

18 March 2021 19:15 GMT

UK and EU regulatory agencies confirm *COVID-19 Vaccine AstraZeneca* is safe and effective

Today the Medicines Health Regulatory Authority (MHRA) and European Medicines Agency (EMA) reaffirmed the benefits of *COVID-19 Vaccine AstraZeneca* continue to far outweigh the risks.

Earlier today, the MHRA announced their review of the small number of thromboembolic events in over 11 million people who received *COVID-19 Vaccine AstraZeneca* in the UK. The UK regulator confirmed that the benefits of the vaccine in preventing COVID-19 far outweigh the risks, and people should continue to get vaccinated when asked to do so. Following the rigorous scientific review, the MHRA concluded there is no evidence that blood clots in veins are occurring more than would be expected in the absence of vaccination. A detailed review of five UK reports of a very rare and specific type of blood clot in the cerebral veins (sinus vein thrombosis) occurring together with lowered platelets (thrombocytopenia) is ongoing. This has been reported in fewer than one in a million people vaccinated so far in the UK, and can also occur naturally – a causal association with the vaccine has not been established.

Subsequently, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) concluded there was no increase in the overall risk of blood clots (thromboembolic events) with *COVID-19 Vaccine AstraZeneca*. However, the PRAC also concluded that, for very rare cases of serious thromboembolic events with thrombocytopenia, a causal link with the vaccine is not proven, but is possible and deserves further analysis. Furthermore, there was no evidence of a problem related to specific batches of the vaccine or to particular manufacturing sites.

AstraZeneca will continue to work closely with health authorities to ensure the appropriate use of *COVID-19 Vaccine AstraZeneca*. The Company recognises and will implement the recommendations of the PRAC, including the update of the product information, whilst continuing to understand the nature and relevance of these events to ensure the safe delivery of the vaccine continues during this public health crisis. Analysis of AstraZeneca's safety database on tens of millions of records for *COVID-19 Vaccine AstraZeneca* did not show that these events occurred any more commonly than would be expected in millions of people.

Ann Taylor, Chief Medical Officer, said: "Vaccine safety is paramount and we welcome the regulators' decisions which affirm the overwhelming benefit of our vaccine in stopping the pandemic. We trust that, after the regulators' careful decisions, vaccinations can once again resume across Europe."

Patient safety remains AstraZeneca's highest priority and the Company has robust processes in place for the collection, analysis and reporting of adverse events and these are shared with regulatory authorities around the world.

***COVID-19 Vaccine AstraZeneca*, formerly AZD1222**

COVID-19 Vaccine AstraZeneca was co-invented by the University of Oxford and its spin-out company, Vaccitech. It uses a replication-deficient chimpanzee viral vector based on a

weakened version of a common cold virus (adenovirus) that causes infections in chimpanzees and contains the genetic material of the SARS-CoV-2 virus spike protein. After vaccination, the surface spike protein is produced, priming the immune system to attack the SARS-CoV-2 virus if it later infects the body.

The vaccine has been granted a conditional marketing authorisation or emergency use in more than 70 countries across six continents, and with the recent Emergency Use Listing granted by the World Health Organization this accelerates the pathway to access in up to 142 countries through the COVAX Facility.

AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter [@AstraZeneca](https://twitter.com/AstraZeneca).

Contacts

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