

# African Union and Africa CDC launches Partnerships for African Vaccine Manufacturing (PAVM), framework to achieve it and signs 2 MoUs

12-13 April, 2021

African Union Heads of State and over 40,000 esteemed participants attended a virtual summit on Expanding Africa's Vaccine Manufacturing for Health Security from 12-13 April 2021.

## PREAMBLE

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

**FURTHER RECALLING** that on June 24-25, 2020, Africa CDC convened over 3000 political leaders and technical experts to discuss COVID-19 vaccine needs on the continent and regional opportunities for driving development, manufacture, distribution and uptake, and translated the results of the discussion into the COVID-19 Vaccine Development and Access Strategy.

**FURTHER RECALLING** that on 20 August, 2020, the African Union (AU) 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."

**RECOGNISING** the efforts by African Union Member States in response to the COVID-19 pandemic, with a focus on how the continent can prepare for the research and development, manufacturing, procurement, financing, regulatory review delivery, and uptake of a potential COVID-19 vaccine.

**COGNISANT** that COVID-19 is spreading rapidly across our continent, including a new variant of the virus that spreads at a faster rate, which will compound the existing health challenges that Africa already faces.

**ACKNOWLEDGING** that any further spread of COVID-19, as well as potential future pandemics, on the continent is a social, economic, and security threat for the continent. Further, taking into consideration that the African Union Agenda 2063, which is a strategic framework for the socio-economic transformation of the continent over the next 50 years, as well as the successes of the implementations of the African Continental Free Trade Agreement (AfCFTA) will be severely disrupted by continued disease outbreaks such as the COVID-19 and other potential pathogens.

**RECOGNIZING** that Africa has faced delays compared to other global regions in accessing life-saving vaccines for COVID-19 and may experience similar delays in accessing vaccines in future pandemic or outbreak situations.

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**COGNIZANT** that the African Union has called for a New Public Health Order, with four pillars and the third emphasising the need for local production of vaccines, therapeutics, and diagnostics.

**RECOGNIZING** that Africa currently has limited vaccine manufacturing capacity and capabilities.

**ACKNOWLEDGING** existing continental efforts and ongoing African pharmaceutical manufacturing strategies and frameworks to promote African pharmaceutical manufacturing, specifically the African Union's Pharmaceutical Manufacturing Plan for Africa (PMPA), the African Medicines Agency (AMA), the African Vaccine Regulatory Forum (AVAREF), etc.

**NOTING** several barriers that have been identified to operationalising and scaling African vaccine manufacturing to date, including but not limited to 1) No operationalized continental strategy, 2) Continent-wide harmonization not yet implemented and national regulators facing constraints, 3) Fragmented and uncertain demand outside of Gavi-supported countries, 4) Limited access to finance due to lack of project preparation and ecosystem support, 5) Skills shortages of relevant talent, and limited technology transfer experience, and 6) Infrastructural barriers including unreliable utilities, limited intra-Africa infrastructure, etc.

**WELCOMING** efforts by the Member States to establish vaccine manufacturing in Africa, with a focus on how the continent can prepare for the R&D, manufacturing, procurement, financing, delivery and uptake of potential vaccines during future outbreaks and pandemics.

## **EXPANDING AFRICA'S VACCINE MANUFACTURING FOR HEALTH SECURITY**

**COMMEND** the efforts of Africa CDC and the African Union to rapidly convene key continental and global stakeholders and experts to share perspectives on:

- The current status of vaccine manufacturing in Africa
- A Framework for Action to be developed by Africa CDC to guide the continent

**AGREE** that identifying opportunities to scale-up African vaccine manufacturing capabilities is critical to establishing Africa's health security by developing the capabilities and capacity to respond to current and future pandemics and outbreaks in a more rapid and agile manner.

**ACKNOWLEDGE AND ENDORSE** the launch of the Partnerships for African Vaccine Manufacturing (PAVM), which aims to leverage pan-African and global partnerships to scale-up vaccine manufacturing in Africa.

**ENDORSE** 1) the continental vision for vaccine manufacturing which aims "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 2) 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** the existing capabilities on the continent today, the African diaspora, and commitments from our private sector partners to strengthen capacity which provide a relevant starting position for African manufacturing.

**ACKNOWLEDGE** the political, technical, and economic complexities associated with vaccine manufacturing, and the unique challenges faced in Africa.

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**FURTHER ACKNOWLEDGE** this, noting that the AU supported waiver at the WTO remains unimplemented there is an urgent need for countries to make full use of legal and policy measures, including flexibilities enshrined under the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement and Doha Declaration, South-South and North-South collaboration to ensure that African manufacturing results in access to vaccines for African populations.

**PROMOTE** the need for a strong continental vision, strategy and roadmap for African vaccine manufacturing, with strong leadership from continental, regional and member state leaders.

**CALL UPON** member states to commit to African vaccine manufacturing over a 10 to 20 year time horizon, leveraging the momentum resulting from the urgency of COVID-19 manufacturing needs, and which has the potential to reduce historically long timelines to develop vaccine manufacturing capacity on the continent.

**ACKNOWLEDGE** that the current COVID-19 pandemic presents a unique opportunity by providing a platform and significant momentum for African vaccine manufacturing, and that this level of interest and commitment may not last, therefore immediate action should be taken.

**REQUEST** global partners, including foundations, bilateral and multilateral donors, financing institutions, African private sector partners, regional and national governments, global pharmaceutical companies, among others, to support African manufacturing of vaccines, both short-term and long-term, to make African vaccine manufacturing a reality.

**WELCOME** the close collaboration and partnership between Africa CDC, Coalition for Epidemic Preparedness Innovations (CEPI), Afreximbank, Africa Finance Corporation (AFC) and many others in supporting some African countries to strengthen their capacity to establish and scale-up vaccine manufacturing capacity for routine vaccines, known pathogens, and unknown pathogens in the future.

**RECOGNISE** specifically, 1) the memorandum of understanding between CEPI and AU aims to establish vaccine development and manufacturing capacity and capability in Africa for public health security and to ensure equitable access to vaccines for Africans and globally, and 2) the AFC and Afreximbank partnership commits to support the development of vaccine manufacturing in Africa by focusing along four areas of support.

**ESTABLISH** a clear allocation of regional hubs through thoughtful distribution of vaccine production across the African continent, both across and within countries, accounting for existing capabilities as well as plans and potential capacity.

**INCLUDE** non-vaccine producing African countries to participate in African vaccine manufacturing indirectly, for example in activities along the value chain (e.g., R&D).

**ESTABLISH** African production of critical raw materials manufacturing industries to provide critical inputs for African vaccine manufacturers, particularly relevant during times of crisis.

**ACCELERATE** ongoing African harmonisation initiatives supported by African political leaders, such as the African Continental Free Trade Agreement (AfCFTA), to ensure a "one-Africa"

**SUGGEST** that Africa establish a step-wise approach to scaling vaccine manufacturing, starting with short-term objectives such as scaling fill and finish manufacturing capacity, with medium- to long-term commitments to backward integrate to include drug product and ultimately drug substance manufacturing, all the while noting that investments into upstream capabilities will need to be made in the short-term to establish the necessary skills and capabilities.

**RECOGNISE** that Africa has a unique opportunity to leapfrog to more novel vaccine platform technologies and manufacturing processes, including those with more flexible applications or quicker ability to scale, all the while noting that investing in multiple technologies will enable Africa more flexibility in responding to future pandemic needs.

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**ENABLE** effective regulatory control structures for vaccine manufacturing, which includes the ratification of the African Medicines Agency (AMA) by member states, further clarification on roles of regional regulatory capacities, and the strengthening of relevant national regulatory bodies, to ensure high quality standards, good manufacturing practice (cGMP) compliance, safety and efficacy, adequate pharmacovigilance, rapid marketing authorisation, and safety data and monitoring of African-made vaccines.

**WELCOME** long-term commitment from vaccines purchasers to secure offtake through committed purchase agreements for African-made vaccines.

**CALL UPON** the African Union Commission, donors, and partners to support Africa's efforts to make necessary investments in vaccine manufacturing by pledging the necessary financial resources.

**ACKNOWLEDGE** that while grants and subsidies play a role in enabling short-term acceleration and de-risking investments, it remains important to focus on developing and creating long-term sustainable, commercially viable business models.

**WELCOME** firm commitments from funders (including public sector, philanthropists, investors, multilateral or bilateral partners, and private sector) to invest in developing the vaccine manufacturing enabling environment, support local African manufacturers to develop and prepare projects for investments, and finance vaccine manufacturing projects in Africa which are sustainable and commercially.

**PARTNER AND COLLABORATE** with relevant global stakeholders to build capacity and capabilities of local manufacturers specifically to enable technology transfer to facilitate vaccine manufacturing to occur domestically at larger scale so Africa can better control its supply of the vaccine over time.

**RECOGNISE** the importance that establishing mechanisms to promote and secure intellectual property and technology transfer and licensing agreements for African manufacturers will have as a critical unlock to accessing certain products and/or processes

**PROMOTE** investment into establishing research and academic hubs to enable Africa to develop its own vaccine products and / or manufacturing processes in the longer term, thereby enabling Africa to develop Africa-relevant products.

**CALL UPON** organisations and partners to set aside the necessary research and development funds and share the relevant capabilities through cross-border programs and exchanges of talent.

**ENSURE** that infrastructural barriers on the continent are addressed (e.g., border clearance, road and freight logistics, cold-chain and warehousing, etc.) to ensure African-made vaccines can be effectively delivered to the target populations. Similarly, further establish strong distribution and supply chain networks in and between countries, including with global partners providing supply chain materials.

**SET UP** appropriate governance mechanism to guide the development of the workstreams with coordinating structures at Ministerial level, addressing key barriers and enabling factors, supported by technical working groups comprised of technical experts and political leaders, which can each be responsible for driving forward efforts related to African vaccine manufacturing.

**CALL ON** the work of the AU COVID-19 Champion, H.E. President Cyril Ramaphosa, and H.E. President Paul Kagame, **champion of health financing of the African Union**, to expand their focus and efforts in support of African vaccine manufacturing.