Medicines & Healthcare products Regulatory Agency

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[redacted]

9 November 2023

Dear [redacted]

FOI 23/776 - Detail of Yellow Card Return by Batch Number of AZ Vaccine - FOIA request)

Thank you for your email dated 12 October 2023 in response to our internal review of request FOI 21/1202. This response is in relation to the information you have requested from us only.

In the meantime, while you are doing this, I would be happy to receive the data that you suggest for the batches which gave the 'Top 10' highest reaction rates (not numbers).

Please could you make sure that batch number PV46677 is included in your analysis.

In terms of your difficulties of matching location, I would be happy to receive this summarised (e.g., by NHS region/Trust) and I would think that using address postcode would be fine as a proxy given we were in lockdown when AZ was administered, and most people would not have travelled far.

In the internal review for FOI 21/102 a suggestion for refinement was provided to you. Your request above deviates slightly from this and as such I can confirm that we only hold some of the information you have requested. The MHRA cannot provide data for the *batches which gave the 'Top 10' highest reaction rates* as we do not hold this information. To calculate a reaction rate for a specific batch, two pieces of information is required:

- The first is the number of people receiving that batch of vaccination. 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. This information is held by the UK Health Security Agency (UKHSA).

- The second is the number of individuals who have suffered adverse reactions to a given batch of vaccination. As the Yellow Card scheme is voluntary, 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 Yellow Card data cannot be

used to determine the incidence of a reaction or compare the safety profile of different batches of vaccination.

We acknowledge that you have a strong interest in receiving information regarding Yellow Card data by batch number of COVID-19 Vaccine AstraZeneca. Therefore, in an attempt to fill your request and to be helpful, we are providing you with Table 1, which we have attached to this response. Table 1 displays the 10 COVID-19 Vaccine AstraZeneca batches with the highest number of Adverse Drug Reaction (ADR) reports, broken down by the area the reporter submitted the ADR report from and the number of reports received from that area.

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 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 UKHSA who hold this information.

When considering the spontaneous ADR data provided in Table 1, it is important to be 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 or events 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 vaccines. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls over time.

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 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
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