Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

03 November 2023

Dear [redacted]

FOI 23/743 Genotoxicity of mRNA products

Thank you for your communication, dated 05 October 2023, in which you requested information relating to genotoxicity of Pfizer mRNA products, further to the MHRA responses dated 20 February 2023 and 20 January 2023 to requests FOI 23/070 and FOI 22/1223, respectively. Please find below, our responses to your queries.

1. **Under FOIA I would like to see all official MHRA letters, emails and correspondence regarding the SV40 genetic sequence in the mRNA products, what testing was conducted by MHRA or outsourced to the EMA, regarding the safety of these products and why informed consent was obstructed.**

The MHRA does not hold any official letters, emails or correspondence regarding the SV40 genetic sequence in the Pfizer Covid-19 vaccine.

The National Institute for Biological Standards and Control (NIBSC) tests each batch of the Covid-19 vaccine prior to release, as described in https://www.nibsc.org/about_us/latest_news/batch-covid-19.aspx.

Further, no testing has been outsourced to the EMA, and we do not consider that any informed consent has been obstructed.

2. **Further, given that under prior FOIA requests you hid information under 'trade secret' and 'commercial confidence' clauses concerning the exact make-up and ingredients of the product, quality and safety testing reports, will you now make that information available to the public writ-large.**

The MHRA considers information for disclosure or non-disclosure, in accordance with the HMA/EMA guidance on transparency of the disclosure of non-confidential information available at:
http://www.hma.eu/fileadmin/dateien/HMA_joint/02-_HMA_Strategy_Annual_Reports/07-Transparency/2012_03_HMA_EMA_Guidance_20120309_ComPersInfo.pdf

We are unaware as to the correspondence to which you refer, as you have not quoted its reference number; however, any information we have not disclose concerning the exact make-up and ingredients of the product, quality and safety testing reports would be in accordance with the HMA/EMA guidance (see pages 33-37) and applied under exemptions Section 41 (Information given in confidence) and Section 43 (Commercial interests)) of the Freedom of Information Act.

3. **Can you supply information regarding the quality testing and any reports of your knowledge of said DNA contamination and any high-level discussions on continued authorization in the UK.**

Independent quality testing of vaccines prior to release is performed by NIBSC as described in the link above.

This is in addition to the company's own quality control batch release testing. All vaccine manufacturers must operate to Good Manufacturing Practices and their facilities are licensed, and are inspected periodically. These procedures ensure that no batches of vaccine that may be contaminated get released in the UK.

We now consider this FOI request closed.

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 2 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,

The FOI Team,
Healthcare Quality and Access.