Medicines & Healthcare products
Regulatory Agency

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

[redacted]

1 November 2023

FOI 23/746

Dear [redacted]

Thank you for your request of 05 October 2023, under the Freedom of Information Act. You requested:

> I assume the MHRA Pharmacovigilance Team have been carefully and repeatedly checking covid vaccine vials for the presence of contaminants including bacterial DNA and SV40. Please provide the dates and the results of these quality control checks, and state how many vials in total the Pharmacovigilance Team have checked to date.

We confirm that the National Institute for Biological Standards and Control (NIBSC), which is the UK's Official Medicines Control Laboratory at the MHRA) process (weblink: Independent batch release testing of COVID-19 (coronavirus) vaccines by the NIBSC - GOV.UK (www.gov.uk)) requires us to undertake a series of specific laboratory tests on sample vials from batches of COVID vaccines. A certificate is applied to those batches that meet the specifications in the product authorisation. This certificate is required by the authorisation holder (the manufacturer / company) before the batch can be released onto the market for use. Over 360 compliant batches across all COVID-19 vaccines authorised for use in the UK have been certificated since December 2020.

Our Safety and Surveillance Group monitors the safety of vaccines following batch release in line with the Commission on Human Medicines COVID-19 vaccine surveillance strategy; this includes reporting and monitoring of suspected side effects and potential product defects, outcomes of which have been regularly published throughout the pandemic.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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
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