting the first reviews as soon as the applications are submitted.

3.5. What fee do I have to pay to participate in the Continental Emergency Use Listing (CEUL)?

Please note that, NO FEES WILL BE PAID TO THE AMRH (AMDF) TO PARTICPATE IN THIS PROCEDURE. FEES SHOULD BE PAID AT COUNTRY LEVEL AS PER EACH COUNTRY'S FEES SCHEDULES AND STRUCTURES.

4. AMDF RECOMMENDATION AND LISTING DIAGNOSTICS TESTS

4.1. Criteria for Decision on an EUL

The following criteria for issuing an EUL will need to be met:

a) Based on the totality of scientific evidence available
b) The known and potential benefits outweigh the known and potential risks of the product when used to diagnose the disease (Mpox)
c) The product is manufactured in compliance with ISO13485 QMS standards.
d) The applicant undertakes to complete the development including monitoring and reporting of the product and apply for full authorization to the countries.

5. SUPPLEMENTARY INFORMATION

Applicants intending to submit EoIs to participate in this AMDF facilitated collaborative review, must meet the following criteria:

a) Provide a consent as part of the EoI letter to allow the AMDF to share process reports with NRAs in Africa
b) Submit a letter demonstrating how the diagnostic test for which a technical file is submitted meets Emergency Use Listing Criteria.
c) To facilitate national level authorisation, Applicants should commit to filing the same information (technical file) to the concerned national regulatory authority

6. CONTACTS

6.1. AMRH Secretariat

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

6.2. SAHPRA

For general enquiries and submissions communication: - Christelna Reynecke (christelna.reynecke@sahpra.org.za.