



DELIVERING THE AFRICAN MEDICINES AGENCY (AMA) IN KENYA:

FROM RATIFICATION TO OPERATIONALIZATION



AN ADVOCACY BRIEF FOR THE MINISTRY OF HEALTH
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I. KENYA'S HEALTH RESEARCH AND DEVELOPMENT LANDSCAPE

Kenya has an ambitious manufacturing target to manufacture at least half of its essential health products domestically, following a presidential directive in October 2023¹. To support this goal, the Ministry of Health launched the Kenya Health Products and Technologies Local Manufacturing Strategy 2026–2030, outlining measures including production-linked incentives, tax relief on pharmaceutical inputs and machinery, blended finance, and a 'Buy Kenya Build Kenya' procurement approach².

The Kenya Health Sector Strategic Plan 2023–2027 identifies health products and technologies, and health information systems as key pillars of the health system³. Despite this, Kenya continues to import an estimated 70 to 80 percent of its health products and technologies, while domestic manufacturing remains largely focused on packaging, labelling and finished-dose production, with limited active pharmaceutical ingredient (API) capacity.

The national regulatory authority is the Pharmacy and Poisons Board (PPB), established under the Pharmacy and Poisons Act (Cap. 244)⁴. The PPB oversees product registration, good manufacturing practice inspections, clinical trials and post-market surveillance⁵. Kenya is continuing to strengthen its regulatory system and is advancing toward WHO Maturity Level 3, a priority linked to quality assurance, local manufacturing and regional market access⁶.

Kenya is an active participant in the East African Community Medicines Regulatory Harmonization programme, the first regional initiative established under the African Medicines Regulatory Harmonisation framework⁷. Between 2015 and 2023, joint review applications increased from 9 to 44, while median review times fell from 553 to 259 days, demonstrating significant efficiency gains. However, the absence of a centralised submission system and binding legal framework remains a constraint⁸.

At the 76th Session of the WHO Regional Committee for Africa in Addis Ababa (August 2026), Kenya called for accelerated action towards African health self-reliance, highlighting sustainable health financing, local manufacturing and digital transformation as key priorities⁹. The country also endorsed the WHO AFRO Vision 2035 strategy and

1 KBC. (2024). Kenya positions itself as regional pharmaceutical production hub. <https://www.kbc.co.ke/kenya-positions-itself-as-regional-pharmaceutical-production-hub/>

2 Ministry of Health, Kenya. (2026). Kenya Health Products and Technologies Local Manufacturing Strategy 2026–2030. Launched 23 June 2026.

3 Ministry of Health, Kenya. (2023). Kenya Health Sector Strategic Plan 2023–2027. <https://www.health.go.ke>

4 Kenya Law. Pharmacy and Poisons Act (Cap. 244), revised edition. <https://new.kenyalaw.org/akn/ke/act/1956/17/eng@2023-12-11/source.pdf>

5 Pharmacy and Poisons Board. Official website. <https://ppb.go.ke/>

6 World Health Organization Regional Office for Africa. (2026). Kenya advances local manufacturing of health products and technologies. <https://www.afro.who.int/countries/kenya/news/kenya-advances-local-manufacturing-health-products-and-technologies>

7 AUDA-NEPAD. African Medicines Regulatory Harmonisation (AMRH): Kenya. <https://www.nepad.org/nepad-oncontinent/african-medicines-regulatory-harmonisation-amrh-kenya>

8 Ngum, N., et al. (2025). Suggested improvements to the current East African Community Medicines Regulatory Harmonization joint review process and a proposed new review model for this initiative. *Pharmaceutical Medicine*, 39(2), 125–141. <https://doi.org/10.1007/s40290-025-00554-1>

9 Ministry of Health, Kenya. (2026, August 26). Kenya calls for action to build a self-reliant African health sector. <https://www.health.go.ke/kenya-calls-action-build-self-reliant-african-health-sector>



advocated for a regional health data hub built on interoperable standards, strong data governance, and Member State ownership.

II. WHAT KENYA CAN DO NOW

The Africa Medicines Agency's 5-year ambition is to become a financially sustainable WHO-Listed Authority with universal AU ratification by 2030. Having ratified the AMA Treaty on 16 July 2023, Kenya is well positioned to help advance these goals while strengthening its own health research, regulatory and manufacturing priorities in the following ways¹⁰.

Recommendation	Responsible actor	Immediate next step
Champion treaty ratification	Ministry of Health; Ministry of Foreign and Diaspora Affairs	Use Kenya's status as a ratifying State Party to encourage remaining non-ratifying AU Member States to complete ratification, supporting AMA's goal of universal African Union ratification by 2030.
Honour financing commitments	Ministry of Health; National Treasury	Provide for Kenya's assessed State Party contribution once the applicable scale of assessment is adopted, and establish a predictable national budget line for AMA participation.
Advance regulatory harmonization	Pharmacy and Poisons Board (PPB)	Adopt relevant continental regulatory guidelines and participate in AMA joint review, reliance and work-sharing mechanisms. The planned WHO Maturity Level 3 assessment provides an opportunity to strengthen Kenya's contribution to regulatory harmonisation initiatives.
Report on implementation progress	Ministry of Health; PPB	Publish regular updates on AMA financing contributions, regulatory harmonisation milestones and participation in AMA mechanisms to strengthen accountability and track implementation progress.

III. HOW KENYA'S PRIORITIES ALIGN WITH AMA'S MANDATE

The African Medicines Agency's implementation agenda is focused on operationalisation, sustainable financing, stronger regulatory cooperation and broader African Union ratification. Kenya ratified and deposited its instrument for the AMA Treaty on 16 July 2023 and is therefore well positioned to help advance these objectives while strengthening its own research, regulatory and manufacturing priorities:

¹⁰ African Union. (2026, May 22). Status list: Treaty for the Establishment of the African Medicines Agency. https://au.int/sites/default/files/treaties/36892-sl-TREATY_FOR_THE_ESTABLISHMENT_OF_THE_AFRICAN_MEDICINES_AGENCY_5.pdf



The brief argues that a fully operational AMA is critical to accelerating clinical research, expanding market access for locally manufactured medicines, and strengthening African governance of health and genomic data. As a continental regulator, AMA is intended to complement national and regional authorities through coordinated, science-based regulation.

These objectives align closely with Kenya's priorities on sustainable financing, local manufacturing, and digital transformation. A fully operational AMA could help advance Kenya's goals to strengthen health research, regulatory capacity, and access to quality medical products. This brief outlines the alignment between Kenya's priorities and AMA's mandate, and highlights opportunities for national implementation.



Clinical trials: strengthening African research leadership

The brief argues that a fully operational AMA is important for accelerating regulatory cooperation for clinical research and improving regulatory pathways for locally manufactured medical products. AMA complements national and regional regulators; wider governance of health and genomic data is led through national frameworks and Africa CDC-led continental initiatives.



Local manufacturing and health sovereignty

Africa produces only about 3% of global medicines while importing more than 70% of those it consumes and relying heavily on imported active pharmaceutical ingredients. Kenya's pharmaceutical manufacturing ambitions continue to expand, including investments through the Kenya BioVax Institute and Konza Technopolis. Realising the full value of these investments will require access to regional and continental markets.

The African Medicine Agency's reliance, harmonisation and coordinated good manufacturing practice (GMP) inspection mechanisms could reduce regulatory duplication and support more efficient regulatory pathways across African markets. While market authorisation decisions remain the responsibility of national authorities and applicable regional bodies, greater regulatory convergence could improve the efficiency and predictability of market access for products manufactured in Kenya. AMA could also strengthen Kenya's efforts to combat substandard and falsified medical products through enhanced cross-border information-sharing, regulatory cooperation and coordinated surveillance.





Health data and genomics: strengthening African governance

African populations hold the world's greatest human genetic diversity yet remain significantly underrepresented in global genomic datasets. Kenya is expanding its genomics capacity, including through a USD 3.5 million partnership announced in 2026 by Biolinx Africa, the YTO Foundation and Nextgen Molecular Lab to establish a large-scale sequencing platform serving Kenya and Côte d'Ivoire¹¹.

As genomics becomes increasingly important for health research and innovation, Kenya has an interest in shaping emerging African frameworks for data governance, research and health technologies. The Africa CDC's Continental Health Data Governance Framework provides the primary continental framework for the governance, sharing and use of health data. Within this broader architecture, AMA can play a complementary role by supporting regulatory cooperation relevant to clinical research, innovative health technologies and related regulatory standards

As genomics becomes increasingly important for health research and innovation, Kenya has an interest in shaping African frameworks for data governance, research and health technologies. Africa CDC's continental health-data governance work provides the broader policy architecture. Within that landscape, AMA can play a complementary regulatory role for clinical research, innovative medical products and related standards.

IV. KEY MESSAGES FOR THE MINISTRY OF HEALTH

01

Strengthening evidence-informed regulatory decision-making: AMA can strengthen evidence-informed regulatory decision-making through regulatory reliance, joint assessments and information-sharing across African regulators. For Kenya, this could allow the Pharmacy and Poisons Board (PPB) to draw on continental expertise and assessments, improving efficiency while maintaining national decision-making authority.

02

Advancing regulatory harmonization and reliance across Africa: AMA can reduce unnecessary duplication through harmonised regulatory approaches, reliance and work-sharing mechanisms. For Kenya, this could strengthen the efficiency of regulatory assessment by enabling the Pharmacy and Poisons Board (PPB) to draw on shared scientific evaluations and regulatory expertise while retaining full authority for national regulatory decisions. This would build on experience gained through the East African Community Medicines Regulatory Harmonisation initiative.

¹¹ Agence Ecofin. (2026, May 25). *Génomique: des acteurs africains unissent leurs fonds pour réduire la dépendance scientifique*. <https://www.agenceecofin.com/actualites/2505-138750-genomique-des-acteurs-africains-unissent-leurs-fonds-pour-reduire-la-dependance-scientifique>



03

Supporting local manufacturing through stronger research and innovation ecosystems: As Kenya seeks to expand local production through initiatives such as BioVax and the Manufacturing Strategy 2026-2030, AMA can support greater regulatory convergence across African markets. While market authorisation remains the responsibility of national and regional authorities, harmonisation and reliance mechanisms could facilitate more efficient access to regional and continental markets for products manufactured in Kenya.

04

Fostering strategic partnerships and sustainable domestic investment in health innovation. Participation in a recognised continental regulatory framework can increase the attractiveness of Kenya's health innovation ecosystem to manufacturers, research sponsors, development partners and investors. For Kenya, this complements national ambitions to strengthen pharmaceutical manufacturing, research and health innovation.

05

Strengthening competitiveness in clinical research: AMA's harmonised review pathways and joint clinical trial assessment mechanisms can support more efficient multi-country clinical research. For Kenya, this could reduce regulatory duplication for regional studies, strengthen the country's attractiveness as a research destination, and support participation in multicountry clinical trials.

V. WHY KENYA SHOULD CHAMPION AMA IMPLEMENTATION AND SUSTAINABLE FINANCING

- **Kenya's manufacturing ambitions require regional market access:** The Health Products and Technologies Local Manufacturing Strategy 2026-2030 aims to substantially increase domestic production of essential health products. Deeper regulatory cooperation can help Kenyan manufacturers access regional and continental markets more efficiently.
- **Kenya already has experience with regulatory harmonisation:** Through the East African Community Medicines Regulatory Harmonisation Initiative, Kenya has seen how joint reviews and regulatory cooperation can reduce duplication and improve efficiency. AMA provides an opportunity to extend these benefits to the continental level.
- **Kenya is well positioned to shape AMA's implementation:** Having ratified the AMA Treaty in 2023 and prioritised sustainable financing, local manufacturing and regulatory strengthening, Kenya can contribute technical expertise and practical experience to continental regulatory cooperation.
- **The costs of limited implementation are increasing:** Kenya has completed ratification, but the national benefits will depend on active participation, predictable financing and engagement in AMA cooperation mechanisms. Continued challenges from substandard and falsified medical products further underscore the value of stronger continental coordination and information-sharing.

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