

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, with a demonstrated efficacy of 66% overall and 57% in a context with predominance of the 501Y.V2 SARS-COV-2 variant.

On 27th February 2021 the U.S. Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) for the use of Janssen COVID-19 vaccine in individuals 18 years of age and older.

On 11th March, the vaccine was authorized in the European Union (EU) and, on 12th March the vaccine was listed by the World Health Organization (WHO) for emergency use in all countries and for COVAX rollout. Outside of Africa, Janssen COVID-19 Vaccine is currently only used in the USA.

On 9th April 2021, the European Medicine Agency (EMA) announced its Pharmacovigilance Risk Assessment Committee (PRAC) had started a review of a safety signal following reports of thromboembolic events in 4 individuals who received the Janssen COVID-19 vaccine in the USA.

On 13th April 2021, the United States Centers for Disease Control and Prevention (US CDC) and Food and Drug Administration (FDA), out of an abundance of caution, have recommended a pause in the use of Janssen's COVID-19 vaccine due to reports of an extremely rare disorder involving blood clots in combination with low platelets in individuals who have received the COVID-19 vaccine.

Details of adverse events temporally related to Janssen vaccine in the USA

- The events reported are similar to cases of thrombotic thrombocytopenia temporally associated with administration of the AstraZeneca COVID-19 vaccine in Europe.
- The cases present with blood clots (cerebral venous sinus thrombosis or CVST) in combination with low platelets (thrombocytopenia).
- These events are extremely rare with 6 cases reported out of more than 6.8 million doses of the Janssen vaccine administered in the USA.
- All six cases – including the report of a death – occurred among women aged between 18 and 48 years. The interval from vaccine receipt to symptom onset ranged from 6 to 13 days.

What do these reports mean?

Reporting of adverse events following immunization (AEFI) is a routine activity for effective monitoring systems to ensure that vaccines are safe and are being safely administered. The US CDC indicated it will convene an emergency meeting of the Advisory Committee on Immunization Practices (ACIP) on 14th April 2021, to further review these cases. The US FDA is also investigating these cases.

What is the situation of the Janssen vaccine in Africa?

The Africa Regulatory Taskforce 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) has endorsed the Emergency Use Authorization for the Janssen COVID-19 vaccine.

The Janssen COVID-19 vaccine is presently only use in South Africa, of all 55 member states.

The Janssen COVID-19 vaccine was registered by the South African Health Products Regulatory Authority (SAHPRA) on April 6th and almost 290,000 doses had been administered.

On 13th April 2021, the South Africa Minister of Health announced that the country had not registered any reports of blood clots and thrombosis following vaccination with the Janssen COVID-19 vaccine. As a precautionary measure, the country has decided to pause the rollout of the vaccine to review and assess the situation along with global regulatory authorities.

Recommendations to AU Member States and health authorities

COVID-19 vaccines remain the only 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.

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.