Africa's 2nd Continental Health Agency- Africa Medicines Agency (AMA)

Introduction in February 2019, the Assembly of Head of State and Government adopted the legal instrument for the establishment of the Africa Medicine Agency (AMA) and called on its member states to sign and ratify the Treaty in order for the Treaty to enter into force as soon as possible (Assembly/AU/Dec.735 (XXXII). The adoption of the Treaty for the establishment of AMA sets the Union on a course towards establishing a second continental health institution that shall significantly contribute to the improvement of health care delivery across the continent and better health overall of African citizens as envisioned in Agenda 2063. Good health will contribute to the human capital that is needed to drive Africa's development. The AMA will serve as the continental regulatory body that will coordinate on-going regulatory systems; strengthen and harmonize efforts of the African Union-recognized Regional Economic Communities (RECs), Regional Health Organizations (RHOs) and Member States; provide regulatory guidance; complement and enhance collaboration and contribute to improving patients access to quality, safe and efficacious medical products and health technologies on the continent.

AMA's functions and responsibilities - Multiple and concurrent epidemic and pandemics could take place at the same time (COVID-19, Ebola and Zika) resulting in severe strains on health systems and continental collaboration is of paramount importance. For example, following the Ebola epidemic in West Africa, the Africa CDC was established by Heads of State and Government with some urgency in 2015 (Assembly/AU/Dec.554 XXIV). In light of the most recent COVID-19 pandemic, the Africa CDC has led and coordinated the Africa Union's response to the pandemic and has taken several actions to assist AU Member States, AMA as a complimentary health institution to the Africa CDC would play a pivotal role by fast tracking approval and monitoring of clinical trials for vaccine and therapeutics (solidarity trials); fast tracking of joint assessments (including RECs); coordinating the initiation and monitoring of primary

medical supplies; encouraging local manufacturing, research and innovation of medical products.

Cost to AU Member States health care, social and economic systems - Between 2013 and 2017, 42 per cent of all reports sent to the WHO Global Surveillance and Monitoring System on substandard and falsified medicines worldwide came from Africa. This poses a serious threat to the achievement of the Sustainable Development Goal (SDG) for good health and well-being (Goal 3), which is concerned with access to universal health care services and safe, effective, quality, and affordable essential medicines (Target3.8). Between 31 March and 2 April 2020, the WHO global surveillance and monitoring system on substandard and falsified (SF) medical products received 14 reports of confirmed falsified chloroquine products from 5 countries (4 from Africa and 1 from Europe). All reported products, were identified at patient level and all have been confirmed as falsified. In the same week the WHO declared coronavirus a pandemic, Operation Pangea, Interpol's global pharmaceutical crime fighting unit, made 121 arrests across 90 countries in just seven days, resulting in the seizure of dangerous pharmaceuticals worth over $14million. According to the WHO, the broader falsified medicines trade, which includes medicines which may be contaminated, contain the wrong or no active ingredient, or may be out-of-date, is worth more than $30billion in low and middle-income countries.

WHO estimates that 10.5% of medicines worldwide are substandard or falsified. Most of the burden falls on low-and middle-income countries because of poor pharmaceutical governance, weak technical capacity, and poor supply-chain management. Guinea-Bissau, Ivory Coast, Liberia and Sierra Leone seized 19 tonnes of counterfeit medicines in 2018. Smugglers in Ivory Coast were intercepted trying to bring in 12 tonnes of counterfeit pharmaceuticals from Ghana in 2019. An Interpol-led operation in seven West African countries seized more than 420 tonnes of illicit pharmaceutical products in 2017. Nearly 19.88 tonnes of fake medicines were seized in Mali between 2015- 2018.

Substandard and falsified medical products and medicines inflict economic burdens on: individual patients and their families, by wasting their funds in the purchase of useless, if not harmful, medicines that additionally increase already high out of pocket expenditures.

Legitimate pharmaceutical companies, also face huge revenues losses due to competition for the market with substandard and falsified medicines and medical products. Governments make additional losses through the loss of revenue from unpaid taxes and spending money in fighting the falsified medicines and medical products menace. Poor-quality medicines result in increased cost, such as resources wasted on ineffective therapies and treating additional complications. It was reported in 2017, that 113 million potentially dangerous and illicit medicines (estimated to be worth €52 million) were seized during an operation called Action Against Counterfeit and Illicit Medicines (ACIM) which was conducted in the African continent in September 2016. The operation was jointly organized by the World Customs Organization (WCO) and the International Institute for Research Against Counterfeit Medicines (IRACM), and it involved 16 African customs administrations, with the largest interceptions in Benin, Kenya, Nigeria and Togo. The global market volume of falsified medicines and medical products could be up to US$200 billion, and up to 70% of the total medicines in circulation could be falsified medicines and medical products in some parts of Africa. In Africa, the estimates of the United Nations Office on Drugs and Crime (UNODC) for the sales of falsified medicines in West Africa alone is US$438 million. This amount, which is being lost for antimalarial medicines alone, has exceeded the Gross Domestic Product (GDP) of Guinea-Bissau. Falsified medicines have caused African countries to lose tax revenues estimated to be worth hundreds of millions of U.S. dollars. In East Africa, Burundi, Kenya, Rwanda, Tanzania and Uganda, have reported unremitted taxes related to falsified medicines and other goods to be more than US$500 million, and the worst scenario is in Tanzania, which is annually losing up to US$617 million as a result of tax evasion associated with falsified products.

AU Policy Organs place strong value of AMA as a continental health institution - The following decisions supported the harmonization of medicines regulatory systems as a foundation for the establishment of a single medicines regulatory agency in Africa ; In 2013 AU Heads of State and Government decision on the Pharmaceutical Manufacturing Plan for Africa (PMPA) (Assembly/AU/Dec.55 IV, 2005), that gives a high priority to quality, safety, efficacy and affordability of medicines; and further recalling their

declaration (Assembly/AU/Decl.2 XIX, 2012) that endorsed the “African Union Roadmap on Shared Responsibility and Global Solidarity for AIDS, Tuberculosis and Malaria Response in Africa. On 17 April 2014 in Luanda, Angola, African Ministers of Health during their first meeting held, jointly organized by the AUC and WHO agreed to prioritize investment in regulatory capacity development, to pursue efforts towards convergence and harmonization of medical products regulation in the RECs and to allocate adequate resources for the establishment of the AMA. In January 2015, the AU Executive Council EX.CL/Dec.857 (XXVI) noting the need to strengthen capacity of medical products regulation in Africa and the harmonization of regulatory systems, requested the AUC, the African Union Development Agency – New Partnership for Africa’s Development (AUDA-NEPAD) and WHO in collaboration with other stakeholders to define the scope of the medical products that would be covered by the work of the AMA, and to work out detailed modalities, institutional framework, legal and financial implications, of the establishment of the AMA. In addition to the commitments of AU policy organs, WHO has also passed a number of resolutions and recommendations relating to the quality, safety and efficacy of medicines at its Sixtieth (WHA60.13 & WHA60.23, 2007) and Sixty-third sessions (WHA63.10 & WHA63.15, 2010) to strengthen the capacity for regulation of medical products.

Status of ratification of the AMA Treaty-The Treaty establishing the African Medicine Agency, will enter into force once ratified by fifteen African Union Member States. At the time of this paper the AMA Treaty has been signed by 16 AU member states and ratified by 3. Due to the value that this second continental health agency will bring to all 55 AU members states and the citizens of Africa, the call on member states of the Africa Union to sign and ratify the AMA legal instrument, in order for it to come into force, as soon as possible should be responded to with some urgency. The African Union Commission will continue to support member states to fast track the ratification processes at national level.