FOI 24/013

FOILicensing <FOILicensing@mhra.gov.uk>
Wed 31/01/2024 16:51
To [redacted]>
Dear [redacted]

Many thanks for your email dated 03 January 2024. Please find our response to each of your questions below:

On October 28, 2020 the Commission on Human Medicines Covid-19 vaccines Benefit Risk group convened a meeting via teleconference.
The minutes show that Agenda item 3 at this meeting was a discussion on the non-clinical assessment of BNT162b2, BioNTech's mRNA Covid-19 vaccine candidate. According to Minute 3.2 of this meeting, the EWG agreed with the MHRA Assessor that 'further points of concern be raised for the company to address.'

Q1. On what date did the MHRA make the request to BioNTech that it provide the answers (justifications, clarifications, discussions etc) to the issues raised in minute numbers 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9 and 3.10?

Our response:
A Request for Further Information (RFI) letter was sent in relation to these points, dated 02 November 2020.

Q2. On what date did BioNTech provide the MHRA with answers to these points of concern?

Our response:
A response was received from the applicant on 01 December 2020.

Q3. On what date did the CHM Covid-19 Vaccines Benefit Risk Expert Working Group meet to review and discuss the answers provided by BioNTech in response to the concerns raised by the EWG and the assessor in the above noted minute items 3.3 – 3.10? Which members of the VBR EWG met to consider / discuss the responses?

Our response:
The usual practice is not to raise issues at CHM again unless they relate to a major objection. The above RFI points were not raised as major objections and so would normally not go back to CHM. Nevertheless, for this vaccine, a rolling review was allowed which meant that some data were received later and reviewed by EWG/CHM in an updated assessment report. The responses to the above RFI questions would be present in the updated assessment report. So, in this step, the CHM could review responses to previous RFIs.
Membership for the Commission on Human Medicines (CHM) and its expert advisory groups (EAGs) can be found at the following link: Membership - Commission on Human Medicines - GOV.UK (www.gov.uk)

Agenda item 4 at this meeting was a discussion on the clinical assessment rolling review report of BNT162b2.
Q4. What specific recommendations did the EWG make with respect to improving the sensitivity of the assay discussed in 4.3? And what follow up efforts were made by the

EWG to confirm if their recommendations were accepted or implemented? Did BioNTech implement the recommendations?

Our response:
The EWG did not make any specific recommendations relating to the sensitivity of the assay. The applicant explained that the assay is a commercially available assay operating under an EUA granted by the FDA and is the only N serology assay actively being used in Pfizer/BioNTech's Phase 3 efficacy trial. The company stated that modifications to the assay are entirely under the discretion of the vendor and out of scope for Pfizer/BioNTech. Pfizer/BioNTech monitor the performance of the assay including an assessment of its sensitivity and specificity. Clinical sensitivity results can vary based on the quantity and characteristics of the samples used, but a 99.5% sensitivity was reported in 185 samples ≥14 days post PCR confirmation. Results from Pfizer's method validation, using pre-COVID-19 and convalescent sera, gave 93.5% sensitivity and 100% specificity, and aligned with what is reported by the assay manufacturer.

As the company provided assurance that the clinical specificity and sensitivity of the assay will continue to be monitored, the response was accepted.

Q5. On what date was BioNTech asked to provide clarifications, justifications or discussions with respect to minute items 4.4, 4.5, and 4.6?

Our response:
An RFI letter was sent in relation to these points, dated 02 November 2020.

Q6. On what date did MHRA receive the response from BioNTech?

Our response:
A response was received from the applicant on 20 November 2020.

Q7. On what date did the CHM Covid-19 Vaccines Benefit Risk EWG meet to consider the responses provided by BioNTech?

Our response:
The items discussed in 4.4, 4.5, and 4.6 of the minutes were assessed in a clinical assessment report, dated 28 November 2020. This assessment report was taken to CHM on 30 November. The Commissioners would therefore have had sight of the full assessment. The actual discussion at CHM would have focused on key issues and questions that the commissioners had.

Q8. The minutes relating to Agenda item 5 have been redacted entirely including the topic of the agenda item. What is the justification for this redaction? I would like to challenge the decision to conceal the topic discussed as agenda item 5.

Our response:
Please refer to our correspondence dated 15 January 2024. Item 5 was removed because it was not relevant to the question you asked in FOI 23/421, which was specifically for "any written advice given by Vaccine BR EWG to the Commission of Human Medicines (CHM) on 11th September 2020, 8th October 2020, 27th October 2020, 28th November 2020 and 30th November 2020, regarding the requirements for authorisation for the temporary supply of COVID-19 mRNA Vaccine BNT162b2."
Item 5 is not about this and was therefore removed, as it was not relevant to your request.

We now consider this request 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