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Department of Health, Humanitarian Affairs and Social Development (HHSD)

Newsletter



**Health, Nutrition
and Population
- In Focus**

**QUARTERLY
NEWSLETTER**



HARMONIZED MEDICINES AND VACCINES REGULATORY SYSTEM IN AFRICA. WHAT STEPS IS AFRICA TAKING?

Status Quo

A pre-requisite for vaccine administration is regulatory and approval processes that assess, inspect and authorize the use of the vaccine. In Africa, this process is being undertaken at national level where the vaccines are subjected to the national medicines regulatory authorities for efficacy, safety and quality assurance. At the Member States level the regulatory authorities establishment and mandate differ from country to country based on availability of both human and financial resources. These regulatory bodies are responsible for registration, market authorization, pharmacovigilance, clinical trials, inspection, licensing, market and quality control, as well as medicines advertising and promotion in order to ensure the roll-out of safe and efficacious pharmaceutical products including vaccines.

While significant progress in being made by some national regulatory authorities, some African Union member states do not have a fully operational pharmaceutical regulatory authority, those that have face numerous limitations particularly weak or non-coherent legislative frameworks, redundant/duplicative processes, slow medicine registration processes and subsequent delayed decision. The slow medicines and medical products registration processes are as a result of minimal infrastructure, and the lack of appropriately trained personnel. Other challenges faced by some member states include inefficiency, limited technical capacity, and lack of adequate and sustainable resources. Some AU member states have reported that the Pharmaceutical policy implementation is not regularly monitored or assessed while some member states lack policies relating to clinical laboratories.

Why the urgency for a Harmonized Medicines and Vaccines Regulatory System in Africa?

The COVID-19 pandemic has amplified the need for a harmonized mechanism that ensures investments in regulatory capacity development towards the achievement of improved standards in the regulation of medicines, medical products and technologies across the continent. For example, a single regulatory agency is essential in obtaining coordinated responses and emergency guidance on vaccines that begins with the clinical development stage, to approval for use.

What steps is Africa taking?

The African Union Assembly of Heads of State and Government adopted the legal instrument for the establishment of the African Medicines Agency (AMA) in February 2019. AMA will serve as the

continental regulatory body that will coordinate on-going regulatory systems; provide regulatory guidance; complement and enhance collaboration. The Agency will also contribute to improving patients access to quality, safe, efficacious and affordable medical products and health technologies on the continent. AMA will coordinate joint reviews of clinical trials applications for vaccines and ensure harmonized legislation.

AMA will also strengthen and harmonize medical products regulation efforts of the African Union recognized Regional Economic Communities (RECs), Regional Health Organizations (RHOs) and Member States. The agency will complement the work of the Africa CDC by fast tracking approval and monitoring of clinical trials for vaccine and therapeutics including solidarity trials. In addition, AMA will advance the implementation of the Pharmaceutical Manufacturing Plan for Africa and the Africa Continental Free Trade Agreement by supporting the local and regional pharmaceutical companies by enhancing and expanding markets across Africa.

The need for a harmonized solution is to fast track development and approval of the vaccines especially during public health emergencies. AMA will in addition have checks and balances for other medicines in the continent and issue licences for their manufacturing and delivery based on scientific evidence. According to WHO Global surveillance and Monitoring system, 42 per cent of all reports on substandard and falsified medical pharmaceuticals world-wide between 2013 and 2017 came from Africa. This is a worrying trend especially in the face of a looming pandemic.

The AMA Treaty recognizes the successes of the African Medicines Regulatory Harmonization (AMRH) since its establishment in 2009, under the management and guidance of the African Union Development Agency (AUDA-NEPAD) working with RECS and RHOs to facilitate harmonization of regulatory authorities (NMRAs) of the AU Member States to meet internationally acceptable standards, and provide a favourable regulatory environment for pharmaceutical research and development, local production and trade across countries on the African continent. In collaboration with WHO and other stakeholders the Commission is working towards fast tracking the establishment of the AMA through strategic advocacy campaigns.

The Treaty establishing the African Medicines Agency, will enter into force once ratified by fifteen African Union Member States. So far, eighteen Member States have signed the AMA Treaty and eight have ratified while 5 have deposited the instrument of ratification. The Commission continues to appeal to Member States to fast track the signing and ratification that will establish the agency to promote quality, safety, efficacy and affordable medicines.

POPULATION GROWTH DYNAMICS AND THE IMPACT ON HEALTH AND NUTRITION



In 2017, Africa was estimated to have a population of 1.25 billion, and with a growth rate of more than 2.6%, the continent is projected to double its population by the year 2050 to 2.4 billion. The continent boasts the highest population share of the youth globally, presenting a potential demographic dividend that if adequately leveraged, can contribute to accelerated, sustainable and equitable development. To better serve the needs for Africa's growing population, food security, nutrition and health should be considered a development priority with a particular focus on the risk factors to their sustainability.

The African Union Commission developed a discussion paper titled "Population, Food Security, Nutrition and Sustainable Development" to guide discussions during the 53rd session of the United Nations (UN) Commission on Population and Development. The Paper provides recommendations that contribute to policy discussions that will impact the health, food security and nutrition sectors, towards the achievement of goal two of the Sustainable Development Goals (SDGs) of the United Nations that seek to end hunger, achieve food security and improve nutrition, and promote sustainable agricultural targets and goal five of Aspiration One of African Union Agenda 2063, that envisions to radically transform African agriculture to enable the continent to feed itself and be a major player as a net food exporter.

While acknowledging that Africa's policy environment has increasingly become more supportive towards nutrition, the paper recognizes the African Union nutrition policy instruments like the 2014 Malabo Declaration, the Africa Regional Nutrition Strategy 2015-2025 and Agenda 2063 and Africa's wide participation in the Cost of Hunger (COHA) studies, the Continental Nutrition Accountability Scorecard and Comprehensive Africa Agriculture Development Programme (CAADP) as a means to be leveraged at country level to catalyze the needed developments.

The paper concludes with some key recommendations as follows:

1. Increasing financing commensurate with the needed effort levels for existing policy instruments and initiatives like those of the CAADP, Africa regional nutrition strategy; Africa Renewed Effort for Stunting Elimination; African Leaders for Nutrition, the African Nutrition Accountability Scorecard, e.t.c as well as increasing investment on proven cost-effective and sustainable strategies and programmes
2. Enhancing alignment, coherence and strengthening multisectoral coordination and programming across policy and program instruments addressing food security and nutrition at national, sub-national and continental levels, to accelerate progress and avoid negative trade-offs
3. It is also paramount to invest in adequate functional capacity and nutrition leadership skills to help navigate multiple stakeholder interests to foster high quality collaboration amid potential conflicts of interest for better coordination and coherence of implementing programs and interventions across different government and development partner stakeholder interests
4. Focusing on Double Duty Actions which are interventions, programmes and policies that simultaneously tackle all forms of malnutrition to mitigate nutrition related harm
5. Identifying and promoting positive dietary patterns for example developing food based dietary guidelines are important tools to inform policy, consumer and private sector decisions and more African countries should initiate efforts to develop food based dietary guidelines.

The above recommendations which are not exclusive will significantly contribute to the implementation of the food security and nutrition related interventions by AU member states.

PRIORITIZING NUTRITION FOR THE DEVELOPMENT AND PROSPERITY OF AFRICA



In the recently concluded forty first ordinary session of Permanent Representatives Committee (PRC) meeting in January 2021, the Republic of Cote D'Ivoire submitted a proposal to have the African Union (AU) theme for the Year 2022 dedicated to strengthening the fight against malnutrition in all its forms. The proposed theme will be submitted for endorsement to the Ministerial Committee on Agenda 2063 and later validated by Member States and the decisions further adopted through the AU policy organs.

The big question is why the focus on nutrition? The continent continues to face various forms of malnutrition and poor health. According to the findings arising from the Continental Nutrition Accountability Scorecard (2019), 36 percent translating to 56 million of children under the age of five are chronically undernourished, and 8.5 percent translating to 13 million are acutely undernourished in Africa. In addition, only Twenty (20) African countries have met the 70 percent threshold for Vitamin A supplementation which makes them vulnerable to infections and diseases and prevents them from developing fully. Good nutrition is the foundation of healthy development and is one of the best investments to boost the economic potential of families, communities and nations.

The African Union has continued to prioritize nutrition, dating way back to the Organization for African Unity (OAU), by putting in place key continental nutrition policy instruments and strategies like Africa Regional Nutrition Strategy 2015-2025, the 2014 Malabo Declaration, all within the framework of Agenda 2063 whose goal number one is set towards ensuring healthy and well-nourished citizens. The Commission is also leading key nutrition advocacy initiatives including; Cost of hunger in Africa (COHA) Study; African Leaders for Nutrition Initiatives; Continental Nutrition Accountability Scorecard advocacy through the African Nutrition Champion; African Day for Food and Nutrition Security; Africa Day for School Feeding among others.

Focusing on nutrition in 2022 offers an opportunity to strengthen commitments at the continental level to end malnutrition in all its forms. It is also an opportunity to secure greater commitment to nutrition investments and finance. The focus on nutrition will also provide an opportunity to take stock of the progress made in the

implementation of the Africa Regional Nutrition Strategy 2015-2025 and also the various sectoral strategies in relation to nutrition, in particular the Malabo Declaration targets.

The proposal to focus efforts on the fight against malnutrition in Africa demands multiple programmatic efforts such as; political and result oriented commitments enhanced at continental and national levels to make it possible to build resilience in nutrition across the African continent. As a result, the commitments will sustain a strong political momentum on nutrition on the African continent, which is imperative, particularly in the context of COVID-19 pandemic.

The political commitments will help to strengthen the commitments at the continental level in terms of domestic resources allocated to financing nutrition through the reinforced innovative financing solutions. Similarly, it is also imperative to strengthen the multisectoral collaboration for nutrition at national level which contributes to numerous health benefits, human and economic development.

Commitments at the continental level also aim to enhance public and private investments by strengthening government efforts for purposes of integrating nutrition in all the relevant sectors and plans. In addition, systemic change efforts towards improving nutrition requires are critical in ensuring that nutrition is integrated into resilient and strong health systems through universal health coverage

In the build-up to the year 2022 a series of nutrition related meetings will be held in 2021 including the Tokyo Nutrition Summit (N4G) and the United Nations Summit on food systems that will both opportunities to build a roadmap on how world tackles the global challenge of malnutrition.

Nutrition as a theme for the Year 2022 of the African Union is critical to the achievement of the African Union's Agenda 2063 and the 2030 Agenda for sustainable development.



THE REPUBLIC OF NAMIBIA RATIFIES THE TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)

The Republic of Namibia becomes the fifth African Union (AU) Member State to ratify the Treaty for the establishment of the African Medicines Agency (AMA) on 19 January 2021 in Windhoek, Namibia and deposited the instrument of accession, to the Commission of the AU on 18 February 2020 in Addis Ababa, Ethiopia. H.E. Amira Elfadil Mohammed, Commissioner for Social Affairs, at the African Union Commission, who has been leading advocacy efforts towards the swift ratification and establishment of AMA, received the instrument from the Namibian delegation. This makes the Republic of Namibia the first Member State from the Southern Africa Region to ratify the Treaty.

Speaking during the official deposit of the instrument, H.E. Emilia Ndiyealo Mkusa, Ambassador of the Republic of Namibia to Ethiopia and Permanent Representative to the African Union, noted the critical role that AMA will play in making essential medicines and medical products accessible in Africa and underscored on the the need for other AU Member States to ratify the treaty. H.E. Mkusa stated that “the Republic of Namibia will advocate and support in mobilizing the Southern Africa Development Community (SADC) Member States to ratify AMA.”

AMA will be the second continental health agency that will enhance capacity of States Parties and Regional Economic Communities (RECs) to regulate medical products in order to improve access to quality, safe and efficacious medical products on the continent. AMA will also promote the adoption and harmonization of medical products regulatory policies and standards, as well as scientific guidelines and coordinate existing regulatory harmonization efforts in the AU recognized RECs and Regional Organizations (RHOs).

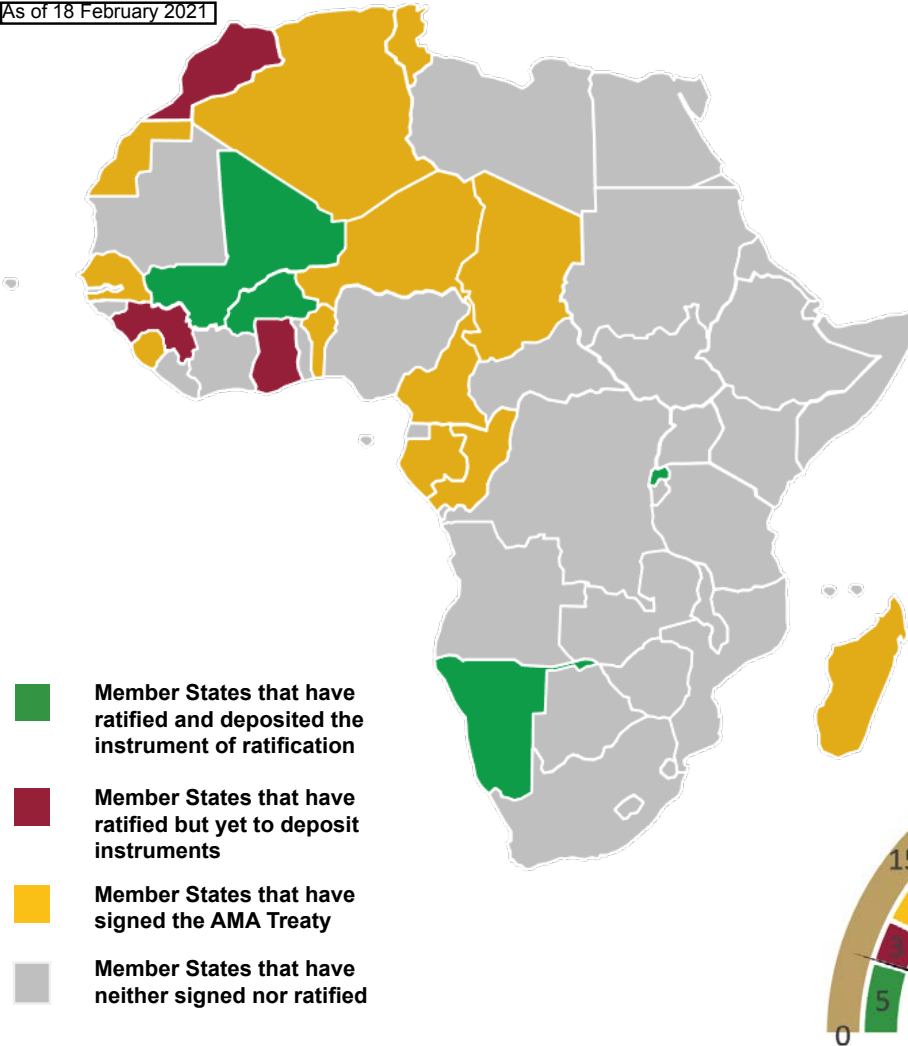
AMA will complement the work of Africa Centres for Disease Control and Prevention (Africa CDC), by providing technical support in the quality control of drugs, at the request of Member States which do not have the structures to carry out these examination/controls/checks. The agency will further coordinate and collaborate, where required, on a regular basis, the inspection of drug manufacturing sites, including the regulatory oversight and safety monitoring of medical products, as determined by State Parties and/or the AMA, and make reports available to State Parties. In addition, AMA will promote cooperation, partnership and recognition of regulatory decisions, in support of regional structures and National Medicines Regulatory Authorities (NMRAs).

The Commission encourages all its Member States to ratify and deposit the instrument of ratification at the Headquarters of the Commission, at the earliest, in the interest of continental public health, safety and security. The African Medicines Agency will enter into force once ratified by fifteen (15) African Union Member States.

The Treaty for the establishment of the African Medicines Agency (AMA) was adopted in February 2019, by the 32nd Session of the Assembly of Head of State and Government. The Assembly further 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)).

AMA will be the second continental health agency after the Africa Centres for Disease Control and Prevention ([Africa CDC](#)), that will enhance the capacity of States Parties and Regional Economic Communities (RECs) to regulate medical products in order to improve access to quality, safe and efficacious medical products on the continent. AMA will also promote the adoption and harmonization of medical products regulatory policies and standards, as well as provide scientific guidelines and coordinate existing regulatory harmonization efforts in the African Union recognized RECs and Regional Health Organizations (RHOs).

As of 18 February 2021



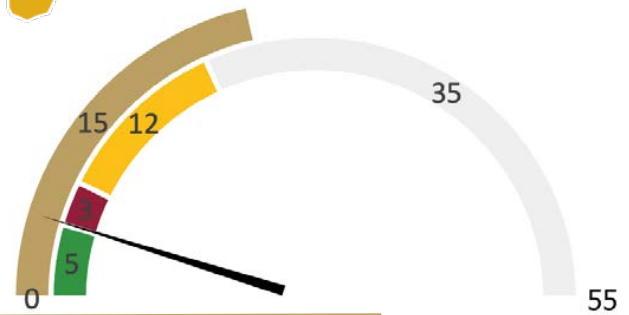
- Member States that have ratified and deposited the instrument of ratification
- Member States that have ratified but yet to deposit instruments
- Member States that have signed the AMA Treaty
- Member States that have neither signed nor ratified

12 Number of Member States that have signed the AMA Treaty but have not yet ratified

5 Number of Member States that have ratified the Treaty and deposited the instrument at the Commission

3 Number of Member States that have ratified the Treaty but not yet deposited the instrument of ratification at the Commission

15 Number of ratifications needed for the AMA Treaty to come into Force



Member States that have signed the AMA Treaty

1. Algeria
2. Benin
3. Cameroon
4. Chad
5. Republic of Congo
6. Gabon
7. Madagascar
8. Niger
9. Saharawi Arab Democratic Republic
10. Senegal
11. Sierra Leone
12. Tunisia

Member States that have ratified but yet to deposit the instrument of ratification at the Commission

1. Ghana
2. Guinea
3. Morocco

Member States that have ratified and deposited the instrument of ratification at the Commission

1. Burkina Faso
2. Mali
3. Namibia
4. Rwanda
5. Seychelles

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