

FOI 24/019

FOILicensing <FOILicensing@mhra.gov.uk>

Thu 01/02/2024 17:47

To

Dear

Thank you for your request for information dated 07 January 2024. Please find our response to each of your questions below:

Q1. On what date did MHRA receive information from BioNTech on BioNTech BNT162b2 batches EJ0724 and EJ1688 for the purpose of completing the preliminary assessment report on their suitability for a temporary supply authorisation under regulation 174?

An email was received on 18 August 2020 regarding the submission of information by the applicant. This information was not specific to the above batches, but the studies submitted after this date supported these and other batches. Further data concerning the quality of these two batches (EJ0724 and EJ1688) were received on 27 November 2020.

Q2. On what date was this information and the associated MHRA assessment reports provided to the Commission on Human Medicine covid-19 vaccine benefit risk expert working group and on what date was this provided to the CHM's C-19 vaccine benefit risk quality sub-group which met to consider the information on November 28, 2020?

The preliminary assessment report on EJ0724 and EJ1688 was sent to the EWG quality sub-group members during the discussion on 28 November 2020. This report was based on the submission received the day before (27 November 2020). The company joined the meeting to address questions on the concerned batches.

We now consider this response closed. If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review. Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 in writing to:

Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF

Yours sincerely,
HQA FOI Team