Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

15 March 2024

www.gov.uk/mhra

Dear Colleague,

RE: FOI 24/163

Thank you for your information request dated 19 February 2024 where you requested *"Please could you indicate what adverse events/ reactions are associated with AstraZeneca batch PV46674, how many vaccinations were known to be given in the UK from this batch, and how many people (to date) have reported adverse reactions from this batch?"*

I can confirm that the MHRA hold some of the information you have requested. Whilst we consider vaccine uptake as part of our analysis of the safety of vaccines, information on the number of individuals administered a specific batch is not held by the MHRA nor is the number of each batch delivered. This information is held by the UK Health Security Agency (UKHSA). UKHSA are a public authority under the FOIA and you may wish to direct a request for this information to them at - InformationRights@UKHSA.gov.uk

Following a search of our database, the MHRA have received 2,135 UK spontaneous suspected adverse reaction reports for the COVID-19 AstraZeneca vaccine with batch PV466674 up to and including 6 March 2024. On a Yellow Card report, batch number is an optional field and is also in free text format. Therefore, this information may not always be provided or when this information is provided, entries will vary between reports depending on how the reporter has entered this information. Providing batch information requires manual review and we cannot guarantee all reports will be included.

Please note that 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.

Please find attached a Vaccine Analysis Print (VAP) which contains information on the reported adverse reactions and the corresponding number of reports for the vaccine. The attached guidance

sheet provides you with further information on how to interpret the print. When viewing this data you should note:

- The likelihood of experiencing an adverse reaction when taking a vaccine cannot be estimated from the information in VAP. This is because we have limited information about how many people have taken the vaccine without experiencing a reaction.
- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report on a VAP does not necessarily mean that the vaccine has caused the reaction.
- It is not possible to compare the safety of different vaccines by comparing the numbers presented in the vaccine reports. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: https://products.mhra.gov.uk/ for details on the possible side effects of these vaccines.

We 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

If you have a query about the information provided, please reply to this email

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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Information Commissioner's Office
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