Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

12th February 2024

MHRA
10 South Colonnade
Canary Wharf
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United Kingdom

www.gov.uk/mhra

Dear [redacted]

MHRA Ref: FOI 24/054 & FOI 24/056

Thank you for your Freedom of Information requests dated 17th and 18th January 2024, where you requested information regarding reported adverse events in association with specific batches of Pfizer and AstraZeneca COVID-19 vaccines.

Further to your request, we have conducted searches within our database for the total number of UK spontaneous suspected Adverse Drug Reaction (ADR) reports for the batches '**FH4751**' (Pfizer/BioNTech COVID-19 vaccine), '**AB0002**' (COVID-19 AstraZeneca vaccine), and '**PV46676**' (COVID-19 AstraZeneca vaccine). Please see Table 1 below which shows the number of ADR reports we have received respective to the batch number requested, up to and including 05/02/2024.

When considering this data, it is important to note that it is not mandatory to provide batch numbers when submitting an ADR report for a medicine or vaccine, and therefore the number of reports provided may not be a true reflection of the number of ADR reports submitted for the respective batches. In addition, not all batches of the COVID-19 vaccines are the same size, and some batches may have had more wastage than others or be distributed more widely outside of the UK. Therefore, we would not expect the number of ADR reports for all batches to be the same as they have been administered to different numbers of patients.

Furthermore, different batches would have been used at different stages of the vaccination campaign, and in different patient groups, which could also impact reporting rates. For example, reporting rates were typically higher at the beginning of the vaccination campaign as individuals received their first dose and the likelihood of experiencing a reaction, as well as the propensity to report it, differs across patients of different ages. Please note that our analysis of these reports, which takes into account product batch number, did not result in any safety concerns. Please be assured that the MHRA reviews this data regularly and we would communicate any concerns raised with the public and healthcare professionals. If you would like further information on batch usage, please contact the UK Health Security Agency (UKHSA) who hold this information.

Table 1. Total number of UK spontaneous suspected ADR reports for specified COVID-19 vaccine batch numbers, up to and including 05/02/2024.

COVID-19 Vaccine batch number	Number of Reports
FH4751	958

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AB0002	3206
PV46676	2181

Please also see the Vaccine Analysis Prints (VAPs) attached which show all reported reactions within the respective ADR reports. The attached Drug Analysis Print (DAP) guidance sheet provides you with further information on how to interpret the prints. It is important to note that the total number of reactions in the table will not be equal to the total number of unique reports, as one report may contain more than one reaction.

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 product information which can be found here: Product Information | Coronavirus (COVID-19) (mhra.gov.uk) for details on the possible side effects of each vaccine. 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.

Please be assured that the MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are assessed and cumulative information reviewed at regular intervals. Vaccines encompass a wide variety of products with different indications, different ingredients and different mechanisms of action and as such safety for each vaccine is considered individually rather than as a group.

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,

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FOI Team,
Vigilance and Risk Management of Medicines Division

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