African Union and the Africa Centers for Disease Control and Prevention's Africa Regulatory Taskforce has endorsed the Emergency Used Authorization for Janssen COVID-19 Vaccine

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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 Vaccines 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 recognized Stringent Regulatory Authorities (SRAs) but not yet through WHO EUL/PQ.
- **Scenario 3:** COVID-19 vaccines that have received neither of the above.

Because the EMA (European Medicines Authority) has granted conditional approval for the Janssen COVID-19 vaccine and WHO has added Janssen vaccine to list of **safe and effective emergency tools against COVID-19,** the Africa Union and Africa CDC's **Regulatory Taskforce has endorsed the Emergency Used Authorization for the vaccine (see scenario #1).**

Because the EMA (European Medicines Authority) has granted conditional approval for the Janssen COVID-19 vaccine and WHO has granted Emergency Use Listing **(WHO EUL),** the Africa Union and Africa CDC's **Regulatory Taskforce has endorsed the Emergency Used Authorization for the vaccine (see scenario #1).** As such, African Union Members States are recommended to waive any review processes and rely directly on the WHO EUL via the AVAREF managed pathway described in Scenario **#1**. For details see *(https://extranet.who.int/pqweb/vaccines/who-recommendation-janssen-cilag-international-nv-belgium-covid-19-vaccine-ad26cov2-s* ; *Regulation and Prequalification (who.int)*; and Africa Regulatory Task Force)

The Africa Regulatory Taskforce will be reviewing rolling data for the Sputnik V and Sputnik Light (Gamaleya National Center) (**see scenario #3**) to ensure that Phase 3 safety, efficacy data and severe adverse events (SAEs) requirements are met by vaccine developers.

Africa CDC will share the outcome of the review with all African Union Member States once we complete the processes.

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