Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00683**

24 July 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 25 June. You wrote:

> *Please disclose the unredacted numerical endotoxin (LAL) test results (including the exact values for both Drug Substance and Drug Product for the following batches and their clinical sub-batch suffixes:*
> - *Main batch EJ0553 and its clinical sub-batch EJ0553Z*
> - *Main batch EE8493 and its clinical sub-batch EE8493Y*
> - *Main batch ER9449 and its clinical sub-batch ER9449Z*
>
> *These batches are linked through the manufacturing genealogy and were all used as shown above as clinical trial material for the booster trial under the "EUA framework".*

MHRA Response

We can confirm that the Agency holds numerical endotoxin test results for the final batches *EJ0553, EE8493* and *ER9449*. We do not hold information for *EJ0553Z, EE8493Y* or *ER9449Z*.

However, the endotoxin results we hold were provided by the Marketing Authorisation Holder in confidence and are commercially sensitive and are therefore exempt from release under Section 41(1) and Section 43(2) of the FoI Act.

Section 41(1) states that information is exempt information if — (a) it was obtained by the public authority from any other person (including another public authority), and, (b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person. We believe that the information requested (i.e. the endotoxin value) was provided to MHRA in confidence by the MAH for this product. To release this information would be considered an actionable breach of confidence, for the reasons stated below concerning the use of this information to overcome regulatory hurdles at the expense of the MAH.

Section 43(2) exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties but also the commercial interests of the Agency. It is intended to protect the ability of a public authority like MHRA to obtain goods or services on

the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category.

These results provide insights into the manufacturer's production processes, purification capabilities, and the quality of raw material utilised. Disclosure of specific quantitative values could enable competitors to benchmark manufacturing efficiency and processes, including the effectiveness of the purification steps. Furthermore, such information may reveal commercially sensitive details relating to the supply chain, as endotoxin levels can serve as an indicator of raw material quality and sourcing standards.

A competitor would be able to gain insight into the manufacturing processes/supply chain without having incurred the costs, time and resources spent by the original MAH, and so overcoming regulatory hurdles at the expense of this MAH.

Furthermore, the redaction of detailed information about drug substance/finished product specifications is in line with the Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) Guidance Document on the Identification of Commercially Confidential Information and Personal Data Within the Structure of the Marketing Authorisation Application, which gives guidance on the type of information that may be considered to be commercially confidential:
https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/02-Transparency/2024-12-HMA-EMA-guidance-on-PD-and-CCI-in-the-MMA.pdf

Providing information, such as quantitative specification results, that is usually considered commercially confidential (in line with the above guidance) could discourage other companies from applying for Marketing Authorisations in the UK as they may be concerned that we will reveal commercially confidential information about their products into the public domain. This could reduce the number of available medicines on the UK market.

Section 43 is a qualified exemption and requires a consideration of the public interest. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in withholding the information outweighs the public interest in releasing the information held by the MHRA. We have carefully considered the public interest arguments in favour of disclosure, including the potential benefit of allowing the public to view the precise endotoxin level for a particular batch to provide further reassurance regarding the safety and quality of the batch of vaccine. However, we can confirm that the result falls within the established acceptance criteria. Given that the test result met the approved specification, it is unclear what additional public benefit would be derived from disclosure of the exact numerical value.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

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

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 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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