

## COMMUNIQUE

# GUIDANCE ON EXPEDITED REGULATORY AUTHORISATION PROCESS FOR EMERGENCY USE OF COVID-19 VACCINES IN AFRICA



## PREAMBLE

**CONSCIOUS** of the fact that the COVID-19 outbreak was declared a public health emergency of international concern (PHEIC) by the World Health Organization (WHO) on 30 January 2020, and declared a pandemic on 11 March 2020, having infected over 91 million persons and caused the deaths of more than 2 million persons globally – including more than 3 million cases and 73,400 deaths on the African continent.

**RECALLING** that during the 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 24-25 June 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 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.

**ACKNOWLEDGE** the launch of the Africa Regulatory Taskforce, a joint effort established by **the Africa Centres for Disease Control and Prevention, African Union Development Agency(AUDA-NEPAD) coordinated African Medicines Regulatory Harmonization (AMRH) Initiative and the World Health Organisation's African Vaccine Regulatory Forum (AVAREF)** to enable and provide support for an effective regulatory framework for the vaccine, which includes implementing indemnification for vaccine manufacturers, appropriately fast-tracked regulatory approvals at country level, and a robust infrastructure for ongoing monitoring of vaccine efficacy and safety.

**ACKNOWLEDGE** that African National Regulatory Authorities, convened by the Africa Regulatory Taskforce, met on 12 January 2021 to discuss the urgent need to establish appropriately fast-tracked processes to review and make decisions on the safety and efficacy of COVID-19 vaccines. A draft guidance was presented to the NRAs which will be iterated and finalized in the week of the 18 of January 2021.



## EXPEDITED REGULATORY AUTHORISATION PROCESS FOR EMERGENCY USE OF COVID-19 VACCINES IN AFRICA

**AGREES** that the Africa Regulatory Taskforce, made up of National Regulatory Authorities, have been mandated by the African Union to expedite the regulatory authorisation process for emergency use of COVID-19 vaccines in Africa. This requires that vaccine dossiers are submitted without delay to the Africa Regulatory Taskforce. The Taskforce will convene a dossier review **Expert Advisory Group** made up of the most preeminent technical experts on regulatory assessment from within and outside the continent. This Group will review dossiers of COVID-19 vaccines that will be destined for use in Africa and will complement the WHO's EUL/PQ and/or COVAX processes before they are delivered. This working group will share findings and results of the review with the regional economic communities to expedite regulatory reviews and advance the principles of reliance and work sharing.

**AGREES** this approach should be coordinated through the African Union, and the regional economic communities, based on the principles of reliance and work sharing for dossier review and approval.

**FURTHER AGREE** to adhere to the highest standards of safety monitoring, in collaboration with manufacturers and immunisation programmes, to ensure the safe rollout of COVID-19 vaccines in Africa.

**COLLECTIVELY AGREE**, as members of the Africa Regulatory Taskforce and National Regulatory Authorities, to commit to a standardized approach to appropriately fast-track regulatory decision-making on COVID-19 vaccines use in Africa.

