Medicines & Healthcare products
Regulatory Agency

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gov.uk/mhra

[redacted]
e-mail: [redacted]

23 January 2024

Dear [redacted]

FOI 23/1012

Thank you for your request of 28 December 2023, under the Freedom of Information Act. You requested the following:

What is the sum total of the number of tests (a+b+c below) defined as the actual analysis of the vial content and excluding the mere visual inspection of any unopened vial performed on any MHRA Approved Covid-19 vaccine product which were carried out by:

a. the MHRA and
b. which the MHRA commissioned to a third-party lab independent from the said vaccine product manufacturer/patent holder and
c. which were carried out by NIBSC in order to determine the level of contamination in the MHRA Approved Covid-19 vaccine product?

To clarify the response that is being provided to your request, it is best to first explain the relationship of NIBSC with respect to MHRA.
The organisation formerly known as NIBSC (National Institute for Biological Standards and Control) has been part of the Medicines and Healthcare products Regulatory Agency (MHRA) since 2013. Its role exists within the wider Agency as the UK Official Medicines Control Laboratory to carry out independent batch release testing of vaccines. (weblink: NIBSC - Independent batch release testing at the NIBSC).

This role of independent batch release testing was carried out for all licenced COVID-19 vaccines certificated for use in the UK. Following a series of 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. (weblink: Independent

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batch release testing of COVID-19 (coronavirus) vaccines by the NIBSC - GOV.UK (www.gov.uk)).

The answer to a. and c. of your request is therefore the same, that typically, between 3 and 5 tests are applied to each batch, depending on the product.

In answer to b. of your request, no third-party lab is commissioned by the MHRA to perform any tests.

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 two 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

MHRA Customer Experience Centre
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