Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

29th April 2024

Dear [redacted]

FOI 24/307

Thank you for your FOI request dated 28th March 2024, where you requested the following information:

> *I am writing to submit a Freedom of Information request about the following five batch numbers of Covid vaccine:*
>
> *Pfizer-BioNTech Batch number: EN1185*
> *Pfizer-BioNTech Batch number: EM4965*
> *Pfizer Ltd Batch number: FH0114*
> *Pfizer Ltd Batch number: FM3092*
> *Pfizer Ltd Batch number: GD6797*
>
> 1. *Have there been any reported suspected adverse incidents, such as side effects, from any of the above batch numbers of Covid vaccine on the Yellow card reporting site? If so, which batch numbers?*
> 2. *How many reports in numbers have there been for each batch number?*
> 3. *How many reports from healthcare professionals for each batch number?*
> 4. *How many reports from members of the public for each batch number?*
> 5. *What side effects have been reported for each batch number?*

I can confirm that the MHRA hold this information. Please find below our response including data for your request.

Please find below Table 1 the number of reports reported for each Pfizer Covid-19 vaccine batch number requested:

Table 1 UK spontaneous Adverse Drug Reaction (ADR) reports up to and including 15/04/2024 for Pfizer BioNTech Covid-19 vaccine batch numbers EN1185, EM4965, FH0114, FM3092 and GD6797

Batch number	Number of Yellow Card reports
EN1185	1745
EM4965	2851
FH0114	488
FM3092	292
GD6797	135

Please find below in Table 2 a breakdown of the number of reports reported by health professionals or members of the public for each batch number requested:

Table 2: UK spontaneous Adverse Drug Reaction (ADR) reports up to and including 15/04/2024 for Pfizer BioNTech Covid-19 vaccine batch numbers EN1185, EM4965, FH0114, FM3092 and GD6797 by reporter qualification.

Batch number	Number of reports reported by health professionals	Number of reports reported by members of the public
EN1185	273	1385
EM4965	637	2089
FH0114	73	399
FM3092	37	240
GD6797	10	118

*It is important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people reporting, as one report may have multiple reporters. In addition, please note that reports from pharmaceutical companies are not included in this table therefore the total reports for each batch here may not equal the totals in Table 1.

It should be noted that Yellow Card data cannot be used to compare the safety profile of different vaccine batches. 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.

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. We can confirm that no safety issues have been identified with any of these batches.

Please find attached Vaccine Analysis Prints (VAP) for each batch number, which contain information on the reported adverse reactions and the number of reports with a fatal outcome. The attached guidance sheet provides you with further information on how to interpret the print.

When considering the spontaneous data within this response, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine/vaccine, only that the reporter had a suspicion it may have. Each year, millions of doses of routine vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that 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 cannot be used to determine the incidence of a reaction or compare the safety profile of different vaccines. Reporting rates are influenced by the seriousness of the reaction, their ease of recognition, the extent of use and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines, vaccines during the first one to two years on the market and then falls over time.

We hope the information provided is helpful, but 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

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

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