Medicines & Healthcare products
Regulatory Agency

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United Kingdom
gov.uk/mhra

21 August 2023

Dear [redacted]

FOI 23/553

Thank you for your email of 28 July 2023, which we are responding to under the Freedom of Information Act.

Please note the first question you have asked contains personal information; the response to any FOIA request is a public disclosure, not a private response to an individual, Due to the public nature of FOI responses, in the list of your questions below, we have removed the personal information that was included in the first question.

1. [redacted] *whether batch number ER1741 relates to COVID-19 vaccine AstraZeneca or COVID-19 vaccine Pfizer/BioNTech?'.*

Your other questions were:

2. *Please provide a copy of the guidance sheet issued for the Pfizer vaccine. If this changed between ER1741 and FF8288, please provide both guidance sheets.*

3. *Have there been any yellow card or VAERS notifications detailing the following complications for FF8288:*

    1. *Deaths*
    2. *Pulmonary Embolism*
    3. *DVT*
    4. *Thrombosis*
    5. *Limb ischaemia*
    6. *Intestinal Ischaemia*

4. *Have you been notified of any Coroners Inquests following administration of FF8288? If so, how many?*

Please see the information requested below.

Request 1

We can confirm that batch ER1741 was a batch of COVID vaccine Pfizer/BioNTech.

Request 2

Information for healthcare professionals and the public about the Pfizer/BioNTech COVID-19 vaccine is available at: https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19 .This includes the current Summary of Product Characteristics (SmPC) for healthcare professionals and the current UK Patient Information Leaflet (PIL). The updates to the SmPC and PIL since this vaccine was first authorised can be viewed by under '**See all updates**' at the top of this webpage.

If you can provide the specific dates for the available information at the time points you are interested in, we will be able to provide the information available at these times.

Request 3

Following a search of our Yellow Card database up to and including 1st August 2023, the total number of UK spontaneous suspected Adverse Drug Reaction (ADR) reports for COVID-19 Vaccine Pfizer/BioNTech batch number FF8288 that had a fatal outcome was 7. The total number of UK spontaneous suspected ADR reports received for each ADR requested in your query are listed in table 1. We are unable to provide data where the number of reports is less than 5 in order to protect patient and reporter confidentiality. Therefore, some of the breakdowns requested have not been fulfilled. Where there are less than 5 reports, numbers have been replaced with a ^.

Table 1: UK spontaneous suspected ADR reports for COVID-19 vaccine Pfizer/BioNTech FF8288 up to and including the 1st August 2023.

Suspected Adverse Drug Reaction	Number of UK Spontaneous Reports
Pulmonary Embolism	10
Deep Vein Thrombosis	13
Thrombosis	38
Limb ischaemia	^
Intestinal Ischaemia	^

When considering this data, it is important to note that it is not mandatory to provide batch numbers when submitting an adverse reaction report for a medicine or vaccine, and therefore the number of reports provided may not be a true reflection of the number of Yellow Card COVID-19 vaccine reports submitted for the respective batches.

In addition, 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.

Finally, when viewing the data provided, you should remember that:

- 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 does not necessarily mean that the vaccine has caused the reaction.

- Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors.

For a vaccine to be considered safe, the expected benefits will be greater than the risk of having harmful reactions. It is important to note that most people receive vaccinations without having any serious side effects.

Please note VAERS data is held by the United States (US) Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration.

Request 4

We have been notified of one Coroner's Inquest following administration of Pfizer/BioNTech COVID-19 vaccine batch number FF8288. However, it is not mandatory for a Coroner to notify the MHRA if they become aware of a death where a COVID-19 vaccination is cited.

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,

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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Water Lane
Wilmslow
Cheshire
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