Medicines & Healthcare products Regulatory Agency

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02 January 2024

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FOI 23/940

Thank you for your email dated 01 December 2023, wherein you requested information concerning MHRA testing of mRNA vaccines for SV40 or other contaminants. Please find below, our responses to your queries:

MHRA response:

1. **Did you tested the vaccines for SV40 yet?**

SV40 stands for Simian Virus 40. It is a naturally occurring virus. The virus itself is not included in either starting material, plasmid DNA, or in the finished product of the Pfizer-BioNTech COVID-19 vaccines. However, specific, non-infectious parts of the SV40 sequence, called promoters and terminators, are commonly used in the pharmaceutical industry, as is the case for the Pfizer-BioNTech COVID-19 vaccines but not for other mRNA vaccines licensed in the UK. It is important to distinguish between the entire SV40 virus sequence and the non-infectious SV40 sequence parts. These non-infectious SV40 sequence parts present in starting material used by Pfizer and BioNTech do not contain oncogenes which are genes that may have the potential to cause cancer. The MHRA has not tested mRNA vaccines for SV40.

However, 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. **If not when you going to test mRNA vaccines for SV40 or other contaminants?**

There are currently no intentions to test mRNA vaccines for the presence of SV40 or other contaminants.

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,

Healthcare Quality and Access (HQA) FOI Team