FOI 23/015

5th February 2023

Dear

Thank you for your email.

We apologise that an incomplete response was sent to you, we had intended to address your question regarding Clinical Trials. Which is to say that the main efficacy and safety results for the Phase I, II and III trials for all authorised vaccines have been submitted to MHRA, sufficient that these vaccines can be authorised for use in the patient populations stated in the Summary of Product Characteristics for each vaccine. Some studies are currently ongoing to follow-up vaccine recipients to collect additional safety data, in the same way that all clinical trials for new medicines follow up their study subjects after the main results of the study have been reported. Other studies that are currently in progress are either for cohorts/subpopulations of recipients or to investigate different regimens (such as giving different brands of vaccine for the first and second doses).

We have not supplied you with nonfactual information, but our reply was incomplete and we hope the above clarification addresses your concerns.

Yours sincerely

MHRA Customer Experience Centre

FOI 23/015

Dear

Thank you for your information request, dated 09 January 2023.

We are pleased to provide you with the information requested, see below.

The agency charges individual pharmaceutical companies fees to cover the work we do as a sovereign regulator. The work we do is impartial and based on the data submitted by companies.

The authorised vaccines are not experimental gene therapy, each has been authorised for use by MHRA, as well as other regulators. Further information on each of the vaccines, including the Summaries of Product Characteristics (SmPCs), Patient Information Leaflets (PILs) https://products.mhra.gov.uk/and Public Assessment Reports (PARs, which contain the non-confidential parts of the assessment of that vaccine) is available on the MHRA website and the European Medicines Agency (EMA) website. https://www.ema.europa.eu/en

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be

carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

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

MHRA Customer Service Centre