**FOI 23/211 – Pfizer protocol deviations**

**MHRA RESPONSE**

**23 March 2023**

Dear

Thank you for your information request dated 19 February 2022 where you asked for **information related COVID-19 Pfizer Vaccine pivotal clinical trial and an imbalance in the occurrence of protocol deviations (PDs) in the treatment group versus the placebo group.**

Specifically, and under FOIA you asked for us to disclose:

- **With this statistical analysis in mind [related to PD imbalance], please disclose all documentation concerning "important protocol deviations" in possession of the MHRA.**
    - **This should include all requests made by the MHRA to Pfizer for clarity on these "important protocol deviations" and all of their responses, an exhaustive list of all 371 "important protocol deviations on or prior to 7 days after Dose 2".**
- **Documentary evidence on the MHRA's internal investigation into this statistical abnormality, assuming the MHRA conducted such an investigation.**

Please find attached the lists of protocol deviations, please note these documents are also available here https://phmpt.org/pfizers-documents/ by searching for 'protocol deviations'.

No formal investigation of the imbalance in protocol deviations occurred, therefore, our response to the second bullet point is data not held. However, the imbalance was noted at assessment; the imbalance in the protocol deviations was not pursued as the proportion of these protocol deviations was very low – 1.4% in the BNT162b2 group and 0.3% in the placebo group.

On recent request, Pfizer have provided the following explanation for the protocol deviation imbalance:
*The reason for the larger number of PDs in the active group relates to the complexity and unfamiliarity (in the early days) of handling an ultralow temperature multidose Investigational Product (IP) that required dilution by the unblinded site staff, as well as temperature excursions; as compared to saline placebo stored at room temperature. The file called c4591001-fa-interim-protocol-deviations-sensitive shows that the vast majority of PDs are IP-related. This is the reason why they (the protocol deviations) were not randomly distributed between the 2 groups.*
If you have a query about the information provided, please reply to this email
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:

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

Yours sincerely