Medicines & Healthcare products Regulatory Agency

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United Kingdom
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[redacted]

19th March 2024

Dear [redacted],

MHRA Ref: FOI 24/170

Thank you for your Freedom of Information request dated 20th February 2024 where you requested details of the number of Adverse Drug Reaction (ADR) reports for the COVID-19 AstraZeneca vaccine, specifically batch 'PV46673'.

I can confirm that the MHRA does hold the information you have requested. Up to the 14 March 2024, the MHRA has received **1669** UK spontaneous suspected adverse reaction reports for the COVID-19 AstraZeneca vaccine, batch 'PV46673', where the reporter stated that the vaccine was administered in April 2021.

It is important to note that reporters are encouraged to provide details of the batch number and the date the vaccine was administered, when reporting to the Yellow Card scheme, however, this is not mandatory. Additionally, batch number is collected in a free text field and therefore entries vary between reports depending on how the information has been entered. Whilst we aim to include all relevant reports in the information provided, this exercise is carried out through manual review and uses a standard set of known variations in batch text, including:

- A space between letters and numbers
- A dash or forward slash between letters and numbers
- Variations between the number 0 and the letter O
- Variations between the number 2 or 7 and the letter Z

Not all batches of the COVID-19 vaccines are the same size, and some batches may have had more wastage than other batches 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.

For details of the suspected adverse reactions included in these reports, please find attached a Vaccine Analysis Print (VAP). The attached guidance sheet provides you with further information on how to interpret the print. 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 of the COVID-19 vaccine AstraZeneca, which can be found here, for details on the possible side effects of each vaccine. 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,

FOI Team,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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