Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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www.gov.uk/mhra

25 March 2024

Dear [redacted]

FOI 24/197

Thank you for your FOI request dated 26th February 2024, where you requested the following information:

> ***Could you please provide all of the information/data that you hold on the Covid-19 vaccine:***
>
> ***Pfizer-BioNTech batch EL0141***
> ***I was administered this batch at Lincoln Hospital on 05.01.2021***
>
> *If the request goes over the time allowance you are given for collating the data, could you please specifically answer the following questions and provide evidence, but if within the limit I look forward to receiving all of the data and information you hold please:*
>
> *1) The rate (number) of yellow card reporting for this batch number including a summary/breakdown of what was reported e.g. stroke? tachiacardia?*
>
> *2) How the rate and side effects/medical conditions for this batch compare to a summary of the other batches e.g does this or other specific batches have higher rates of reporting of stroke? Tachiacardia ectopic beats?*
>
> *3) The process by which the vaccine was approved for release to the public?*
>
> *4) I would also like to know please if people who were already disabled were given specific batches which were different to non-disabled people?*

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Regarding your request for "*all of the information/data that you hold on the Covid-19 vaccine: Pfizer-BioNTech batch EL0141*" unfortunately MHRA estimate that compliance with this would exceed the appropriate limit under Section 12 of the Freedom of Information (FOI) Act 2000, which is set at 24 working hours per request. Public authorities are not obliged to work past the appropriate limit under Section 12(1) of the FOI Act 2000 and we are, therefore, refusing your request.

A wide range of different information would need to be retrieved and reviewed in order to identify and extract information relevant to your request. The information that you have requested may be held within the vast number of documents submitted by the company (both within the initial marketing authorisation submissions and subsequent updates) and also within MHRA assessment reports, Expert Committee papers and minutes. In terms of post-authorisation information, we would need to review Periodic Update Safety Reviews, safety summary reports, post authorisation safety study reports, minutes of signal detection meetings and data from Yellow Card reports.

To determine whether we held information relevant to your request, and to extract/compile this information, would take over 24 working hours.

We will, therefore, address each of your questions in turn, in order to provide advice and assistance.

1. We can confirm that the MHRA have received 1841 UK spontaneous suspected Adverse Drug Reaction (ADR) reports concerning the monovalent COVID-19 Vaccine Pfizer/BioNTech with a reported batch number of EL0141, via the Yellow Card scheme up to and including 08/03/2024.

   Please find attached Vaccine Analysis Prints (VAP) 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.

As you may know the coronavirus vaccine – summary of Yellow Card reporting, is available here which includes summaries of our assessment on particular safety topics surrounding the COVID-19 vaccinations. The MHRA has revised the format of the Summary of Yellow Card reporting to focus on the COVID-19 vaccines administered from the beginning of the Autumn 2022 booster campaign. Any new assessments or safety issues regarding vaccines used in the primary and initial booster campaigns will also be included in this record, however previous and known information on these vaccines will remain available as a record only and can be viewed on the government website (Coronavirus (COVID-19) vaccines adverse reactions - GOV.UK (www.gov.uk)).

2. 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 this specific batch.

3. The temporary authorisation of the Pfizer/BioNTech vaccine was done through an expedited rolling review. A ‘rolling review’ can be used to complete the assessment of a promising medicine or vaccine during a public health emergency in the shortest time possible. This is done as the packages of data become available from ongoing studies on a staggered basis. The temporary authorisation under Regulation 174 permits the supply of identified vaccine batches, based on the safety, quality and efficacy data submitted to MHRA. These authorisations do not constitute a marketing authorisation.

All vaccines are tested through three phases of clinical trials to ensure they meet the required standard. Phase 1 trials are with a small group of people to make sure there are no safety concerns and determines the appropriate dosage for the best immune response. Phase 2 trials are conducted on a larger group of people to check the vaccine works consistently and that the immune response is sufficient. Phase 3 trials test the vaccines on thousands of people for scientists to assess if the vaccine is producing immunity that will prevent disease. Usually, these phases are run in sequence, but in an effort to find a safe and effective Covid-19 vaccine as quickly as possible, once safety has been ascertained through Phase 1, Phases 2 and 3 are being run in parallel. Extensive checks and balances are required at every stage of the development of a vaccine, and this is no different for a Covid-19 vaccine. No stages in the vaccine development processes were bypassed.

Information on the study conducted using the Pfizer/BioNTech vaccine and its results are available in a peer-reviewed journal, the New England Journal of Medicine (NEJM). A link to this is provided below:
https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=featured_home

The temporary authorisations for use of the COVID-19 vaccines in the UK followed a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness by the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA expert scientists and clinicians reviewed data from the laboratory pre-clinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine, and also considered the conditions for its safe supply and distribution. The decision was made with advice from the Commission on Human Medicines (CHM), the government's independent expert scientific advisory body. Regarding the MHRA approval of the Pfizer/BioNTech vaccine, further information (including information for physicians and recipients of the vaccine, and Public Assessment Reports [PARs] for each vaccine) are available on the MHRA website. Links to these are provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

Please note that a marketing authorisation was granted for the Pfizer/BioNTech vaccine (Comirnaty) following a European Commission (EC) decision on 21 December 2020 (PLGB 53632/0002). Further information is available on the European Medicines Agency (EMA) website, a link to this is provided below:
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

The EMA have also published the data from the clinical studies for the authorisation of Comirnaty. A link to their clinical repository holding this data is provided below:
https://clinicaldata.ema.europa.eu/web/cdp/home

Independent laboratory testing of vaccines is carried out by the MHRA's Official Medicines Control Laboratory (OMCL). Batches of vaccine that meet the specifications

in the approval are certificated allowing the manufacturer to market them in the UK for use before the batch expiry date.

4. The MHRA does not hold information whether disabled people were given specific batches which were different to non-disabled people.

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

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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