Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

[redacted]

29 January 2024

FOI 24/003

Dear [redacted]

Thank you for your information request, dated 31 December 2023 where you asked:

1. *Please could you tell me how you did the monitoring to ensure there was no particular issue with a batch then?*

2. *Surely you must know how much of these batches were delivered/used in the UK if you had any controls at all?*

Please will you provide me with the following:

For the number/type of adverse reactions for each and every batch used in the UK:

3. *Database of yellow card reports for adverse reactions for the AZ Covid Vaccine. I do not need any personal identifiable details but DOB/age and postcode is required where given.*

For the Exposed to Risk.

4. *Database of vaccinations administered in the UK by batch number. Again I do not need personal identifiable details but DOB/age and postcode of administration centre is required.*

5. *Of course if you have already got an analysis which you are willing to share which shows the adverse reaction rate by batch number you can send me that instead!*

Firstly, it should be noted that your requests listed above have largely been answered in your previous requests. To confirm, we either do not hold the information you have requested, or the information is exempt for reasons again explained below.

In response to your first question on how the monitoring was performed, I would like to repeat what was stated in the internal review of FOI 22/1202. All adverse drug reaction reports are added to our database and are assessed together with additional sources of

evidence, by a team of safety experts. This cumulative assessment will include review of the information provided, including the batch number of the vaccine administered. Additionally, for certain adverse events of special interest, we can apply statistical techniques that can tell us if we are seeing more events than we would expect to see, based on what is known about background rates of illness in the absence of vaccination. This aims to account for factors such as coincidental illness and would also help to identify an increase in reports if there was a batch specific safety issue for example. However, it is important to consider that the reporting of suspected ADRs is voluntary and reporting rates are influenced by a number of factors including how new a medicine is and how widely it is used. As such, reporting rates can fluctuate over time. The batches of COVID-19 vaccines were distributed at different times and used in different patient groups. Therefore, Yellow Card reports alone should not be used as an indication of batch safety.

In regard to your second question on the number of each batch delivered/used and administered in the UK, as detailed in our response to FOI 23/776, 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). Please note that the MHRA certify vaccine batches prior to their release onto the UK market, however the MHRA does not have a role in how the vaccines are deployed, this responsibility lies with 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

In answer to your third question where you requested Yellow Card data broken down by batch, DOB/age and postcode, I would like to restate our previous response from the internal review of FOI 21/1202. The information regarding batch you have requested is exempt under Section 12 of the FOIA. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information. The review which was completed for the internal review of FOI 21/1202 in October 2023, estimated that this would take approximately 30.3 hours. Since this time the MHRA have received further reports and as such this time will have increased further.

As you know when Section 12 is applied, we are required to provide advice and assistance to the requester, to help them make a new request which could be dealt with within the 24-hour appropriate limit. Previously we have provided you with a table which displayed the number of reports for the 10 batch numbers associated with the highest volume of reports broken down by geographical location, as well as the number of ADR reports received for batch number PV46677 broken down by geographical area. As such we believe we have provided a suitable alternative and provided this to you within your last request. We are able to provide similar information to that provided in your last refined request, including if you are interested in other batches or alternatively other COVID-19 vaccinations. However please bear in mind that the section 12 time/cost exemption applies to 24-hours of retrieval within a 60-day time period; as such you should schedule your requests accordingly. If you interested in receiving data under a refined request as suggested, please email MHRACustomerServices@mhra.gov.uk.

Please also be aware that due to data protection laws, we are unable to provide individual patient's ages or dates of birth or their address/postcode if the patient is themselves the reporter of the Yellow Card. This data would be exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the Freedom of Information Act. Therefore, any information on age provided would be in the form of aggregated tables.

Further to question 4, please see above response to questions 2 and 3 covering vaccine administrations and vaccinee age/DOB. You also requested information on the postcode of the vaccination centre. I would like to restate our previous response which was given in FOI 23/776 and again further clarified in the internal review of FOI 23/776. This is not information that is held by the MHRA. Whilst Yellow Card reports collect reporter contact details this could be an email or a postal address. However, if address is provided this could be a patient's home address or a GP address for instance and not where the vaccine was administered. Further, reporter contacts details would not be releasable under section 40 (personal information) of the FOIA.

Concerning your fifth and last question, I would again like to restate our previous response which was given in FOI 23/776 and again further clarified in the internal review of FOI 23/776. This response stated that the MHRA cannot provide data on reaction rates of batches as we do not hold this information. To calculate a reaction rate for a specific batch, two pieces of information are required:

- The first is the number of people receiving that batch of vaccination. Again 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.

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
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF