Medicines & Healthcare products
Regulatory Agency

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[redacted]

31 August 2023

Dear [redacted]

FOI 23/600

Thank you for your email dated 9 August 2023, where you requested a weekly breakdown of all Adverse Drug Reaction (ADR) reports that report the COVID-19 Vaccine AstraZeneca as the suspect vaccination, from 1 November 2020 to date, broken down by reaction reported and whether that reaction was reported with a fatal outcome.

As you are aware, from February 2021 to March 2023 the MHRA published a weekly, then monthly summary of coronavirus Yellow Card reporting. This was initially accompanied by Vaccine Analysis Prints (VAPs) in PDF format, which you have described in your correspondence. These VAPs were then replaced by data published in an interactive format, which we continue to update regularly.

From your request, I understand that you would like to be provided with a VAP in PDF format for the COVID-19 Vaccine AstraZeneca, for each week between November 2020 and August 2023. I can confirm that the MHRA holds the information that you have requested. However, we have also determined that the information is exempt under Section 12 of the Freedom of Information (FOI) 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.

As described above, the MHRA produced a VAP in PDF format for each COVID-19 vaccine until we moved the data to a more interactive format which is regularly published on our website. To create one VAP, an individual would need to extract and validate the data for a given week, before presenting this in the PDF format. We estimate that this process takes at least 1 hour. As the MHRA only already holds the data in PDF format until November 2022, we would need to conduct this exercise for approximately 40 weeks' worth of additional data which would mean an individual would spend over 24 hours locating, retrieving, and

extracting the information for your request, therefore exceeding the time limit defined under the FOI act.

You also noted within your correspondence that if your request was refused under Section 12, you'd like to be supplied with the number of ADR reports for COVID-19 Vaccine AstraZeneca per week since November 2020. Please find attached Annex 1 which details the number of UK spontaneous suspected ADR reports received by the MHRA for the COVID-19 Vaccine AstraZeneca per week since November 2020. Weeks begin on Mondays, starting with the first full week in the year, thus: Week 1 of 2021 is Monday 4 January through Sunday 10 January. Please note that these dates differ from those provided within the published weekly summary of COVID-19 reporting.

When considering the spontaneous ADR data provided it is important to be aware of the following points:

- Different vaccines would have been used at different stages of the vaccination campaign, and in different patient groups, which could impact reporting rates. For example, reporting rates were typically higher at the beginning of the vaccination campaign as individuals received their first dose. The likelihood of experiencing a reaction, as well as the propensity to report it, differs across patients of different ages.
- 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.

Additionally, the MHRA are happy to provide the VAPs that we already hold, dated between January 2021 and November 2022 if this would be helpful. Furthermore, if you are able to refine your request further by limiting the time period you would like the weekly data for, or increasing the intervals in which you would like the data provided, please submit a new request to MHRACustomerServices@mhra.gov.uk and we would be happy to consider this.

Unfortunately, we have only partially fulfilled your 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

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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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