FOI 23/413 – master batch records for clinical supply of Pfizer/BioNTech COVID-19 vaccine BNT162b2

Dear

Thank you for your request submitted under FOIA dated Monday, June 12, 2023, where you asked:

"Under the Freedom of Information Act, please provide all master batch records (MBRs) for the clinical supply of Pfizer/BioNTech COVID-19 vaccine BNT162b2. Provide all MBRs prior to and after MHRA granted the Conditional Marketing Authorisation for Comirnaty.

In particular, ensure this includes RNA fragment analysis (and DNA fragment analysis, if applicable), and the DNA percentage of the final product."

We hereby confirm that under Section 1(1) (a) of FOIA, that we do not hold master batch records, as these do not form part of a Marketing Authorisation Application.

However, they are kept by the manufacturers, an option would be to approach the relevant company for these records but we cannot confirm whether they would be released to members of the public.

We note that your enquiry mentions RNA fragment analysis, this type of information relates to the quality of the active substance and/or finished product, and documentation is present in the MHRA records of the BNT162b2 vaccine, for example, in the form of relevant test parameters, limits, and batch analysis data. However, these data are typically exempt from FOI release under to Sections 38(1), 43(2) and 41 of the FOIA. However, we assess each unique FOI request on a case-by-case basis.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would 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 your request unless you have first contacted us to conduct an internal review.

The Information Commissioner can be contacted online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or

by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Yours sincerely
MHRA Customer Service Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Yours sincerely,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000