Betta Health Equity

REVIEW

OPEN ACCESS

Collaborative Models For Strengthening Pharmaceutical Regulation in Africa: Lessons From Egypt's Milestone

Dimeji Abdulsobur Olawuyi [1], Temiwunmi Shobanke [2], Susan Olalere [3]

Correspondence: Olawuyi Dimeji Abdulsobur **(lokidimeji@gmail.com)**

01 June, **2025**

Abstract

Egypt's achievement of Maturity Level 3 (ML3) for medical products, as assessed by the World Health Organization's (WHO) Global Benchmarking Tool (GBT), highlights a significant milestone in Africa's pharmaceutical regulation landscape. This paper explores the collaborative strategies employed by the Egyptian Drug Authority (EDA), including partnerships with the WHO and industry stakeholders, to strengthen local manufacturing and regulatory frameworks. Additionally, it examines the challenges faced by African National Regulatory Authorities (NRAs), such as limited autonomy, resource constraints, and disjointed regulatory systems. The paper concludes with recommendations for fostering regulatory harmonization, enhancing autonomy, and leveraging WHO initiatives to strengthen pharmaceutical regulations and improve health outcomes across Africa.

Keywords: Maturity level | Pharmaceutical regulation | Egyptian drug authority | Nigeria | Maturity level 3

Background

In December 2024, Egypt achieved Maturity Level 3 (ML3) for medical products, as assessed by the World Health Organization's (WHO) Global Benchmarking Tool (GBT) revision VI for regulatory authorities, just two years after attaining ML3 for locally produced and imported vaccines. This made Egypt the first African country to locally produce two of the four product categories evaluated by the WHO GBT and the only Northern African country with an ML3, a significant milestone given that only 30% of National Regulatory Authorities (NRAs) globally have effective regulatory oversight and only about 15% of African NRAs have achieved ML3 status. [1,2] The GBT assesses eight regulatory functions using 268 indicators and scoring systems from levels 1 to 4 and helps ensure medical products adhere to safety, efficacy, and quality standards while also verifying product information accuracy [3]. Notably, at least 75 member states have undertaken GBT self-assessments or formal benchmarks to declare their regulatory maturity. [3,4]

Egypt's Collaborative Method

In an attempt to create an autonomous body for better regulation of medical and pharmaceutical products in Egypt, the Egyptian Drug Authority (EDA) was established in 2019 through the merger of three organizations: the National Organization for Drug Control and Research, the National Organization for Research and Control of Biologicals and the Central Administration of Pharmaceutical Affairs. [5] Egypt's recent ML3 milestone is linked to the EDA's collaboration with the WHO regional office for the Eastern Mediterranean region [1] and partnerships with regulatory support and harmonization initiatives. The EDA also engaged industry leaders like Johnson & Johnson, Bayer International, Zeta Pharma, and RotaBioGen to promote the development and localization of pharmaceutical industries in Egypt. [6] These efforts promote collaborative models as key strategies for strengthening pharmaceutical regulations across Africa.

10.63558/betta.0003

How to Cite: Olawuyi D. et al. Collaborative Models For Strengthening Pharmaceutical Regulation in Africa: Lessons From Egypt's Milestone. *Betta Health Equity* 2025, 1(1), e4-e9. doi: 10.63558/betta.0003

Betta

www.bettaopen.com/journals/healthequity

Moreover, previous disease outbreaks have repeatedly emphasized the benefits of collaborative models and benchmarking tools for regulatory improvement. The Ebola outbreak revealed systemic regulatory and infrastructure weaknesses in low and middle-income countries (LMICs), delaying vaccine development and causing preventable losses [7, 8].

Challenges

While celebrating Egypt's progress, no African regulatory authority has achieved the ML4 status. This emphasizes the continuing challenge of improving the continent's regulatory capacity. African leaders have pledged to boost the continent's local production of vaccines, medicines, and diagnostics to 60% by 2040. [11] However, meeting this ambitious target requires overcoming several challenges, particularly the gap between market demand and local production capabilities. The annual demand for packaged medicines in Africa is approximately USD 18 billion, with 61% of these products being imported, while only about 3% of this demand is met through intra-African trade. [12] Furthermore, customs and trade regulations are major obstacles for 40% of African businesses, which is notably higher than the global average. [13]

These challenges reflect the continent's chronic shortages of financial, human, and technological resources. Moreover, inadequate political will by African governments, poor logistics and supply chain oversight, and limited enforcement capacity undermine both the supply and quality of medical products in the market. [8,10,14] Addressing these systemic issues is critical to strengthening regulatory frameworks and supporting increased local manufacturing.

Furthermore, the differences in African countries regulatory capacity hinder timely access to medical interventions, exacerbating global health inequalities. Countries with robust regulatory systems can act quickly, while those with weaker systems fall behind [14]. These disparities also exist between national and regional regulatory frameworks, discouraging inter-agency collaboration, reliance, and harmonization. As a result, resources are wasted, approval processes become prolonged and fragmented, and duplication occurs [10]. Additionally, African regulatory authorities face challenges related to ethical and safety concerns when approving products with limited data, as well as inefficient post-market surveillance systems that fail to adequately track adverse events [10].

Recommendations

As evident by the success of EDA's collaborative effort with the WHO to strengthen the local pharmaceutical

regulatory systems and improve the speed and quality of vaccine and drug approvals in Egypt, this model can be expanded to other African nations. The first major step is to evaluate and strengthen existing African NRAs with the WHO GBT. A WHO assessment of 26 medicines regulatory systems in sub-Saharan Africa revealed that 65% of these NRAs lacked autonomy to manage their funds and human resources, instead relying on other health departments. In addition, many regulatory functions were either handled by external bodies, left unperformed, or not assigned to NRAs, with pharmacovigilance being the most neglected regulatory function. [15] (Figure 1)

Addressing these challenges by granting NRAs autonomy, clearly defining their functions, and closely monitoring their performance will optimize existing systems and enhance the local manufacturing capacity of African nations.

These measures will enable African NRAs to establish regulatory frameworks aligned with global standards. We encourage NRAs to release their benchmarking reports and roadmaps publicly to improve regulatory transparency and serve as a valuable learning resource for other nations. While eight African NRAs have been successfully benchmarked by the GBT at ML3, only Zimbabwe made its report public in 2024. [16] This will motivate neighbouring nations to strengthen and benchmark their regulatory systems, creating a ripple effect of improved regulatory capacity across the continent. [3]

For countries with limited regulatory resources, we recommend that the NRAs apply for either of the two collaborative procedures designed by WHO to fast-track the regulation of medical and finished pharmaceutical products (FPPs). These include procedures to facilitate the assessment and accelerated national registration of WHO-prequalified pharmaceutical FPPs and that to accelerate registration of FPPs that have already received approval from a stringent regulatory authority. [17]

Figure 1; Performance of Regulatory functions

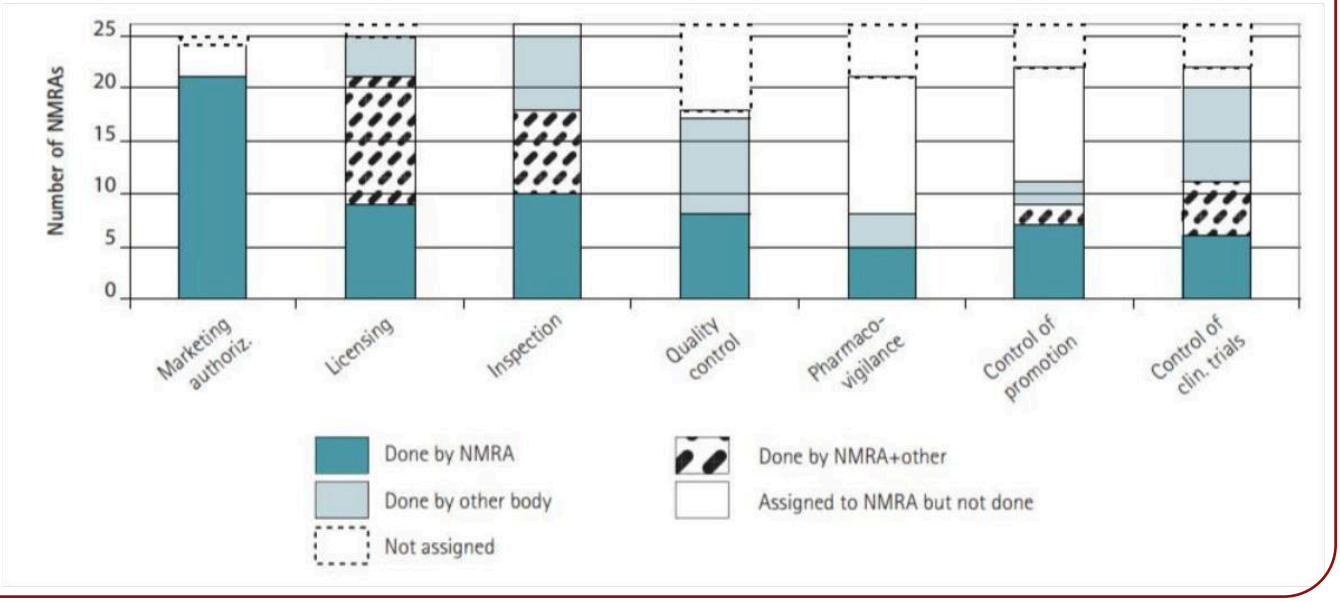

Table 1: African countries' medicines regulatory systems and their maturity levels

Country	Regulatory Authority	Maturity Level (ML)	Scope of Products	Year of Announcement	Region
Egypt	Egyptian Drug Authority (EDA)	ML3	Medicines, Vaccines (producing)	2002(Vaccines), 2024 (Medicines)	North Africa
Ghana	Food and Drugs Authority (FDA)	ML3	Medicines, Vaccines (non-producing)	2020	West Africa
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)	ML3	Medicines, Vaccines (non-producing)	2022	West Africa
Senegal	Agence Sénégalaise de Réglementation Pharmaceutique	ML3	Medicines, Vaccines (non-producing)	2024	West Africa
Rwanda	Food and Drugs Authority (Rwanda FDA)	ML3	Medicines, Vaccines (non-producing)	2024	East Africa
Tanzania	Tanzania Medicines and Medical Devices Authority (TMDA)	ML3	Medicines, Vaccines (non-producing)	2018	East Africa
South Africa	South African Health Products Regulatory Authority (SAHPRA)	ML3	Medicines, Vaccines (producing)	2022	Southern Africa
Zimbabwe	Medicines Control Authority of Zimbabwe (MCAZ)	ML3	Medicines, Vaccines (non-producing)	2018	Southern Africa

Table 1 shows the NRAs in African countries operating at Maturity Level 3 as of December 2024. Of the 55 African countries, only 8 have NRAs with good maturity levels and majority are West African countries. These NRAs are classified as having ML3; defined as having a stable, well-functioning, and integrated regulatory system. [16]

This effort by WHO is to ensure timely access to these products and the factors of capacity building, collaboration and regulatory alignments on the part of
the pharmaceutical companies, regulatory authorities and WHO are components of both procedures. [17]

African NRAs are encouraged to contribute to and collaborate with regional harmonization initiatives such as the African Medicines Regulatory Harmonization (AMRH) initiative which is part of the African Union (AU) Pharmaceutical Manufacturing Plan. By promoting policy development, implementation, and cooperation among African countries, the AMRH tackles the continent's disjointed, inefficient, and weak regulatory systems. [18,19] Similarly, the African Medicines Agency (AMA), another AU regulatory agency initiative, plays an important role in creating a supportive framework for enhancing local medical and pharmaceutical manufacturing and registration. [20]

African governments should enhance their political commitment and establish legal frameworks to facilitate the signing and ratification of the AMA Treaty. [21] While several member states have not yet taken these steps, due to issues such as a lack of understanding of the process, competing national priorities, and bottlenecks at the ministerial level, addressing these challenges will improve the effectiveness of medicine and pharmaceutical regulation. [22] By consolidating continental regulatory and technical resources, this strategy can help resolve challenges such as disparities in regulatory capacity, ethical and safety concerns, weak post-market surveillance, and inefficiencies in logistics and supply chains.

Furthermore, African NRAs should encourage and facilitate technology transfer by adopting strategies that tackle public health priorities, manage intellectual property rights, and utilize flexibilities within Trade-related Aspects of Intellectual Property Rights, along with voluntary licensing options. [23] This objective can be supported through collaborations with initiatives like the WHO's technology transfer hub in South Africa, the Biomanufacturing Workforce Training Initiative, the Health Technology Access Pool, the African Pharmaceutical Technology Foundation by the African Development Bank, the Medicines Patent Pool, and other partners focused on development and research [23].

Lastly, we recommend that customs and trade barriers be mitigated by implementing the African Continental Free Trade Area (AfCFTA) framework, streamlining processes, and harmonizing documentation. Also, ethical concerns over limited-data product approvals require adaptive licensing frameworks with stringent post-market monitoring and regional collaborative reviews. For inefficient post-market surveillance, African NRAs should invest in digital pharmacovigilance platforms, mobile reporting tools, and training programs.

By implementing these recommendations strategically, Africa can address its regulatory challenges, enhance pharmaceutical manufacturing, and improve healthcare outcomes across the continent.

Conclusion

Strengthening Africa's pharmaceutical regulatory frameworks and enhancing local manufacturing capabilities have made considerable progress, though significant challenges persist. Egypt's achievement of ML3 demonstrates how collaboration, regulatory assessments, and partnerships with international organizations can enhance regulatory oversight and speed up the approval of vaccines and medicines. The strategies employed by Egypt, along with insights from other nations that have reached ML3 status, should inform the approaches of other African National Regulatory Authorities (NRAs). However, issues such as ensuring regulatory independence, defining roles clearly, and addressing systemic inefficiencies must be addressed. To further this objective, various recommendations have been outlined. If implemented cooperatively and strategically, Africa has the potential to lead in pharmaceutical regulation and production, thereby reducing health disparities and moving closer to achieving universal health coverage.

Authors' Affiliation

1. Department of Environmental Health Sciences, University of Ibadan
2. Department of Global Health and Population, Harvard School of Public Health, Boston, Massachusetts
3. School of Nursing, Eleyele, Ibadan

Ethical Approval

Not applicable

Funding

This research received no specific grants from any funding agency in the public, commercial, or not-for-profit sectors.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Consent for Publication

All the authors have consented to publish the work in Betta Health Equity Journal

Acknowledgments

None.

Data availability statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

References

[1] WHO. Egypt's regulatory system reaches WHO maturity level 3 in medicines regulation. 2024. https://www.who.int/news/item/20-12-2024-egypt-s-regulatory-system-reaches-who-maturity-level-3-in-medicines-regulation. [Accessed 15 January 2025].

[2] WHO. WHO essential medicines & health products annual report 2017: towards access 2030. 2018. https://apps.who.int/iris/bitstream/handle/10665/272972/WHO-EMP-2018.01-eng.pdf?sequence=1&isAllowed=y. [Accessed 15 January 2025].

[3] Guzman J, O'Connell E, Kikule K, Hafner T. The WHO Global Benchmarking Tool: a game changer for strengthening national regulatory capacity. BMJ Glob Health. 2020;5(8):e003181. http://dx.doi.org/10.1136/bmjgh-2020-003181.

[4] WHO. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory system of medical products: Manual for benchmarking and formulation of institutional development plans. 2023. https://www.who.int/publications/i/item/9789240087637. [Accessed 15 January 2025].

[5] EDA. Guideline for Good Regulatory Oversight of Clinical Trials by Egyptian Drug Authority. 2022. https://www.edaegypt.gov.eg/media/4nphsrk0/guideline-for-good-regulatory-oversight-of-clinical-trials-by-egyptian-drug-authority-v2.pdf. [Accessed 15 January 2025].

[6] EDA. Egyptian Drug Authority Publications [Internet]. 2024. https://edaegypt.gov.eg/ar/. [Accessed 15 January 2025].

[7] Bell BP, Damon IK, Jernigan DB, Kenyon TA, Nichol ST, O'Connor JP, et al. Overview, control strategies, and lessons learned in the CDC response to the 2014-2016 Ebola epidemic. MMWR Suppl. 2016;65(3):4–11. http://dx.doi.org/10.15585/mmwr.su6503a2.

[8] Khadem Broojerdi A, Alfonso C, Ostad Ali Dehaghi R, Refaat M, Sillo HB. Worldwide assessment of low- and middle-income countries' regulatory preparedness to approve medical products during public health emergencies. Front Med. 2021;8:722872. http://dx.doi.org/10.3389/fmed.2021.722872.

[9] Kieny MP, Rägo L. Regulatory policy for research and development of vaccines for public health emergencies. Expert Rev Vaccines. 2016;15(9):1075–1077. https://doi.org/10.1080/14760584.2016.1188695.

[10] Adione JO. The role of regulatory agencies in public health emergencies: A critical review of global approaches and challenges. Int J Sci Res Arch. 2024;13(2):381–389. http://dx.doi.org/10.30574/ijsra.2024.13.2.2132.

[11] Africa CDC. Addressing regulatory challenges to advance local manufacturing in Africa. 2024. https://africacdc.org/news-item/addressing-regulatory-challenges-to-advance-local-manufacturing-in-africa/. [Accessed 15 January 2025].

[12] WEF. AfCFTA: A new era for global business and investment in Africa. 2023. https://www3.weforum.org/docs/WEF_Friends_of_the_Africa_Continental_Free_Trade_Area_2023.pdf. [Accessed 15 January 2025].

[13] Dong J, Mirza Z. Supporting the production of pharmaceuticals in Africa. Bull World Health Organ. 2016;94(1):71–72. http://dx.doi.org/10.2471/BLT.15.163782

[14] Saint-Raymond A, Valentin M, Nakashima N, Orphanos N, Santos G, Balkamos G, et al. Reliance is key to effective access and oversight of medical products in case of public health emergencies. Expert Rev Clin Pharmacol. 2022;15(7):805–10. http://dx.doi.org/10.1080/17512433.2022.2088503.

[15] WHO. Assessment of medicines regulatory systems in sub-Saharan African countries: An overview of findings from 26 assessment reports. 2010. https://www.afro.who.int/sites/default/files/2017-06/Assessment26African_countries.pdf. [Accessed 15 January 2025].

[16] WHO. List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4), (as benchmarked against WHO Global Benchmarking Tool (GBT). 2024. https://www.who.int/publications/m/item/list-of-nras-operating-at-ml3-and-ml4. [Accessed 15 January 2025].

[17] WHO. Collaborative procedure for accelerated registration [Internet]. In: WHO – Prequalification of Medical Products. 2023. https://extranet.who.int/prequal/medicines/collaborative-procedure-accelerated-registration. [Accessed 15 January 2025].

[18] Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo A, Kaale E. Medicines regulation in Africa: Current state and opportunities. Pharmaceut Med. 2017;31(6):383–397. http://dx.doi.org/10.1007/s40290-017-0210-x.

[19] Ncube BM, Dube A, Ward K. Establishment of the African Medicines Agency: progress, challenges and regulatory readiness. J Pharm Policy Pract. 2021;14:29. http://dx.doi.org/10.1186/s40545-020-00281-9.

[20] African Union. African Medicine Agency (AMA) Treaty [Internet]. 2020. https://au.int/sites/default/files/treaties/36892-treaty-0069_-_ama_treaty_e.pdf. [Accessed 15 January 2025].

[21] Abdulwahab AA, Okafor UG, Adesuyi DS, Miranda AV, Yusuf RO, Eliseo Lucero-Prisno D 3rd. The African Medicines Agency and Medicines Regulation: Progress, challenges, and recommendations. Health Care Sci. 2024;3(5):350–359. http://dx.doi.org/10.1002/hcs2.117.

[21] Abdulwahab AA, Okafor UG, Adesuyi DS, Miranda AV, Yusuf RO, Eliseo Lucero-Prisno D 3rd. The African Medicines Agency and Medicines Regulation: Progress, challenges, and recommendations. Health Care Sci. 2024;3(5):350–359. http://dx.doi.org/10.1002/hcs2.117.

[22] Ncube BM, Dube A, Ward K. The process of ratifying the treaty to establish the African Medicines Agency: perspectives of national regulatory agencies. Health Policy Plan. 2024;39(5):447–456. http://dx.doi.org/10.1093/heapol/czae017

[23] WHO Regional Committee for Africa, 74. Framework for strengthening local production of medicines, vaccines, and other health technologies in the WHO African Region 2025–2035: report of the Secretariat. World Health Organization. Regional Office for Africa. 2024. https://iris.who.int/handle/10665/378851. [Accessed 15 January 2025].