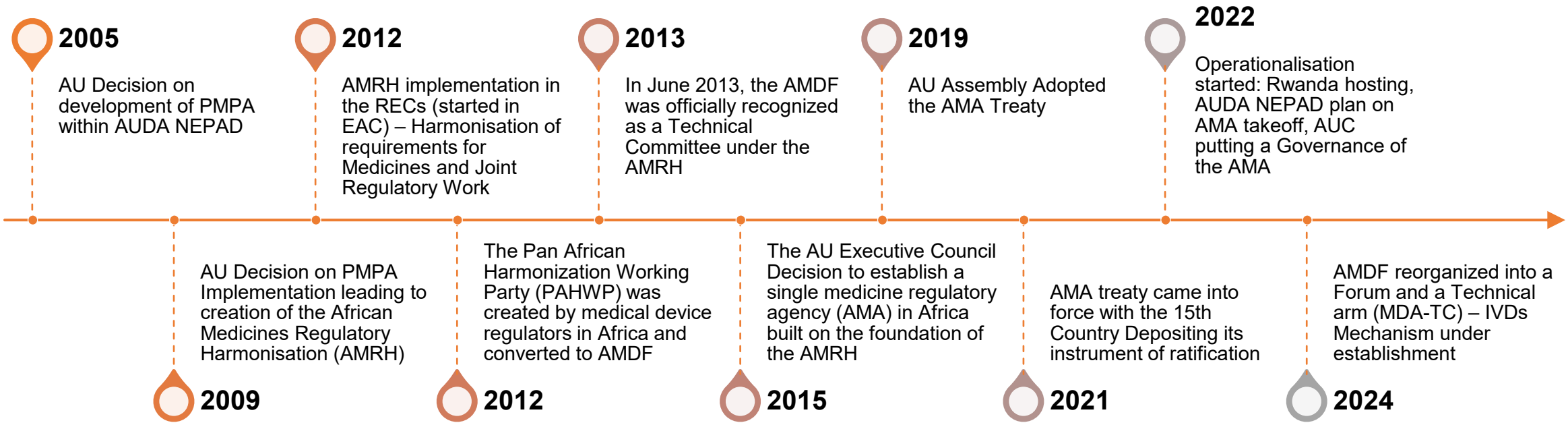
AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

The African Continental Listing Procedure of in-vitro diagnostics (IVDs) building on the emergency use listing *of Monkeypox IVDs*

Dr. Lerato Moeti, AMRH, AUDA-NEPAD

29th GHWP Annual Meeting and 29th GHWP TC Meeting, 1st - 4th Dec 2025
Bangkok, Thailand

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY



Progress made so far in joint continental regulatory

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

AMDF reformed to establish a technical arm (i.e. the MDA-TC) – Held its inaugural meeting 28-29 Oct 2024

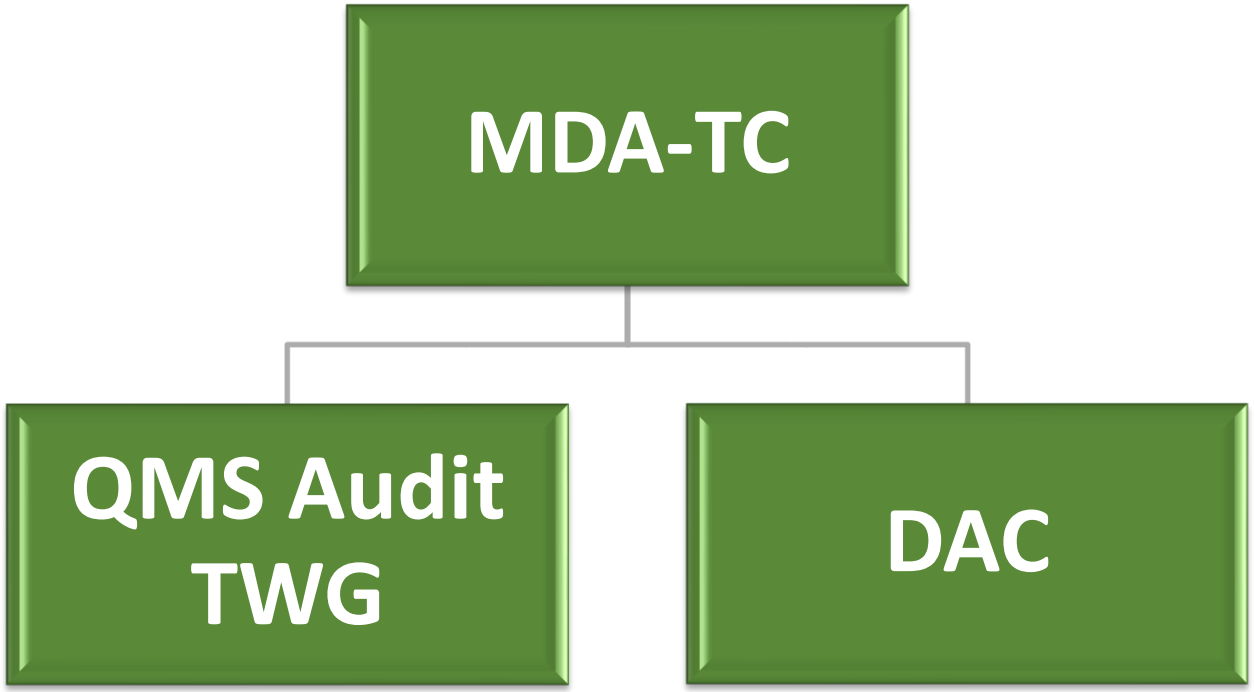
Developed Continental tools for responding to Mpox

- 3 continental standard operating procedures
- Templates for Evaluation of IVDs New, Renewal and Variations and a Public Assessment Template
- Guidance for assessments based on the IMDRF of the ToC
- Developed Guidelines for Industry submission
- Draft for QMS Audit Based on ISO

Reviewed the Overarching Continental Procedures after Mpox experience to be piloted or used as routing process under AMA next year (starting, 2026)

AMRH Technical Committees for medical products regulation

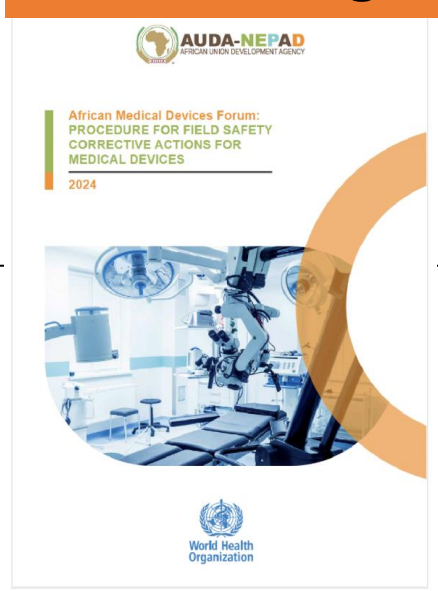
- MDA-TC was established to oversee the assessments, clinical performance and audits of Medical devices and IVDs

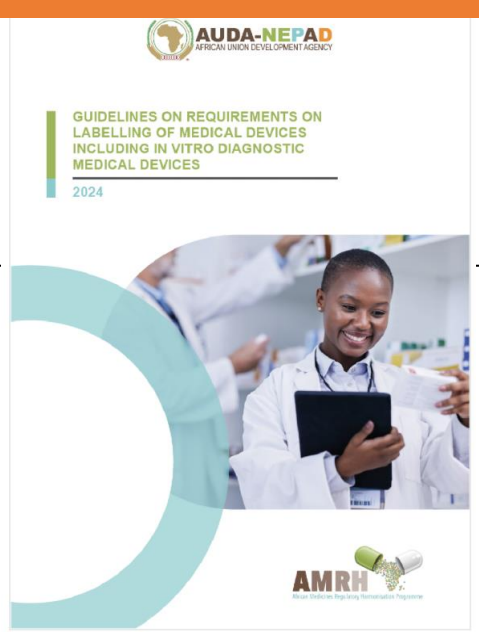


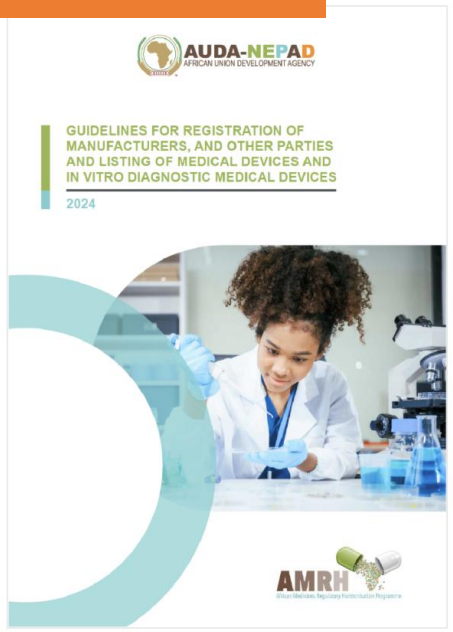
African Medical Devices Forum (AMDF) members as NRA reps.

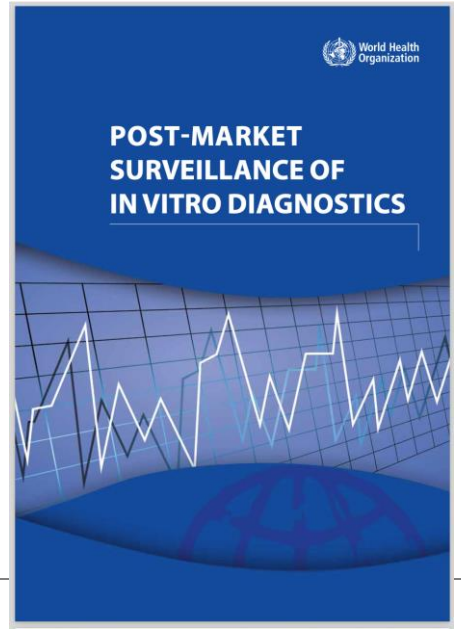
Medical devices Assessment – MDA-TC
Quality Management system Audit technical working group – QMS Audit TWG
Diagnostics Advisory Committee – DAC (coordinated by Africa CDC and reports to MDA-TC)

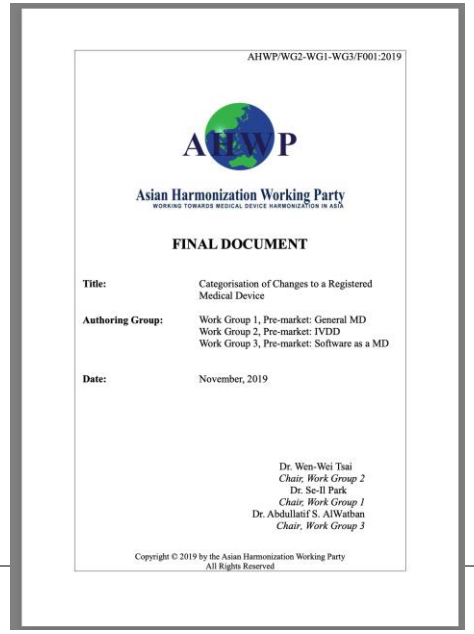
Continental guidelines adopted

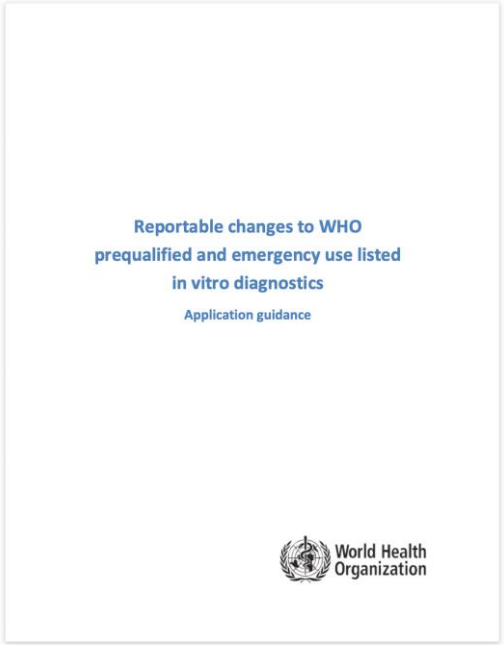


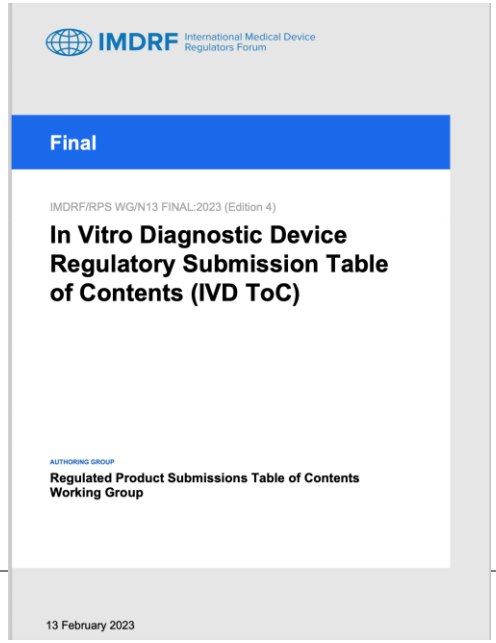












Standard Listing Procedure for IVDs

- Applicant submits Expression of Interest (EoI) + full dossier

- MDA-TC conducts dossier screening and evaluation

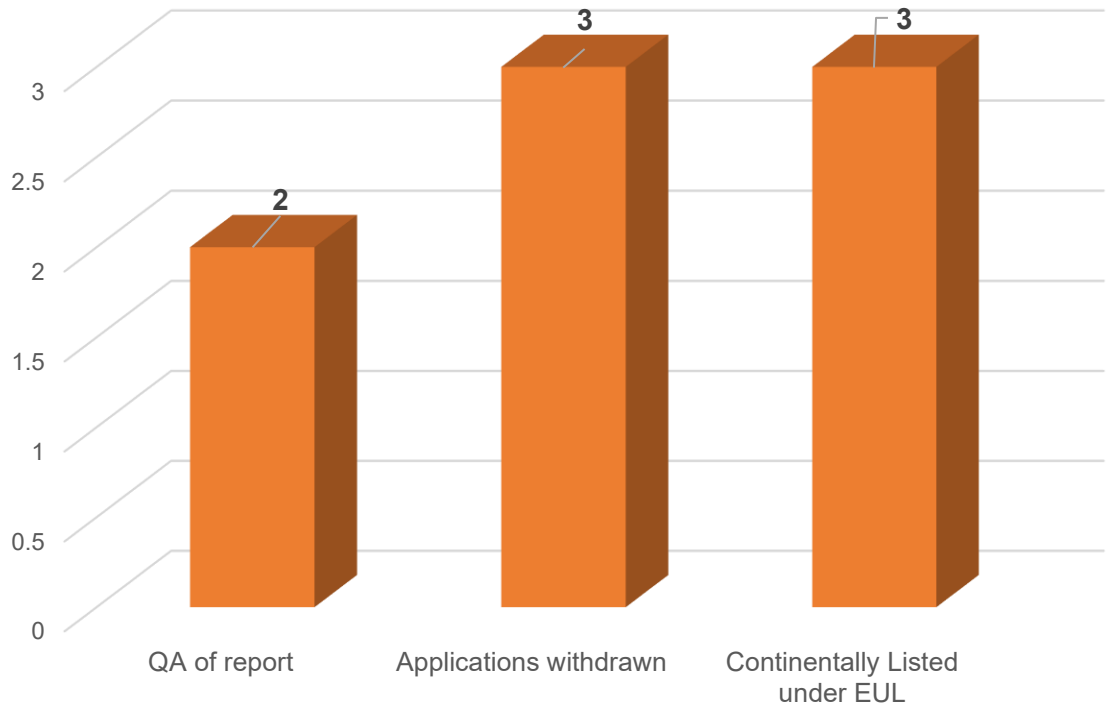
- DAC provides scientific opinion from performance studies

- Outcome: listing recommendation or rejection. Adoption of listing recommendation by Steering Committee/AMA

- NRAs adopt decisions through reliance pathway

EUL status November 2025

- 3 Products withdrawn
- The independent clinical performance verification had a sensitivity lower that WHO allowed limit.

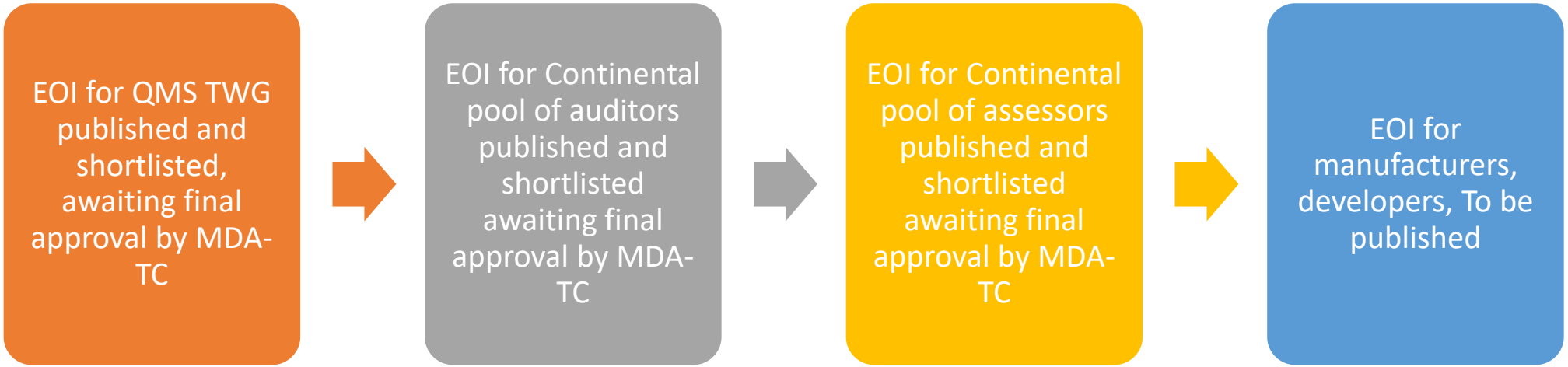


National level status of 3 Listed IVDs under EUL

Product	Date of Continental Listing	AMRH Time	Countries of interest	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. 123 CD	1. Kenya 2. Ghana 3. South Africa	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. 40 CD	1. Ghana	1. Ghana – 60 CD or 44 WD	60 CD or 44 WD
RADIONE Mpox and skin rash panel kit(AMDF/EUL/007)	20 October 2025	1. 57 CD	1. Ghana		11 CD

Overall = 34 CD or 24 WD

Work done and potential next steps



OPPORTUNITIES FOR IMPROVEMENT

- Refinement of the process for the continental routine procedure to incorporate a parallel screening phase for confirmation of technical file requirements, QMS status and independent clinical performance
- Alignment of the timelines for the routine procedure.
- Adequate monitoring of complete process for efficient timelines.
- Increase of the pool of experts within the continents for IVDs assessment including auditors
- Continuous capacity building of continental experts especially with current emerging technologies within the medical device field.

Timeline on potential next steps

29 Sept. 2025

Expression of interest for pool of assessors, auditors and the QMS TWG

27 Nov. 2025

Finalisation of the continental pool of assessors, auditors and the QMS TWG

TBC Q1 2026

Expression of interest published for manufacturers, innovators and developers

TBC Q1 2026

Initiation of assessments by MDA-TC and independent performance evaluation by DAC

TBC Q2 2026

Conclusion of the IVD assessments

TBC Q1 2027

Regulation of Medical Devices including SaMD and AI/MD

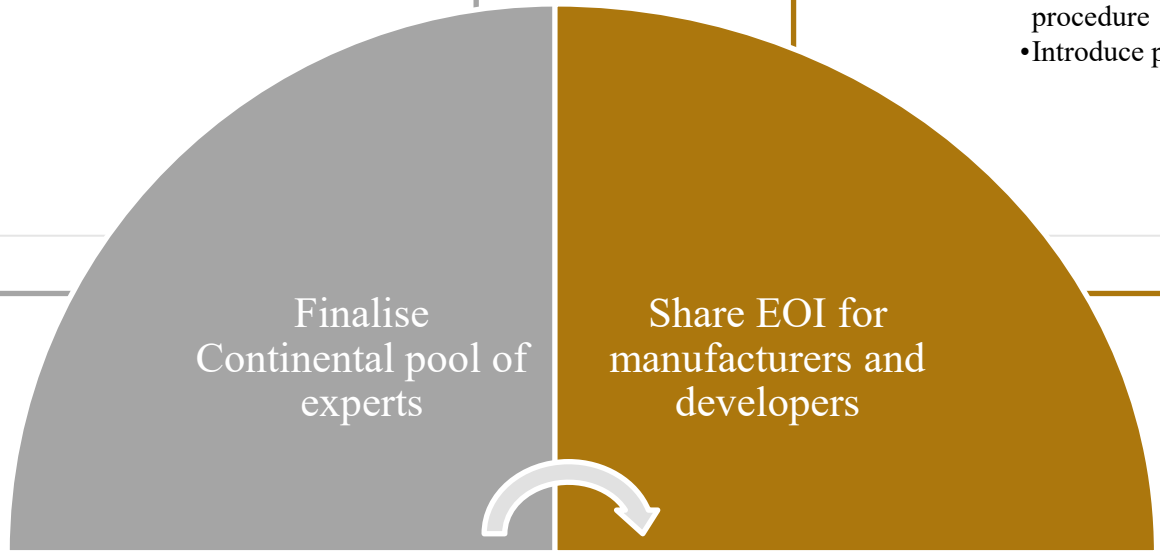
Priority products for continental listing of IVDs

- CLASS C and CLASS D in -vitro diagnostics
- Dengue, Measles, Cholera, Mpox, Bacterial Meningitis
- Locally manufactured*

IMPROVED ROADMAP

- The QMS Technical working group for audit facilitation
- Pool of assessors
- Pool of auditors

- Based of the identified and finalised priority groups
- Webinars for sensitization of the procedure
- Introduce pre-submission meetings



- Conduct assessments, allocate first reviewer, second reviewer then QA by MDA-TC
- QMS TWG to establish necessity for undertaking audit, conduct an audit if required.
- DAC to receive samples and conduct field studies, reports shared with experts once concluded.
- MDA-TC to recommend once assessments, tests and audits concluded.

- A parallel rigorous technical screening to establish all requirements are met.
- Screen technical file, QMS accreditation or necessity for audit and requirements for independent verification

Thank you