FOI 23/256 - Pfizer/BioNTech vaccine authorisation

MHRA RESPONSE
21 April 2023

Dear

Thank you for your Freedom of Information (FOI) request dated 6 March 2023.

We have replicated the questions which you asked and have placed our answers beneath each question.

Q1 - If the EUA was issued on the 01st December 2020 how can it be based on an assessment of data for the period October 2020 to December 2020?
Response: The assessment was based on the receipt of data collected over a period that pre-dates Oct. to Dec 2020.
Q2 - How much data was supplied on the 01st December 2020 between the time that the MHRA office opened and the time the EUA was authorised that day?
Response: No further data was provided on the 1st of December in relation to initial decision on temporary authorisation of R.174. A small amount of information was received on the 1st Dec. in relation to final amendments to the product information but this information did not alter or contribute to the overall decision on the R.174.

Q3 - How can only 2 months (October 2020 to November 2020) of a trial for a medicinal product that has never before been used in humans and which contains ingredients that have never before been used in humans be deemed as sufficient to give even a marginal or possibly "safe" designation?
Response: This does not meet the criteria of a question under FOI e.g. a request for data or information held. The PAR for the Pfizer/BioNTech vaccine is a 74 page document specifically written for to aid the public's understanding the basis of the temporary authorisation.

Q4 - Was there any documentation available from Pfizer prior to 01st December 2020 which was used to base the initial MHRA PAR on and then to "write" it?
Response: Documentation was available prior to this date. It is essential for the assessment of medicines to rely upon data submitted by the manufacturer / applicant. The PAR is a document produced based upon MHRA's assessment of the dossier and information provided by the third party Pfizer/BioNTech.

Q5 - Was the Pfizer document that described the future running of the vaccine trials that was published in November 2020 used as part of the authorisation process?
Response: It is unclear specifically which document you are referring to—a final clinical trial protocol was available from April 15 2020.

Q6 - if the Pfizer trial had not yet commenced in November 2020 how could possible side-effects be considered prior to the MHRA authorisation that was issued on 01 December 2020?
Response: The trial had commenced by Nov. 2020.

Q7 - between 01 October 2020 and the 21 February 2021 was the MHRA advised by either the EMA, Pfizer or other authority of any possible side-effects that had been reported from the trial that commenced at an unknown date?
Response: The trial has known start dates which relate to the different trial phases. For the clinical trial referred to, EudraCT 2020-002641-42, C4591001, no Sponsor ever made a request for approval of a clinical trial authorisation (CTA) for that study protocol to the MHRA. That trial was not conducted in the UK. Contemporary trial events would not be reported to the UK during the conduct of that trial in relation to that trial.

Trial events were provided to the MHRA Clinical Investigations and Trial (CIT) unit in a CTA application for another clinical trial, in which the investigator's brochure (IB) , dated 29 January 2021, provided in that trial CTA application, contained a summary of data from the study EudraCT 2020-002641-42. The MHRA **Clinical Investigations and Trials unit** did not receive contemporary information about toxicity of BNT162b2 from any Sponsor or Regulatory Authority in the context of trial EudraCT 2020-002641-42 **during the specified time period**.

As mentioned in the PAR the data were submitted in a rolling data submission procedure, and therefore, during the period from 01 October 2020 and the 21 February 2021 side effect data will have been received. Section 4.8 of the SmPC integrates comprehensive safety data from different sources (clinical trials, post-authorisation safety studies, spontaneous reporting) and should be regularly reviewed and updated to ensure that appropriate information is continuously provided.

Q8 - How can a medicinal product that has never before been used in humans and which contains ingredients that have never before been used in humans be deemed as sufficiently "safe" enough to be give a temporary authorisation for use when it seems that the clinical trial to determine it's safety and efficacy had been running for only a matter of days when the authorisation was issued?
Response: This is not a question under FOI; it is not a request for information held. Please refer to the PAR and other publicly available documentation about the Pfizer/BioNTech vaccine. Please refer to our answers given within our correspondence with you in relation to 22/1117.

Q9 - what was the exact date that the Pfizer clinical trial study commenced as referred to in their document referenced above?

Response: Phase I/II commenced April 29, 2020, and phase III commenced 27 July 2020.
Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals - Full Text View - ClinicalTrials.gov

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 you receive this response and addressed to: info@mhra.gov.uk
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 at:
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