Africa Centres for Disease Control and Prevention (Africa CDC)

Africa Regulatory Taskforce has Endorsed the Emergency Used Listing for Two Versions of the AstraZeneca-Oxford Vaccine (AstraZeneca-SKBio in South Korea and Serum Institute of India)

The Africa Regulatory Taskforce is a joint effort established by the Africa Centres for Disease Control and Prevention (Africa CDC), the African Union Development Agency (AUDA-NEPAD) coordinated African Medicines Regulatory Harmonization (AMRH) Initiative and the World Health Organisation's (WHO) African Vaccine Regulatory Forum (AVAREF) to enable and provide support for an effective regulatory framework for COVID-19 Vaccine in Africa.

In order to properly guide Member States, the Africa Regulatory Taskforce has developed a framework (https://africacdc.org/download/guidance-on-emergency-expedited-regulatory-authorisation-and-access-to-covid-19-vaccines-in-africa/) for market authorisation of COVID-19 vaccines, which include three scenarios:

- **Scenario 1:** COVID-19 vaccines that have received WHO Emergency Used Listing /Pre-qualification (EUL/PQ) approval.
- **Scenario 2:** COVID-19 vaccines that have received approval from one or several Stringent Regulatory Authorities (SRAs) but not yet through WHO EUL/PQ.
- **Scenario 3:** COVID-19 vaccines that have received neither of the above.

Because WHO has granted approval for the **two versions of the AstraZeneca-Oxford vaccine (AstraZeneca-SKBio in South Korea and Serum Institute of India) (Scenario 1)**, the African Union countries are permitted to waive the AVAREF-led joint review process and commit to reliance directly on the WHO EUL/pre-qualification process (https://www.who.int/news/item/15-02-2021-who-lists-two-additional-covid-19-vaccines-for-emergency-use-and-covax-roll-out).

The Africa Regulatory Taskforce will be reviewing rolling data for the Sputnik V (Gamaleya National Center) and Ad26.COV2.S (Johnson and Johnson) to ensure that phase III clinical trial safety, efficacy data and severe adverse events (SAEs) requirements are met by vaccine developers. These two COVID-19 vaccines fall under scenario 3. The evaluation outcome will be provided after the review process is completed.

About the COVID-19 Vaccine AstraZeneca, formerly AZD1222

COVID-19 Vaccine AstraZeneca was co-invented by the University of Oxford and its spin-out company, Vaccitech. It uses a replication-deficient chimpanzee viral vector based on a weakened version of a common cold virus (adenovirus) that causes infections in chimpanzees and contains the genetic material of the SARS-CoV-2 virus spike protein. After vaccination, the surface spike protein is produced, priming the immune system to attack the SARS-CoV-2 virus if it later infects the body.

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Africa Centres for Disease Control and Prevention (Africa CDC), African Union Commission
Roosevelt Street W21 K19, Addis Ababa, Ethiopia
+251 11 551 7700 africacdc@africa-union.org www.africacdc.org africacdc @AfricaCDC