

## \*3rd Biennial Scientific Conference on Medical Products Regulation in Africa\*

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Significant strides have been made over the years to enhance and modernize the regulation of pharmaceutical manufacturing and product quality across the world. However, the drug registration system in Africa remains complex and varied, and separate national review processes currently in place impact patients' access to medicines in Africa. Harmonisation of the processes for medicine registration is long overdue.

Under the African Medicines Regulatory Harmonization (AMRH) initiative, there are some ongoing pilot projects that are aimed at improving national registration processes, and these will go a long way towards meeting the goal of regulatory harmonization and convergence.

The proposed African Medicines Agency is at the centre of the *3rd Biennial Scientific Conference on Medical Products Regulation in Africa* taking place at Alisa Hotel in Accra from 27-28<sup>th</sup> November.

Organised by international stakeholders with support from the West African Health Organisation, (WAHO), NEPAD, the Government of Ghana, the Federation of African Pharmaceutical Manufacturers Associations (FAPMA), and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the meeting brings together the key stakeholders including regulators, policymakers, academia, the scientific community, private sector and civil society from across Africa.

The theme for the conference is "Sustaining the Momentum for Regulatory Harmonisation in Africa". This theme will enable participants to contribute towards the future of regulation and harmonisation in Africa, which affects both industrial and regulatory aspects, as well as the aspirations of civil society and its wish to benefit from best practice, and best medicine.

Currently, many countries deal with regulatory issues independently, which means that the manufacturers have to make a formal registration in every country, and each country's regulatory agency will assess whether the drug is right for its market. These assessments may include visits to the manufacturing country to determine whether medicines are produced using good manufacturing systems and processes. What is needed is a single agency, which can do all this work once (rather than 50+ times) and then allow applicants and individual countries to benefit from it.

The conference will provide a platform for stakeholders to brainstorm on the role of ethical and regulatory approval of clinical trials of new medicines. With many neglected tropical diseases, mechanisms need to be found to encourage greater research and ethical clinical testing to find solutions for these diseases.

Delegates are expected from across the continent, as well as from industry and international regulatory agencies.

The organizing committee for the Conference is comprised of the <u>NEPAD Agency</u>, <u>the African Union Commission (AUC)</u>, <u>the World Health Organization (WHO)</u>, National Medicines Regulatory Authorities (NMRAs), Regional Economic Communities (RECs) and Regional Health Organizations (RHOs), <u>the IFPMA</u>, and <u>FAPMA</u>.

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