Medicines & Healthcare products Regulatory Agency

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

[redacted]

20 September 2023

FOI 23/473

Dear [redacted]

Thank you for your information request, dated **21 June 2023**, where you asked the following:

- I would like to make a request under the Freedom of Information Act with regard to 3 batch numbers of Covishield Vaccine.
- 4120Z001/4120Z002 and 4120Z003.
- Were these batch numbers tested by yourselves and if so please could I have the relevant batch certificate for each one. NIBSC or OCABR certification.
- Dates the batches were tested and findings.
- If these were not tested before release by yourselves could you tell me where I may get the information from.

Apologies for the delay in replying.

We can confirm that the three batch numbers of vaccine stated in your request, 4120Z001, 4120Z002 and 4120Z003 underwent independent control testing by the MHRA prior to certification. By way of background, the vaccine batches stated in your request as Covishield were supplied by the manufacturer, Serum Institute of India, to the UK as COVID-19 vaccine AstraZeneca.

As outlined in the Conditions for Use, the Serum Institute of India is an authorised manufacturer of the COVID-19 Vaccine AstraZeneca (which is now known

commercially as ‘Vaxzevria’). All vaccines from India supplied to the UK were the COVID-19 Vaccine AstraZeneca, tested to UK specifications in EU laboratories and independently tested by the UK’s National Institute for Biological Standards and Control (NIBSC). It was also certified by an EU Qualified Person with oversight of the manufacturing process and released for supply under the Regulation 174 authorisation. These differences set the two vaccines apart.

Before Covishield could be marketed in the UK, an application to do so must be made to, and approved by the MHRA.

A NIBSC certificate for each batch of COVID-19 Vaccine AstraZeneca, 4120Z001, 4120Z002 and 4120Z003, was issued to the company in March 2021. Certificates are only issued for batches of vaccine that meet all the specifications laid down in the marketing authorisation.

While we hold these certificates, we consider that these are exempt from disclosure under the FOIA as section 43(2) applies. This exemption applies because we believe disclosure would be likely to prejudice the commercial interests of any person, including third parties or the public authority that holds the information. Section 43 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. In favour of disclosure, we consider that there is a general public benefit from allowing access to information which helps protect the public from unsafe products or dubious practices, however this is met in this case by confirming that the appropriate certificates were issued, and the stronger public interest favours maintaining the exemption.

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.

You may ask the manufacturer directly for these at https://www.astrazeneca.co.uk/contactus.html, however, please be aware that as a private company, they are not covered by the FOIA.

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.

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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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