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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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BACKGROUND

1. Considering the urgent need to improve regulatory efficiency and curtail substandard and falsified (SF) medical products, the Sixty-sixth session of the World Health Organization (WHO) Regional Committee for Africa adopted the Regional strategy on regulation of medical products, 2016-2025 (resolution AFR/RC66/R2). The strategy pursues the following objectives: improve governance of regulatory systems for medical products in Member States; strengthen the capacity of National Medicines Regulatory Authorities (NMRAs) to perform comprehensive regulatory functions; reduce the incidence of SF medical products; and strengthen regional regulatory harmonization and convergence.
2. From 2016 to 2020 WHO assessed regulatory capacity in Member States of the African Region using the Global Benchmarking Tool¹ (GBT) and conducted surveys on the quality of medical products. The implementation of the Regional strategy on regulation of medical products has contributed to better health outcomes by ensuring availability of quality medical products, particularly in primary health care facilities. The progress made has contributed to the efforts of Member States in addressing COVID-19 challenges related to medical product regulation.
3. This is the first report outlining the progress made since the adoption of the strategy.

PROGRESS MADE/ACTION TAKEN

4. All Member States have regulatory systems in place, with different capacities to fulfil regulatory functions. The number of autonomous or semi-autonomous regulatory bodies increased from 16%² in 2015 to 51%³ in 2020, which marks substantial progress in this area. Member States continue to transition to greater regulatory autonomy for better sustainability, accountability of institutions and evidence-based decision-making.
5. The average timeline for issuing marketing authorization across the Region has been substantially shortened to one year compared to two years in 2015. The African Vaccine Regulatory Forum (AVAREF) has also substantially reduced the time for assessing clinical trial applications to 30 days. Member States pooled expertise and conducted reviews of registration dossiers and clinical trial applications for therapeutics and vaccines.
6. The introduction of vaccines in the context of Ebola epidemics and the COVID-19 pandemic was largely a result of expedited processes, regulatory harmonization, and technical support to Member States. The only malaria vaccine in use was backed up by regulatory oversight and approvals in Ghana, Kenya, and Malawi.

¹ The Global Benchmarking Tool represents the primary means by which the World Health Organization objectively evaluates regulatory systems (https://www.who.int/medicines/regulation/benchmarking_tool/en/, accessed on 1 March 2021)

² Botswana, Eritrea, Ethiopia, Gambia, Ghana, Kenya, Liberia, Malawi, Namibia, Nigeria, Sierra Leone, South Africa, South Sudan, United Republic of Tanzania, Uganda, Zambia.

³ Algeria, Benin, Botswana, Burkina Faso, Comoros, Côte d'Ivoire, Democratic Republic of the Congo, Eritrea, Ethiopia, Gambia, Ghana, Kenya, Liberia, Madagascar, Malawi, Namibia, Nigeria, Rwanda, Sierra Leone, South Africa, South Sudan, United Republic of Tanzania, Uganda, Zambia.

7. Member States with authorities mandated to regulate medical devices increased from 32% to 51%,⁴ which is in line with the targeted participation of 83.5%. Member States have joined the Programme for International Drug Monitoring, strengthened the functionality of their national pharmacovigilance frameworks and achieved a two-fold increase of individual case safety⁵ reporting for the WHO African Region. This marks substantial progress in pharmacovigilance.

8. The Global Monitoring and Surveillance System for SF medical products includes 96% of Member States from the WHO African Region. Despite increased awareness of this threat, the incidence of SF medical products remains high. In 2020 WHO issued alerts on falsified Chloroquine and Hydroxychloroquine circulating in Central and West Africa. The WHO medicines quality surveys carried out in 2019-2020 collected 1700 samples, and out of 437 antibiotic and antimalarial samples comprehensively tested in laboratories contracted by WHO, 190 samples were found to have quality issues. Market surveillance and counteracting SF medical products require further strengthening.

9. All regional economic communities (RECs) are implementing medicines regulatory harmonization programmes. This progress was due to the support provided by WHO, the African Union Development Agency-NEPAD (AUDA-NEPAD), and the secretariats of the regional economic communities.⁶ The African Blood Regulators Forum was established in 2019 to strengthen blood regulation, while the African Advisory Committee on Vaccine Safety was established in 2020 to provide advice on the safety and use of vaccines. The treaty for the establishment of the African Medicines Agency (AMA) was approved by the African Union (AU) Heads of State and Government Summit in February 2019. Twenty African Union Member States⁷ have already signed the treaty and 14⁸ have ratified it.

10. The Region has witnessed substantial progress in improving medical product regulation. However, the following challenges persist and need to be addressed: insufficient funding and investment in regulatory capacity, infrastructure, and functionality; retaining qualified and experienced staff; the heavy burden of SF medical products.

NEXT STEPS

11. Member States should:

- (a) Increase investment in regulatory systems including providing adequate training to regulatory personnel and improving regulatory infrastructure;
- (b) Urgently enhance market surveillance to curtail SF medical products;

⁴ Angola, Benin, Botswana, Burkina Faso, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Eritrea, Ethiopia, Gabon, the Gambia, Ghana, Guinea, Kenya, Mauritania, Mozambique, Namibia, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, United Republic of Tanzania and Uganda.

⁵ Individual Case Safety Reports are a pillar of the International Drug Monitoring Programme launched in 1968 to improve the safety of medicines. The reporting rate of the Member States in the WHO African Region increased from 15 636 reports in 2016 to 38 620 in 2020.

⁶ Regional economic communities include Communauté Économique et Monétaire de l'Afrique Centrale, East African Community, Economic Community of West African States, Intergovernmental Authority on Development, Southern African Development Community.

⁷ Algeria, Benin, Burundi, Cameroon, Chad, Congo, Gabon, Ghana, Guinea, Madagascar, Mali, Morocco, Niger, Rwanda, Sahrawi Arab Democratic Republic, Senegal, Seychelles, Sierra Leone, Tunisia and Zimbabwe.

⁸ Algeria, Benin, Burkina Faso, Cameroon, Gabon, Ghana, Guinea, Mali, Morocco, Namibia, Niger, Rwanda, Seychelles and Sierra Leone.

- (c) Implement emergency expedited processes for regulatory decisions, intensify joint efforts, reliance and cross-border collaboration and accelerate the ratification of the AMA treaty.
12. WHO and partners should:
- (a) Coordinate support to Member States for regulatory systems strengthening through coalitions of interested parties to promote alignment with national policies and plans;
 - (b) Facilitate information sharing and documentation of lessons learnt, and enhance the efficiency of measures put in place by Member States for preventing, detecting and responding to the incidence SF medical products.
13. WHO should continue to assess Member States' capacity against the WHO GBT and support implementation of institutional development plans.⁹
14. The Regional Committee is invited to take note of the progress report and endorse the proposed next steps.

⁹ An institutional development plan is a set of recommendations based on the outcome of the regulatory system benchmarking. It aims at increasing functionality and sustainability of medical product regulation by strengthening the regulatory institutions underpinning it.

ANNEX: Maturity levels of regulatory systems in the WHO African Region

Level of maturity	Member States
<i>Formally benchmarking in 2016–2020</i>	
Maturity level 3	2
Maturity level 2	0
Maturity level 1	6*
<i>Self-benchmarking in 2016–2020</i>	
Maturity level 3	0
Maturity level 2	1
Maturity level 1	34
No data	4

* includes Zanzibar Food and Drugs Authority