For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

Updates on the Emergency Use Continental Listing Procedure for IVDs by AMRH

AMRH Progamme officer,
Dr. Lerato Moeti

ROLE OF THE MDA-TC

General objective

The MDA-TC established by the AMRH Steering Committee plays a vital role in the scientific evaluation of medical devices and in-vitro-diagnostics at continental level.

The MDA -TC will also facilitate harmonization of requirements and standards for assessments, registration and marketing authorization activities at REC and NRA levels in Africa.

TECHNICAL CONTINENTAL WORK

- ✓Develop documents, technical requirements, and guidelines to support regulation of medical devices activities at Continental and Regional level
- ✓Select and endorse experts to support continental work
- ✓Lead the development of a continental regulatory procedure for listing/certification of priority medical devices
- ✓Adapt the Summary of Technical Documentation/ Table of Content (STED/ ToC) format
- ✓Convening of joint evaluation of priority medical devices including IVDs
- ✓Support the harmonization and alignment of guidelines and procedures to be used for joint assessments done at RECs level.
- ✓Supports and advocate for use of reliance models including WHO CRP

Linkage between MDA-TC, AMDF and NRA

Initiation	MDA-TC completes continental assessments and inspections and issues a recommendation for Listing of priority IVDs (with Positive Outcome)
Notification to the Forum (AMDF)	MDA-TC through Secretariat notifies the Forum and concerned countries electronically through RISP on the listed products and availability of reports followed by tabling before the forum all IVDs listed by the MDA-TC (physical/**virtual**) Product with –Ve opinion will also be tabled as appropriate
Verification and Endorsement by the Forum	Forum verifies the list of IVDs and endorses the recommendations for adoption by concerned countries through a a harmonised checklist for ensuring that all required information is provided by the MDA-TC to assist countries in making decisions ✓ Information for the checklist will include reports and availability of dossiers to concerned countries and if there is a need for any additional information or assistance/support from the MDA-TC, Forum or the Secretariat
Review and implementation of the Recommendation by the Concerned NRAs	Within 90 days NRAs will review and address any country specific requirements and make a final decision on the IVD (national MA)
Feedback	Concerned NRAs to provide feedback periodically on the implementation of National decision (status of implementation after every 30 days within the 90 days window

Emergency Use Listing (EUL) of Mpox

- Triggered by public health emergency declaration (e.g. Mpox)
- Rapid assessment based on dossier + DAC lab performance and where applicable QMS Audit (ISO13485 Based)
- Templates: EUL application form (EOI), checklist, Abridged assessment template (Mpox specific), QMS audit
- Decision timelines: Screening (1 day), Evaluation (15 - 45 days)
- Listed product supports country-level emergency authorization

AFRiSUMMIT

Issued a call for applications to Expedited Collaborative Review and Emergency Use Listing at Continental Level

1

The MDA-TC facilitated a Collaborative Review of Mpox 16 Affected Countries and work in Collaboration with Africa CDC DAC - Work sharing model

2

Publish outcome and public assessment reports

3

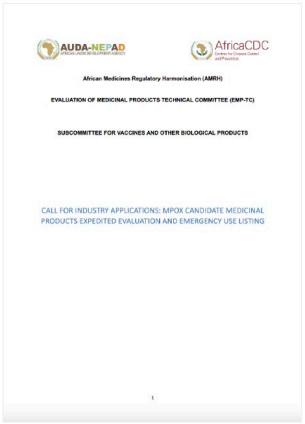
AMRH will share full reports with only concerned countries for their national decisions

4

Will implement reliance but ensure NRAs ownership of the processes (As Approriate)

5

8 EOIs received for the Diagnostic Tests – All PCR based


AUDA-NEPAD
AfricaCDC
African Medicines Regulatory Harmonisation (AMRH)
EVALUATION OF MEDICINAL PRODUCTS TECHNICAL COMMITTEE (EMP-TC)
SUBCOMMITTEE FOR VACCINES AND OTHER BIOLOGICAL PRODUCTS
CALL FOR INDUSTRY APPLICATIONS: MPOX CANDIDATE MEDICINAL PRODUCTS EXPEDITED EVALUATION AND EMERGENCY USE LISTING

PU

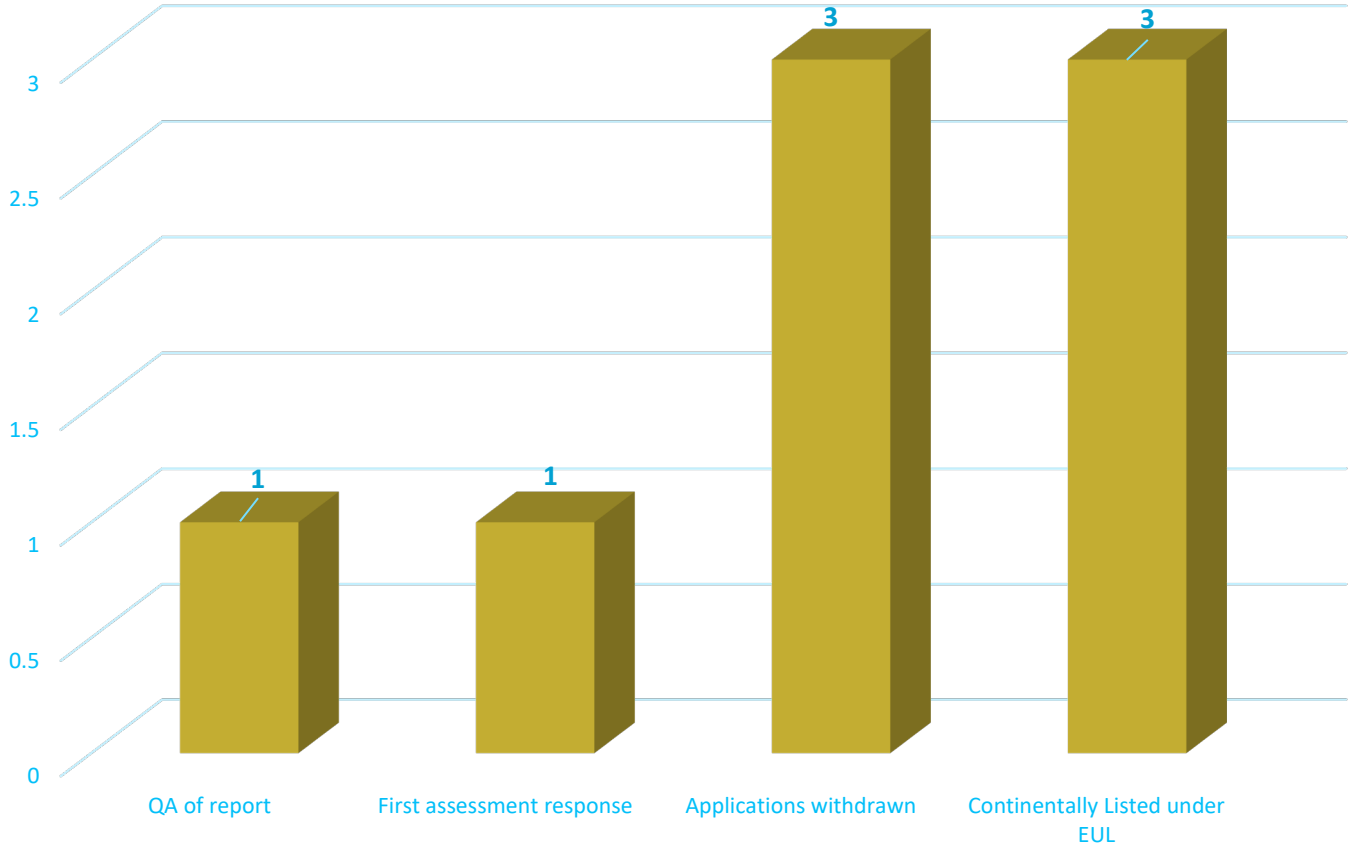
Call for Industry Applications: MPOX Candidate Medicinal Products Expedited Evaluation and Emergen Use Listing

Download

EUL status November 2025

- 3 Products withdrawn with 2 as Local Manufacturers – **Morrocco** and **Kenya**

- Kenya manufacturer put under Africa CDC local production support - now assisted in obtaining panels for Clinical Performance – This will need a redesigning of the kit and resubmission



Continental Templates and Guidelines

3 continental standard operating procedures

- Receiving, distribution and evaluation of MDs and IVDs
- Receiving, distribution and evaluation of query response of MDs and IVDs
- Emergency Use Listing SOP

Templates for Evaluation of IVDs New, Renewal and Variations and a Public Assessment Template

- Template for Assessment of New Applications for Registration of In-vitro Diagnostic Devices
- Template for Abridged Assessment of New Applications for Registration of In-vitro Diagnostic Devices and Medical Devices
- Template for Assessment of Query Response for Registration of In-vitro Diagnostic Devices and Medical Devices
- Template for the Public Assessment Report
- Template for the steering committee final report
- Template for Assessment of Variations/Alterations of In-vitro Diagnostic Devices and Medical Devices. Medical devices
- Query letter template

Developed Continental tools for responding to Mpox

Guidance for assessments based on the IMDRF ToC

Developed Guidelines for Industry submission

NATIONAL LEVEL STATUS OF 3 LISTED UNDER EUL

Product	Date of Continental Listing	Countries of interest	Status as of October 2025	Country Timeline (from Continental Listing Working Days (WD) or Calendar Days (CD)	Median Timelines (from continental listing) Working Days (WD) or Calendar Days (CD)
Cobas® MPXV (AMDF/EUL/002)	18 July 2025	1. Kenya 2. Ghana 3. South Africa	1. Kenya approved - 21 August 2025 2. Ghana approved - 16 September 2025 3. South Africa approved - 20 August 2025	1. Kenya – 34 CD or 24 WD 2. Ghana – 60 CD or 44 WD 3. South Africa – 33 CD or 23 WD	34 CD or 24 WD
RADIONE Mpox Kit (AMDF/EUL/006)	18 July 2025	1. Ghana	1. Ghana approved - 16 September 2025	1. Ghana – 60 CD or 44 WD	60 CD or 44 WD
RADIONE Mpox and skin rash panel kit	20 October 2025	1. -	1. -	1. -	-

Overall = 34 CD or 24 WD

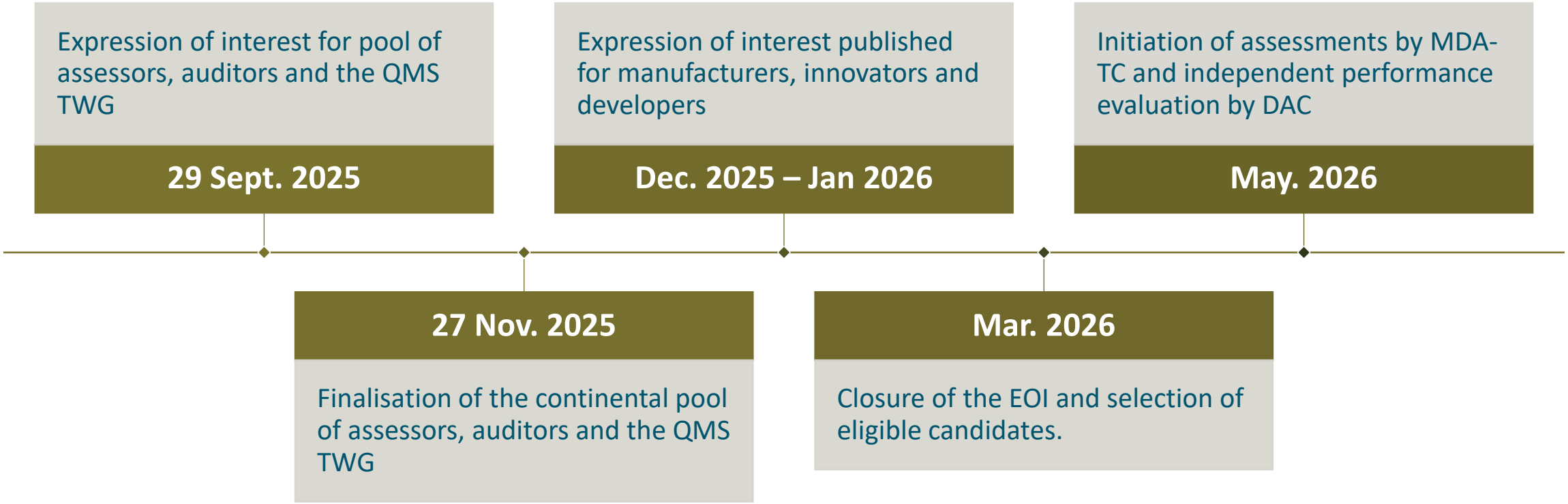
Lessons from the Mpox Pilot

- Guidelines, SOPs and Templates tested and refined through 3 collaborative sessions
- Some applicants requested extension from the assigned 10 working days
- Assessment Timelines achievable with dedicated expert pool
- Adoption of continental EUL is highly positive by NRAs

Next Steps


FINALIZE AND PUBLISH STANDARD AND EMERGENCY GUIDELINES
TRAIN ASSESSORS & AUDITORS AND ESTABLISH E-SUBMISSION PLATFORMS
PROMOTE ADOPTION AT NATIONAL LEVEL VIA AMDF FORUM
MONITOR POST-LISTING IMPLEMENTATION AND FEEDBACK FROM NRAS

NEXT STEPS & TIMELINES



Priority products for continental pilot

- CLASS C and CLASS D in -vitro diagnostics
- For the following epidemic-prone diseases: Dengue, Measles, Cholera, Mpox, Bacterial Meningitis
- Locally manufactured*

For A Healthier Africa

AFRiSUMMIT

2nd - 5th November 2025

Hilton Grand Nile Hotel, Cairo - Egypt

THANK YOU