

Africa Centres for Disease Control and Prevention (Africa CDC)

UPDATE: Statement to Member States regarding thromboembolic events after vaccination with Janssen COVID-19 vaccine (Johnson & Johnson)



Context

The COVID-19 vaccine Ad26.COV2.S, developed by Janssen (Johnson & Johnson), is a human adenovirus based vaccine which is administered as a single dose regimen to prevent COVID-19.

The Janssen COVID-19 vaccine has been issued an Emergency Use Authorization by the United States (U.S.) Food and Drug Administration (FDA). It is authorized in the European Union (EU) and it is also listed by the World Health Organization (WHO) for emergency use in all countries and for COVAX rollout. The Africa Regulatory Taskforce has endorsed the Emergency Use Authorization for the Janssen COVID-19 vaccine.

On 14th April 2021, Africa CDC released a statement informing Members States of a safety signal for the Janssen COVID-19 vaccine following reports of extremely rare and unusual blood clots in combination with low platelets (**thrombotic thrombocytopenia**) temporally associated with the administration of the vaccine in the USA. Six cases had been reported, including one death.

The USA and South Africa were the only 2 countries who had initiated roll out of the vaccine with 6.8 million and 290,000 doses administered by 13th April 2020, respectively. Out of an abundance of caution, they both recommended to pause the rollout, as global regulatory authorities reviewed and assessed the situation

Details of adverse events temporally related to Janssen vaccine

- The cases present as blood clots involving unusual sites such as, but not exclusively, veins in the brain (cerebral venous sinus thrombosis or CVST), the abdomen (splanchnic vein thrombosis) and the arteries, in combination with thrombocytopenia.
- These cases are similar to the cases of thrombotic thrombocytopenia temporally associated with the Astra Zeneca COVID-19 vaccine.
- Specific risk factors have not yet been identified.
- Cases have occurred in people below 60 years of age, all women, within three weeks of vaccination in the USA.
- By 23rd April 2021, a total of 15 cases had been reported in more than 6.8 million persons vaccinated, which corresponds to **a very low frequency of 2.2 cases per 1million individuals**.
- No case has been reported in South Africa.
- An autoimmune heparin induced thrombocytopenia (HIT) like disorder could possibly explain these cases of thrombotic thrombocytopenia.
- Thrombotic thrombocytopenia require early specialised clinical management to avoid complications.



Outcomes of review of adverse events temporally related to Janssen vaccine

Review of the South African Health Products Regulatory Authority (SAHPRA)

- SAHPRA undertook the review of safety data reported from the Sisonke Janssen COVID-19 vaccine implementation study in South Africa and from adverse events reported in the USA
- On 17th April 2021, SAHPRA recommended that the pause in the vaccine roll out under the Sisonke protocol be lifted under specific conditions to ensure strengthened screening and monitoring of study participants.

Review of the European Medicine Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC):

- On 20th April 2021, the PRAC concluded that reported cases of thrombotic thrombocytopenia should be listed as side effects of the vaccine.
- The EMA stated that the benefits of the Janssen vaccine in preventing COVID-19 associated risk of hospitalization and death outweigh the extremely low risk of side effects.

Review of the US CDC Advisory Committee on Immunization Practices (ACIP)

- On 23rd April 2021, after review of available safety data, the ACIP concluded that thrombotic thrombocytopenia is a very rare event whereas the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older
- The U.S. CDC and the U.S. FDA determined that the recommended pause regarding the use of the Janssen COVID-19 Vaccine in the U.S. should be lifted and use of the vaccine should resume.

Recommendations to AU Member States and health authorities

COVID-19 vaccines remain a key tool to prevent severe cases and deaths from COVID-19 infection. As such rapid access to safe and effective vaccines is paramount to the African Union vaccination strategy to achieve control of the pandemic.

The currently available evidence underscores the safety and efficacy of Janssen COVID-19 vaccine, notably in settings with high prevalence of the 501Y.V2 (or B.1.351) SARS CoV2 variant.

The position of Africa CDC is that ***the benefits of the Janssen COVID-19 vaccine outweigh the risks for people who receive it.***

National health care authorities should reinforce vaccine safety monitoring. Health care providers and clinicians should be informed of the risk of thrombotic thrombocytopenia in order to recognize and properly manage this very rare adverse event.

Africa CDC will continue to monitor reports of adverse events following immunization, for all COVID-19 vaccines, including the Janssen COVID-19 vaccine, and will provide further guidance to Member States.

