Medicines & Healthcare products
Regulatory Agency

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

[redacted]

30 October 2023

FOI 23/732

Dear [redacted]

Thank you for your information request, dated **03 October 2023**, where you asked the following:

Under Freedom of information request please provide results of Independent Batch Testing of the following products ~

*AZD1222 Vaxzevria /covishield astra zeneca/Vaccitech COVID-19 Vaccine (ChAdOx1-S)

*BNT162 pfizer biontech Comirnaty covid19 vaccine

*mRNA 1273 Moderna spike vax covid 19 vaccine.

We can confirm that the MHRA has undertaken independent batch release testing of batches of these vaccines through its Official Medicines Control laboratory and has provided a NIBSC release certificate to the manufacturers. Batches that meet the specifications detailed in the product authorisation receive a NIBSC certificate which is required before the company can subsequently market the batch.

Details of tests and copies of certificates cannot be provided as we consider that these are 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. 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.

We have also applied a prejudice test to 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 our commercial interests with 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.

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

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
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