Medicines & Healthcare products Regulatory Agency

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[redacted]

19 March 2024

Dear [redacted]

FOI 24/184

Thank you for your Freedom of Information (FOI) request dated 23 February. Following your original request, FOI 24/108, we asked for some clarification on the data you wished to receive and provided you with examples information we were able to provide within the appropriate limit under Section 12 of the FOIA. Your new request asks for a larger volume of data than what was suggested as advice and assistance in our previous response. Your new requests asks for, '*the 20 most frequently reported batch numbers for each of the four vaccines listed on my original request* (FOI 24/108)*, including separate aggregated tables for patient age and patient sex, for each of the vaccines specified in the original request*'.

I can confirm that we do hold the requested information on batch numbers, patient age and patient sex where these are provided by the reporter of the Yellow Card. However, we have determined that the information is exempt under Section 12 of the Freedom of Information Act, and we cannot process your request any further.

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.

Batch number is a free text field on a Yellow Card form and as such includes vast amounts of variation where reporters have mistyped, added spaces/hyphens, or included expiry dates, for example. Upon review of the data held, there are 10969 variations of the batch number field for COVID-19 AstraZeneca vaccine Yellow Card reports, 9919 variations of the batch number field for COVID-19 Pfizer/BioNTech Vaccine Yellow Card reports, 2367

variations of the batch number field for COVID-19 Vaccine Moderna Yellow Card reports and 184 variations of the batch number field for GSK/Sanofi VidPrevtyn Beta Yellow Card reports. To be able to provide this information, initially all variations will have to be reviewed in order to discount any that definitively do not relate to batch numbers. Based on a crude search this step took approximately 1 hour.

The remaining variations will then need cross-checking against known batch numbers to exclude any that do not correspond to a Covid-19 vaccine.

Subsequently, the four most common variations of batch number are used to group into established batches:

- A space between letters and numbers
- A dash between letters and numbers
- Variations between the number 0 and the letter O
- Variations between the number 2 and the letter Z *

After this is complete the remaining batch number variations are reviewed to ensure no further variation should be included where it is obvious the text provided relates to a known batch number. Based on a sampling exercise this step took approximately 18 minutes for each batch and in some instances longer, totalling 24 hours for the 80 batches which we would need to provide in this request.

Lastly, after each run is complete the data needs to be put into an acceptable format to complete retrieval which is estimated to take approximately 30 minutes for all of the vaccines requested. In total it is estimated that this will take a minimum of 25.5 hours for us to complete the first part of your request.

For the second part of your request, we have understood this as a request for age and sex data for each of the four vaccines you requested rather than by individual batch. Whilst we do hold this information, it is exempt from release under Section 21 of the FOIA (Information accessible by other means), as this is already publicly available and can be found here: https://yellowcard.mhra.gov.uk/idaps.

The COVID-19 vaccine reports contain a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for all COVID-19 vaccines. The reports can be filtered by age and sex. Conclusions on the safety and risks of the vaccines cannot be made on the data shown in the reports alone. Therefore, when reviewing the data within the reports it is important to do so in the context of the essential guidance at the bottom of the report to ensure that you do not misinterpret the data. If you would like aggregated age and sex tables for VidPrevtyn Beta, this can be provided separately in a new request as this vaccine data is not currently published.

In accordance with Section 16 of the FOI, concerning the provision of advice and assistance to those requesting information under FOI, we previously provided some examples of what we are able to provide for you based on your request, within the appropriate limit under Section 12 of the FOIA. We would recommend that you ask for one of the below:

- The most frequently reported batch number for each of the four vaccines listed on

your original request, including separate aggregated tables for patient age and patient sex, for each of the four batches.

OR –

• The three most frequently reported batch numbers for each of the four vaccines listed on your original request. Including separate aggregated tables for patient age and patient sex, for all the three batches combined, for each of the four COVID-19 vaccines requested.

OR –

• The ten most frequently reported batch numbers for each of the four vaccines listed on your original request.

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
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SK9 5AF