Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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5th May 2021

Dear Ms Maria Imaz,

FOI 21/344

Thank you for contacting the MHRA regarding the reports we have received concerning a specific type of blood clot in the brain, known as cerebral venous sinus thrombosis (CVST) and other blood clotting cases (thromboembolic events) occurring together with low levels of platelets (thrombocytopenia).

Under the Freedom of Information (FOI) act, you have requested to be provided with the following:

Please provide clarity on the age of the 30+ patients who have been registered as having CVST or other thrombosis-related events with Thrombocytopenia following at least one dose of the COV-19 AstraZeneca (Vaxzevria) Vaccine.

Please provide clarity as to whether these patients had any underlying health issues.

The MHRA publishes a weekly summary of Yellow Card reporting which can be found on this link: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting. In this publication, you will find the specific information you have requested surrounding these case reports, including a breakdown of the age and sex of these patients.

The estimated number of first doses of COVID-19 Vaccine AstraZeneca administered in the UK by 21st April was 22 million giving an overall case incidence of 9.3 per million doses. Taking into account the different numbers of patients vaccinated with COVID-19 Vaccine AstraZeneca in different age groups, there is a higher reported incidence rate in the younger adult age groups compared to the older groups and the MHRA advises that this evolving evidence should be taken into account when considering the use of the vaccine.

Public Health England (PHE) has provided advice on vaccination in different age cohorts in its leaflet on COVID-19 vaccination and blood clotting document: Information on vaccination.

It is important to note that Yellow Card reports are not proof of a side effect occurring due to a vaccine but a suspicion by the reporter that the medicine or vaccine may have caused the side effect. Some events may have happened anyway, regardless of vaccination. This is particularly the case when millions of people are vaccinated.

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Unfortunately, we are unable to provide details of past medical history for individual cases. Because of the way this information is captured within our database, this would require manual extraction of the information from each individual case. Please be reassured that any information provided regarding a patient's past medical history or concurrent conditions is taken into account during the routine assessment of all cases that we receive.

As a precaution, administration of COVID-19 Vaccine AstraZeneca in people of any age who are at higher risk of blood clots because of their medical condition should be considered only if benefits from the protection from COVID-19 infection outweighs potential risks.

Anyone who experienced cerebral or other major blood clots occurring with low levels of platelets after their first vaccine dose of COVID-19 Vaccine AstraZeneca should not have their second dose. Anyone who did not have these side effects should come forward for their second dose when invited.

Pregnancy predisposes to thrombosis; therefore, women should discuss with their healthcare professional whether the benefits of having the vaccine outweigh the risks for them.

Dr June Raine, MHRA Chief Executive said:

"Over 44 million doses of vaccines against COVID-19 have now been administered in the UK, saving thousands of lives through the biggest vaccination programme that has ever taken place in this country.

"No effective medicine or vaccine is without risk. These specific kinds of blood clots with low platelets reported following COVID-19 Vaccine AstraZeneca remain extremely rare and unlikely to occur. The benefits of the vaccine continue to outweigh the risks for most people.

"It is still vitally important that people come forward for their vaccination when invited to do so.

"We ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report it to the Coronavirus Yellow Card website."

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,

Vigilance and Risk Management of Medicines Division

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