



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2024/00390**

21 August 2024

Dear [REDACTED],

Thank you for your Freedom of Information (FOI) request received on 6 August 2024. You wrote:

I am making a freedom of information request for the following information.

Escherichia coli (E. coli) bacteria is a bacteria which has been subject to enhanced mandatory surveillance by the NHS since 2011 as it can produce toxins that can make people sick.

<https://www.gov.uk/government/publications/vero-cytotoxin-producing-escherichia-coli-symptoms-how-to-avoid-how-to-treat/vero-cytotoxin-producing-escherichia-coli-symptoms-how-to-avoid-how-to-treat>

*<https://www.gov.uk/government/collections/escherichia-coli-e-coli-guidance-data-and-analysis>
escheria*

As the MHRA informed the public on 2 December 2020 in the summary of the public assessment report, BioNTech's BNT162b2 mRNA COVID vaccine was manufactured 'through fermentation in an established and well-controlled Escherichia coli cell line, extracted and purified.'

The purification method used by BioNTech to manufacture process 1 product which was used during the phase 1, 2 and 3 clinical trials was not scalable and could not be used to manufacture the mass manufactured process 2 product supplied to the UK under the December 2020 Regulation 174 authorisation.

How did the MHRA establish that batch EJ-0553 and the other Regulation 174 batches were free of e-coli toxin (endotoxin) contamination in order to ensure that they were safe?

If it was not free of e-coli endotoxin, on what scientific basis did the MHRA determine that the endotoxin was at a safe level?

And who conducted the endotoxin testing of the Regulation 174 batches for the MHRA (eg was it the NIBSC or the manufacturer of the product)?

Please provide the endotoxin values as tested by the NIBSC for the following batches of BNT162b2

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Batch number

NIBSC certificate issued on:

1

EJ0553

2.12.20

2

EJ0724

7.12.20

3

EJ1688

7.12.20

4

EL0141

7.12.20

5

EL0739

14.12.20

6

EK1768

17.12.20

7

EK4243

18.12.20

8

EK4237

21.12.20

9

EE8492

21.12.20

10

EE8493

21.12.20

Given the known risks of e-coli toxins, if no independent testing for e-coli endotoxin was commissioned by the MHRA for BNT162b2, please provide copies of any written policy statements or rationals explaining or justifying why such testing was deemed unnecessary.

MHRA Response

Testing of batches of the Pfizer/BioNTech Covid-19 vaccine authorised under Regulation 174 was performed by the National Institute for Biological Standards and Control (NIBSC) to ensure that the batches were within specification limits defined during the assessment of this vaccine.

The results of the tests performed by NIBSC are commercially sensitive and are, therefore, exempt from disclosure under Section 41 (information provided in confidence) and Section 43 (commercial interests) of the FOI Act.

We will explain these exemptions below.

Section 41:

(1) 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.

Section 43:

- (1) Information is exempt information if it constitutes a trade secret.
- (2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

Section 41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of the FOI Act. Section 43 is a qualified exemption and requires that we consider the public interest.

Public interest test

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying of a qualified exemption. 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. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in withholding. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of releasing the information

To release of this information would be of benefit in general to show transparency in MHRA's day-to-day work for the public to see how MHRA has considered quality aspects of the vaccine and found it to be acceptable for use.

Considerations in favour of withholding the information

Information concerning the quality aspects of the vaccine, including concerning its control (finished product specification), is commercially sensitive information that has been provided to MHRA in confidence. The marketing authorisation holder has spent time and resources in developing the vaccine and consulting with MHRA, in order to meet the regulatory guidelines. This information can be used by rival companies in developing their own products, thus overcoming regulatory hurdles at the expense of the marketing authorisation holder.

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.

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/>