

## **African Union Ministers of Health adopt treaty for the establishment of the African Medicines Agency**

*Treaty to be submitted to the Specialised Technical Committee on Justice and Legal Affairs later on this year*



**Geneva–20 May 2018:** African Ministers of Health, Saturday meeting as a Working Group of the Specialised Technical Committee on Health, Population and Drug Control unanimously adopted the Treaty for the establishment of the African Medicines Agency (AMA).

AMA seeks to ensure the coordination and strengthening of continental initiatives to harmonise medical products regulation, provide guidance and technical support to improve access to quality, safe and efficacious medical products and health technologies on the continent. AMA will work within the existing continental architecture of Regional Economic communities (RECs) and Regional Health Organizations (RHOs) to support AU Member States.

“The African Medicine Agency is a key element of the architecture for harmonisation of continental, institutional, scientific and regulatory resources to improve access to safe, efficacious and quality medicines” said Ambassador Ajay Kumar Bramdeo, the Permanent Observer of the African Union to the United Nations Office at Geneva.

The African Medicines Agency will promote the adoption and harmonization of medical products regulatory policies and standards, and scientific guidelines, and coordinate existing regulatory harmonization efforts in the Regional Economic Communities and

Regional Health Organisations. It will further provide regulatory guidance, scientific opinions and a common framework for regulatory actions on medical products, as well as priority and emerging issues and pandemics.

The Specialised Technical Agency will also provide regulatory guidance and provide technical assistance on regulatory matters to countries that lack the capacity and resources to do so. It will further provide guidance on regulation of clinical trials on medical products and health technologies as well as traditional medical products.

“It is increasingly becoming evident that no single country has enough resources and capability to efficiently and effectively regulate the whole supply chain system alone in this globalised world. AMA thus occupies a distinct position to leverage various regulatory assets and capabilities to improve access to safe, effective, good quality and affordable essential medicines and health technologies” said Gugu N. Mahlangu, Director-General at Medicines Control Authority of Zimbabwe who also Chairs the AMA Taskforce.

The new institution will also lead the establishment and strengthening of Regional Centres of Regulatory Excellency in order to develop the capacity of medical products regulatory professionals. Other key mandates will include the promotion of international cooperation and partnerships for the mobilization of financial and technical resources. The agency will promote and advocate for the use of the AU Model Law on Medical Products Regulation in Member States and RECs to facilitate regulatory and legal reforms at continental, regional and national levels.

Through AMA systems to monitor, evaluate and assess the comprehensiveness of national medical products regulatory systems will be further enhanced to ensure efficiency and effectiveness. The Agency will play a lead role in mobilising regulatory expertise across the continent and beyond to provide scientific opinions in consultation with affected Member State National Medical Regulatory Agencies in the event of a public health emergency on the continent with cross border or regional implications where new medical products are to be deployed for investigation and clinical trials.

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