African Union and the Africa Centers for Disease Control and Prevention's Africa Regulatory Taskforce has endorsed the Emergency Use Authorisation for COVID-19 Vaccine BIBP/ Sinopharm

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 Use 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.

The vaccine has been authorized by the Chinese National Regulatory Authority (NRA) – the National Medicinal Product Administration (NMPA) - as well as other regulatory authorities. Because WHO has granted Emergency Use Listing (EUL) for the COVID-19 Vaccine BIBP/ Sinopharm, the Africa Union and Africa CDC's **Regulatory Taskforce has endorsed the Emergency Use Authorisation for the vaccine (see scenario #1) and the specification is 0.5ml/dose, 1 dose/vial; or 2 doses/ vial; or 5 doses/vial.** As such, African Union Member 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-covid-19-vaccine-bibp*).

The Africa Regulatory Taskforce will discuss clinical data on Covaxin from phase 1, 2 and 3 clinical trials (**see scenario #3**) to ensure that phase 3 safety, efficacy data requirements are met by the vaccine developer.

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

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