Medicines & Healthcare products Regulatory Agency

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

15 September 2023

Dear [redacted]

FOI 23/560

Thank you for your email dated 28 July 2023 which requested the following information:

"With respect to modRNA COVID-19 vaccines, please provide all documentation available to the MHRA on throughout 2023 to date. This request covers Pfizer-BioNTech monovalent/bivalent and Moderna monovalent/bivalent vaccine batches/vials.

Please include all documentation covering the following areas:

- batch/vial identifiers
- reason for the disposal/rejection
- quantification of the contaminants/impurities (e.g., molecular weight, percentage of formulation affected)
- date contaminated batch/vial identified
- date contaminated batch/vial disposed/rejected
- name and address of affected manufacturing site
- all relevant communications between the MHRA and manufacturers/pharmaceuticals, other regulatory bodies and other government agencies"

Under the FOI Act, we confirm that we hold the information for all parts of your request apart from *"quantification of the contaminants/impurities", "date contaminated batch/vial disposed/rejected,"* we do not hold this information.

With regard to "name and address of affected manufacturing site" the following information is publicly available in the Patient Information Leaflet for both Pfizer-BioNTech monovalent/bivalent and Moderna monovalent/bivalent vaccine:

- Pfizer-BioNTech monovalent/bivalent: https://www.medicines.org.uk/emc/files/pil.12740.pdf
- Moderna monovalent/bivalent vaccine: https://www.medicines.org.uk/emc/files/pil.13983.pdf

Further to your request, the MHRA has conducted a search of its records and in the period 2023 to date, the MHRA has received a total of 1 suspected defect report for batches and vials disposed and/or rejected due to contamination and/or impurities for the Pfizer-BioNTech monovalent/bivalent vaccine and 0 reports for Moderna monovalent/bivalent vaccine.

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The report related to particulates (Batch Number FN1665) and it was identified that no quality issue was observed. As a result of the MHRA assessment of the MAH investigations, no market action was considered, and the batch impacted was not considered to be defective.

The date the contaminated batch/vial was identified is based on the date the report was received by the Defective Medicines Report Centre (DMRC) which was on 10/01/2023.

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 this report 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.

With regards to all relevant communications between the MHRA and manufacturers/pharmaceuticals, please find the attached document received from the Marketing Authorisation Holder which summarises their investigation of the report following us sending details of the report to them.

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We do not hold any information from other regulatory bodies and other government agencies in relation to your request.

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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