African Medicines Agency Q&A

January 2020

1. **Why an African Medicines Agency – why now?**
   National regulatory authorities (NRAs) play a vital role in the health system by evaluating the quality, safety and efficacy of medical products on the market and promoting patient safety. However, WHO estimates that at least three out of 10 NRAs in the world are not fit for purpose, largely due to limited resources and low recognition of their crucial role in their countries' health systems. When not addressed, these challenges result in long waiting times for products to receive authorization and reach patients, shortages of vital medicines in health facilities, and the risk of unsafe, unregulated products on markets.

   One solution African countries have been working with through the African Medicines Regulatory Harmonization (AMRH) initiative is harmonization of technical requirements and greater collaboration between NRAs within Regional Economic Communities to improve efficiency, cut costs and expedite market entry of life-saving products. These approaches, as well as other initiatives such as the African Vaccines Regulatory Forum (AVAREF), have laid the ground for the creation of an African Medicines Agency (AMA).

2. **How will AMA work?**
   The main objective of AMA is to have strong national regulatory systems, with excellent technical backup at regional and continental levels. In an increasingly globalized world, no one country has sufficient resources and capacity to effectively regulate the whole supply chain for health products. AMA would leverage African regulatory assets and capacities to improve access to essential medicines and health products that are safe, effective, affordable, and quality-assured.

3. **Who will pay to set up AMA?**
   Funding to build the agency is being identified. It will probably be a mix of global partners' contributions. In terms of the regulatory work, once the agency is up and running, there will be a fee structure put in place, much like fees already charged by national regulatory authorities.

4. **How long will it take to establish?**
   Once at least 15 AU member states have ratified the AMA treaty, it could take 5-10 years for AMA to be fully operational, depending on AU governments' political will.

5. **Why should countries ratify?**
   Once AMA is up and running, countries will be better equipped to:
   - increase access to medicines and health products that are safe, effective and of good quality, thereby improving health and, as a consequence, economic growth;
   - combat substandard and falsified medical products;

- Improve efficiency;
- Lower overheads;
- Expedite market entry of life-saving products;
- enhance regulatory services, research and innovation;
- take a further step towards local production.

6. **Are there examples of successful joint regulatory initiatives?**

   Harmonization efforts have already proved successful at a regional level in the East African Community (EAC) and the Southern African Development Community (SADC) through the ZAZIBONA initiative (a collaboration between national medicines regulatory authorities in Botswana, Namibia, Zambia, and Zimbabwe). Other regions have also rolled out regulatory harmonization initiatives at various stages of implementation: the Economic Community of West African States (ECOWAS) through collaborative efforts between the West African Health Organization (WAHO) and the West African Economic and Monetary Union (WAEMU), the Inter-Governmental Authority on Development (IGAD), and the Organization of Coordination for the Fight against Endemic Diseases (OCEAC) under the Economic and Monetary Community of Central Africa (CEMAC).

   In Europe, since 1995, the European Medicines Agency (EMA) has been ensuring quality, safe and effective medicines to a market of 500 million people living in EU countries.

7. **What are the next steps?**

   The African Union (AU) Heads of State and Government adopted and endorsed the treaty for the establishment of AMA on 11 February 2019 in Addis Ababa, Ethiopia. At least 15 governments of the AU must ratify the treaty for the AMA to come into force. This is a unique opportunity for the African continent to tackle well-known challenges in access to quality health products and make progress towards universal health coverage.

8. **What does ratification require?**

   Ratification requirements vary from country to country. In some countries, parliamentary approval will be required. There may also be a need to adjust the country's law that governs regulation of medicines to allow for the role of the AMA. Francophone countries are likely to have different requirements to anglophone countries. More information about the legal requirements is being compiled currently by the AU and will be made available once complete.