Medicines & Healthcare products Regulatory Agency

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

[redacted]

20th February 2024

FOI **24/125**

Dear [redacted]

Thank you for your information request, dated **24 January 2024**, where you asked the following:

'Dear Sirs,

The enclosed does not answer the FOI question originally raised.

I would be grateful if to the very least for clarity you would provide:
- a. the test procedure which is actually applied for the test of the contents of the opened Covid vaccine vial, and
- b. copy of the most recent test result for a Covid vaccine batch.'

In our original response to FOI 23/1012 we provided an explanation of the role played by the MHRA and also by the organisation formerly known as NIBSC (National Institute for Biological Standards and Control) which is part of the MHRA. We interpreted your request as requiring the number of tests that were carried out for 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. We provided this as the tests applied to each batch.

You state that we have not answered this question. If your request was asking for the total number of tests carried out for all the COVID-19 vaccine batches authorised for use in the UK that have been certificated by MHRA, we can state that over 360 compliant batches, each with between 3 to 5 tests per batch, have been certificated. This is therefore in the range of 1080 to 1800 tests carried out by MHRA as part of its independent testing role as an Official Medicines Control Laboratory (OMCL).

With regards to the new question in this request, we can confirm that we do hold the information you are requesting.

For part a) details of test procedures applied for the test of contents of opened Covid vaccine vials and part b) of your request, for a copy of the most recent test result for a Covid vaccine batch, this information cannot be provided as we consider it is exempt from disclosure under the FOIA as section 43(2) applies. S43 applies when disclosure would be likely to prejudice the commercial interests of a third party, i.e. the manufacturer of the vaccine. We have considered the prejudice test required for the use of exemption under Section 43. We would argue that data related to different vaccines, if disclosed, would be likely to, prejudice or harm the commercial interests of the relevant vaccine manufacturing companies. This harm could ultimately undermine the confidence for manufacturers to send materials for testing to MHRA/NIBSC and is therefore subject to an exemption under section 43.

This is a qualified exemption and requires a consideration of the public interest. We have considered the public interest and while there is a public interest in disclosure where this would demonstrate transparency and accountability, on this occasion this does not outweigh the public interest in maintaining the exemption and protecting against commercial harm to a third-party.

To assist, information that we can provide is a further explanation of the role played by MHRA in its capacity as an Official Medicines Control Laboratory (OMCL). The independent testing assesses key parameters that focus on the biological quality of the specific product, such as potency/sequence ratio, identity, RNA encapsulation, RNA content, RNA integrity, for example. 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.

Please see the link below for further information on the independent batch release testing process:
NIBSC - Independent batch release testing at the NIBSC

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

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

Medicines & Healthcare products
Regulatory Agency

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
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Telephone 020 3080 6000