MATAHARI

Critical Path Analysis of New TB Diagnostics in Africa

Final report

African Centers for Disease Control/Africa Medicine Agency continental regulatory harmonization initiatives

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June 2025

Executive summary

The 2021 Lancet Commission revealed a critical global diagnostic access gap, with 47% of the population lacking diagnostic access, particularly at the primary healthcare level. Similarly, tuberculosis (TB) diagnosis is a critical bottleneck to achieving targets of the End TB strategy.

This report presents findings from a Critical Path Analysis (CPA) of new TB diagnostics in Africa developed by Matahari Global Solutions and funded by the Gates Foundation. It describes continental-level regulatory and market entry processes, explores challenges, and identifies opportunities to accelerate access to quality TB diagnostics in Africa. It aims to complement CPA findings from four high-burden TB countries (Ethiopia, Gabon, Kenya, and South Africa).

The African Medicines Agency (AMA) and the African Medicines Regulatory Harmonization (AMRH) program are central to ongoing continental efforts to harmonize and strengthen regulatory frameworks. The Africa CDC Diagnostic Advisory Committee (DAC) complements these efforts by advising on priority diagnostics. Its collaboration with AMRH and AMA further operationalizes continental regulatory harmonization.

The CPA methodology combined desk reviews, stakeholder consultations, and thematic analysis across nine areas along the end-to-end approval and uptake pathway of new medical devices and *in vitro* diagnostics (IVDs). Engagement with the above-mentioned key continental regulatory stakeholders was ensured to validate findings and develop actionable roadmaps directly addressing CPA-identified bottlenecks in country approval and policy inclusion pathways

Key findings highlight the potential of continental regulatory harmonization to accelerate approval processes and support procurement and supply chain integration. Harmonized frameworks can also stimulate local innovation and facilitate post-market surveillance. The pilot of a continental joint review and listing of new diagnostics during the ongoing Mpox public health emergency has demonstrated the feasibility and benefits of such approaches

Challenges remain, including the need for broader AMA treaty ratification and capacity building for technical dossier assessment. Nevertheless, future opportunities for synergy and collaboration include leveraging existing continental platforms such as the African Union, Africa CDC, and AMRH forums to disseminate CPA findings, advocate for regulatory reforms, and facilitate alignment between national policies and continental regulatory advances. Public-private dialogues and industry webinars are recommended to foster innovation and address regulatory challenges faced by diagnostics developers and manufacturers.

In conclusion, the harmonized continental regulatory framework and CPA findings are mutually reinforcing. Together, they provide a strategic roadmap to accelerate the introduction and scale-up of new TB diagnostics in Africa. Harmonized regulatory pathways, capacity strengthening, and multi-stakeholder collaboration will be critical to closing the TB diagnostic gap and improving public health outcomes continent-wide

Contents

Acknowledgements and Impressum

This report was developed by Matahari Global Solutions Sdn Bhd, registered in Malaysia, Company Registration No. (1339222-P), and authored by Marguerite Massinga Loembé, project lead. The project team included Fifa Rahman (principal consultant and focal point for Kenya), Alaine Umubyeyi Nyaruhirira (external consultant and focal point for Ethiopia and South Africa), and Sam Acellam (associate consultant: health data analytics).

This document outlines the methodology used to collect, collate, and validate publicly available data to define a critical pathway analysis (CPA) for new tuberculosis (TB) diagnostics. It aims at providing in-depth understanding and documentation of the key steps, timelines, and interdependencies for the market entry and placement of new TB tests that will assist countries, donors, and manufacturers in the selection of high-quality TB diagnostics appropriate for their setting and complement the different ongoing initiatives focused on market shaping and increasing access to TB diagnostics in low- and middle-income countries (LMICs). The particular focus of this report is to outline ongoing continental-level efforts to strengthen and harmonize regulatory frameworks and processes in Africa.

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Abbreviations and acronyms

Africa CDC	African Centers for Disease Control and Prevention
AMA	Africa Medicines Agency
AMDF	Africa Medical Device Forum
AMD TC	Medical Devices Assessment Technical Committee
AMRH	African Medicines Regulatory Harmonization
AU	African Union
AUDA-NEPAD	African Union Development Agency
CoE(s)	Center(s) of excellence
CPA	critical path analysis
DAC	Diagnostics Advisory Committee
EUL	Emergency Use Listing
IMDRF	International Medical Device Regulators Forum
IVDs	*in vitro* diagnostics
LMIC(s)	low- and middle-income countrie(s)
NRAs	national regulatory authorities
POC	point of care
R&D	research and development
REC(s)	regional economic community(ies)
STED	Summary of Technical Documentation
TB	tuberculosis
TC(s)	technical committee(s)
ToC	table of content
TWG(s)	Technical Working Group(s)
UNFPA	United Nations Population Fund,
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WHO AFRO	World Health Organization African region
WRDs	WHO recommended rapid diagnostics

Introduction

Background:

The 2021 Lancet Commission on Diagnostics[1] unveiled the critical gap in access to diagnostics, with 47% of the population lacking access globally. This gap was higher in countries with the lowest income and was particularly exacerbated at the last mile (decentralized, primary health care level)[2]. Similarly, diagnosis remains a weak step in the TB cascade of care. Notably, access to WHO-recommended rapid diagnostics (WRDs) has been stagnating just below 50% globally over recent years. Critical transitions are needed to accelerate approval, adoption, and scale-up of simple, non-sputum-based POC molecular technologies to enable decentralized diagnostic services for timely access[3]. To close the diagnostic gap, one of the key recommendations of the Lancet Commission is to implement governance and regulatory frameworks to support and oversee diagnostic quality and safety with the specific suggestion that "device regulation could be simplified by regional harmonisation"[1].

A recent study[4] looking at timelines along the end-to-end pathway for the launch and scale-up of (non-COVID-19) health products indicates that the median time to bring a product from ideation to at least 20% uptake could be as high as 17.5 years in LMICs, with a median time of 2.62 years to get regulatory approval. This situation is mirrored in Africa, where 94% of medical health products and technologies are imported from outside the continent[5], barriers to access and delayed time uptake are vulnerabilities that have been exposed by the COVID-19 pandemic. This situation is exacerbated by the limited capacity of national regulatory authorities (NRAs) and inefficiencies of approval and market authorization processes for health products, including medical devices and IVDs, related to limitations in financial and human resources and a lack of technical expertise, among other challenges[6]. As of December 2024, only eight African countries, including South Africa, have attained maturity level 3 on the WHO global benchmarking tool, consistent with the availability of "stable, well-functioning, and integrated regulatory systems". To address the fragmentation of regulatory systems on the continent and address capacity limitations at the country level, the African Union has launched several initiatives since 2009 (figure 1).

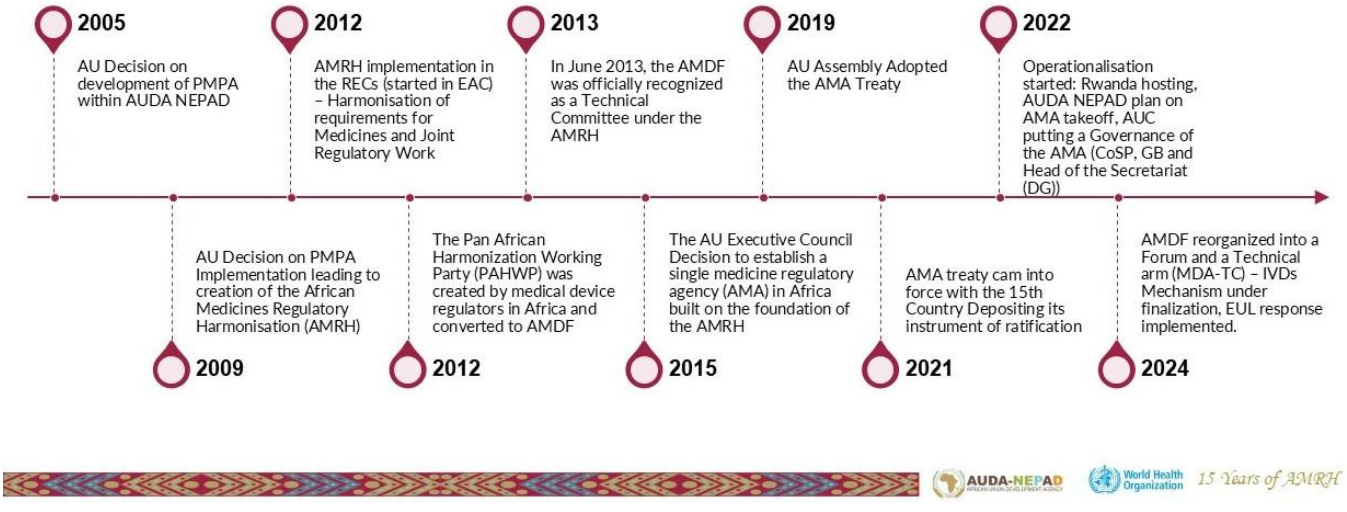


Figure 1: The journey of medical devices regulation in Africa. Source: AUDA-NEPAD

[1] Fleming KA et al. The Lancet Commission on diagnostics: transforming access to diagnostics. *Lancet* 2021; 398: 1997–2050
[2] Yadav, Harika et al. Availability of essential diagnostics in ten low-income and middle-income countries: results from national health facility surveys. *Lancet Glob* 2021 9: e1553 - e1560
[3] Pai, M. et al. Transforming tuberculosis diagnosis. *Nat Microbiol* 2023; 8: 756–759.
[4] Mao W et al. Development, launch, and scale-up of health products in low-income and middle-income countries: a retrospective analysis on 59 health products. *Lancet Glob Health* 2025; 13: e1132–39
[5] Concept note: Strengthening Africa's Pharmaceutical Industry– learning the lessons from COVID19. Accessed 7th June 2025
[6] Nasir N, et al. Medical device regulation and oversight in African countries: a scoping review of literature and development of a conceptual framework. BMJ Glob Health 2023; 8:e012308.

The African Medicines Agency (AMA)

In 2019, during the 32nd ordinary session of the African Union Assembly, the African Heads of states adopted the treaty[7] establishing the African Medicines Agency (AMA) as an Africa-owned independent institution charged with providing strategic direction and strengthening and harmonizing medical product regulations among Member States to improve public health protection. The establishment and operationalization of the AMA is founded on the African Union Model Law on Medical Products Regulation[8], which is aligned with WHO recommendations and best practices on medical products regulation. As of 31st May 2025, a total of 39 out of 55 African Union countries have signed and/or ratified the AMA Treaty[9]. Furthermore, on 4th June, Dr. Delese Mimi Darko from the Republic of Ghana was appointed as the inaugural Director General of the AMA[10], an important step to ensure the ongoing operationalization of the agency following the treaty entry into force on 5th November 2021. Among the countries included in this critical path analysis, Ethiopia, Gabon, and Kenya have ratified and deposited the AMA Treaty, whereas South Africa has not yet signed the treaty. More details are included in the respective country reports.

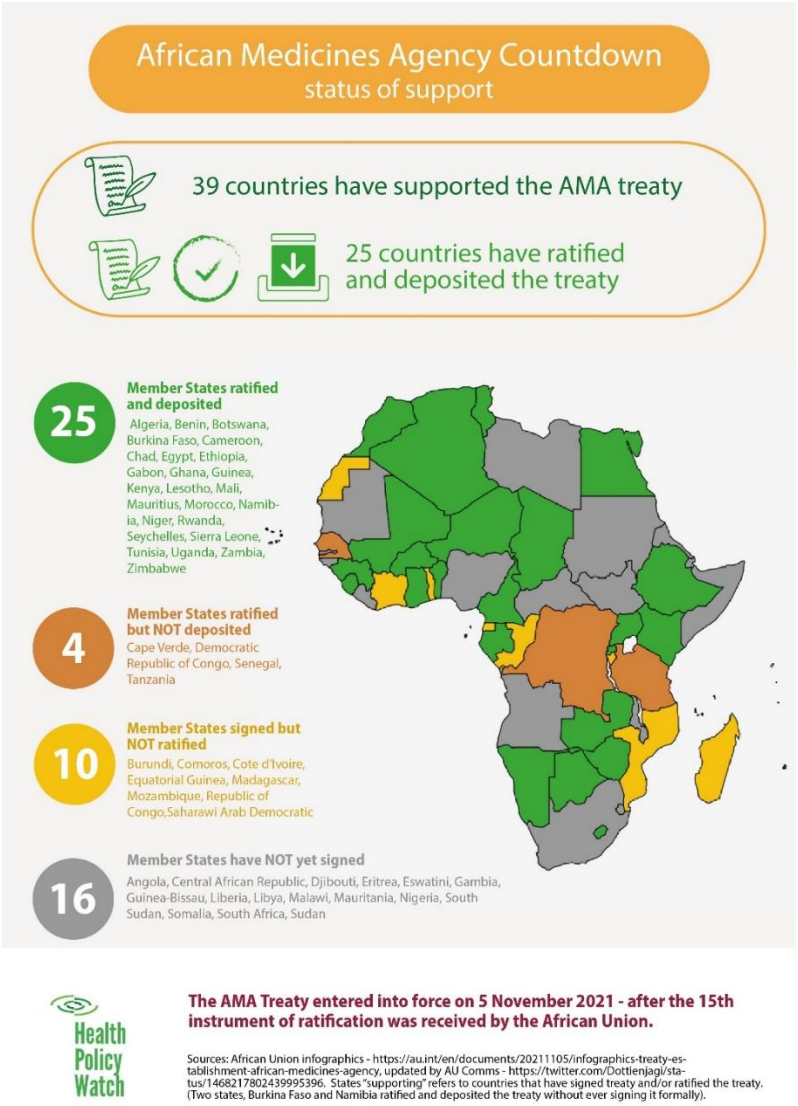
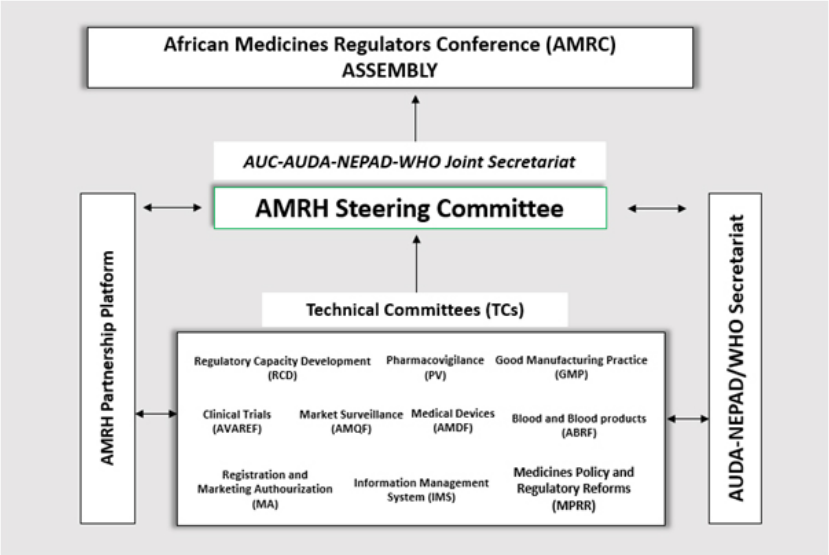


Figure 2: Status of support for the Africa Medicines Agency (AMA) treaty.

[7] Treaty for the Establishment of the African Medicines Agency (AMA). 2019. Accessed 7th June 2025
[8] AU Model Law on Medical Products Regulation. Accessed 8th June 2025
[9] AMA countdown. Accessed 7th June 2025
[10] Press release: *Dr. Delese Mimi Darko Appointed Inaugural Director General of the African Medicines Agency (AMA),* 4th june 2025.. Accessed 7th June 2025

The African Medicines Regulatory Harmonization (AMRH) program

To address the challenges faced by National Regulatory Authorities (NRAs) in Africa and create an enabling environment for pharmaceutical sector development, the African Medicines Regulatory Harmonization (AMRH) program was launched in 2009 as part of the African Union Framework on Pharmaceutical Manufacturing Plan for Africa, effectively representing the precursor to the AMA. However, AMRH, while technically effective, does not have an independent regulatory status.



The African Union Development Agency (AUDA-NEPAD), in collaboration with the World Health Organization (WHO), serves as a joint secretariat to the AMRH, working in collaboration with the African Union (AU) Commission. AMRH is hosted at the AUDA-NEPAD headquarters office in Johannesburg, South Africa.

AMRH functions are delivered through dedicated technical committees (figure 3), whereas the program operates through Regional Economic Communities (RECs) to strengthen the continental regulatory ecosystem across 4 focus areas (figure 4).

Figure 3: African Medicines Regulatory Harmonization (AMRH) Governance Framework.
Source: AUDA-NEPAD infographics.

Regional integration and harmonization of regulatory processes for medical devices and IVDs fall under the remit of the African Medical Devices Forum (AMDF), a continental-level forum with representation from one (1) head of medical devices regulation/registration for all 55 AU member states, complemented by the Medical Devices & Diagnostics Assessment Technical Committee (MDA-TC), composed of expert representatives from each REC, whose specific tasks include:

- Development of standards, guidelines, and procedures.
- Leading the development of a continental regulatory procedure for listing/certification of priority medical devices and IVDs.
- Convening joint evaluations of priority medical devices and IVDs
- Supporting the use of reliance models, including the WHO collaborative registration procedure.

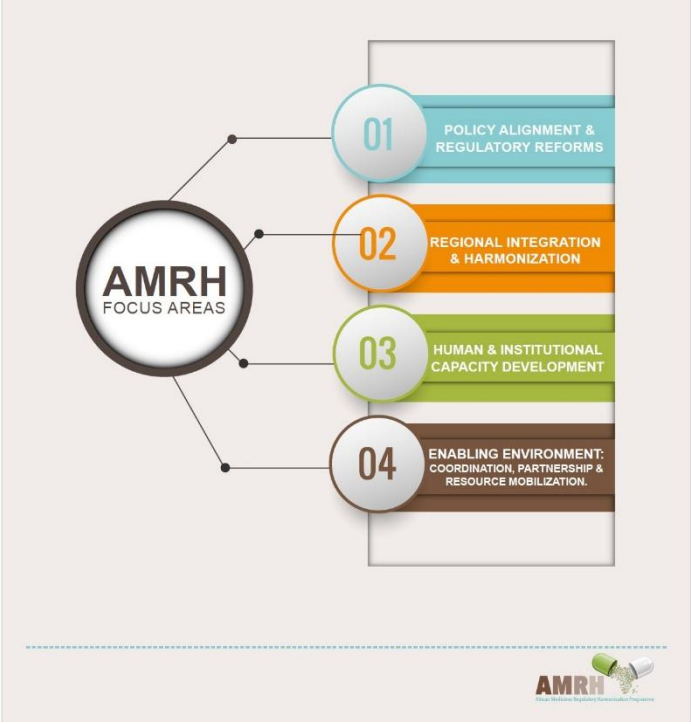


Figure 4: Areas of focus of the African Medicines Regulatory Harmonization (AMRH). Source: AUDA-NEPAD infographics.

The African Centers for Disease Control and Prevention (Africa CDC) Diagnostic Advisory Committee

The continental Diagnostic Advisory Committee (DAC) for IVDs[11], is a complementary initiative established by Africa CDC in 2023 to support the AMRH program through the AMDF and MDA-TC. This initiative aims to accelerate access to quality-assured diagnostics across Africa. Its roles encompass advising on diagnostic lists for priority diseases, boosting local diagnostics production, introducing diagnostic solutions, and mobilizing resources. The DAC comprises experts from national public health institutes, national reference laboratories, and global partners. Together the AMDF, MDA-TC, AMRH Joint Secretariat, and the Africa CDC Diagnostic Advisory Committee (DAC), are collaborating to develop a continental regulatory procedure for certification or listing of priority IVDs to support the technical operationalization of the AMA.

The continental joint expedited review and emergency use listing for new Mpox diagnostics

The declaration of the Mpox public health emergency of continental security by Africa CDC on 13th August 2024, and the ensuing need to ensure testing capacity scale-up in the face of the worsening outbreak prompted the launch of a pilot continental joint expedited review and emergency use listing for new Mpox diagnostics facilitated by the AMRH in collaboration with Africa CDC DAC. These efforts to establish a harmonized regulatory framework for medical devices and IVDs are transforming the regulatory ecosystem in Africa and can create efficiency gains that may positively impact the critical pathway and market entry of new TB diagnostics at the country level if expanded beyond outbreak prone diseases and public health emergency situations. Significant benefits are expected for diagnostic innovators/manufacturers and national health systems alike.

The Critical Path Analysis of TB diagnostics in Africa

In Africa, WRDs reach 54% of patients, slightly above the global average, a rate that still falls short to reach the targets of the End TB Strategy. Accordingly, the WHO AFRO has called for urgent action to close the diagnostic gap[12]. A critical path analysis (CPA) exercise, funded by the Gate Foundation, was undertaken by Matahari Global in four high TB burden African countries (Ethiopia, Gabon, Kenya and South Africa) to identify relevant context and obstacles along the approval to launch and scale up pathway of new TB diagnostics and to generate usable information for manufacturers, national and global stakeholders to inform the initial introduction and early uptake of new TB diagnostics (in the format of country-specific roadmaps).

In the scope of this CPA engagement and consultations with Africa CDC, AU AMRH/AMA, and NRAs representatives were deemed essential both at the project inception and project closure stages to achieve the following objectives:

- To present and review the protocol (at inception) and findings (at closure) of the country CPAs.
- To map continental regulatory harmonization initiatives underway for accelerating access to new diagnostics for outbreak prone diseases in Africa.
- To explore how these processes will impact market entry and placement of medical devices and IVDs for other priority diseases on the continent, with TB as a case study.
- To explore potential mechanisms and appropriate fora in which Africa CDC and AMRH could be engaged for advising countries (NTPs and NRAs) for ensuring dissemination of CPA findings and ensuring advocacy and follow-up on recommended follow-up actions at the country, regional, and global levels.

Outcomes of these engagements are captured in the present report.

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[11]Diagnostic Advisory Committee (DAC). https://africacdc.org/africa-cdc-diagnostic-advisory-committee-for-in-vitro-diagnostics/. Accessed 7th June 2025

[12] African region records further decline in TB deaths, cases. Accessed 10th June 2025

Summary of Methods

This critical pathway analysis was led by Matahari, funded by the Bill and Melinda Gates foundation with McGill University School of Population and Global Health coordinating the project across the African and South/ Southeast Asian regions.

The CPA methodology involved a blended approach involving a desk review, virtual and face-to-face outreach, and consultations with key stakeholders focusing on the following nine thematic areas (the first three being specifically considered in the scope of this present report):

- ***Regulatory approval at the global and continental level (including WHO and the African Union)***
- ***Regulatory approval at country level***
- ***Validation, review of evidence, and inclusion into policy by national TB program***
- *Product use cases*
- *Advocacy and demand creation*
- *Early adoption and rollout: health systems & implementation needs*
- *Health insurance & pricing*
- *Supply chain and procurement*
- *Scale up: network improvement/optimization and M&E*

An operational protocol was developed for a thorough desk review of documents (including file name or link, type of source, and date of publication where available) collected through a combination of systematic online searches and engagement with country stakeholders. These were categorized in a repository to enable triangulation of insights consistent with the nine thematic areas above. The analysis involved four distinct stages.

- **Phase I (Inception):** A first consultation, facilitated by the Africa CDC Centre for Laboratory Diagnostics and Systems, was held with representatives of the AMRH and AMDF Secretariat to present and review the CPA scope and protocol on the sidelines of a regional meeting with NRAs of West Africa and Mpox-Affected Countries on 7th-11th October 2024 in Accra, Ghana.

- **Phase II (Data collection and analysis):** A standardized questionnaire encompassing the 9 thematic areas of interest was developed and guided a desk review of the repository using DocAnalyser.ai, a document parsing and data extraction software. Findings were consolidated into a standardized report, which was shared with Africa CDC and AMRH stakeholders.

- **Phase III (Sensemaking and validation):** A presentation of country CPA findings from Ethiopia, Gabon, Kenya, and South Africa and a second consultation were organized during the Africa CDC meeting with the DAC, the MDA-Tc, and the NRAs of Eastern and Northern African countries on 26th-30th May 2025, in Addis Ababa, Ethiopia. Insights from the consultation (Annex III: framing questions) were triangulated with outputs from the desk review and inform the development of a roadmap using Microsoft Office Visio diagramming and flowcharting software, mapping out the critical steps, key stakeholders and decision points involved along a continental regulatory pathway for the introduction of new TB diagnostic tools.

- **Phase IV (Dissemination):** Insights from participants in the second consultation were collected to inform and complement an initial dissemination plan to increase awareness of CPA findings and recommendations with continental and country-level stakeholders and foster buy-in towards the introduction of TB medical devices and IVDs.

Findings

Overview of the harmonized continental regulatory processes for review and listing of medical devices and in vitro diagnostics in Africa.

The continental joint review of Mpox diagnostics for EUL was initiated by a call for expression of interest to manufacturers for submission of a technical file on 7th September 2024[13]. Regulatory assessors, drawn from Mpox-affected countries, facilitated a collaborative rolling review of technical files for candidate IVDs to assess product quality, efficacy, and performance claims using continental standards developed through the MDA-TC and AMDF[14,15, 16]. Manufacturing site compliance is assessed according to ISO13485 and as required, Africa CDC DAC provided an independent verification of product performance. Estimated timelines are **1 day for initial screening of the dossier and 15 - 45 days for the evaluation**. IVDs that meet the established standards were included in the list of IVDs recommended by the AMRH or AMA and published to facilitate reliance by NRAs and pooled procurement through the African Union. While granting marketing authorization/registration of IVDs is the prerogative of NRAs, this process was deemed essential to enable countries to adopt the recommendations for granting a national marketing authorization through a reliance mechanism enabling review and implementation of recommendations **within 90 days**. Leveraging the experience, tools and lessons learnt from this joint continental listing under EUL, AMRH and Africa CDC have initiated the implementation of the pilot routine continental collaborative review of medical devices and IVDs in January 2025, which should be completed by December 2026. Guiding principles for the routine review notably include:

- Alignment with Africa CDC list of priority diseases[17]
- Complementarity with WHO PQ processes (i.e.: non duplication and principle of reliance)

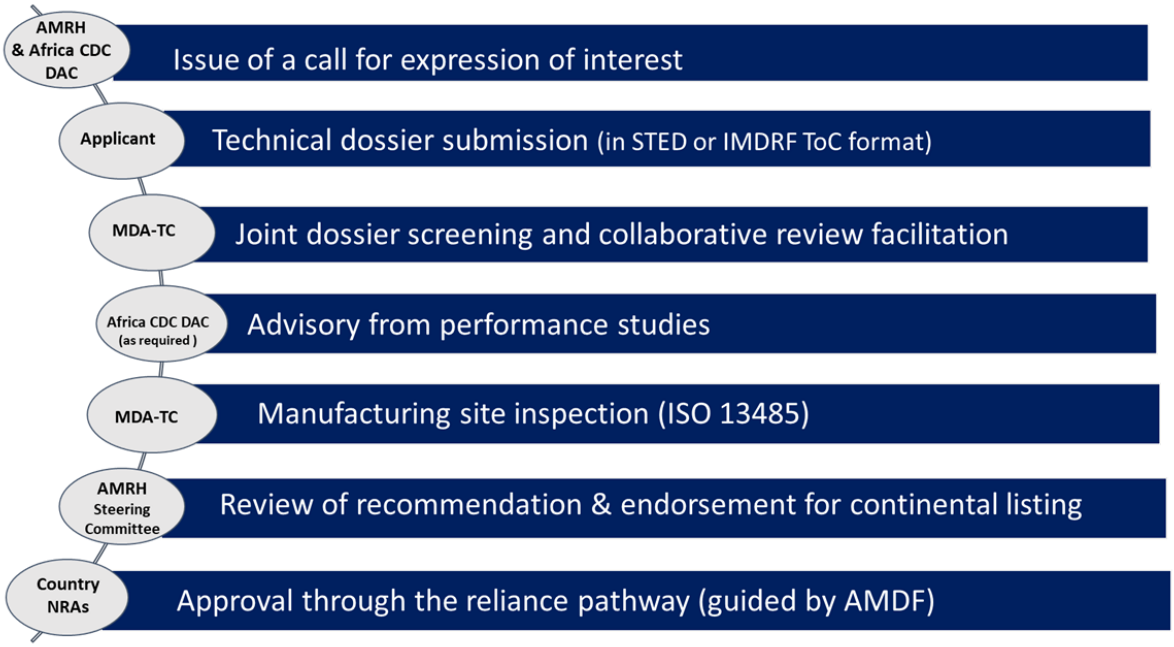

Figure 5: Stakeholders and details of the continental joint review and listing of new Mpox diagnostics

[13] Invitation of expression of interest to manufacturers/developers of mpox diagnostic tests to a continental facilitated joint review and emergency use listing. http://102.37.211.11/wp-content/uploads/2024/09/Invitation-for-EOIs-to-Manufacturers_Mpox-Diagnostic-Tests-.pdf . Accessed 10th June 2025

[14] AMDF Guidelines on regulatory requirements for issuance of market authorization of medical devices including in-vitro diagnostic medical devices Accessed 7th June 2025

[15] AMDF Guidelines on import and export of medical devices including IVDs Accessed 7th June 2025

[16] AMDF Guidelines for inspection of manufacturing site(s) for assessment of the quality management system of medical devices based on ISO 13485:2016. Accessed 7th June 2025

[17] Newsflash: Africa Lists Diagnostics for Priority Diseases. Accessed 7th June 2025

Roadmap for the harmonized continental regulatory review and product listing.

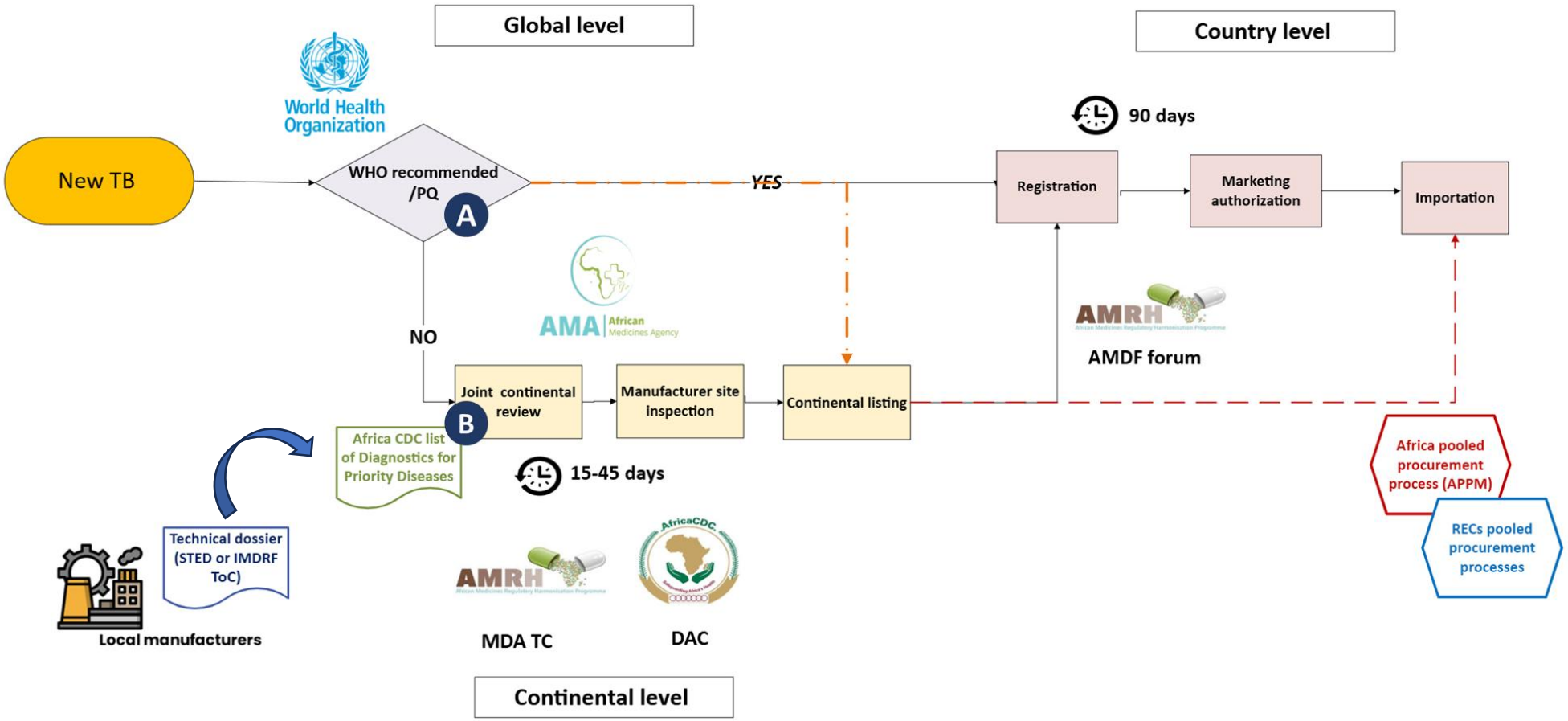

Figure 5: Overview of the harmonized continental process for regulation of medical devices and IVDs in Africa, and intersection with global and country-level approvals.

Outcome of a consultation with Africa CDC DAC, AMRH MDA-TC, and national regulatory authorities of Eastern and Northern Africa.

The continental harmonized regulatory framework for the review and listing of medical devices and in vitro diagnostics spearheaded by the AMRH and Africa CDC offers a unique opportunity to accelerate the market entry of new TB diagnostic tools in Africa.

The potential role of AMDF/DAC-led harmonized continental reviews and product listings in facilitating the market entry of new diagnostic tools in Africa, including for TB, can be summarized as follows:

- **Accelerating regulatory approval**: The implementation of harmonized regulatory reviews at the continental level can significantly reduce duplicative efforts among NRAs by enabling joint dossier assessments that will expedite simultaneous approvals across multiple countries, thereby shortening time-to-market entry (and potentially reducing costs) for manufacturers.

- **Enhancing confidence and trust**: Continental listing can enhance confidence and trust in new diagnostics by providing regionally recognized expert reviews. Additionally, resolving potential backlogs through the abridged examination of listed TB diagnostics could contribute to improving NRAs performance and reputation.

- **Creating an enabling policy environment:** national policy decisions for diagnostic tool adoption often require both WHO endorsement and local regulatory approval, potentially creating a bottleneck to rapid market entry. The continental harmonized framework offers an opportunity to close the gap between national policy and global endorsements by fostering regional consensus: Africa CDC and AMRH, through the AMDF, possess the necessary mandate to convene Ministries of Health to update national essential diagnostics lists and develop joint TB strategies, which are key facilitators for the adoption of innovation, including for yet-to-be-approved WHO prequalified or recommended products or those with, e.g., CE marking.

- **Supporting procurement and supply chain integration:** continental listings, usable by donors and pooled procurement mechanisms, can help establish a more predictable market for new diagnostic tools.

- **Stimulating local innovation and manufacturing:** by offering clear regulatory pathways and support for African diagnostic developers and manufacturers to meet regional standards and by helping to position locally developed tools on the local market (see figure 5, pathway B).

- **Promoting post-market surveillance:** the harmonized framework may play a critical role in the coordination of post-market surveillance efforts, notably by enabling data sharing to ensure ongoing quality and safety of diagnostics and inform future regulatory decisions.

However, challenges remain for the implementation of the continental harmonized regulatory framework

The operationalization of the AMA and the implementation of the harmonized continental review and listing framework hold considerable promise for enhancing Africa's regulatory ecosystem. Nevertheless, some challenges need to be addressed to achieve impact.

The need for strategic focus as AMA is setting its scope and mandate has been reviewed in detail elsewhere[18] with particular emphasis on 1) ensuring wide ratification across all 55 AU member states to avoid disparity between regulators: 2) integrating and leveraging AMRH TCs and workstreams and 3) creating an enabling regulatory environment for locally manufactured health products. It should be mentioned that the newly appointed AMA director general is a co-author on this paper. Participants also highlighted the need **to officialize the collaboration with WHO to enable the sharing of assessment reports and expedite reviews as part of the reliance pathway, and to align with other, RECs led, ongoing regional harmonization initiatives**.

From a technical standpoint, a recent AUDA-NEPAD survey[19] of training needs for pre-market authorization of medical devices and IVDs in Africa has highlighted the *"very important need to increase knowledge and skills to medical devices and IVDs reviewers in order to be able to make appropriate decision during market authorization of these products which in turn will improve access to medical devices and IVDs of good quality, safety and performance to meet healthcare needs"*. Specific technical challenges and priorities identified during this consultation include:

- **Strengthening capacity for technical dossier assessment of medical devices and IVDs:**
    - Ensuring training of medical devices and IVDs dossier assessors to improve their competency in reviewing technical files, notably leveraging GTB plus medical devices guidelines as well as AMRH guidance.
    - Expanding the cohort of continental assessors and ensuring intentional knowledge transfer to incoming professionals.
    - Leveraging local academic/research CoEs, laboratory professionals and disease experts to complement the expertise of dossier assessors and enable efficient review across disease areas.

- **Improve the NRAs/laboratory interface:** to ensure their processes are complementary and synergistic rather than duplicative.

- **Enhancing collaboration with applicants** e.g. through dedicated manufacturers engagement webinars and training sessions, development of guidance (e.g. FAQ on responding to queries) etc. Face-to-face interactions during the regulatory conference (e.g. the annual Joint UNICEF-UNFPA-WHO meeting with manufacturers and suppliers or similar regional meetings) are also warranted.

- **Expanding the scope of Africa CDC priority diseases list** (i.e. based on disease burden in addition to the current risk ranking approach) for transitioning from emergency to routine regulatory reviews, including for TB diagnostics.

- **Developing national standards such as National Essential Diagnostics Lists** (or NEDLs) to bridge the gap between regulatory approval and policy uptake.

- **Ensuring digitalization of continental processes**.

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[18] Wairagkar N, et al. (2025) The African Medicines Agency - A potential gamechanger that requires strategic focus. *PLOS Glob Public Health* 2025. 5(2): e0004276.

[19] AUDA-NEPAD. Pre-market authorization of medical devices and in-vitro diagnostics in Africa training needs assessments report. 2023; (37/AUDA/DPDC/HCID/ICS/2023).

Synergies are possible for the implementation of follow-up action on CPA recommendations at the national, continental, and global level in line with identified needs and priority areas for the harmonized regulatory framework and capacity strengthening of NRAs. Recommended venues and channels to foster dissemination of CPA findings and ensure advocacy and follow-up action include:

- **For global and continental stakeholders:** Engagement through African Union and Africa CDC platforms, including the Health Economics or Laboratory Networks programs, is advised to secure strategic buy-in. Additionally, leveraging existing partnerships with organizations like WHO, UNITAID and the Global Fund could allow integration of CPA insights into country-level TB and diagnostics programming. Side events at global health meetings such as the Union World Conference on Lung Health or WHO TB Symposiums would provide additional strategic opportunities for dissemination and advocacy

- **For Country National Regulatory Authorities (NRAs) and Ministries of Health (MoH)**: regional AMRH forums and working groups as well as RECs Medicines Regulatory Harmonization meetings can provide institutional platforms for cross-country regulatory discussions based on CPA insights. At the country level, national health sector coordination platforms such as Health Sector Working Groups or Technical Working Groups (TWGs) on diagnostics, TB, or laboratory systems may also be leveraged. Targeted, country-specific policy briefs summarizing CPA findings and tailored recommendations, alongside regulatory roundtables with officials and health decision-makers, are essential to align on follow-up actions.

- **For manufacturers and diagnostic innovators,** appropriate channels include the Africa Medical Devices Forum (AMDF) or regulatory dialogues that can facilitate public-private discussions to understand regulatory trends and respond to CPA insights. Targeted industry webinars co-hosted with partners like AMRH, WHO, and PATH can support knowledge sharing to address regulatory pathways and entry barriers. Investment and innovation platforms such as the African Health Innovation Summit, Africa Health Business Symposium, African MedTech Conference, and Afrisummit also represent key venues for presenting CPA insights to drive strategic decisions. Engagement with global health procurement and innovation networks such as, e.g., the Global Fund's pool procurement mechanisms and Unitaid innovation showcases is also recommended.

Conclusion

The CPA findings and the project's key recommendations for improving regulatory procedures in four African countries (Ethiopia, Gabon, Kenya, and South Africa) are closely reflected in the priority areas for implementing the continental harmonized regulatory framework for medical devices and IVDs. Moreover, the emphasis on digital processes, capacity building, knowledge transfer, and defining priority diseases for transitioning from emergency to routine regulatory reviews aligns with the CPA project's core objective of expediting review and approval of new diagnostic tools while maintaining safety and quality standards to close the TB diagnostic gap on the continent.

WHO global TB program recently announced the convening of its Guideline Development Group, scheduled in November to evaluate quality evidence on the use of new, near point-of-care molecular tests for the initial diagnosis of TB as well as tongue swabs as new diagnostic sample type, which were both products that underpinned the country CPA projects. In view of the anticipated publication of related WHO recommendation late 2025 or beginning of 2026, there was broad consensus among participants that this represents a timely opportunity to pilot the continental review and listing of medical devices and IVDs in routine, non-EUL conditions, and they recommended a joint program of work to be submitted to potential sponsors for funding consideration.

Annexes

Annex I: List of participants sideline meeting to the regional workshop with NRAs of West Africa and Mpox-Affected Countries on 7th-11th October 2024 in Accra, Ghana (face to face).

Name	Organization
Alex Juma Ismail	AUDA-NEPAD
Noah Takah Fongwen	Africa CDC
Paulyne Wairimu	Kenya Pharmacy and Poison board (SAHPRA)/Chair AMDF-TC
Dimakatso Mathibe	South African Health Products Regulatory Authority (SAHPRA)/ Vice Chair AMDF-TC
Emmanuel Nkrumah	Zambia Medicines Regulatory Authority (ZAMRA) / Chair MDA-TC
Frank Nkonde Laban	Zambia Medicines Regulatory Authority (ZAMRA) /Vice Chair MDA-TC
Keneni Benti	Ethiopian Food and Drug Authority (EFDA)

Annex II: List of participants to Africa CDC meeting with the DAC, the MDA-Tc, and the NRAs of Eastern and Northern African countries on 26th-30th May 2025, in Addis Ababa, Ethiopia (face to face).

Name	Organization
Alex Juma Ismail	AUDA-NEPAD
Lerato Moeti	AUDA-NEPAD
Washington Dengu	AUDA-NEPAD
Halifa Mbae Said	Africa CDC
Noah Takah Fongwen	Africa CDC
Janiva Jasson Rugaiza	WHO
Blaise Mboringong Akenji	DAC
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Yusuf Omar Mayow	National Medicine Regulatory Authority (NMRA), Somalia
Placide Muhayimana	Rwanda Food and Drug Authority (FDA)
Tite Uwambajineza	Rwanda Food and Drug Authority (FDA)
Dimakatso Mathibe	South African Health Products Regulatory Authority (SAHPRA)
Khanyisile Nkuku	South African Health Products Regulatory Authority (SAHPRA)
Aguek Deng Aler Deng	Sudan Drugs & Food Control Authority
Engerasia Mtui	Tanzania Medicines and Medical Devices Authority (TMDA)
Murinke Joseph Karara	Uganda national Drug Authority (NDA)
Kapunda Masuwa	Zambia Medicines Regulatory Authority (ZAMRA)
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Annex III: Framing question for final stakeholders' consultation

Topic	Question
Role of AMRH	Based on the context and situational analysis presented, what could be the potential role of AMRH processes (AMDF/DAC-led reviews/listings) for facilitating the market entry of new TB diagnostic tools in Africa?
Capacity strengthening	The countries indicated the need to further support capacity within the NRA for the review of medical devices/IVDs and to perform CPA on their own. To define capacity strengthening needs at the country level, how would it be possible to gather more data on • Number and qualification of staff involved in review and approval of medical devices and IVDs • Volume of applications received Any other consideration for capacity strengthening in your view?
Dissemination and use of CPA findings	What would be the appropriate channels/platforms to disseminate findings from this CPA analysis and foster advocacy and follow-up action on proposed recommendations (country NRAs and MoH, manufacturers)?
Other	Any other recommendations that the group would have?

Annex IV: List of desk review resources (appended)