Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

13 October 2023

Dear [redacted]

FOI 23/560: further query

Thank you for your email dated 17 September 2023 which asked the following query about our response to FOI 23/560:

> "Thank you for providing this information. Given your reply, I still require further clarification before considering this FOI request to be complete.
>
> In particular, please clarify whether the Pfizer-BioNTech batch (FN1665) concerned by the report to the DMRC (dated 10/01/2023) was disposed and/or rejected due to contamination and/or impurities by either the MAH or MHRA. Please note such reports are the exact subject of my FOI request.
>
> I need this clarification because your reply states that the MHRA "do not hold" information on the "date contaminated batch/vial disposed/rejected". In a different part of your reply, the following appears: "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". These two statements from the MHRA appear to be in conflict.
>
> Please therefore clarify whether batch FN1665 was ever temporarily rejected (and/or any of the batch disposed) by order of the MHRA (or other relevant body), including the date of rejection, prior to the "MHRA assessment of the MAH investigations."

In relation to your initial clarification, "In particular, please clarify whether the Pfizer-BioNTech batch (FN1665) concerned by the report to the DMRC (dated 10/01/2023) was disposed and/or rejected due to contamination and/or impurities by either the MAH or MHRA," the MHRA can confirm that the impacted vial from batch FN16665 was not disposed and/or rejected due to contamination and/or impurities by either the MAH or the MHRA. The vial was stored by the reporting healthcare professionals in quarantine at the time of reporting the issue to the DMRC and the DMRC are not aware of the date the vial was disposed of.

With regard to your clarification on the following, " Please therefore clarify whether batch FN1665 was ever temporarily rejected (and/or any of the batch disposed) by order of the MHRA (or other relevant

body), including the date of rejection, prior to the "MHRA assessment of the MAH investigations.," the MHRA can confirm that batch FN1665 was not temporarily rejected (and/or any of the batch disposed) by order of the MHRA. 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

Or online at:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/