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

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 US Food Drug Administration (US FDA) has granted approval for the Janssen COVID-19 vaccine, the Africa Union and Africa CDC's **Regulatory Taskforce has endorsed the Emergency Used Authorization for the vaccine (see scenario #2)**. As such, African Union Members States are recommended to waive the AVAREF-led joint review process (see scenario #2) and rely directly on the US FDA's Emergency Use Authorization. For details see (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine).

The Africa Regulatory Taskforce will be reviewing rolling data for the Sputnik V (Gamaleya National Center), Sinovac and Sinopharm vaccines (**see scenario #3**) to ensure that Phase III 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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