Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref:
FOI2026/01145
FOI2026/01286
FOI2026/01386
FOI2026/01416
FOI2026/01425

26 October 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) requests received on 28 September, 01 October, 08 October, 14 October and 18 October. These are attached in Annex 1.

MHRA Response
Section 12(4) of the FoI Act and also the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 provides that requests can be aggregated for the purpose of estimating whether the cost limit applies, providing they relate to any extent to the same or similar information and the requests are received from the same individual or different persons who appear to the public authority to be acting in concert or in pursuance of a campaign.

In this case more than one request has been made within 60 consecutive working days relating to the same or similar information and the requests have been made by the same person. This includes adding to the estimated costs of complying with a later request, the cost of complying with a request that has already been answered. We have therefore aggregated the following requests under this provision:

- FOI2026/00975 (closed)
- FOI2026/01145 (open)
- FOI2026/01286 (open)
- FOI2026/01386 (open)
- FOI2026/01416 (open)
- FOI2026/01425 (open)

All the requests relate to quality aspects regarding Covid-19 Vaccines and involve searching overlapping records.

We estimate that the cost of complying with your aggregated requests would exceed the appropriate limit for central Government, set by regulations at £600. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours)

in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(4) of the Freedom of Information Act the Agency is not therefore obliged to comply with your requests as we have aggregated the cost of processing them together and as such, we will not be processing them any further. The reason we are not able to locate the information within the cost limit is described below.

In FOI2026/01145 you have asked for any gap analysis, or any check-sheet entry, held by MHRA that addresses bacterial endotoxin or the validated state of the bacterial-endotoxins test (Ph. Eur. 2.6.14) for EJ0553 or for any batch in the table. The table includes a further 39 batches of vaccine. In order to establish if this information is held, we would need to review the documentation submitted for each of the 39 batches individually. This information is not held in a table or easily accessible list; we would need to locate and manually review the documentation held for each batch. We have already provided the batch release documentation that we hold for batch EJ0553 in response to FOI2026/00187, it took a substantial amount of MHRA and NIBSC staff time to verify that nothing further was held, including a review of documents in the MHRA and NIBSC databases, assessment reports and archived email accounts of former staff members. We would need to repeat this process with the other 39 batches. The work required for this element of the request alone is therefore likely to exceed the applicable cost limit.

We conducted a sampling exercise for the 39 batches of vaccines and assessed a sample batch which took 40 minutes to locate, retrieve, extract the information. There were 39 batches in total that must be processed to answer this part of your request.

Calculation: 40 minutes x 39 batches = 1,560 minutes (26 hours)

For the remaining questions in this request for which document searches would be required, we estimate this would take 60 minutes per question to locate, review and extract the information.

Calculation: 60 minutes x 10 questions = 600 minutes (10 hours).

Estimated total time: 26 hours + 10 hours = 1,260 minutes (36 hours).

This would exceed the cost limit and the aggregate total for all 5 requests will exceed the limit.

In FOI2026/01286 you have asked for the plasmid name, identifier and length used for the drug-substance template of each Pfizer/BioNTech COVID-19 vaccine authorised in the United Kingdom, including each variant and adapted vaccine. This will involve searching through numerous quality documents as there are over 40 currently granted or cancelled Comirnaty licences. Whilst some quality sections of the dossier will be shared between different licences, it will still involve reviewing a large number of documents in order to locate and extract the information.

We assessed a sampling exercise which took 20 minutes to locate, retrieve and extract the information for one licence. There are over 40 licences in total to process your request for questions 2 and 3.

Calculation: 20 minutes x 40 licences = 800 minutes (13.33 hours).

We assessed a sampling exercise for the remaining questions (1, 5 and 6), and estimated it would take 780 minutes (13 hours) to locate, review and extract the information.

Estimated total time: 13.33 hours + 13 hours = 1,580 minutes (26.33 hours).

This would exceed the cost limit as earlier request and the aggregate total for all 5 requests will exceed the limit.

The searches described above form only part of the work required to respond to the five open requests. The requests contain additional questions and sub-questions, many of which would require separate manual searches, retrieval and review of records held across different sources. When the estimated work involved in identifying, locating and extracting the requested information across the five open and one closed request is considered together, the MHRA considers that the applicable cost limit would be exceeded.

Advice and assistance
Under section 16 of the FoI Act we should help you narrow your requests so that they may fall beneath the cost limit.

We feel that you should limit your request to only one or two documents or specific questions that you are interested in at a time. Please allow us to respond to one request before submitting a new request.

Please note, that following the UK's departure from the European Union (EU), the centralised authorisation for the Pfizer/BioNTech Covid-19 vaccine was automatically converted to a Great Britain (GB) Marketing Authorisation on 01 January 2021 (PLGB 53632/0002). The subsequent Comirnaty licences were granted via the Reliance/International Recognition routes, with the EMA as Reference Regulator. The quality documentation that we hold in the dossiers submitted to MHRA will largely be the same as that held by the EMA.

The EMA has published a large number of quality documents for the Comirnaty vaccine at the link below (please scroll down to the section entitled 'exceptional transparency measures'). https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

Documents regarding the plasmid are published within the **3.2.S Drug substance** folder in the **Module 3.2 body of quality data** section. Within 3.2.S you can find numerous documents such M.3.2.S.2.3 'Control of materials- generation of plasmids', which gives detailed quality information in regard to the plasmid/cell banks. Please note that the plasmid map and the precise sequence data regarding the functional elements of the plasmid are considered to be commercially confidential information and so are redacted within the document.

Once you have reviewed the quality material released by the EMA, you may want to refine your request regarding plasmids. Please note that in line with the EMA exceptional transparency quality disclosure, we are highly likely to consider specific sequence data to be provided in confidence.

We can confirm that regarding batch EJ0553 the "QP certificate of Compliance" and "QP check sheets" named in the Letter of No Objection (FOI2026/00975) are the preliminary Certificate of Compliance and the check sheets already disclosed under FOI2026/00187.

Regarding the endotoxin tests mentioned in FOI2026/01386, we can confirm that endotoxin testing was not undertaken by NIBSC, it was performed by the company for NIBSC/MHRA review.

Please bear the above information in mind when making a revised request. We will consider afresh any revised request however we cannot guarantee that any revised request will fall within the cost limit.

If you have any queries about this letter, please contact us quoting the reference numbers 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/

Annex 1 – wording of the requests:

FOI2026/01145 received 28 September 2026

Thank you for IR2026/00976 and FOI2026/00975. I accept both as statements of what MHRA holds. IR2026/00976 said new questions in the review should be submitted as a new request. This is that request. It does not ask again for the Letter of No Objection or for the Qualified Person check sheets already disclosed under FOI2026/00187.

The recorded accounts
These four accounts are already on the public file. I set them out only so each question can be answered as held or not held.
1. BNT162b2 PAR of 15th December 2020 (File 944544), page 6: MHRA "has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place" and each batch is subject to Qualified Person certification and "batch evaluation by an independent control laboratory."
2. Letter of No Objection, 2 December 2020 (FOI2026/00975): issued after review of "the QP certificate of Compliance and the QP check sheets."
3. IR2026/00976: the final Certificate of Compliance is not held; a related final Qualified Person checklist is not held; MHRA "cannot confirm whether any gap analysis took place"; batches were "expected to fall in line with the quality standards authorised."
4. FOI2026/00187: the independent control laboratory performed five tests on EJ0553. Bacterial endotoxin is not one of them.

File 944544, page 8, states that BNT162b2 RNA "is not the subject of a European Pharmacopoeia monograph (Ph. Eur.) or other pharmacopoeial monograph" and that "production of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and adequate starting material specifications are applied."

File 944544, page 9, states that "the manufacturer is working on the validation of the final commercial process, which follows process optimisation." The same page states that "further in-process details are expected from the manufacturer however the information provided to date are acceptable," and that "a condition of authorisation under this regulation is that the manufacturer will provide further data on the drug product manufacturing process as it is scaled up."

The Information Commissioner's guidance Finding and preparing the information states that the Act covers recorded information whether or not it is accurate or complete, and that to avoid misleading the requester the authority should explain the nature of what it holds or supply the extra recorded context. Determining whether we hold information states that section 1(1)(a) requires the authority to say, accurately, whether it holds information of the description requested. An incorrect "held" or "not held" answer is a breach of section 1(1)(a) (see decision notice IC-413268-M6S9).

I do not ask MHRA to write a new narrative of those accounts. I ask for the recorded information that was on the file under each of them, or a formal statement that it is not held.

The information requested
If a document is not held, say so. "Expected to meet authorised standards" is not an answer under section 1(1)(a).

IR2026/00976 used that formula. After stating that the final Certificate of Compliance and the related final checklist are not held, and that a gap analysis cannot be confirmed, it added: "any batches of Pfizer vaccine used in the UK would have been expected to fall in

line with the quality standards authorised under either the Regulation 174 authorisation (and any amendments) or the subsequent granted marketing authorisation." That sentence describes what batches were supposed to meet. It does not say whether a gap analysis, a recovery-after-hold study, or a laboratory endotoxin result was on the file. I ask again only for what is held or a formal statement that it is not held. Please do not substitute that expectation for a section 1(1)(a) answer.

The conditions of authorisation of 2 December 2020 required Qualified Person certification applying Annex 16. The Qualified Person was to declare compliance with all stages of EU GMP. Where any stage was not compliant, a gap analysis had to be performed and captured on the Qualified Person check sheet, and those sheets were to be provided to MHRA for each batch. Questions 1, 4, 5, 6 and 7(d) ask only whether that recorded entry is held for bacterial endotoxin, or for the validated state of the bacterial-endotoxins test, on EJ0553 and on the batches in the table. They do not ask MHRA to decide whether the condition was met.

1. Copies of any gap analysis, or any check-sheet entry, held by MHRA that addresses bacterial endotoxin or the validated state of the bacterial-endotoxins test (Ph. Eur. 2.6.14) for EJ0553 or for any batch in the table below (UKHSA FOI 273 and 02/09/24/LS/324). If none is held beyond the sheets disclosed under FOI2026/00187, confirm that formally.

2. The date and reference under which any such document for EJ0553 was received.

3. A copy of any recorded decision that FOR-070-025A was sufficient without a final Qualified Person checklist or final Certificate of Compliance. If none is held, say so.

4. Confirm, from the file as it stood on 2 December 2020, that the "QP certificate of Compliance" and "QP check sheets" named in the Letter of No Objection (FOI2026/00975) are the preliminary Certificate of Compliance and the check sheets disclosed under FOI2026/00187, including FOR-070-025A. If any other certificate or checklist was on that file that day, provide a copy or identify it. If none other was held, say so.

5. A copy of any entry on those check sheets that records recovery of a known amount of endotoxin after hold in the active-substance liquid and in the filled vial. If no such entry exists, confirm that formally.

6. A copy of any recorded decision that a recovery-after-hold study was not required. If none is held, say so.

7. For the file as it stood when the Letter of No Objection was issued, state held or not held for a recorded review or note of each of the following:

(a) prior release of 1,950 unlabelled clinical vials as EJ0553Z;

(b) endotoxin testing on relevant intermediates designated only as in-process monitoring (IPT-M);

(c) the drug-substance endotoxin test executed as a limit test, or with values below the limit of quantification;

(d) low endotoxin recovery and hold-time validation for the method in the relevant matrix recorded as incomplete or pending;

(e) a defined sample hold time, or time limit, for the endotoxin test used for drug-substance in-process control and release testing;

(f) the method used on drug substance 20Y513C501 compared with TM100001884 in the August 2020 drug-substance specification;

(g) whether the endotoxin tests on that drug substance and on the finished drug product were executed as quantitative assays or only as limit tests;

(h) batch EJ0070 as the parent lot for EJ0553.

8. Copies of any laboratory result for bacterial endotoxin on EJ0553 held by MHRA or by the independent control laboratory. If none is held, say so.

9. A list, so far as it is recorded, of the documents on which the page 6 statement in file 944544 that acceptable GMP "are in place" was based. If no such list is held, say so.

The first 40 United Kingdom batches
From UKHSA FOI 273 and UKHSA 02/09/24/LS/324:

n	Batch	Date shown	Doses in batch
1	EJ0553	2.12.20	812,175
2	EJ0724	7.12.20	194,025
3	EJ1688	7.12.20	696,150
4	EL0141	7.12.20	780,000
5	EL0739	14.12.20	1,379,625
6	EK1768	17.12.20	708,825
7	EK4243	18.12.20	595,725
8	EK4237	21.12.20	68,250
9	EE8492	21.12.20	337,350
10	EE8493	21.12.20	272,025
11	EN3924	15.1.21	886,860
12	EN1185	19.1.21	978,120
13	EL7834	21.1.21	408,330
14	EK4244	25.1.21	698,490
15	EK4176	25.1.21	325,260
16	EJ6790	26.1.21	394,290
17	EL8713	1.2.21	580,320
18	ER1741	11.2.21	3,526,380
19	ER1749	23.2.21	3,535,740
20	ER7934	24.2.21	896,220
21	EM4965	26.2.21	1,941,030
22	ER9449	19.3.21	203,580
23	EW4109	22.3.21	2,609,100
24	EW2245	1.4.21	538,200
25	ET8885	23.4.21	1,846,260
26	EY5456	4.5.21	407,160
27	EW3143	6.5.21	1,994,850
28	FA5843	7.5.21	253,890
29	FA1027	21.5.21	1,912,950
30	FC8289	26.5.21	411,840
31	FC9001	6.6.21	1,200,420
32	FD5613	8.6.21	1,200,420
33	FE1510	17.6.21	1,200,420
34	FD8813	25.6.21	1,740,960
35	FF3319	29.6.21	2,572,830
36	FE3380	7.7.21	2,825,550
37	FF2153	12.7.21	1,178,190
38	FE8087	13.7.21	1,521,000
39	FF8222	27.7.21	3,418,740
40	FG3712	30.7.21	3,876,210

After EJ0553 those 39 batches supplied about 50 million doses in the United Kingdom by 30 July 2021.

I require copies of the recorded information. Personal data may be redacted. If an exemption is applied, name it and set out the public-interest test, as in FOI2026/00187 and FOI2026/00975.

FOI2026/01286 received 01 October 2026

This request follows FOI2026/00187, your letter of 17 June 2026. That disclosure released the preliminary certificate of compliance for batch EJ0553, CoC-EJ0553-01, and the corrected NIBSC release request of 1 December 2020, with the lot-release protocol and genealogy. The genealogy records the starting material as item SM-001372, material

PF-07305883, described as pST4-1525 linearised plasmid, 1 g/L, Chesterfield, feeding drug substance 20Y513C501, item DS-001477, material PF-07305885.

I am aware that I have made earlier requests about batch EJ0553. This is not a repeat but a follow up. FOI2026/00187 has already disclosed the genealogy, and that genealogy names the starting material as pST4-1525.

The only new question is whether the origin of replication on the dossier held by the Agency is the sequence at bases 7068 to 7741, and whether later authorised Pfizer/BioNTech COVID-19 vaccines kept that sequence or changed it. That information has not been requested before.

The purpose is to interpret a marker the Agency has already released. I ask that the request should not be refused under section 14 as it is a legitimate follow up inquiry. A series of related requests is not, by itself, vexatious, and this one is confined to recorded information on a single element of a plasmid the Agency has already named.

The United Kingdom Public Assessment Report of 15 December 2020, file 944544, does not name that plasmid and does not give the bases of its origin of replication. It records that production of the active substance had been described in the dossier supplied for the regulation 174 authorisation. It does not cite any third-party copy of an EMA report.

https://web.archive.org/web/20201217073152/https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/944544/COVID-19_mRNA_Vaccine_BNT162b2__UKPAR___PFIZER_BIONTECH__15Dec2020.pdf

The EMA public assessment report for Comirnaty, EMA/707383/2020, 19 February 2021, says the active substance is manufactured by in vitro transcription using a linear DNA template produced via plasmid DNA from transformed Escherichia coli cells, and that endotoxins are among the impurities quantified on the plasmid DNA. It does not name pST4-1525 and does not give the bases of the origin of replication.

https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf

A leaked copy of the EMA rapporteurs' rolling-review quality report of 19 November 2020, section 3.2.S.2.3, Table S.2.3-4, describes pST4-1525 as a 7,824-base-pair plasmid and places an Escherichia coli origin of replication at bases 7068 to 7741.

https://archive.org/details/EmaRolling

I do not ask the Agency to adopt that leak, and I do not treat it as proof of what the Agency relied on. I ask the Agency to answer from the dossier it holds.

Public interest

The Agency has already disclosed, under FOI2026/00187, that the template for batch EJ0553 was pST4-1525. Neither the United Kingdom public assessment report nor the EMA public assessment report names that plasmid or gives the bases of its origin.

The public interest is whether the origin of replication on the United Kingdom file stayed the same in later authorised Pfizer/BioNTech COVID-19 vaccines. A 100-base-pair match to that origin identifies this manufacturing template. Without a confirmation of sameness or change, a vial result or a tissue result cannot be read. Section 43 is a qualified exemption.

The Agency has already named this plasmid in its own disclosure under FOI2026/00187. The remaining question is whether the origin of replication stayed the same. A commercial-interest refusal is not justified for a sequence whose plasmid has already been identified by the Agency, and the public interest in being able to recognise that plasmid in a vial or a tissue sample outweighs any remaining commercial interest.

I ask that any redaction be confined to sequence text, and that sameness or difference still be confirmed.

Please disclose the recorded information held by the Agency on the following.

1. The dossier section relied on for the regulation 174 authorisation of 2 December 2020 for the identity of the production plasmid, and whether that section is 3.2.S.2.3.
2. From the dossier held by the Agency, the recorded name, length and functional elements of pST4-1525, including the start and end bases of the Escherichia coli origin of replication. Please confirm whether those bases are 7068 to 7741, or other bases.
3. The plasmid name, identifier and length used for the drug-substance template of each Pfizer/BioNTech COVID-19 vaccine authorised in the United Kingdom after the original BNT162b2 authorisation, including each variant and adapted vaccine.
4. For each such plasmid, whether the Escherichia coli origin of replication is the same sequence as the origin of pST4-1525 on the Agency's file, or a different sequence. If different, the recorded start and end bases and the name of the element.
5. Whether the master cell bank prepared from pST4-1525 at Chesterfield remained the cell bank for any later authorised Pfizer/BioNTech COVID-19 vaccine, or whether a new cell bank was established, and the date of any change.
6. Any assessment, correspondence or query in which the Agency considered the origin of replication as a marker for residual plasmid DNA in the drug substance or drug product of batch EJ0553, or of any later authorised batch.
I ask for the recorded information. I do not ask for a new analysis. Where a sequence is withheld, please still confirm whether it is the same as, or different from, the origin of replication of pST4-1525 on the dossier held by the Agency.

FOI2026/01386 received 08 October

I want to raise a matter of concern regarding apparently inconsistent information provided in response to similar FOI requests

I am aware you are under huge pressure to provide many answers to many people in time constraints. However I must draw your attention to a significant inconsistency in your public responses about the same subject matter.

In FOI2024_00390 redacted for publication the question is

As the MHRA informed the public on 2 December 2020 in the summary of the public asessment 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 n Batch number 1NIBSC 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.

That implies very strongly that NIBSC tested Batch EJ0553 and the rest of bnT162b2 batches for endotoxin level.

If so, that reply contradicts the interim rely sent to me. The further evidence of contradiction is the Batch release certificate also supplied. This shows the manufacturer not NIBSC performed the endotoxin active substance test. The certificate of release does not provide a result only a limit. The letter sent to me did not list the endotoxin test as an IBSC requirment.

In order to clear up this matter, please confirm that NIBSC did not test the batch EJ0553 for endotoxin and only performed the five tests you state it ran in your reply to me.

New supplementary question

Please also provide evidence if held of confirmation that NIBSC/MHRA had in place a validation of the LAL testing method to detect masked endotoxin (l ow endotoxin recovery) in active substance chelated by EDTA added to the product. EDTA is referenced in the EMA EPAR.

If not, was that validation requirement waived by the letter of no objection, responding to the Pfizer endotoxin test result provided to NIBSC in the redacted certificate for EJ0553

FOI2026/01416 received 14 October

This is a new request under the Freedom of Information Act 2000, following the guidance in your internal-review response relating to FOI2026/00828.

NIBSC is the custodian of the WHO 3rd International Standard for Endotoxin (NIBSC code 10/178).
https://cdn.who.int/media/docs/default-source/biologicals/blood-products/catalogue/who-catalogue-with-ecbs-link_mhra.pdf?sfvrsn=fc055271_5

The C of C for EJ0553 notes 2 endotoxin time point tests one for substance one for product. MHRA letter of no objection is based on that information.

However Pfizer has publicly stated that PDA Technical Report No. 82 requires a minimum of four time-points for a valid LER hold-time study and that formal EMA guidance on LER was published only in September 2023. https://www.casss.org/docs/default-source/cmc-strategy-forum-europe/2026-speaker-presentations/peraino-jody-pfizer-inc-2026.pdf

Please confirm or deny whether the MHRA or NIBSC holds recorded information answering the following points:

1. Records of LER technical evaluation
Any recorded information within internal MHRA or NIBSC laboratory assessment reports, validation reviews, or technical panel minutes dated on or before 2 December 2020, showing an evaluation of whether a multi-time-point Low Endotoxin Recovery (LER) hold-time study was required or performed for the BNT162b2 formulation or for batch EJ0553.
2. Awareness of PDA Technical Report No. 82
Any recorded information (including internal briefing documents, regulatory-intelligence files, or scientific correspondence) dated on or before 2 December 2020, that refers to PDA Technical Report No. 82 (or TR82) or to a minimum of four time-points for an LER hold-time study, in connection with the Regulation 174 authorisation or batch EJ0553.
3. Internal technical correspondence on method limits
Any internal correspondence or emails exchanged between MHRA reviewers and NIBSC laboratory staff on or before 2 December 2020 concerning the endotoxin method used for batch EJ0553 (or parent DS lot 20Y513C501), including any reference to the number of time-points, the use of a limit test, or the absence of a quantitative multi-time-point hold-time assessment.
Scope note
This request seeks only confirmation or denial of whether recorded information is held. It does not request new scientific opinions, justifications or interpretations. If no such recorded technical entries or internal communications exist for the period on or before 2 December 2020, a formal statement that the information is "not held" will fully satisfy this request.

FOI2026/01425 received 18 October

I am writing to submit a refined request for recorded information under the Freedom of Information Act 2000. This request builds directly upon the MHRA's previous response to FOI 22/1041, where Question 5 regarding the specific mechanism of test validation for product matrices did not receive a direct answer.

To remain narrow, precise, and compliant with section 12 cost limits, this request is strictly limited to the AstraZeneca COVID-19 vaccine (known as Vaxzevria, AZD1222, or ChAdOx1 nCoV-19). The relevant timeframe spans from the initial rolling review in October 2020 through to the product's official global withdrawal and discontinuation in May 2024.

Context of Request This request is informed by international regulatory disclosures and newly available legal pleadings from the Supreme Court of the State of New York (People of the State of New York v. Robert G. Kramer, Index No. 450441/2026).

Specifically:

1. *The Australian TGA Mandate: The Australian Therapeutic Goods Administration (TGA) provisional approval conditions from February 2021 https://www.tga.gov.au/sites/default/files/foi-2494-02.pdf explicitly required*

AstraZeneca to submit site-specific "Validation of Analytical Procedures: Endotoxin inhibition/enhancement (test for interfering factors) data" for commercial lots.

[cid:49b01c12c0e84958bf37f5d157e50e69@open-xchange.com] 2. The US Manufacturing Evidence: Evidentiary text in the New York State civil complaint explicitly documents that by October 23, 2020, senior AstraZeneca leadership noted that contamination hits for Endotoxin and Bioburden had been "found it in the buffer solution" at the Emergent BioSolutions contract manufacturing facility, raising alarms over a "bigger and more systematic issue at the Site." 3. The Scientific Masking Mechanism: Published peer-reviewed toxicological literature, specifically "Masking of endotoxin in surfactant samples: Effects on Limulus-based detection systems" (Tsuchiya, 2016; doi:10.1016/j.biologicals.2016.06.002) https://www.sciencedirect.com/science/article/pii/S1045105616300252 demonstrates that ethylenediaminetetraacetic acid (EDTA)-a key inactive stabilizing excipient inside the unique AstraZeneca formulation buffer-functions as a potent chelating agent that causes significant matrix interference. When combined with surfactants (such as Polysorbate 80, also present in the Vaxzevria buffer), EDTA actively masks bacterial endotoxins, modifying their micellar structure and rendering them chemically undetectable by standard compendial Bacterial Endotoxin Testing (BET / Limulus Amebocyte Lysate assays), thereby presenting a severe risk of false-negative clearance.

Information Requested I request the following specific recorded information held by the MHRA and/or the National Institute for Biological Standards and Control (NIBSC):

1. *Recorded Protocols and Laboratory Guidelines: Copies of the specific recorded validation protocols, assessment templates, or laboratory SOPs used by the MHRA/NIBSC to evaluate how AstraZeneca's chosen endotoxin assay overcame matrix interference and false-negative masking specifically caused by the complex concentration of EDTA and Polysorbate 80 inside the Vaxzevria formulation buffer matrix.*
2. *Product-Specific EDTA Inhibition/Enhancement Data Packages: Copies of the analytical validation reports, summary protocols, or data sheets submitted by AstraZeneca to the MHRA demonstrating the successful completion of product-specific inhibition/enhancement testing (test for interfering factors via spiked endotoxin recovery curves) to verify that EDTA did not mask bacterial endotoxins during routine batch release.*
3. *Overseas CDMO Non-Compliance and Endotoxin Risk Appraisals: Copies of any recorded risk assessments, technical briefs, or regulatory alerts held by the MHRA/NIBSC between October 2020 and May 2024 regarding downstream endotoxin failures, buffer contamination events, or batch rejections reported by overseas contract development and manufacturing organizations (CDMOs), such as Emergent BioSolutions, supplying intermediate drug substance for the UK AstraZeneca supply chain.*

Detailed Justification for the Public Interest Test (Section 43 Consideration) Should the MHRA consider withholding these records under Section 43 (Commercial Interests) or any related qualified exemption, the following parameters demonstrate that the public interest in disclosure overwhelmingly outweighs any perceived commercial prejudice:

- *Preclusion of Commercial Detriments Due to Product Discontinuation: Because AstraZeneca officially withdrew Vaxzevria from the global market and discontinued its manufacturing lines in May 2024, the disclosure of historical raw analytical validation and testing records can no longer disrupt ongoing commercial competition, market placement, or current proprietary advantage. The product has no active commercial lifespan to protect.*

- *Public Safety and the Prevention of False-Negative Diagnostics:*

1. *As established by the Tsuchiya (2016) matrix study, the structural masking property of EDTA in surfactant buffers presents a documented technical vulnerability where dangerous pyrogens can bypass standard LAL screening. https://www.sciencedirect.com/science/article/pii/S1045105616300252*
2. *Given the US legal disclosures confirming that endotoxin contamination actively breached the vaccine's buffer solution during production, para 59 "59. "On October 23, 2020, an AstraZeneca SVP emailed Kirk and stated: "The situation is clearly deeply concerning as [also] the most recent batch has endotoxin/Bio hits and my understanding is that we now have found it in the buffer solution. This really makes me concerned that we may have a bigger and more systematic issue at the Site . . . . " " https://ag.ny.gov/sites/default/files/court-filings/new-york-v-robert-g-kramer-complaint-2026.pdf there is an existential public health interest in verifying exactly how British regulators validated the test mechanics to guarantee that contaminated buffer batches were not inadvertently cleared into the UK supply chain via false-negative readings.*
    a. *Transparency of Accelerated Regulatory Oversight: Vaxzevria was authorized and deployed under unprecedented emergency rolling reviews. Public confidence in the integrity of the MHRA's regulatory enforcement relies entirely on transparency. Disclosing the recorded data packages proving that the MHRA actively audited and resolved the known masking properties of the vaccine's buffer components is vital to demonstrate that safety standards were never compromised for deployment speed. If any portion of these documents contains sensitive personal identifiers, please apply localized redactions under Section 40 rather than withholding the records in their entirety.*

Thank you for your time and assistance. I look forward to your response within the statutory 20 working days.