Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

18 August 2023

Dear [redacted]

FOI 23/526

Thank you for your email dated 18 July 2023. This requested all information which MHRA hold relating to this batch number (FN5254), including:

- The number, age and ethnicity of recipients.
- The period of time over which, and the locations in which, this batch number was administered;
- the dates of its production and distribution
- Any quality reports; and any reports of adverse effects.

Further to your request, the MHRA has conducted a search of its records relating to batch number FN 5254 and detailed below the data held. Please note the MHRA does not collect data on every individual who is administered a Covid-19 vaccination and therefore does not hold information in relation to the number, age or ethnicity of recipients of COVID-19 vaccine Pfizer/BioNTech, nor the period of time or in which locations batch FN5254 was administered.

Batch FN 5254 is *not* one of the clinical, process performance qualification (PPQ) or stability batches, and it was manufactured after approval of the marketing authorisation. This means that information on this batch will not be held within a regulatory dossier which would contain information provided to MHRA prior to market authorisation; we confirm information is not held in the regulatory dossier; this conclusion is based on the above and a reasonable search.

With regard to your query about production dates and quality reports, whilst the MHRA does hold some of this information we have determined that it is exempt under Section 41 (S41) and Section 43 (S43) of the Freedom of Information Act. S41 applies when the information has been provided to a public authority in confidence. This is an absolute exemption, and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence.

S43 applies when disclosure would be likely to prejudice the commercial interests of a third party. This is a qualified exemption and requires a consideration of the public interest. We have considered the public interest and while there is a public interest in disclosure where this would demonstrate transparency and accountability, on this occasion this does not outweigh the public interest in maintaining the exemption and protecting against commercial harm to a third-party.

The MHRA, through its National Control Laboratory (NIBSC), is required to independently assess the quality of every batch of COVID-19 vaccine that has been approved by the MHRA. I can confirm this

batch underwent independent testing by the MHRA (NIBSC) and a certificate was issued to the manufacturer.

In your request you have asked for any quality reports and any reports of adverse effects. The MHRA collects data on suspected adverse drug reaction reports to medicines and vaccines, we are therefore able to provide you with the data we hold on UK spontaneous suspected adverse drug reaction reports we have received for COVID-19 vaccine Pfizer/BioNTech, batch FN5254.

The MHRA has received a total of 901 spontaneous suspected Adverse Drug Reaction (ADR) reports following vaccination with COVID-19 vaccine Pfizer/BioNTech batch FN5254. Of these, less than 5 had a fatal outcome. A summary is provided in the attached tables. Where there are less than 5 reports, numbers have been replaced with a ^ in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters. As outlined in our privacy policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, and as such is exempted under Section 40 and 41 of the FOIA.

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 batch.

A list of the recognised adverse effects of the COVID-19 vaccines is provided in the information for healthcare professionals and the recipient information. Conclusions on the safety and risks of the vaccines cannot be made on the data shown in the report alone.

When viewing these data, 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.

- It may be difficult to tell the difference between something that has occurred naturally and an adverse reaction. Sometimes reactions can be part of the condition being treated rather than being caused by the vaccine.

- 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.

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.

The MHRA has also received a total of 53 Yellow Card reports of suspected quality defects following administration of the COVID-19 vaccine Pfizer/BioNTech batch FN5254. Of these, 41 related to visible particulates in the vial and the remaining 12 considered insufficient volume. The reports were

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shared with the Marketing Authorisation Holder (MAH) for their investigation and as a result of the MHRA assessment of the MAH investigation, no market action was considered, and the batch was not considered to be defective.

As outlined in our privacy policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, and as such further details from these 53 Yellow Card reports is exempted under Section 40 and 41 of the FOIA. These exemptions apply when the requested information is personal information, and when the information has been provided to the MHRA under conditions of confidentiality.

I 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