FOI 23/796

Dear

Thank you for your request for information dated Friday, October 20, 2023, where you asked:

> *"Please could you inform me:*
> *1. Has the MHRA ever independently tested the Pfizer/BioNTech vaccine at the vial level?*
> *2. Does the MHRA intend to test the Pfizer-BioNTech COVID-19 mRNA vaccine for the presence of fragmented DNA and SV40 enhancer?"*

1. Has the MHRA ever independently tested the Pfizer/BioNTech vaccine at the vial level?

Our response:

In the context of fragmented DNA and SV40 enhancer MHRA has not tested the Pfizer/BioNTech vaccine at the vial level.

Independent laboratory testing of vaccines is carried out by the MHRA's Official Medicines Control Laboratory (OMCL) (with a NIBSC certificate being applied to compliant batches). The independent testing does not verify the composition of the vaccine, rather it assesses key parameters that focus on biological quality of the product. Independent assessment also confirms that the manufacturer has reported on its wide-ranging tests on the product. Batches of vaccine that meet the specifications in the approval are certificated allowing the manufacturer to market them in the UK for use before the batch expiry date. In terms of the Pfizer/BioNTech vaccines tests conducted at the MHRA include:
Potency/sequence ratio, identity, RNA encapsulation, RNA content, RNA integrity.

All vaccine manufacturers must operate to Good Manufacturing Practices and their facilities are licensed, and are inspected periodically. These procedures help to ensure that no batches of vaccine that may be contaminated get released in the UK.

2. Does the MHRA intend to test the Pfizer-BioNTech COVID-19 mRNA vaccine for the presence of fragmented DNA and SV40 enhancer?"

Our response:
There are currently no intentions to test the Pfizer-BioNTech COVID-19 mRNA vaccine for the presence of fragmented DNA and SV40 enhancer.

We trust that you will find this information of use.

Your right to seek a review
If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to:
Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF

Yours sincerely,

HQA FOI Team