



# Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of  
Information Team  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU

[foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk)

[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00270**

01 May 2025

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 20 March. You wrote:

*This is a Freedom of Information request regarding the delivery of Covid vaccines from the Serum Institute, Pune , India, to the UK.*

*Three batches of the Oxford/Astra Zeneca vaccine, batch numbers 4120Z001/002/003 were manufactured in India in October 2020, prior to authorisation. They were subsequently supplied to different countries under the brand name Covishield. On March 5th 2021 4.5. millions doses were delivered by air to the UK and deployed within a week. Prior to that, the MHRA had expressed concerns about aspects of manufacturing at the Serum Institute; as a consequence the SII provided " a robust corrective action plan" according to Dame June Raine's evidence to the Hallett Inquiry. Dame June also told the inquiry that inspectors had been sent to India.*

*My questions are as follows:*

- 1 Exactly when were these inspectors sent to the SII?*
- 2 How was MHRA convinced by SII's action plan?*
- 3 Given that the three aforementioned batches were manufactured in October 2020 and were nearing their expiry dates, how could the action plan be applied, retrospectively, to them?*
- 4 How and where were these batches tested for efficacy and safety?*
- 5 What were the contents of a letter to Dame June from Professor Van Tam and Antonia Williams mentioned at the inquiry (INQ000400201) which have not yet been made public, even though this is a public inquiry?*

## **MHRA Response**

We confirm that we hold the information you have requested, however we are withholding some information as it is exempt under the Freedom of Information Act.

Please note that various manufacturing organisations around the world produced the AstraZeneca Covid-19 vaccine. Three batches of the vaccine manufactured by the Serum Institute of India (SII) were deployed in the UK, as explained in Annex 1 of the following link: [ARCHIVE: Conditions of Authorisation for COVID-19 Vaccine AstraZeneca \(Regulation 174\) - GOV.UK](#)

The MHRA reviewed quality and clinical data on the SII-manufactured vaccine to satisfy itself that the vaccine met the UK's Regulation 174 requirements. In addition, MHRA inspectors attended the site and inspected the manufacturing facilities to ensure that they met the required quality standards.

The three SII batches were considered by the MHRA and the Commission on Human Medicines (CHM) to be equivalent to the AstraZeneca Covid-19 vaccine deployed in the UK and manufactured at other sites.

The three batches in question were labelled by SII as 'COVID-19 Vaccine AstraZeneca' – there was no relabelling or repackaging.

Bilthoven Biologicals BV and AstraZeneca were responsible for the final Qualified Person (QP) certification of the three SII-manufactured batches and for placing them on the market in the United Kingdom.

We will address each question separately for clarity.

### ***1 Exactly when were these inspectors sent to the SII?***

SII were inspected following a Regulation 174 supply request received by MHRA from DHSC dated 03 February 2021.

The inspection was performed between 8<sup>th</sup> February 2021 and 16<sup>th</sup> February 2021 including an on-site visit that took place between 10<sup>th</sup> and 12<sup>th</sup> February 2021. The total inspection duration was 16 days.

A certificate confirming compliance with Good Manufacturing Practice (GMP) was issued by MHRA on 23 February 2021.

### ***2 How was MHRA convinced by SII's action plan?***

No issues were found during the inspection that were critical in nature, and would prevent supply of vaccines manufactured at the site.

Conformity testing, to confirm that manufactured vaccine batches meet the product specification was reviewed during the inspection and compliance confirmed within the GMP certificate and subsequently included within the authorisation granted under regulation 174.

### ***3 Given that the three aforementioned batches were manufactured in October 2020 and were nearing their expiry dates, how could the action plan be applied, retrospectively, to them?***

The MHRA carried out a rigorous scientific assessment of all the available evidence on safety, quality and effectiveness as well as a detailed inspection of good manufacturing practice (GMP) by Serum Institute India and its activities concerned with manufacture. The inspectors were satisfied that the manufacturing processes were aseptic and reproducible and did not find any issues that were critical in nature, and which would prevent supply from the site.

The batches were tested at the MHRA laboratories and a separate NIBSC certificate was issued to the manufacturer for each batch, as described in the response to Q4 below.

#### **4 How and where were these batches tested for efficacy and safety?**

The MHRA conducted a careful review of the quality, non-clinical and clinical data for the AstraZeneca Covid-19 vaccine which underpinned the recommendation that the benefits of this vaccine outweighed the risks, and that the vaccine is effective and acceptably safe.

The views of the independent Commission on Human Medicines (CHM) and, where appropriate, its COVID-19 vaccine or therapeutics benefit risk expert working groups were sought prior to temporary authorisation under Regulation 174. The public assessment report captures the detailed assessment of the quality, safety, quality and efficacy that underpinned the recommendation for the vaccine.

The public assessment report can be accessed here:

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca>

The safety and efficacy of individual batches is reliant upon demonstrating that the individual batch meets the product specification. The results for every batch must be consistent with those which were previously shown to be safe and effective in clinical trials or routine clinical use.

The Covid-19 vaccines undergo independent batch release testing by the MHRA through its Official Medicines Control Laboratory at the MHRA. The purpose of this testing is to ensure that each batch of products meets the quality standards defined in their marketing authorisations (product licences), and it involves the thorough laboratory evaluation of their quality and biological activity. The MHRA examines every batch that is manufactured for use in the UK, independently of the testing required by the manufacturer. Medicines batches (including vaccines) that comply with the required specifications are certified, the manufacturer is issued with a NIBSC certificate specific to the batch that has been tested, and the batch can then and only then be released by the manufacturer onto the UK market.

The three batches of 'COVID-19 Vaccine AstraZeneca', 4120Z001, 4120Z002, 4120Z003 were subject to testing by the Official Medicines Control Laboratory at the MHRA from February to March 2021, prior to certification. The batches were tested at the MHRA laboratories at South Mimms, UK and a NIBSC certificate was issued to the manufacturer for each batch on 6 March 2021 allowing them to subsequently market the batches.

MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are assessed and cumulative information reviewed at regular intervals.

The MHRA's analysis of Yellow Card reports did not identify any safety concerns related to specific batches. Manufacturing site details for each batch are included in the information supplied by the marketing authorisation holder and reviewed as part of the MHRA independent batch testing process. When assessing for any batch-specific issues, numbers of Yellow Card reports were considered alongside information about the size and source of the batch.

#### **5 What were the contents of a letter to Dame June from Professor Van Tam and Antonia Williams mentioned at the inquiry (INQ000400201) which have not yet been made public, even though this is a public inquiry?**

We have provided the referenced letter along with this response, however we are unable to provide you with some of the information requested as it constitutes personal data of

someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that "Personal data shall be processed lawfully, fairly and in a transparent manner...".

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team  
Medicines & Healthcare products Regulatory Agency

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## **Your right to complain under the Freedom of Information Act**

If you are not happy with this response you may request an internal review by e-mailing [foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk) or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>