FOI 23/510

Dear

Thank you for your email.

Please find below answers to the questions you have raised below.

Question
1. Temporary Authorisation of the Pfizer Covid vaccine on 2 December 2020 permitted public use of Batch EJ0553 based, *inter alia*, on the clinical trials in 2020 defined in Pfizer document C4591001. The vaccine used in the 2020 clinical trials was manufactured using 'Clinical Supply' 'Process 1'. Batch EJ0553 was manufactured in September 2020 using 'Commercial Supply' 'Process 2'.
Request 1 : please can you tell me if any human was vaccinated (in UK or elsewhere) using 'Process 2' product prior to 2 December 2020, and if so, when and where.

Answer
The clinical data submitted for the Pfizer vaccine has been published by the EMA in their clinical repository. This includes the clinical study reports, which should contain information on the batches of vaccine that were used in each trial. Link to the EMA clinical repository is below:
https://clinicaldata.ema.europa.eu/web/cdp/home

Questions 2 & 3
2. Pfizer amended C4591001 in October 2020 to add, inter alia, at para 9.4 : *"The safety and immunogenicity results for individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" and each lot of "Process 2" will be summarized descriptively. A random sample of 250 participants from those vaccinated with study intervention produced by manufacturing "Process 1" will be selected randomly for the analysis."*
Request 2 : Please can you send me a copy of Pfizer's report of this. Alternatively, if you exempt its release, tell me the Pfizer reference and date.

3. Page 69 of https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf states that "*The scale of the BNT162b2 manufacturing has been increased to support future supply. BNT162b2 generated using the manufacturing process supporting an increased supply (commercial process) will be administered to approximately 250 participants 16 to 55 years of age, per lot, in the study. Data are expected in February 2021.*
Request 3 : Please can you send me a copy of Pfizer's report of this. Alternatively, if you exempt it release, tell me the Pfizer reference and date.

Answer
2. & 3. The clinical data submitted for the Pfizer vaccine has been published by the EMA in their clinical repository. If the report has been submitted to the EMA and

MHRA, it will be available in the clinical repository. Link to the EMA clinical repository is below:
https://clinicaldata.ema.europa.eu/web/cdp/home

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 at:

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

Yours sincerely

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