UK regulator confirms that people should continue to receive the COVID-19 vaccine AstraZeneca

Today the UK regulator, following a rigorous scientific review of all the available data, said that the available evidence does not suggest that blood clots in veins (venous thromboembolism) are caused by COVID-19 Vaccine AstraZeneca. This follows a detailed review of report cases as well as data from hospital admissions and GP records. This has been confirmed by the Government's independent advisory group, the Commission on Human Medicines, whose expert scientists and clinicians have also reviewed the available data.

A further, detailed review into 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 less than 1 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.

The MHRA's advice remains that the benefits of the vaccines against COVID-19 continue to outweigh any risks and that the public should continue to get their vaccine when invited to do so.

Dr June Raine, MHRA Chief Executive, said:

> We continually monitor safety during use of all a vaccines to protect the public, and to ensure the benefits continue to outweigh the risks.
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> Our thorough and careful review, alongside the critical assessment of leading, independent scientists, shows that there is no evidence that that blood clots in veins is occurring more than would be expected in the absence of vaccination, for either vaccine.
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> We have received a very small number of reports of an extremely rare form of blood clot in the cerebral veins (sinus vein thrombosis, or CSVT) occurring together with lowered platelets soon after vaccination. This type of blood clot can occur naturally in people who have not been vaccinated, as well as in those suffering from COVID-19.
>
> Given the extremely rare rate of occurrence of these CSVT events

among the 11 million people vaccinated, and as a link to the vaccine is unproven, the benefits of the vaccine in preventing COVID-19, with its associated risk of hospitalisation and death, continue to outweigh the risks of potential side effects.

You should therefore continue to get your jab when it is your turn.

While we continue to investigate these cases, as a precautionary measure we would advise anyone with a headache that lasts for more than 4 days after vaccination, or bruising beyond the site of vaccination after a few days, to seek medical attention.

However, please remember that mild flu-like symptoms remain one of the most common side effects of any COVID-19 vaccine, including headache, chills and fever. These generally appear within a few hours and resolve within a day or two, but not everyone gets them.

We will continue to robustly monitor all the data we have on this extremely rare possible side effect.

Professor Sir Munir Pirmohamed, Chair of the Commission on Human Medicines, said:

The independent COVID-19 Expert Working Group of the Commission on Human Medicines, together with leading haematologists, conducted a rigorous analysis of all available evidence regarding reports of blood clots (thromboembolic events) and COVID-19 Vaccine AstraZeneca.

Our review has found that the available evidence does not suggest that blood clots are caused by COVID-19 Vaccine AstraZeneca.

We have been closely reviewing all reports of blood clots in the vein (venous thromboembolism, or VTE) following vaccination. There is no evidence either that VTE is occurring more often in people who have received the vaccine than in people who have not, for either vaccine.

However, we will continue to closely monitor the reports where

cerebral sinus venous thrombosis has occurred in conjunction with lowered platelets to understand whether there is any potential association. This type of blood clot can rarely occur naturally in unvaccinated people as well as in people with COVID-19 disease. In the UK, 5 possible cases of this have been reported to us so far, after 11 million doses of COVID-19 Vaccine AstraZeneca.

Further work with expert haematologists is under way to further understand the nature of these cases and whether there is a causal association with any of the vaccines. Given the extremely rare rate of occurrence of these events, the benefits of the AstraZeneca COVID vaccine, with the latest data suggesting an 80% reduction in hospitalisation and death from COVID disease, far outweigh any possible risks of the vaccine in the risk groups currently targeted in the UK.

Notes to Editor

- The British Society for Haematology has issued guidance on thrombosis and thrombocytopenia possibly occurring after vaccination with COVID-19 vaccines. This includes information on presentation and typical laboratory features, and treatment recommendations. The guidance also includes advice on recommended investigations for possible cases.
- The action taken by some countries to temporarily pause the use of the AstraZeneca vaccine has been based mainly on isolated reports of cerebral sinus vein thrombosis occurring together with thrombocytopenia (lowered platelets) shortly after vaccination. This type of thrombosis can also occur naturally in the absence of vaccination, can occur in association with COVID disease and is extremely rare, and a causal association with the vaccine has not been established. The reporting rate of this following vaccination in Germany has been 4 per million doses of the vaccine. In the UK, 5 possible cases of this form of blood clot with low platelets have so far been reported after 11 million doses of the AstraZeneca vaccine.
- The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- The Medicines and Healthcare products Regulatory Agency (‘the agency’) has three centres. The MHRA, the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The agency is an executive agency of the Department of Health and Social Care.
- The COVID-19 Vaccines Benefit Risk Expert Working Group of the Commission on Human Medicines is formed from 27 experts from outside of the MHRA, including virologists, epidemiologists, immunologists and toxicologists.
- The MHRA encourages anyone to report any suspicion or concern they have beyond the known, mild side effects on the Coronavirus Yellow Card site.

Reporters do not need to be sure of a link between a vaccine and a suspected side effect but are still encouraged to report.

- For more information on COVID-19 vaccine adverse reactions, see the MHRA's weekly report