

COMMUNIQUE ON PROGRESS MADE ON VACCINE MANUFACTURING IN AFRICA

Kigali, Rwanda 06-07 December, 2021

On 6th-7th December 2021, the African Union, Africa Centres for Disease Control and Prevention (Africa CDC), the AUDA-NEPAD, and the African Continental Free Trade Area (AfCFTA) convened a stakeholder's meeting in Kigali, Rwanda to review progress made in manufacturing vaccines in Africa. The objective of the meeting included: a) an update on progress made so far on the Partnerships for African Vaccine Manufacturing (PAVM) in Africa (PAVM), b) agreement on an AU-endorsed approach to facilitate regulatory approval of vaccines produced in Africa, c) discuss critical market shaping needs once African countries produce vaccines, and d) review progress on vaccine manufacture hubs and pilot a drug Active Pharmaceutical Ingredient (API)-final drug product Hub program. The meeting was attended, either by online or in person, by some African Union Heads of State (or their representatives), partners, stakeholders, and over 15,000 participants from Africa and the world.

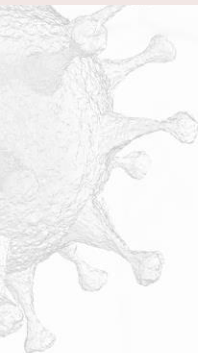
PREAMBLE

RECALLING that on the 22nd of February 2020 African Ministers of Health endorsed the Africa Joint Continental Strategy for COVID-19 outbreak, including the AU and Africa CDC's leadership role in coordinating the response on the continent.

RECALLING that on the 24th-25th of June 2020, the African Union and Africa CDC convened over 3,000 political leaders, policy makers, and technical experts to discuss strategies for COVID-19 vaccine on the continent: access, development and manufacturing of vaccines.


FURTHER RECALLING that on the 20th of August 2020, the African Union Bureau of Heads of State and Government, chaired by His Excellency President Cyril Ramaphosa of South Africa, endorsed the Continental COVID-19 Vaccine Development and Access Strategy aimed at the "Successful immunisation of a critical mass of the African population with one or several safe and efficacious COVID-19 vaccines."

FURTHER RECALLING that on the 12th-13th April 2021, the Africa Union and Africa CDC convened a Summit where several Heads of State and 40,000 participants attended to discuss the need to accelerate the development of vaccines in Africa to guarantee Africa's health security.



RECOGNIZING that one of the main outcome of the 12th-13th April 2021 Summit was the launch, by H.E Felix Tshisekedi (current chair of the African Union), of the Partnerships for Africa Vaccine Manufacturing (PAVM). The Summit also agreed on the continental vision for vaccine manufacturing “to ensure Africa has timely access to vaccines to protect public health security, by establishing a sustainable vaccine development and manufacturing ecosystem in Africa”, and the proposed ambition to manufacture 60% of Africa’s routine immunisation needs on the continent by 2040, aligned with the call for a New Public Health Order.

NOTE that the AU Executive Council Decision EX.CL/Dec.1129 (XXXIX) recognised and endorsed the PAVM as the coordinating mechanism and its leadership of the development of a continental vaccine manufacturing strategy and a Framework for Action.



RECOGNIZE the great importance of the continuous and fruitful collaboration across the continent amongst African nations; and continuing to build on strong partnerships with international organizations, NGOs, different stakeholders, global funders, and the pharmaceutical industry.

COMMEND progress made so far across the continent to accelerate vaccine manufacturing. For instance, Morocco signed an Memorandum of Understanding (MOU) with Recipharm; Egypt signed agreements with VASCERA and Sinovac and has produced 25 million doses of the COVID-19 vaccine to date; Rwanda and Senegal signed MOUs with BioNTech to produce mRNA vaccines; South Africa and Partners established the mRNA hub, Biovac has signed an MOU to produce Pfizer mRNA vaccines and Aspen partnered with Johnson & Johnson to acquire IP licenses; Ghana announced plans for COVID-19 production, Algeria launched local Sinovac COVID-19 vaccine production and announced partnership with Russia to produce the Sputnik V COVID-19 vaccine; and Nigeria published a national vaccine policy and Biovaccines signed an MOU to manufacture COVID-19 doses.

NOTE that on the 5th of November 2021, the African Medicines Agency (AMA) treaty came into force officially – clearing the way for the AMA to begin operations as a formal entity. AMA will clearly play a critical role in regulatory harmonization to enable vaccine manufacturing on the continent.

ACKNOWLEDGE the need to continue to strengthen African-led solutions such as the African Vaccine Acquisition Trust (AVAT) & Africa Medical Supplies Platform (AMSP) and expand beyond COVID-19 in-line with the strategy blueprints for vaccines.

ACKNOWLEDGE a real need to invest in regional quality approved API and finished product manufacturing facilities on the continent.

ACKNOWLEDGE consensus on the need for rapid operationalisation of African Medicines Agency (AMA), to harmonize vaccine manufacturing regulation on the continent.

ACKNOWLEDGE the role that the Agreement Establishing the African Continental Free Trade Area (AfCFTA), and in particular the Intellectual Property Rights Protocol of the AfCFTA can play in the market shaping for COVID-19 vaccines, development of value chains in pharmaceutical products, private sector engagement and removing trade policy-related barriers with measures, including harmonizing standards.



NOTED that after considering several options the regulators agreed on two potential pathways for Emergency Use Authorisation (EUA) of vaccines including those for the SARS-COV-2, the virus that causes COVID-19:

- 1) **Use and strengthen** the Africa Medicines Regulatory Harmonization (AMRH), as a mechanism to provide EUA for COVID-19 vaccines produced in Africa pending the full operationalization of AMA.
- 2) **Create** a network of National Regulatory Authorities (NRAs) from countries with intent to produce vaccines and other NRAs with advanced maturity levels, using AMRH structure with close coordination by PAVM, and develop a step-wise process for strengthening them to facilitate the issuance of EUA.
- 3) **Collaborate** with the AfCFTA Secretariat to support manufacturing and Intra-Africa Trade for COVID-19 vaccines and pharmaceuticals products through appropriate Intellectual Property Framework.

PROPOSE the submission of the options proposed above to the AMA Conference of States Parties in January 2022.

