IFPMA-IAPO Webinar: The African Medicines Agency: An important step towards increasing timely availability and access to medicinal products for patients in Africa

On December 8, 2020 the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the International Alliance of Patient Organisations (IAPO) organised a webinar that brought together regulators, patients and industry representatives as well as officials from Food and Drugs Authority of Ghana, the African Union Development Agency–New Partnership for Africa's Development (AUDA-NEPAD) and the World Health Organization (WHO) to discuss the future of the African Medicines Agency (AMA).

Background

The Treaty establishing the African Medicines Agency (AMA) was endorsed by the African Heads of States in February 2019. For AMA to come into existence, a minimum of 15 African Member States are needed to ratify the AMA Treaty. By December 2020, 18 countries have signed the Treaty however, only 6 (including Mali, Burkina Faso, Rwanda, Guinea, Seychelles, and Ghana) have ratified the Treaty. The key to optimising sustainability in the supply of medicinal and healthcare products for diseases disproportionately affecting Africa includes a fully established continental agency. COVID-19 has thrown a spotlight on the urgency of signing and ratifying the Treaty to enable a harmonized approach of regulation of medicinal and healthcare products, and to help avoid supply chain disruptions.

EVENT HIGHLIGHTS

The event was moderated by **Catherine Fiankan - Bokonga, Senior UN Correspondent** who introduced the session with the AUDA-NEPAD Video on AMA: 'Everyone has a right to effective healthcare and a well-functioning healthcare system.'

Discussing the possible reasons for the delay of Treaty ratification, **Paul Tanui, Senior Programme Officer, AUDA-NEPAD** explained the importance of effective communication to address the perceived "*lack of political will*" due to lack of understanding of how the AMA will work in practice and operate on the ground, within the sovereignty of national decision-making. A Presidential decree is usually enough to get the Treaty signed but most countries with a dual system require Parliamentary approval which can add to the delay of signing and ratification. In addition, during C19 pandemic several parliaments meetings were cancelled, reducing drastically the opportunities for AMA advocacy and slowing down the ratification process.. One of the unintended advantages of the pandemic is that it will further deepen the understanding of the importance of strong regulatory systems to help mitigate supply chain disruptions as well as handling public health emergencies effectively.

Most regulatory agencies are struggling in terms of shortage of expertise and financial and technical resources. AMA will bring value to these countries in regulating some of the complex molecules and where the regulatory agency does not have the legal framework or capacity to evaluate the dossier. For instance, medical diagnostics and in-vitro diagnostics for COVID-19 posed various challenges. AMA will help entrench and institutionalise the regulatory harmonisation.

Mimi Darko, Chief Executive Officer, Food and Drugs Authority, Ghana shared her views on how Ghana paved the way for the Treaty being signed and ratified. The whole process involved different departments including legal, fiscal and governmental. The stakeholders included, Parliamentary Select Committee, Ministries of Health and Foreign Affairs, Ministry of Finance and the Office of the Attorney General and the regulators. Nominating a dedicated lead person at the Ministry of Health to work closely with the regulator and Ministry of Foreign Affairs helped to accelerate the ratification process. There was a strong political will, underpinned by teamwork and collaboration driving the signing and ratification.

AMA builds on strengthening regulatory systems that already exist, for example during the pandemic, African regulators and ethics committees combined their expertise to conduct joint reviews of clinical trials under the umbrella of the Africa Vaccines Regulatory Forum.

Access to a common database and smart safety surveillance systems would have been useful in the context of roll out of COVID-19 vaccines, as would the oversight, preparedness, and logistics of the cold chain supply of the COVID-19 vaccines and even the local manufacture of medicinal products and personal protection

equipment. AMA is expected to streamline all these elements.

Karim Bendhaou, Head of Africa Affairs, Merck and IFPMA Chair, Africa Engagement Committee explained alignment of regulatory systems strengthening and harmonization efforts is key for optimizing pharmaceutical markets and sustainability in the supply of medical products and technologies for diseases disproportionately affecting Africa.

AMA will help overcome the current regulatory fragmentation and complexity, which arise from convoluted and duplicative requirements imposed on drug manufacturers by each National Regulatory Agency before granting initial market authorization or renewal.

Moreover, COVID-19 has accelerated trends such as 'digitalization' and 'regional cooperation' which are creating new opportunities for NRAs to accelerate the implementation of efficient regulatory policies and practices. In addition to regulatory harmonization, two digital innovations—serialization, which is the assignment of unique, traceable numbers to individual items, and mobile technology-based product verification—hold promise in fighting the scourge of falsified medicinal products and devices.

Hiiti Sillo, Team Lead, Regulatory Systems Strengthening Team, WHO said WHO had been involved in the process for setting up the AMA building on the African Medicines Regulatory Harmonization (AMRH) initiative which is aimed at strengthening local regulatory agencies promoting timely approval and access to quality assured medicinal products.

AMA will enhance the efficiency in timely approval of medicinal products for quality and effectiveness by pulling together limited resources in each country to support joint assessments of complex products and joint inspections. In addition, it will provide a continental response in combating falsified and substandard medicinal products through information sharing and also coordinate capacity building.

AMA will also encourage inward investment to produce quality assured medicinal products and vaccines in Africa.

The WHO Director-General fully backs this initiative. Following discussions with the African Union Commission, the WHO's Director General has written to 23 WHO country representatives and the Ministers of Health to encourage them to ratify the Treaty and shared a Q&A to help address any issues raised about the plans for the AMA.

Ellos Lodzeni, Board Member of IAPO and Patient advocate from Malawi, explained the benefits for patients of a 'one stop shop' like AMA, to ensure quality medicinal products to be available in an expeditious way.

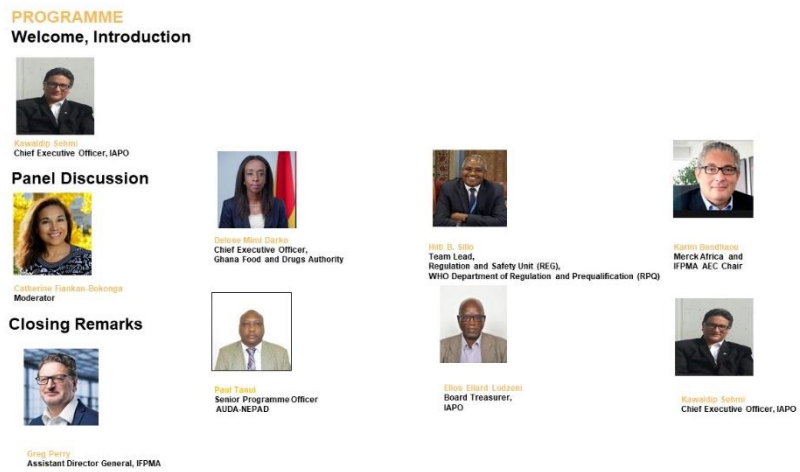
He said that more simplified information to advocate for AMA is needed and called for AMA to include a patient-centric governance structure.

Kawaldip Sehmi, CEO of IAPO said that patients are ready to convene an AMA Treaty Alliance going forward, inspired by the model of the World Health Organization (WHO) Framework Convention on Tobacco Control.

He stressed that AMA would pose no threat to sovereignty and would indirectly help boost local R&D and manufacturing.

Drawing a parallel with the European Medicines Agency, he highlighted the role of patients in the regulatory field and called for "Patients to be co-creators" of the African Medicines Agency.

Greg Perry, Assistant Director-General, IFPMA concluded the session by expressing Industry's commitment to the establishment of AMA to deliver timely access of quality safe and effective medicinal products to patients on the continent.



The event was attended by 121 participants from patient, civil society and philanthropic organizations, as well as regulatory agencies, non-for-profit research institutions, academia, the industry and the media.

The recording of the Webinar can be found on the website of the IFPMA and the Geneva Health Forum.

MEDIA COVERAGE

Pink Sheet (Pharma Intelligence) African Countries Urged To Back New Medicines Agency
Africa Science News The rising level of fake medicine worries Africa
The East African Access, funding stand in Africa's path to getting Covid-19 vaccine