Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2025/00089**

28 February 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 2 February. You wrote:

> *I am writing to request information under the Freedom of Information Act 2000 regarding batch FL9994 of the Comirnaty (Pfizer COVID-19) vaccine.*
>
> *Specifically, I would like to request the following details:*
>
> *1. Adverse Events Reports: Any reports of adverse reactions associated with batch FL9994.*
>
> *2. Quality Assurance Data: Details of any testing, safety inspections, or quality control measures conducted on batch FL9994 before its release.*
>
> *3. Batch Recall or Investigation Records: Information on whether batch FL9994 was ever flagged, recalled, or investigated for any safety or efficacy concerns.*
>
> *4. Distribution Information: Geographic areas or vaccination centers where batch FL9994 was distributed in the UK.*

MHRA Response

The Agency has completed its search for the information you have requested and we are able to confirm that we do hold some of the information you have requested.

Please note that information related to question 4 is not part of MHRA's remit and therefore is not held by this Agency.

The information responding to the remaining questions are below:

1. Adverse Events Reports: Any reports of adverse reactions associated with batch FL9994.

We can confirm that the MHRA has received a total number of 516 UK spontaneous suspected Adverse Reaction (ADR) reports relating to the COVID-19 Comirnaty vaccine with batch number FL9994 up to and including 20th February 2025.

Please note that reporters have the option to include batch number within a free text field, however this is not mandatory. As this information is collected in a free text field, entries within that field may vary between reports depending on how the reporter details the batch number. For the purpose of this FOI request, we have searched the batch number field for batch numbers as they are listed below and have also accounted for the following variations:

- A space between letters and numbers
- A dash between letters and numbers

FL9994

FL 9994

FL-9994

Fl9994

Fl 9994

Fl-9994

fL9994

fL 9994

fL-9994

Once approved for marketing and supply, the Covid-19 vaccines were batch tested by the MHRA Official Control Laboratory. The purpose of this testing is to ensure that each batch of products meets the quality standards defined in their marketing authorisations (product licences), and it involves the thorough laboratory evaluation of their quality and biological activity. The MHRA examines every batch that is manufactured for use in the UK, independently of the testing required by the manufacturer. Medicines batches (including vaccines) that comply with the required specifications are certified, the manufacturer is issued with a certificate specific to the batch that has been tested, and the batch can then and only then be released by the manufacturer onto the UK market.

The MHRA's analysis of Yellow Card reports did not result in any safety concerns considered to be batch-related issues. Manufacturing site details for each batch are included in the information supplied by the marketing authorisation holder and reviewed as part of the MHRA independent batch testing process. When assessing for any batch-specific issues, numbers of Yellow Card reports were considered alongside information about the size and source of the batch

2. Quality Assurance Data: Details of any testing, safety inspections, or quality control measures conducted on batch FL9994 before its release.

We can confirm that batch FL9994 underwent independent control testing by the MHRA. This included testing for Appearance, Identity, RNA content, Encapsulation, Integrity and In vitro expression. The batch passed with no issues and a certificate was issued on 30th Nov 2021

3. Batch Recall or Investigation Records: Information on whether batch FL9994 was ever flagged, recalled, or investigated for any safety or efficacy concerns.

The Defective Medicines Report Centre (DMRC), within the MHRA have received 28 total reports from January 2022 to March 2022, pertaining to Pfizer-BioNTech COVID-19 Vaccine, Batch Number FL9994. Of these 28 reports, 27 relate to the defect classification: Product Contamination Physical and 1 report relates to the defect classification: Package Quantity Incorrect. As a result of the MHRA assessment of the Marketing Authorisation Holder (MAH) investigations in relation to quality and safety, no market action was considered, and the batch impacted was not considered to be defective. There have been no product recalls for any batches of Pfizer-BioNTech COVID-19 Vaccine. The DMRC is part of the Medicines and Healthcare products Regulatory Agency (MHRA). The role of the DMRC is to minimise the hazard to patients arising from the distribution of defective medicines by providing an emergency assessment and communication system between manufacturers, distributors, wholesalers, pharmacies, regulatory authorities and users.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/