World Health Organization

Statement of the WHO Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 subcommittee on safety signals related to the AstraZeneca COVID-19 vaccine

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As of 17 March 2021, more than 120 million cases of COVID-19 infections, with more than 2 million deaths, had been reported globally. Vaccination remains a critical tool to help prevent further illness and death and to control the pandemic.

So far, more than 20 million doses of the AstraZeneca vaccine have been administered in Europe and more than 27 million doses of the Covishield vaccine (AstraZeneca vaccine by Serum Institute of India) have been administered in India.

The GACVS COVID-19 subcommittee met virtually on 16 and 19 March 2021 to review available information and data on thromboembolic events (blood clots) and thrombocytopenia (low platelets) after vaccination with the AstraZeneca COVID-19 vaccine.

The subcommittee reviewed clinical trial data and reports based on safety data from Europe, the United Kingdom, India, and Vigibase, the WHO global database of individual case safety reports.

Based on a careful scientific review of the available information, the subcommittee came to the following conclusions and recommendations:

- **The AstraZeneca COVID-19 vaccine (including Covishield) continues to have a positive benefit-risk profile, with tremendous potential to prevent infections and reduce deaths across the world.**
- **The available data do not suggest any overall increase in clotting conditions such as deep venous thrombosis or pulmonary embolism following administration of COVID-19 vaccines. Reported rates of thromboembolic events after COVID-19 vaccines are in line with the expected number of diagnoses of these conditions. Both conditions occur naturally and are not uncommon. They also occur as a result of COVID-19. The observed rates have been fewer than expected for such events.**
- **While very rare and unique thromboembolic events in combination with thrombocytopenia, such as cerebral venous sinus thrombosis (CVST), have also been reported following vaccination with the AstraZeneca COVID-19 vaccine in Europe, it is not certain that they have been caused by vaccination. The European Medicines Agency's Pharmacovigilance and Risk Assessment Committee has reviewed 18 cases of CVST out of a total of more than 20 million vaccinations with the AstraZeneca COVID-19 vaccine in Europe. A causal relationship between these rare events has not been established at this time** *(1)*.
- **Adequate education should be provided to health-care professionals and persons being vaccinated to recognize the signs and symptoms of all serious adverse events after vaccinations with all COVID-19 vaccines, so that people may seek and receive prompt and relevant medical care and treatment.**
- **The GACVS subcommittee recommends that countries continue to monitor the safety of all COVID-19 vaccines and promote reporting of suspected adverse events.**
- **The GACVS subcommittee also agrees with the European Medicines Agency's plans to further investigate and monitor for these events.**

The GACVS COVID-19 subcommittee will continue to review the safety data from all COVID-19 vaccines and update any advice as necessary. The WHO COVID-19 vaccine safety surveillance manual provides guidance to countries on the safety monitoring and adverse events data sharing for the new COVID-19 vaccines, and can be accessed here.

(1) EMA Statement: https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots

UK MHRA statement: https://www.gov.uk/government/news/uk-regulator-confirms-that-people-should-continue-to-receive-the-covid-19-vaccine-astrazeneca