FOI 23/497

Dear

Thank you for your request of 11 July 2023 under the Freedom of Information Act, we apologise for the delay in response. You asked:

> *1. Did NIBSC undertake testing of The Batches and if so on what date.*
>
> *2. Were The Batches tested as 'Covishield' or 'AstraZeneca'?*
>
> *3. What was the result of the testing?*
>
> *4. Were The Batches cleared for use in the UK as 'Covishield' or AstraZeneca'?*

By way of background, we can confirm that the vaccine manufactured by the Serum Institute of India and supplied to the UK was COVID-19 vaccine AstraZeneca – for it to be Covishield it would have had to have been labelled as such.

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.

Our responses to your questions are set out below:

1. *Did NIBSC undertake testing of The Batches and if so on what date.*

   Yes, 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. Were The Batches tested as 'Covishield' or 'AstraZeneca'?

The batches were tested against the specifications for 'AstraZeneca'.

3. What was the result of the testing?

The batches were found to be compliant with the specifications under Regulation 174.

4. Were The Batches cleared for use in the UK as 'Covishield' or AstraZeneca'?

The batches cleared for use were 'AstraZeneca'.

The Serum Institute of India (SII) manufactures both Vaxzevria and Covishield. All SII-made doses approved by the MHRA and administered in the UK were branded as the 'COVID-19 vaccine AstraZeneca' which is now known commercially as 'Vaxzevria'– no 'Covishield' doses were exported to or administered in the UK.

Regulation 174 permits the supply to and by the Crown of COVID19 Vaccine AstraZeneca, based on the safety, quality and efficacy data submitted by AstraZeneca (AZ) to MHRA in the period from 24/09/2020 to 29/12/2020 and by The Serum Institute India Pvt. Ltd (SIIPL) in the period from 01/02/2021 to 19/02/2021 to support the addition of a manufacturer.

For these purposes, the batch numbers; 4120Z001, 4120Z002, 4120Z003 of the SIIPL COVID-19 Vaccine (ChAdOx1-S [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]), subject to the special arrangements for regulatory responsibility for SIIPL COVID-19 Vaccine (ChAdOx1-S [recombinant]) set out in these conditions.

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
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Yours sincerely
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