The African Medicines Agency: Vision and Strategy for the African Continent

The COVID-19 pandemic has highlighted the importance of international cooperation. Health challenges and crises have no borders. Promoting the consultation, development and implementation of a common strategy among African countries, the African Medicines Agency will provide an essential technical support in the prevention and the fight against emerging diseases.

Moreover, it represents, for many countries, the promise of the development of local production, and the development, across the continent, of centers of excellence for research, the strengthening and security of supply chains, for the maintenance of a healthy environment and the fight against falsified medicines.

While the functions and status of the Agency are now clearly defined, a common vision and strategy remain to be built that will give it its impetus and enable it to outline the first lines of work.

It is in this framework, and at the initiative of the Special Envoy of the African Union for the African Medicines Agency, Mr. Michel Sidibé, that IFPMA, LEEM and IAPO **organized on 22 June 2021** a roundtable bringing together African Ministers of Health and high-level representatives of various stakeholders, namely international organizations, patient associations, and the pharmaceutical industry.

Opening the meeting, **Mr. Philippe Lamoureux, Managing Director of Leem**, mentioned that the African Medicines Agency (AMA) will be key to accelerating access to medicines and vaccines on the continent to people who need them throughout the African continent. This will be done through speedy approval and using the principle of regulatory reliance. **Mr. Greg Perry, Assistant Director General, IFPMA**, reiterated that for the implementation of the AMA, it will be vital to have a clear vision for the future. In this endeavour, effective financing and dialogue with all stakeholders will be vital. **Mr. Kawaldip Sehmi, Chief Executive Officer, IAPO**, announced the launch of the **African Medicines Agency Treaty Alliance** (AMATA), a multi-stakeholder alliance set up to advocate for the ratification and implementation of the AMA Treaty and for meaningful engagement with patients and other relevant parties, in all aspects of the Agency framework.

Kicking off the Ministerial panel, **Mr Michel Sidibe, Special Envoy of the African Union,** said that we are at a critical moment to establish the African Medicines Agency. The COVID-19 crisis is not only a public health crisis, but also a human security crisis. While incredible efforts have been undertaken to develop safe and effective vaccines, only a fraction of vaccines have been administered on the African continent. This brings forth the need for the AMA to provide a system to encourage research excellence and local production of medicines.

Dr. Margareth Ndomondo Sigonda, **AMRH Coordinator, AUDA NEPAD**, explained that the African Medicines Agency has its roots in the African Medicines Regulatory

Harmonization (AMRH) initiative, which was started as a mechanism to address regulatory challenges on the continent. Working with different partners, including the African Union Commission, the Bill and Melinda Gates Foundation, the AMRH has been able to deliver positive results in helping countries harmonize regulatory standards, starting with the registration of medicines and slowly expanding the scope from generic medicines to new chemical entities to vaccines. The scope was also expanded in terms of functions – such as safety monitoring, clinical trials. The positive results achieved by the AMRH can be shown through:

- the reduction of timelines for granting marketing authorizations
- the creation of robust legal frameworks at national level, through the AU model law for medical production
- the creation of 11 regional centres of regulatory excellence to sustain capacity-building.

It is important to build on the current momentum gained with the ratification of the AMA Treaty. The Treaty was adopted in February 2019 by the AU Assembly and there are currently 9 ratifications, inching closer to the 15 ratifications needed. Preparations for the establishment of the AMA therefore need to be started and there are a few critical elements:

- **The first critical element is to ensure a smooth transition from the AMRH to the AMA.** There are good governance structures put in place, including steering committees, political committees that have provided guidance to Member States including during the COVID-19 pandemic. Guidance has been issued to all Member States, so they are able to approve COVID-19 vaccines faster.
- **The second is to ensure the financial stability of the AMA**. The AMRH is currently funded by donor countries. Luckily, the Treaty provides for this aspect, with contribution from Member States, industry and through grants.
- **The third is to resolve the human resource capacity.** There is a robust team of experts in place, but expertise needs to also be mapped at national, regional level.
- **Fourth**, **there is a need to ensure that there is a proper regulatory infrastructure to deal with, for instance, self-monitoring of medical products**.

Dr. Lotfi Benbahmed, **Minister of Pharmaceutical Industry, Algeria**, drew attention to how Algeria has been able to foster a local pharmaceutical market. At present, 76% products are made locally, a movement that has been achieved in 12 years. This has been achieved through three main factors:

- The implementation of universal health coverage and broad access to medicines
- The establishment of a dedicated Ministry to the pharmaceutical industry, which is a clear sign that health is an investment – not just a cost, but also a growth factor for the country.

According to the Minister, pharmaceutical products are one of the most regulated products in the world. A coordinated approach to regulatory harmonization is therefore absolutely needed. This would also allow the creation of excellence poles. The Minister proposed that the harmonization of requirements for the most used

medicines would allow to address a significant number of diseases that have a high burden on health systems. The Minister echoed remarks about the need to find the financial means for the establishment of the Agency.

Dr. Jean-Jacques Mbungani Mbanda, **Minister of Health, Hygiene and Prevention, Democratic Republic of Congo,** said that high morbidity and mortality are due to preventable diseases, due to differences in health systems, insufficient resources and low availability of good quality drugs. It is important for the African Medicines Agency (AMA) to take off, as it will have an impact – during our lifetime- on the regulation of pharmaceuticals on the continent.

The AMA will enable a continental regulatory voice, which will benefit patients, regulators and health systems. This is an essential component in improving health systems. In fact, it will coordinate and strengthen initiatives to harmonize pharmaceuticals on the continent and promote access to good quality medicines on the continent. It will be the catalyst for enhanced regulatory oversight, which will help to fight against counterfeiting. The DRC estimates that over 60% of pharmaceutical products on the market are counterfeit medicines.

While the DRC has not yet signed the treaty establishing the AMA, it is a priority for the government.

Dr. Hala Zayed, **Minister of Health and Population, Egypt**, emphasized her country's financial and technical support to in establishing the AMA, mentioning that Egypt will soon also sign the Treaty. Dr. Zayed highlighted that Egypt will channel lessons learnt from successful initiatives in this regard, such as the eradication of hepatitis C, early screening of for breast cancer, or the introduction of a new universal health insurance law.

Egypt has also been one of the largest supporters of the establishment of the AMA. With the challenges, and the gaps identified during the COVID-19 pandemic, the operationalization of AMA has become more urgent than ever before, securing access to vaccines, treatments, diagnostics and other health technologies. Under the umbrella of AMA, Egypt would like to have a framework that would regulate the technology transfer and share of experiences in medical production, as well as applying good manufacturing practices. The development of stronger regulatory systems across the continent will enable efforts to deal with counterfeit, and low-quality medical products.

The delay in delivery and the rolling out of COVID-19 vaccines, especially in Africa, urges to act rapidly towards realizing local production capabilities and expanding manufacturing capacities, creating support capacities for accreditation process of local factories, not only in vaccines, but also in raw materials API.

Dr. Arlindo Nascimento do Rosário, Minister of Health, Cabo Verde, mentioned that his country has great expectations on the development of the African Medicines Agency. For small states, like Cabo Verde, it will enable better access to quality, safe and effective medicines. He further explained that the country already has a

domestic pharmaceutical industry that produces a relatively high range of essential medicines, covering about 30% of domestic consumption needs. Nevertheless, the national industry faces many difficulties associated with exporting to other African countries as there is no medicines regulatory body at the continental level that facilitates these processes.

In his view, the establishment of the AMA will entail gaining a continental dimension for national medicines producers. It also has the potential to reduce costs, reduce countries' workload, improve the quality of suppliers, unify medicines' standards, improve regulatory governance systems, intensify collaboration, harmonise standards and favour the implementation of joint laboratories. Therefore, Dr. Arlindo stated that small island states can only gain from the AMA and confirmed they will be ratifying the treaty.

Ms. Emer Cooke, **Executive Director, European Medicines Agency**, explained the benefits of regulatory harmonization seen over the years at the level of the European Union, helping countries work together. While the EU model is an excellent fit for the AMA, the regulatory network was not established in one day. The European system has significantly evolved over the last five decades from cooperation to collaboration to working within a unique set of laws, regulations, processes and scientific standards.

Today, it's a success story and a reference model. It has demonstrated its resilience during the COVID-19 pandemic. Ms Cooke saluted the initiative of the International Alliance of Patient Organizations in launching the AMA Treaty Alliance, as patient engagement will steer the AMA in the right direction to serve all African patients across the continent. Experience with the EMA has shown that this type of collaboration is a catalyser for delivering delivery of meaningful medicines to patients.

Ms Cooke added that building manufacturing capacity in Africa is also necessary - as witnessed during COVID-19 with the vulnerability of global supply chains, and the need to ensure that high quality medicines and vaccines can be delivered locally, avoiding shortages, preventing the distribution of falsified medicines.

Finally, Ms Cooke outlined some ideas of how EMA can help the development of AMA and build regulatory and scientific capacity, and to support regulatory reliance: capacity-building on medicines regulation, and through sharing experience on joint clinical assessment.

Dr. Karim Bendhaou, **Chair of Africa Engagement Committee, IFPMA**, reiterated industry's support for the establishment of the AMA. The AMA will contribute to regulatory harmonization across Africa, enable collaboration and work sharing, and the use of reliance procedures, which will mean a win-win for national regulators, patient, and industry. It will also be a pillar for UHC in Africa. A strong unified regulatory system could contribute to fight falsified products and to bring high quality, safe, and innovative products to the market.

Ms. Bisi Bright, **Board Member, Nigeria, IAPO**, highlighted the importance of African patient engagement in advocating and establishing the AMA, but also continuing to carry the patient voice once the Agency is operational. The idea of AMATA was born out of this necessity and will be driven forward by IAPO and different partners.

Involving patients in all aspects of the Agency framework will be a crucial factor for its success.