

Statement to African Union Member States on the deployment of the AstraZeneca COVID-19 vaccine to the continent and concerns about adverse event reports coming from Europe

Context

On 15 February 2021, the World Health Organization listed the AstraZeneca/Oxford COVID-19 vaccine for both emergency use and distribution via the COVAX facility.¹ The African Regulatory Taskforce subsequently endorsed the WHO emergency use listing for this vaccine and the first shipments to Africa were initiated from the COVAX facility, with Ghana receiving the first consignment.

On 10 March 2021, the European Medicines Agency announced that four European countries suspended the use of the AstraZeneca COVID-19 vaccine (batch no. ABV5300) following reports of blood clots and bleeding disorders from Austria.²


Similar events were reported by additional European member states during this time and by 15 March 2021, six countries³ suspended the use of the AstraZeneca vaccine (batch no. ABV5300), 11 countries⁴ paused their AstraZeneca vaccination campaigns *entirely regardless of batch*, while three countries⁵ indicated that they will continue use of the vaccine.

What do these reports mean?

Reporting of **adverse events following immunization** is part of the routine monitoring system put in place to ensure that vaccines remain safe and are being safely administered.

The adverse events reported from Europe are **not listed as side effects associated with the AstraZeneca vaccine**. To date, there has been no causal link established between the administration of the vaccine and the events reported. Most importantly, the number of blood clots and bleeding disorders reported is no more than would normally occur in the population.

- ¹ <https://www.who.int/news/item/15-02-2021-who-lists-two-additional-covid-19-vaccines-for-emergency-use-and-covax-roll-out>
- ² <https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-prac-preliminary-view-suggests-no-specific-issue-batch-used-austria>
- ³ *Austria, Estonia, Lithuania, Luxembourg, Latvia and Italy.*
- ⁴ *Denmark, Norway, Iceland, the Netherlands, Ireland, Bulgaria, Italy, Spain, Portugal, France and Germany.*
- ⁵ *Czech Republic, Poland and the United Kingdom.*



As a precautionary measure, some European member States have opted to either suspend use of the specific vaccine batch concerned, or to pause their vaccination campaigns with the AstraZeneca vaccine entirely as investigations are ongoing.

Statement from the European Medicines Agency (EMA)

- On the 16th of March 2021,⁶ the European Medicines Agency issued a statement that its Pharmacovigilance Risk Assessment Committee (PRAC) is reviewing all reports of thromboembolic events occurring post vaccination.
- As of the 10th of March 2021, 30 thromboembolic events have been reported among more than 5 million people vaccinated with the AstraZeneca COVID-19 vaccine (batch no. ABV5300) in the EU. **This number of thromboembolic events is no higher than what is seen in the general population in absence of the vaccine.**
- Accordingly, the PRAC position is that the **vaccine's benefits continue to outweigh the risks** and the vaccine can continue to be administered while investigations are ongoing. The PRAC will conclude its investigations and advise on any further actions needed during an extraordinary meeting scheduled for the 18 March 2021.

Statement from the World Health Organization

- On the 17th of March 2021,⁷ the World Health Organization indicated that its Global Advisory Committee is carefully assessing the latest safety data regarding the AstraZeneca vaccine. The World Health Organization reiterated the EMA position that **the benefits of the AstraZeneca vaccine outweigh its risks and recommends that vaccination campaigns continue.**

Statement from vaccine manufacturer, AstraZeneca

- On the 14th of March 2021, AstraZeneca noted it had undertaken a review of available safety data of more than 17 million people vaccinated in the European Union and United Kingdom. AstraZeneca found no evidence of an increased risk of pulmonary embolism, deep vein thrombosis, or thrombocytopenia in any defined age group, gender, batch or country.
- Furthermore, during clinical trials, the number of thrombotic events was small, and was lower in those receiving the vaccine as compared to those who did not. There has also been no evidence of increased bleeding in over 60,000 participants enrolled.

⁶ <https://www.ema.europa.eu/en/news/investigation-covid-19-vaccine-astrazeneca-thromboembolic-events-continues>

⁷ <https://www.who.int/news/item/17-03-2021-who-statement-on-astrazeneca-covid-19-vaccine-safety-signals>

- AstraZeneca highlighted that during production of the vaccine, more than 60 quality tests were conducted by AstraZeneca and over 20 independent testing laboratories. There have been no confirmed issues related to any batch of the vaccine used in Europe, or the rest of the world.

AstraZeneca vaccine use in Africa

Africa is facing significant challenges in securing access to the COVID-19 vaccines needed to achieve its goal of vaccinating at least 60% of the continent's population. As of 15 March 2021, 23.6 million doses of vaccine had been distributed on the continent. This corresponds to a continental coverage of only 1.7%. The AstraZeneca vaccine, allocated principally via the COVAX facility, accounts for 20.5 million (87%) doses and is the main vaccine used in Africa.

Africa CDC's recommendations to AU Member States and health authorities

COVID-19 vaccines remain a strategic approach for the prevention of severe cases of and COVID-19 related deaths. Africa CDC encourages AU member States to facilitate rapid access to safe and effective vaccines that reduce COVID-19 severity and COVID-19 related hospitalizations. This is strategic for the control of the epidemic and the rapid return of the growth and development of the continent.

On Tuesday 16th of March, Africa CDC called for a special session of the African Taskforce for Coronavirus (AFTCOR), which include experts from across Africa and the world, to review the AstraZeneca situation. From the evidence available and discussed during the AFTCOR special session, Africa CDC concluded that the benefits accruable from the AstraZeneca COVID-19, continue to outweigh its risks. Accordingly, Africa CDC recommends:

- AU Member States continue to roll-out the AstraZeneca vaccine as part of their vaccination campaigns.
- AU Member States ensure the routine monitoring, reporting and evaluation of Adverse Events Following Immunization.
- Policy decisions pertaining to vaccination roll-out be based on evidence and thorough regulatory review processes.

Africa CDC will continue to monitor the adverse events following immunization with all the COVID-19 vaccines and provide evidence-based recommendations as the situation evolves.