Medicines & Healthcare products Regulatory Agency

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

[redacted]
By email: [redacted]

15 January 2024

FOI **23/987**

Dear [redacted]

Thank you for your request for information under the Freedom of Information Act request, dated **15 December 2023.**

Your request

The following batches of the AstraZeneca/Covishield vaccine were manufactured in India by the Serum Institute of India in October 2020. The batches are 4120Z001, 4120Z002 and 4120Z003. 5 million doses of these batches were imported into the UK to be used as part of the UK vaccination programme. The Serum Institute of India has acknowledged that they manufactured these batches as Covishield, therefore at some stage in the manufacturing process the vials were relabelled as AstraZeneca vaccine.

1. At what date (day/month/year) did the testing of the batches by MHRA (NIBSC) take place?

2. At what location either in the UK or in Europe did the testing of the batches take place?

3. Whilst it is understood the NIBSC testing certificates relating to batches 4120Z001, 4120Z002 and 4120Z003 cannot be disclosed for reasons relating to section 43(2) and would prejudice commercial interests, please can you confirm the date given on each of the certificates? This will in no way prejudice commercial interests and is relevant to confirm and reassure me that the testing had taken place prior to the administration of the vaccines.

4. It has been acknowledged by Serum Institute of India that batches 4120Z001, 4120Z002 and 4120Z003 supplied to the UK were part of a larger Covishield production run. On this basis would it normally be acceptable for a batch shipped to

other territories, for example Canada, to be also labelled for administration in the UK as AstraZeneca vaccine?

I am pleased to provide the information below.

I confirm that MHRA holds the information under s1(1) FOI Act.

Our response

1. At what date (day/month/year) did the testing of the batches by MHRA (NIBSC) take place?

The batches were tested by NIBSC. Furthermore, the company's batch data was reviewed by MHRA. Three batches of 'COVID-19 Vaccine AstraZeneca', 4120Z001, 4120Z002, 4120Z003 were subject to testing by the MHRA (NIBSC) February to March 2021, prior to certification.

2. At what location either in the UK or in Europe did the testing of the batches take place?

The batches were tested at the MHRA (NIBSC) laboratories at South Mimms, UK.

3. Whilst it is understood the NIBSC testing certificates relating to batches 4120Z001, 4120Z002 and 4120Z003 cannot be disclosed for reasons relating to section 43(2) and would prejudice commercial interests, please can you confirm the date given on each of the certificates?

Batches 4120Z001, 4120Z002 and 4120Z003 were certified on 6 March 2021.

4. It has been acknowledged by Serum Institute of India that batches 4120Z001, 4120Z002 and 4120Z003 supplied to the UK were part of a larger Covishield production run. On this basis would it normally be acceptable for a batch shipped to other territories, for example Canada, to be also labelled for administration in the UK as AstraZeneca vaccine?

Under normal circumstances, a Patient Information Leaflet will provide information on the Marketing Authorisation Holder and on the Manufacturer of the product, i.e. the site of Qualified Person batch certification. See for example Page 6 of the PIL for Vaxzevria:
https://assets.publishing.service.gov.uk/media/655def4b046ed400148b9e00/PLGB_17901_0355_AZ_PIL.pdf

In the case of the Astra Zeneca vaccine supplied during the early part of 2021, a Marketing Authorisation was not issued but the 'Conditions for authorisation for emergency supply under Regulation 174 for COVID-19 Vaccine AstraZeneca' document' states that " …. the batch numbers; 4120Z001, 4120Z002, 4120Z003 of the SIIPL COVID-19 Vaccine (ChAdOx1-S

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[recombinant]) manufactured by Serum Institute India Pvt. Ltd located at 212/2 Hadapsar, Pune 411028, India (hereinafter SIIPL and SIIPL COVID-19 Vaccine (ChAdOx1-S [recombinant]) were assessed and are treated as COVID-19 Vaccine AstraZeneca (also known as (ChAdOx1-S [recombinant]) …"

https://assets.publishing.service.gov.uk/media/61391d078fa8f503ba3dc864/AZ_Conditions__-_9SEPT21.pdf

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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

FOI Team
MHRA Customer Service Team