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Progress report on the implementation of the Regional strategy on regulation of medical products in the African Region, 2016–2025

Information Document

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Annex

Background

1. The World Health Organization (WHO) is mandated by Resolution WHA 67.20 of May 2014 to support Member States to strengthen regulatory systems and promote equitable access to quality, safe, efficacious and affordable medical products.

2. The "Regional Strategy on regulation of medical products in the African Region 2016–2025" urged Member States, with support from WHO, to improve medical products regulatory **governance**, **strengthen the capacity** of their national medicines regulatory authorities (NMRAs), **reduce the incidence of substandard and falsified** (SF) medical products, and strengthen regional **regulatory harmonization** and **convergence**.

3. Notable progress has been made in pursuance of the Strategy through intensified efforts by Member States and WHO. Meanwhile, WHO continues to assess regulatory capacities of Member States using the WHO Global Benchmarking Tool (GBT)[1] and conducts surveys on the quality of medical products.

4. This is the second and last report outlining the progress made since the adoption of the Strategy.

Progress made/action taken

Governance and implementation of regulatory functions

5. Member States have regulatory systems at varying levels of maturity based on the WHO GBT.[2] Forty-five (95.7%) and 15 (31.7%) NMRAs underwent self and WHO formal benchmarking, respectively,[3] resulting in NMRAs operating at maturity level 3 (ML3), from 2 in 2018 to 7 in 2025.

6. Overall, Member States with authorities mandated to regulate medical devices increased from 51% in 2021 to 85.0% in 2025, surpassing the 83.5% target.

7. Up to 46 (98%) Member States are able to conduct quality assessment for medical products with reduced timelines for issuing marketing authorization. Although pharmacovigilance system and individual case safety reports are reported to the WHO Collaborating Centre for International Drug Monitoring,[4] currently only 25 countries regularly perform market surveillance of all medical products.

Capacity-building of the NMRAs

8. Between 2018 and 2024, at least 673 NMRA staff from 39 countries were supported through capacity-building initiatives to effectively carry out their regulatory functions. The WHO prequalification programme facilitated the prequalification of 24 pharmaceutical products and 13 vaccines for the management of COVID-19.[5]

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1 WHO GBT represents the primary means by which the WHO objectively evaluates regulatory systems by identifying strengths and areas for improvement, and facilitates the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps.

2 Global Benchmarking Tool (GBT).

3 WHO RSS Database 4 December 2024.

4 https://who-umc.org/about-the-who-programme-for-international-drug-monitoring/member-countries/.

5 https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products.

Harmonization and convergence

9. WHO continues to provide support to the African Medicines Regulatory Harmonization initiative[6] and established the African Vaccine Regulatory Forum (AVAREF)[7]. AVAREF has reduced the turnaround time for assessing clinical trials from between 6 months and 1 year to 30 days for expedited applications and 10 to 15 days for emergency applications.

10. WHO supported the African Union Commission (AUC) in the deployment of a special envoy to engage African Heads of State and advocate for the signing of the African Medicines Agency (AMA) Treaty resulting in its establishment and entry into force after the required 15 ratifications.

11. WHO supported the expansion of medicines regulation in subregional economic communities from two subregions in 2016 to all six subregions in 2025. These are expected to serve as a foundation for the AMA. Currently, thirty (64%) Member States have signed, ratified and deposited the AMA ratification instruments with the AU commission. The WHO African Regional Office has seconded two employees to support the operationalization of AMA[8].

Combating substandard and falsified medical products by all Member States

12. At least 96% of the WHO African Region Member States are members of the Global Surveillance and Monitoring System for SF medical products. Despite SF awareness, the prevalence of SF products remains a challenge; WHO issued 36 alerts on various SF antimicrobials and cough syrup medicines circulating in the Region between 2020 and 2022[9] and supported the prequalification of 10 quality control laboratories[10] in the African Region to improve analytical services for medical products.

13. WHO supported initiatives to foster local production in the Region through enhanced collaboration. For instance, WHO supported Botswana, Ethiopia, Kenya, Rwanda, Senegal, South Africa and Uganda to drive local production initiatives and established a messenger ribonucleic acid (mRNA) vaccines technology transfer hub in Cape Town, South Africa, to capacitate low- and middle-income countries and produce mRNA vaccines.

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6 WHO supported the AUC in the deployment of a special envoy to engage African Heads of State and advocate for the signing of the AMA Treaty resulting in the establishment of the AMA after the required ratification by 15 countries was achieved. Since then, thirty (30) African Union (AU) Member States have now completed the AMA ratification processes (Algeria, Benin, Botswana, Burkina Faso, Cabo Verde, Cameroon, Chad, Côte d'Ivoire, Egypt, Ethiopia, Gabon, Ghana, Guinea, Kenya, Lesotho, Mali, Mauritius, Morocco, Namibia, Niger, Rwanda, Sahrawi Arab Democratic Republic, Senegal, Seychelles, Sierra Leone, Tunisia, Uganda, United Republic of Tanzania, Zambia and Zimbabwe).

7 AVAREF is a network of African national regulatory authorities and ethics committees that uses harmonization and reliance as pillars for capacity-building.

8 Two WHO staff took office in 2024 (one in the AUC and the second in the Liaison Office to the AU) and their deployment has resulted in enhanced and more focused support being provided to the AMA interim secretariat.

9 The WHO medicines quality surveys carried out in 2019–2020 collected 1700 samples. Out of 437 antibiotic and antimalarial samples comprehensively tested in laboratories contracted by WHO, 190 samples were found to have quality issues.

10 Ghana, Kenya (2), Nigeria, South Africa (3), Tanzania, Uganda and Zimbabwe. Aside from the Central African subregion, every other regional economic community has at least one prequalified laboratory to facilitate access to laboratory analytical services. Kenya and South Africa have two and three pre-qualified laboratories, respectively.

Issues and challenges

14. Varying maturity of national regulatory authorities; most of them (40/47 see Annex 1) lack full functionality.

15. Inadequate funding in Member States for regulatory system strengthening activities.

16. Prevalence of SF medical products.

17. Irregular regional medical product assessments due to dependence on donor funding.

18. Limited capacity to regulate innovative medical products.

Next steps

Member States should:

19. invest in the medical products' regulatory ecosystem[11] and intensify harmonization efforts and regulatory reliance;

20. intensify market surveillance and reporting to curtail SF medical products.

WHO should:

21. continue to support Members States to strengthen their medical products regulatory ecosystem and finalize the continental plan for SF medical products;

22. continue to support the operationalization of the AMA and ensure its establishment with a foundation to become an ML3/ML4 regulatory system in the near future;

23. develop a new Regional Strategy on Regulation of Medical Products in the African Region for the period 2026–2035.

24. The Seventy-fifth Regional Committee is invited to take note of the progress report.

[11] This should be achieved through improving regulatory infrastructure, training, attracting and retaining regulatory personnel, enhancing pharmacovigilance and the market surveillance system, implementation of national action plans and multi-stakeholder collaboration, and supporting the operationalization of the AMA to strengthening the continental regulatory ecosystem.

Annex: WHO GBT maturity levels of WHO African Region Member States' NMRAs at the end of 2025

Maturity level	No. of NMRAs
Maturity level 3 (ML3)[12]	7[13]
Maturity level 2 (ML2)[14]	1[15]
Maturity level 1 (ML1)[16]	37
No data	2
Members States' totals	47

[12] ML3 means a stable, well-functioning and integrated regulatory system.
[13] Ghana, Nigeria, Rwanda, Senegal, South Africa, United Republic of Tanzania and Zimbabwe.
[14] ML2 means an evolving national regulatory system that partially performs essential regulatory functions.
[15] Ethiopia.
[16] ML1 means some elements of a regulatory system exist.