Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: **FOI2026/00187**

17 June 2026

Dear [redacted]

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

> *this is an FOI to see the five tests mentioned in this Covid Inquiry report relating to Batch EJ0553*
>
> *Please also supply the Lot release protocol accomanying the batch. I note there is aleady such a protocol in existence empdicte in a Baych release certificated produced under FOIA in USA . I give the url and screen shot below.*
> *As this type of onformation is alrady in the pbilic domain I do not expect information to be witheld inder an exemption unless it is similarly redacted as below,*
> *I do note at this staghe MHRA has confirmed to me that the "agreed" contractual endotoxin limits in drug product are 12.5EU/ml and I am also aware the "agreed " limit for active substacne is also 12.5 EU/ml and so these redactions are quite useless but if you are to redact them please let me know why you are redacting them as thery are also verifiable in EMA open source documentation.*

**MHRA Response**

Following on from our ad-hoc letter of 29 April 2026, we are now providing the formal response to your FOI request.

We can confirm that the Agency holds the information you are seeking.

In relation to question 1. Our response is to release the requested information in full:

For the independent batch release (control testing) of batch EJ0553, the MHRA performed laboratory tests to assess the following parameters: appearance, identity, RNA content/encapsulation, RNA integrity, *in vitro* expression.

In terms of the second part of your request related to *the Lot release protocol and the related to similar information available in the FDA disclosure.*

Please find attached two files:

- EJ0553 Corrected NIBSC Release Request (redacted)

- Prelimenary CoC EJ0553 with attachments _ manf comments JP 02Dec20 (1) (redacted)

**Note on the file names**
One of the files mentions 'corrected' in the filename, this had initially caused concern, so a member of staff checked the file's history and the change was made a day after the file was first created and thus was likely due to an editorial error being corrected.

Some of the information within the requested information (documents mentioned above) is commercially sensitive and is therefore exempt from release under Section 43(2) of the FoI Act.

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.

In this instance we feel that the release of this information would be likely to harm commercial interests of the third party. We also wish to describe the information which has been redacted under this Section of FOIA.

- EJ0553 Corrected NIBSC Release Request (redacted)

| |
|---|
| Total quantity (of batch) |
| Quantity: drug substance and formulated batches, and target concentration |
| Number of containers manufactured and number of containers for release. |
| Selective redactions to specification criteria and results (multiple tables) |
| Medium and temperature for Fill Vaccine Quality Control Test |
| Consumed Quantity: |

- Prelimenary CoC EJ0553 with attachments _ manf comments JP 02Dec20 (1) (redacted)

| |
|---|
| Batch size |
| Additional details related to a deviation |
| Additional details related to site inspections |
| Selective redactions to specification criteria and results (multiple tables) |
| Non-EU/EEA inspection details |

***Selective redactions to specification criteria and results (multiple tables)**
You may note some variation in the information which has been redacted, which on first inspection may appear to be inconsistent. However, the redactions have been made in accordance with the HMA/EMA guidance which explains that:

"A general description of the type of test methods used and the appropriateness of the specification is usually not CCI. However, detailed information on the test methods used and the specification and **quantitative** acceptance criteria established for the starting materials,

intermediates and active substance may be considered CCI, **unless** it complies with the monographs in the European Pharmacopoeia or another national Pharmacopeia."

As required by the FoI Act the use of this exemption requires the public interest for and against disclosure to be assessed.

Before we enter into the public interest factors, we wished to mention that, to our knowledge, our organisation is releasing this type of documentation for the first time, not just for a Covid-19 vaccine but a first for information held for any vaccine or biological product registered with MHRA. While some redactions have needed to be made, we carefully considered these in detail and sought advice from subject matter experts as part of this process.

We recognise that there is a public interest in the disclosure of commercial information relating to the below, but have provided balancing points as sub-bullets:

- The Covid-19 vaccines attracting a higher public interest, even though your FOI request was received long after the start of the pandemic; module 4 of the Covid-19 inquiry has completed recently. Therefore, Covid-19 is a topic that is a feature of present public debate.
    - The information being withheld is not expected to have a consequential influence on the furthering of public debate related to Covid-19 vaccination.
- How information related to manufacturing can help to inform on the public about the safety of the vaccine and can provide reassurance. Publishing information to the public domain could help to better educate and to foster greater trust in vaccines.
    - The information being withheld carries the risks of commercial harm to the third party, but is unlikely to, on its own, improve education about, or to provide greater trust, in vaccines.
- That while information can be technically complex and can be at risk of being misunderstood, steps can be taken to provide context to help to mitigate against misunderstandings.
    - The redactions are made considering the guidance applied to other medicines and vaccines according to the HMA/EMA guidance. While the release of further technical information could be provided with supporting context, the benefit of the information to the public is considered not to outweigh the scope for commercial harm.
- That the vaccines have been given to a vast number of the UK population, and that serious vaccine harms are recognised to have occurred in some instances. This is a factor of considerable weight.
    - We must keep in mind that, however unfortunate, there is always the potential for a person to be harmed by a medicine or vaccine. The sharing of information to the public domain needs to be considered alongside information typically shared for other vaccines.
    - The information proposed to be redacted was not deemed to have a decisive effect on the safety of the given batch. To emphasise this point, we confirm that this batch met the requirements / met the applied testing criteria.

However, when considering arguments against disclosure:

- According to HMA/EMA guidance EMA/51079/2025, detailed information on batch size/production scale (development scale and commercial scale) can considered to be

commercially sensitive. Information that allows conclusions to be drawn about batch sizes also considered trade and business secrets. If released the information would be expected to provide significant insights into BioNTech/Pfizer's position in the market and could enable competitors to adjust their own market strategy based on any disclosed information.

- As per HMA/EMA guidance EMA/51079/2025 information concerning the manufacturing of the active substance, including technical and industrial process parameters and in-process/intermediate specifications can be considered to be commercially sensitive. If this information was disclosed, it would allow competitors to benefit from the third party's know-how and investment in researching the optimal process with minimum investment of time. If competitors are able to accelerate their own product development, it would negatively impact the third party's competitive position.
- As per HMA/EMA guidance EMA/51079/2025 detailed information on the test methods used and the specification and quantitative acceptance criteria established for the active substance and finished product may be considered to be commercially sensitive. Testing results can be used to calculate the acceptance criteria of a testing method by using statistical approaches. Therefore, in addition to the quantitative acceptance criteria the testing results are considered commercially sensitive.
- As per HMA/EMA guidance EMA/51079/2025, detailed information on the analytical methods including used medium and temperature, used for testing of finished product can be considered to be commercially sensitive.
- The detailed scope and focus of an inspection can be considered to be commercially sensitive, as outlined in the Annex of the HMA/EMA guideline. Information such as the scope of activities for vaccine laboratories not only provides detailed insights into the operational scope of that manufacturing facility but also reveals the third party's business and investment strategy, which is developed based on internal know-how and manufacturing/supply strategy.

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

We are also 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

MHRA maintains the following policy on disclosure of personal information:

"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised must be able to demonstrate that at least one of the above criteria apply.

Under the FoI Act, MHRA is not obliged to confirm or deny that it holds personal information about third parties.

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 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.

**Re-use of our information**
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/