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RESOLUTION

REGIONAL STRATEGY ON REGULATION OF MEDICAL PRODUCTS IN THE AFRICAN REGION, 2016–2025 (Document AFR/RC66/13)

The Sixty-sixth session of the Regional Committee for Africa,

Having considered Document AFR/RC66/13 on "Regional strategy on regulation of medical products in the African Region, 2016–2025";

Welcoming the efforts of the Regional Director, and recognizing the pivotal role that WHO plays in supporting countries in strengthening their regulatory capacity of medical products, and in promoting equitable access to quality, safe, efficacious and affordable medical products;

Recalling Resolutions WHA65.19, WHA67.20, WHA67.22, WHA67.25 all of which encompass aspects of the need to prevent and control substandard/spurious/falsely-labelled/ falsified/counterfeit (SSFFC) medical products as well as antimicrobial resistance, strengthen regulatory systems, promote the quality, safety, efficaciousness and affordability of medicines, including blood products;

Recalling Documents AFR/RC63/7 and AFR/RC56/11 on strengthening the capacity for regulation of medical products in the African Region and on Medicines Regulatory Authorities: Current Status and the way forward, respectively, that emphasize the need to establish a strong and fully functional regulatory system for medical products;

Recognizing the significant efforts of global health initiatives, including WHO's prequalification programme and networks of regulators to enhance access to quality medical products and regulatory convergence at the continental level, all of which contribute to Universal Health Coverage and Sustainable Development Goals;

Noting with concern that the regulatory systems in many countries of the African Region remain weak delaying access to quality medical products and resulting in the proliferation of SSFFC medical products;

Further noting the need to establish functional pharmacovigilance systems in all countries with the involvement of all relevant stakeholders;

Noting the protracted timelines for Marketing Authorization of essential medical products such as vaccines, paediatric medicines, life-saving commodities, medicines for managing noncommunicable diseases and reproductive health, as well as snakebite antivenoms and biotherapeutic and similar biotherapeutic products;

Deeply concerned about the need to strengthen the capacity of national medicines regulatory authorities (NMRAs) to review clinical trials applications and marketing authorization for medical products that meet national criteria and WHO norms and standards of quality, safety and efficacy;

Recognizing the urgent need to expand the scope of NMRAs' responsibilities to cover medical devices, blood, food and related products, biotherapeutics and biosimilar products;

Welcoming the African Medicines Regulatory Harmonization (AMRH) initiative in supporting regional economic communities and the decision of the First African Ministers of Health meeting; jointly convened by the AUC and WHO, that endorsed milestones for the establishment of the African Medicines Agency (AUC/WHO/2014/Doc.2);

Further welcoming the African Vaccines Regulatory Forum (AVAREF) that has been expanded to medicines as a platform for building regulatory capacity through harmonization of standards and joint evaluations and authorizations of clinical trials;

1. ENDORSES Document AFR/RC66/13 entitled Regional strategy on regulation of medical products in the African Region, 2016–2025.

2. URGES Member States:

(a) to set the agenda for strengthening regulatory capacity for medical products in countries, including assessment and ensuring government leadership in the development and implementation of policies, strategies and plans;

(b) to ensure availability of adequate human, financial and technical resources for the NMRAs' operations and to establish procedures for the collection and use of financial resources generated by the NMRAs;

(c) to participate in regulatory harmonization and convergence initiatives for sharing best practices and pooling regulatory expertise;

(d) to create mechanisms for tracking progress and generating evidence on regulation of medical products in the African Region;

(e) to establish a legal framework and systems for enforcing regulatory systems;

(f) to expand the mandates of NMRA regulatory responsibility to cover all products, including vaccines, medical devices, blood, food and related products, non-vaccine biologicals and diagnostics;

(g) to establish programmes for continuing education and capacity strengthening of regulators and stakeholders involved in the enforcement of regulatory decisions;

(h) to support NMRAs to monitor alerts on SSFFC medical products, to improve risk management for informed decision-making to strengthen market surveillance and protect public health in countries;

(i) to strengthen quality control laboratories through provision of funding and support certification of laboratories to international standards;

(j) to implement framework for linkages and alignment for AVAREF and the AMRH initiative;

(k) to implement a strategy for clinical trials application reviews and approval timelines;

(l) to mobilize adequate resources for establishment of the African Medicines Agency; and

(m) to develop, review and update their medicine legislations based on the African Union Model Law on medical products regulation.

3. REQUESTS the Regional Director:

(a) to support countries to adopt and adapt evidence-based policies, WHO norms and guidelines, and align their regulatory practices with international recognized standards;

(b) to support initiatives and networks for harmonization and convergence of regulatory practices including establishment of the African Medicines Agency;

(c) to carry out comprehensive external assessment of NMRAs using the WHO assessment tool, at least once every four years and implement mitigation plans to address gaps;

(d) to support expansion of the AMRH initiative and AVAREF to cover all countries in the region;

(e) to create mechanisms to track progress and generate evidence on regulation of medical products at regional level;

(f) to provide training through the WHO Global Learning Opportunities, WHO Collaborating Centres and Regional Centres of Regulatory Excellence (RCOREs);

(g) to support countries to establish their pharmacovigilance systems;

(h) to support countries to adopt tools for monitoring progress on regulation of medical products; and

(i) to support countries to develop regulatory capacity for food and related products.