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New African-led initiative confronts substandard and falsified medicines across the continent

Regulatory experts, partners and stakeholders develop action-plan for the new African Medicines Quality Forum (AMQF) to protect Africans from poor-quality medicines.

Regulatory leaders, policymakers, executives and experts from more than 18 countries within and beyond Africa developed a work-plan for the new African Medicines Quality Forum (AMQF) at a four-day meeting in Dar Es Salaam, held February 12-15, 2018. The plan outlines how AMQF will improve coordination across African regulatory authorities and strengthen their capacity to address challenges posed by poor-quality medicines and help ensure access to safe, effective, quality medicines. According to the World Health Organization (WHO) data, Africa has the highest number of reported cases of substandard and falsified products (42 percent).

Faustine Ndugulile, the deputy minister for Health, Community Development, Gender and Elderly and Children of Tanzania, welcomed attendees and spoke of the challenges of poor-quality medicines and the need for strategic action. "Substandard and fake medical products are a serious challenge in many parts of Africa," he noted. "This requires strategic and apt approaches if we are to protect people from such drugs." Margareth Ndomondo-Sigonda, head of health programmes at the African Union's (AU) New Partnership for Africa's Development (NEPAD) Agency, agreed that access to quality medicines is critical to achieving positive health outcomes. "Poor-quality medicines undermine confidence in our health systems, exacerbate drug resistance, and endanger patients' live," she said. NEPAD hosted the meeting with USP and the Tanzania Food and Drug Authority (TFDA), in collaboration with WHO and the European Directorate for the Quality of Medicines (EDQM).

AMQF's work will include strengthening and harmonising regional quality control capacity, post-marketing surveillance, quality control laboratory proficiency testing and certification, bioequivalence studies for generic medicines, and advocacy to protect African patients from substandard and falsified medicines.

The initiative is transitioning from the African Network of Official Medicines Control Laboratories (NOMCoL-SSA), which was established in 2009 by Promoting the Quality of Medicines, a program funded by the US Agency for International Development (USAID) and implemented by USP. An announcement was made in March 2017 that NOMCoL-SSA would move to African leadership as AMQF, through the African Medicines Regulatory Harmonisation (AMRH) initiative.

USP will continue to support AMQF during its first year, said Emily Kaine, M.D., USP senior vice president of global health. “USP is proud to collaborate with NEPAD, WHO, Tanzania FDA and others toward our common objective of increasing patient access to safe, quality medicines by advancing smart, risk-based regulatory practices and harmonisation.” The WHO also affirmed their support. “We will work with NEPAD and we will work with our partner, USP,” said Mr. Rutendo Kuwana, from WHO’s technical assistance and laboratory services. “Our role [in AMQF] is to really support the activities of NEPAD and the African Union,” he added.

Ms. Agnes S. Kijo, TFDA Ag. director general noted the importance of “supporting efforts to strengthen harmonisation in Africa by sharing ideas, innovations, and jointly finding solutions for the greatest impact in our regulatory systems to ensure only safe and quality medicines are available in the market.”

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