FOI 22/1214 - Covid vaccine advice 26 January 2023

Dear

Thank you for your request under the Freedom of Information Act (FOIA).

Apologies for the delayed response.

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

Regarding the below questions:

- 1. Did any of the Covid vaccine manufacturers advise that they had carried out human testing of the vaccines prior to delivery to the UK Government?
- 1.1 Did any of the vaccine manufacturers advise that the vaccines provided prevented acquiral/transmission or both of the Covid virus?
- 1.2 If the manufacturers provided such advice, could I please be provided with copies of minutes of meetings and documentation confirming this?
- 1.3 Did the MHRA carry out any testing on the vaccines to confirm if they prevented acquiral/transmission, or both?

All authorised medicines assessed by MHRA, including the Covid vaccines, are expected to provide clinical data to show the use of the medicine in humans, typically through clinical trials. It was expected by MHRA that data from clinical trials in humans would be submitted and assessed by the agency before any of the Covid vaccines could be authorised. As the submission of this data is expected by the agency and a requirement in order to acquire a marketing authorisation, no advice was provided or required from the manufacturers. MHRA does not carry out any clinical trials itself, however, clinical trials are performed by others under strict guidelines and the data from these trials submitted to MHRA for assessment.

- 2. Did the MHRA advise the Scottish Government at any time, either prior to supply that the covid vaccines would prevent acquiral/transmission of the Covid virus?

 2.1 If the answer to question 2 is Yes, can I please be provided with minutes of meetings and any other documents confirming this?
- 2.2 Similarly, if the advice from the MHRA did not advise that the vaccines precluded acquiral/transmission or both, could I have the minutes of meetings and any other documents confirming this please?

MHRA did not specifically advise the Scottish government that any of the authorised vaccines would prevent acquiral/transmission of the Covid virus. The authorisation of the Covid vaccines, including conditions of authorisation, MHRA's assessment of the data and information for clinicians and patients, is published on our Products Portal of our website. A link to this is provided below:

https://products.mhra.gov.uk/

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 Experience Centre

Communications and engagement team Medicines and Healthcare products Regulatory Agency 10 South Colonnade, Canary Wharf, London E14 4PU Telephone 020 3080 6000