



Interim statement of the COVID-19 subcommittee of the WHO Global Advisory Committee on vaccine safety on AstraZeneca COVID-19 vaccine

7 April 2021 Statement - The COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) has reviewed reports of rare cases of blood clots with low platelets following vaccination with the AstraZeneca COVID-19 vaccine (including Covishield) since their onset a few weeks ago.

At its most recent meeting on 7 April, 2021, the subcommittee reviewed latest information from the European Medicines Agency along with information from the United Kingdom's Medicines and other Health products Regulatory Agency (MHRA), and other Member States and noted the following:

Based on current information, a causal relationship between the vaccine and the occurrence of blood clots with low platelets is considered plausible but is not confirmed. Specialised studies are needed to fully understand the potential relationship between vaccination and possible risk factors.

The GACVS subcommittee will continue to gather and review further data, as it has done since the beginning of the COVID vaccine programme.

It is important to note that whilst concerning, the events under assessment are very rare, with low numbers reported among the almost 200 million individuals who have received the AstraZeneca COVID-19 vaccine around the world.

Rare adverse events following immunizations should be assessed against the risk of deaths from COVID-19 disease and the potential of the vaccines to prevent infections and reduce deaths due to diseases. In this context, it should be noted that as of today, at least 2.86 million people have died of COVID-19 disease worldwide.

Side effects within two- or three-days following vaccination, the majority of which are mild and local in nature, are expected and common. However, individuals who experience any severe symptoms – such as shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms, such

as severe and persistent headaches or blurred vision, tiny blood spots under the skin beyond the site of the injection - from around four to 20 days following vaccination, should seek urgent medical attention. Clinicians should be aware of relevant case definitions and clinical guidance for patients presenting thrombosis and thrombocytopenia following COVID-19 vaccination. To this end, the GACVS subcommittee also suggested that a committee of clinical experts including haematologists and other specialists is convened, for advice on clinical diagnosis and case management.

Active surveillance, including sentinel site / hospital case-based investigations should be considered, to further characterise these rare events. WHO has developed template protocols that countries could adapt for such studies. The GACVS will meet again next week to review additional data and will be issuing further recommendations as relevant

WHO is carefully monitoring the rollout of all COVID-19 vaccines and will continue to work closely with countries to manage potential risks, and to use science and data to drive response and recommendations.

In extensive vaccination campaigns, it is normal for countries to identify potential adverse events following immunization. This does not necessarily mean that the events are linked to vaccination itself, but they must be investigated to ensure that any safety concerns are addressed quickly. Vaccines, like all medicines, can have side effects. The administration of vaccines is based on a risk versus benefit analysis.

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