Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

4th April 2024

**MHRA**
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

Dear [redacted]

**MHRA Ref: FOI 24/237**

Thank you for your Freedom of Information request dated 6th March 2024, where you requested:

- ***Any known adverse reaction concerns and/or figures that could cause unexplained death or death in someone known to take alcohol.***

Firstly, I'm sorry to hear of the unfortunate and unexpected death of the patient referenced within your email. If you suspect an adverse drug reaction (ADR) occurred and would like to submit a Yellow Card report on behalf of this individual, this can be made via the Yellow Card Website, Yellow Card App or via e-mail (yellowcard@mhra.gov.uk). However, if you would prefer to discuss this over the phone you can call us on our freephone line between 10am – 2pm on **0800 731 6789.** You may also be interested to know that you can download the free Yellow Card mobile app from iTunes Yellow Card for iOS or Playstore Yellow card for Android devices.

In response to your request, I can confirm that we have received a total of **18** spontaneous suspected UK Adverse Drug Reaction (ADR) reports with fatal outcomes, including the suspect drug COVID-19 vaccine AstraZeneca, where the patient's past medical history features one of these terms: *'alcohol abuse', 'alcohol use', 'alcohol use disorder', 'alcohol problem', 'alcoholic' or 'alcoholism'*. Please see a breakdown of these reports in Table 1 below. Please be aware that past medical history is an optional field and thus reporters do not have to provide this information in order to submit a report.

*Table 1: UK spontaneous suspected ADR reports for COVID-19 vaccine AstraZeneca with a fatal outcome, where the patient reported a past medical history of alcohol abuse, up to and including 22/03/2024.*

| Patient Medical History Term | Number of Fatal Reports |
|---|---|
| ALCOHOL ABUSE | 6 |
| ALCOHOLIC | 3 |
| ALCOHOLISM | 9 |
| ALCOHOL PROBLEM | 1 |
| ALCOHOL USE | 5 |
| ALCOHOL USE DISORDER | 1 |

We have also identified one additional spontaneous suspected UK ADR report with a fatal outcome, where the suspect drugs include both COVID-19 vaccine AstraZeneca and Alcohol, up to and

including 22/03/2024. A search was also conducted for any fatal reports where the suspect drug was COVID-19 vaccine AstraZeneca and alcohol was included as a concomitant drug (used alongside or up to 3 months before the suspect drug). We were unable to locate any reports for this search. To note, only one suspect drug is required to submit a report and it is based on suspicion that it has caused an adverse reaction alone. As a result, the true number of fatal reports where the patient was using alcohol concomitantly could be greater.

When considering the attached spontaneous ADR data, it is important to be additionally aware of the following points:

- A reported reaction **does not** necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine, and are reported via the Yellow Card Scheme, does not in itself mean that they are proven to have been caused by the vaccine. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug, and may be stimulated by promotion and publicity about a drug.

As these data do not necessarily refer to proven side effects, you should refer to the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) for details on the possible side effects of the COVID-19 vaccine AstraZeneca. The MHRA has been proactively monitoring the safety of all approved COVID-19 vaccines for near real-time safety monitoring at the population level, you can also use the interactive Drug Analysis Profiles (iDAPs) that provide a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for medicines and COVID-19 vaccines. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. Following this, if you would like more information on the COVID-19 vaccines, you can find a further summary and analysis of all licensed COVID-19 vaccines here, and general statistics on vaccine uptake here.

I feel it is important to note, the Medicines and Healthcare products Regulatory Agency (MHRA) has closely monitored the safety of the COVID-19 vaccines since the initial roll out in December 2020. Since this time, over 158 million doses of COVID-19 vaccines have been given in the UK alone, and no link has been found between vaccination and increased risk of adverse events or death in association with alcohol use.

Unfortunately, it is impossible to accurately predict how different individuals will react to a medicine or vaccine. Whilst medicines can be safe and effective in thousands of patients, other individuals seem to be particularly susceptible to side effects and it is very unfortunate that it is impossible to predict who will experience side effects to a medicine or vaccine prior to use. It is also true that an individual may suffer no ill effects from one dose of a vaccine but may suffer them from another. Currently the guidance remains that the benefits outweigh the risks for the available COVID-19 vaccines.

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.

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Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division



If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
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