Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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MHRA

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3rd June 2021

Dear Z. Dare,

Our Ref: FOI 21/496

Thank you for contacting the MHRA regarding the reports we have received concerning 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 share details of the so far reported six incidents of VITT following second dose of Astra Zeneca's Covid-19 vaccine, including:

- Degree to which symptoms matched typical VITT cases following first dose
- Age of patients (or decade of age if required for patient confidentiality)
- Time of onset following second vaccination
- Any pre-existing auto-immune conditions or blood clotting disorders suffered by the patients
- Fatality rate

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.

In regard to your first two points, and in reference to the above publication, the MHRA are using the same criteria to identify reports of thromboembolic events and thrombocytopenia regardless of the dose administered. Most of the COVID-19 Vaccine AstraZeneca vaccinations administered in this Yellow Card reporting period (up to 19 May 2021) were second doses with approximately 10.7 million second doses now administered in total. This means that we are now able to more confidently estimate the incidence rates for second doses. The overall estimated incidence rate following the second dose is considerably lower than that estimated for the first dose, with no cases at all reported in patients under the age of 50. While the evidence on the risks following the second dose continue to evolve, the current data should provide those awaiting their second dose, especially those in younger age groups, with information that will help them make an informed choice about attending their second dose.

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Regarding your question about the time of onset following the second vaccination, although reports of thromboembolic events and thrombocytopenia remains extremely rare, there appears to be a higher risk in people shortly after the first dose of the AstraZeneca (AZ) vaccine. This is seen slightly more often in younger people and tends to occur between 4 days and 2 weeks following vaccination.

For the majority of reports received, the time from receiving a vaccination to when the events occurred were within 4 days to 2 weeks; however, some reports do include an event onset later than 2 weeks whilst others have not been provided. It is important to note that when submitting a Yellow Card, reporters may report the time to onset as the time when the first symptoms began, the time at which an admission occurred or a diagnosis. The MHRA consider all ADR reports in our ongoing analysis regardless of time to onset and look at a range of risk windows in our statistical analysis; we never exclude a case.

In reference to your fourth point, 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.

Finally, in regards to your question about fatality rates, up to 19 May 2021, the MHRA had received Yellow Card reports of 332 cases of major thromboembolic events (blood clots) with concurrent thrombocytopenia (low platelet counts) in the UK following vaccination with COVID-19 Vaccine AstraZeneca. These events occurred in patients aged from 18 to 93 years and the overall case fatality rate was 17% with 58 deaths. 17 cases have been reported after a second dose.

We fully evaluate all reports of serious suspected side effects as soon as they are received to consider whether the vaccine may have caused the event, or whether the event was likely to be purely coincidental. The reports we've received of thromboembolic events occurring together with low platelets have also been analysed by the Government's independent advisory body, the CHM and its COVID-19 Vaccines Benefit Risk Expert Working Group, which includes lay representatives and advice from leading haematologists. On the basis of this ongoing review, the advice remains that the benefits of the vaccine outweigh the risks in the majority of people.

Please note that a report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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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