



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2025/00359**

07 May 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 7 April. You wrote:

“FOIA Request: Full Disclosure of Plasmid DNA Backbone Sequences and Related Studies for Pfizer and Moderna COVID-19 Vaccines

Date: April 7 2025

To Whom It May Concern,

Under the Freedom of Information Act, I am requesting detailed information regarding the full genetic sequence of the plasmid DNA backbone used in the manufacturing process for Pfizer-BioNTech and Moderna COVID-19 vaccines. Specifically, I seek:

1 Complete Plasmid DNA Backbone Sequence Data: The full genome of any and all plasmid DNA backbones used in the production of mRNA for these vaccines, including:

- SV40 promoter/enhancer sequences.*
- Any additional regulatory elements (e.g., origins of replication, antibiotic resistance genes).*
- The spike protein gene sequence and any modifications made to stabilize or enhance its expression.*
- All other genetic elements intentionally included in the plasmid DNA backbone.*

2 Purpose and Function of Genetic Elements: Documentation explaining the function and purpose of each genetic element within the plasmid DNA backbone design, including why specific sequences (such as SV40 regulatory elements) were chosen.

3 Safety Assessments on the Full Plasmid DNA Backbone: All studies or analyses conducted to evaluate whether the plasmid DNA backbone is associated with:

- Carcinogenesis: Risks of cancer development due to genomic integration or other mechanisms.*
- Mutagenesis: Risks of inducing mutations in human genomic DNA.*
- Impairment of Fertility: Effects on male and female reproductive health, including germline cells.*
- Teratogenicity: Risks of congenital malformations or developmental abnormalities.*

4 Batch-Specific Variations: Information on whether different batches of Pfizer and

Moderna vaccines used distinct plasmid DNA backbone designs or sequences, particularly between clinical trial materials and commercial production batches.

This request is made because it is already known that Pfizer's COVID-19 vaccine contains residual plasmid DNA, including SV40 promoter/enhancer sequences within its plasmid backbone. However, the full genome of this plasmid DNA backbone has not been disclosed, nor have the results of any studies evaluating its safety. Americans were not informed that these vaccines contain plasmid DNA capable of integrating into human genomic DNA. Such integration could theoretically lead to permanent mutations, genomic instability, activation of oncogenes, or heritable genetic changes.

Additionally, Pfizer has documented over 1,200 diseases linked to adverse events following vaccination. Despite this alarming list, these vaccines continue to be widely promoted without full transparency about their contents or risks. Understanding the complete composition of the plasmid DNA backbone and reviewing related safety studies are critical for ensuring public trust in vaccine safety.

If any portion of this request cannot be fulfilled due to exemptions under FOIA, please provide a detailed explanation. I look forward to your prompt response."

MHRA Response

We are unable to deal with your Fol request without clarification of the information you seek. The reasons we require clarification of your request are described below.

- **Entire scope (all questions)** Your request mentions the Pfizer-BioNTech and Moderna COVID-19 vaccines. However, there are numerous iterations of these vaccines that are currently or were previously authorised by the MHRA to target different variants of the SARS CoV-2 virus. We have included a table of these vaccines in Annex I.
 - Under Section 16 of the Fol Act we should assist you in helping you focus your request. To help us do so, we would like to know to which specific vaccines your request should apply to. Please include the vaccine name/s and PL number/s. The greater the number of products the increased likelihood that the cost limit will be exceeded by a request for information. We would generally recommend requesting information on one or two PL numbers for a single question, and one PL number for requests consisting of multiple questions.
- **Question 2** of your request. Please consider the guidance on the number of search avenues outlined on page 2 of this letter.
- **Question 3** of your request. Consideration of these aspects (carcinogenesis, mutagenicity, fertility and teratogenicity) was applied to the use of the mRNA vaccine products, not to the DNA plasmid, either in the form of review of studies or judgements made that studies were not required. Please consider if the material you request is for the plasmid or for the mRNA in the vaccine(s).
- **Question 4** of your request, commences with 'batch specific variations'. Yet, we note that under this subheading your question asks "*Information on whether different batches of Pfizer and Moderna vaccines used distinct plasmid DNA backbone designs or sequences, particularly between clinical trial materials and commercial production batches*". This seems to be a separate subject from batch specific variation/s. A batch-specific variation is a variation application to request agreement for a single or small number of batches of product to be released outside of the usual conditions of the

marketing authorisation¹ To help us meet our obligations under Section 16 of the FoI Act, please could you clarify which option applies, or specify another option.

- **Option A** – *Specifically, I seek: Batch-Specific Variations (for the product name/s and PL/s you intend your request to cover). Information you could request:*
 - A copy of the cover letter/s requesting the Batch-Specific Variation/s
 - The documentation submitted for the batch specific variation/s. Please note, without first conducting a search we will not know how many electronic locations will need to be searched. Therefore, we cannot confirm such a request would be within the cost limit. Please also, refer '**Commercially Sensitive information**' on page 4.
- **Option B** – *information on the differences between COVID19 variant strains. For example, omicron, bivalent BA4.5., XBB1.5, JN.1, (KP.2; Pfizer only)*
 - If option B applies, please be aware that we expect this to require a considerably wide search. Therefore, we cannot confirm such a request would be within the cost limit.

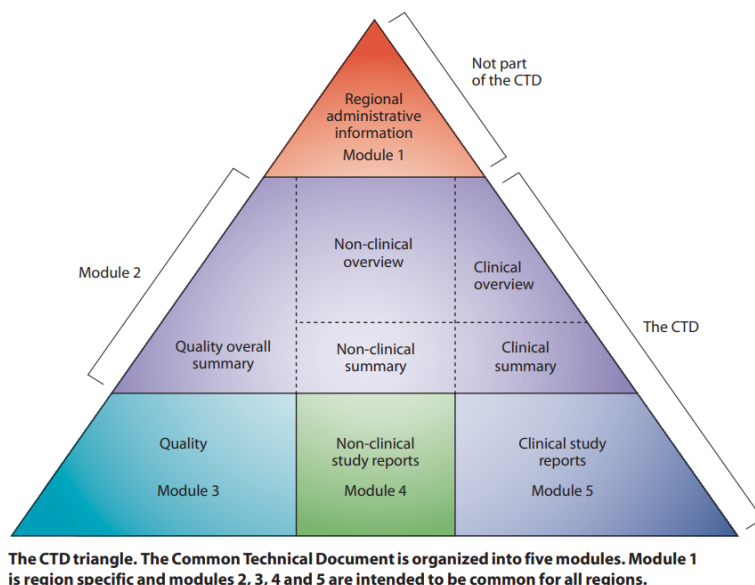
Search avenues

We would also like to take this opportunity to discuss the breadth of your request and our potential search strategies.

Information mentioned in your request related to the Pfizer-BioNTech and Moderna COVID-19 vaccines is likely to be held in multiple areas of the Agency. For example, for some of the information requested, if held, this is most likely to be present in Modules 2 and 3 of a vaccine's regulatory Common Technical Document (dossier). To help to visualise the organisation of the Common Technical Document, we have provided Figure 1, below. However, information is also likely to be held in other areas of the organisation, for example, the Scientific, Research and Innovation Executive formerly NIBSC. This operating group covered activities including batch testing of the Covid vaccines. Furthermore, the administrative arm of the Commission on Human Medicines may also hold information on these topics in minutes, papers, and perhaps, though less likely so, in meeting agendas. Therefore, we need to establish if you wish us to include the above-mentioned areas in our search, or if our search is to be confined to Module 3 of the Common Technical Document of the relevant vaccine or vaccines (once you have provided us with the name and PL number/s of the vaccines that you intend a request to cover).

¹ [When the unexpected happens: Batch Specific Variations – MedRegs](#)

Figure 1.



When creating an FOI request, it is important to note that requests requiring searches in fewer locations are more likely to result in a successful request. For further information please refer to the following guidance.

[Requests where the cost of compliance exceeds the appropriate limit \(section 12\) | ICO](#)

We have noted the following paragraph was included to justify the need for the FOI request, we provide our reply to these points beneath:

“This request is made because it is already known that Pfizer’s COVID-19 vaccine contains residual plasmid DNA, including SV40 promoter/enhancer sequences within its plasmid backbone. However, the full genome of this plasmid DNA backbone has not been disclosed, nor have the results of any studies evaluating its safety. Americans were not informed that these vaccines contain plasmid DNA capable of integrating into human genomic DNA. Such integration could theoretically lead to permanent mutations, genomic instability, activation of oncogenes, or heritable genetic changes.”

The SV40 promoter enhancer sequence is considered as a residual DNA fragment in Pfizer-BioNTech COVID-19 vaccine. The fragment is inactive, has no functional role. Any potential residual DNA present (if found in the vaccine) has been quality control tested and was measured to be consistently below the limit required in accordance with the agreed specifications.

It is important to note that all the Covid-19 vaccines released in the UK to date have passed their release specifications for DNA levels. The specifications are set in line with, and in accordance with, their respective controlled manufacturing process, as well as the WHO guidance on the quality, safety and efficacy of vaccines. The purification and quality control process ensures that any residual DNA is within acceptable regulatory limits.

Due to the public concerns about presence of the SV40 promoter enhancer sequence in the Pfizer-BioNTech COVID-19 vaccine, since authorisation, the manufacturer specifically conducted further tests to confirm that the level of residual DNA is definitely below the acceptable limits, in line with the required specifications.

Independent batch release certification is also performed during the pandemic for all Pfizer-BioNTech COVID-19 vaccine. Furthermore, with reference to TGA (Australian Therapeutic

Goods Administration)'s published findings ([Summary report of residual DNA and endotoxin on COVID-19 mRNA vaccines conducted by TGA Laboratories | Therapeutic Goods Administration \(TGA\)](#)), the vaccines are also found to be below the World Health Organization recommended limit of up to 10 ng per dose, which is consistent with the authorised specification limit.

In addition, there is no clinical evidence that any residual DNA (below the acceptable level), if found in the vaccine, could transfect into cells and integrate into the DNA of a vaccinated person.

Indeed, the Marketing Authorisation Holder (MAH) has a responsibility of declaring and providing relevant data to support their application, including the manufacture of the starting material, any drug substance and drug product intermediates, and the final product to be administered to patients. The dossier should be consistent with the manufacturing process performed in practice. No non-compliance to GMP has been noted since the authorisation of this product, providing reassurance of the necessary adherence to current GMP requirements.

Vaccines are the best way to protect people from COVID-19. As with all vaccines and medicines, the safety of COVID-19 vaccines is being continuously monitored. The benefits of the vaccines in preventing COVID-19 and serious complications associated with COVID-19 far outweigh any currently known side effects in the majority of patients

There is already some related information in the public domain related to some of the subject matter in your request which can be found here:

[\(Summary report of residual DNA and endotoxin on COVID-19 mRNA vaccines conducted by TGA Laboratories | Therapeutic Goods Administration \(TGA\)\) \(cited in text above\).](#)

Guidance on Commercially Sensitive information

The HMA and EMA have published guidance on data transparency in medicine regulation, which the Agency currently uses, alongside the Freedom of Information Act to help to guide its decision making on matters of Freedom of Information. The below press release introduces the purpose the document below. Based on the topics covered by your questions, at minimum, I would recommend reading the guidance on page 10-11 under the header of 3.1. Information on the Quality and Manufacturing of medicine.

[A common EU approach to data transparency in medicine regulation | European Medicines Agency \(EMA\) HMA/EMA guidance document](#)

We trust that you have found the above guidance useful. Please consider making a request in line with the bullet pointed list on page 2 of this letter and the guidance below. We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

We also recommend that you familiarise yourself with the Information Commissioners Office guidance on how to submit an FOI to a public authority. We have provided these links below to aid in future requests:

<https://ico.org.uk/for-the-public/official-information/preparing-and-submitting-your-information-request/>

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/>

Pfizer/BioNTech's Covid-19 vaccines registered with MHRA		
PL number	Product name	Status
PLGB 53632/0002	COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE	CANCELLED
PLGB 53632/0004	COMIRNATY 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED)	CANCELLED
PLGB 53632/0006	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	CANCELLED
PLGB 53632/0008	COMIRNATY 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	CANCELLED
PLGB 53632/0010	Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose Dispersion for Injection	CANCELLED
PLGB 53632/0012	COMIRNATY ORIGINAL/OMICRON BA.4/5 (15/15 MICROGRAMS)/DOSE DISPERSION FOR INJECTION	CANCELLED
PLGB 53632/0014	COMIRNATY ORIGINAL/OMICRON BA.4-5 (5/5 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	CANCELLED
PLGB 53632/0016	COMIRNATY 30 MCG/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	CANCELLED
PLGB 53632/0018	COMIRNATY ORIGINAL/OMICRON BA.4-5 15/15 UG PER DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	CANCELLED
PLGB 53632/0020	COMIRNATY ORIGINAL/OMICRON BA.4/5 (1.5/1.5 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	CANCELLED
PLGB 53632/0022	COMIRNATY ORIGINAL/OMICRON BA.4-5 (5/5 MICROGRAMS)/DOSE DISPERSION FOR INJECTION	CANCELLED
PLGB 53632/0024	COMIRNATY ORIGINAL/OMICRON BA.4-5 (5/5 MICROGRAMS)/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	CANCELLED
PLGB 53632/0026	COMIRNATYOMICRON XBB.1.5 (30 MICROGRAMS)/DOSE DISPERSION FOR INJECTION	GRANTED
PLGB 53632/0028	COMIRNATYOMICRON XBB.1.5 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	GRANTED
PLGB 53632/0030	COMIRNATYOMICRON XBB.1.5 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	GRANTED
PLGB 53632/0032	COMIRNATYOMICRON XBB.1.5 (10 MICROGRAMS)/DOSE DISPERSION FOR INJECTION	GRANTED
PLGB 53632/0034	COMIRNATYOMICRON XBB.1.5 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	GRANTED

PLGB 53632/0036	COMIRNATY OMICRON XBB.1.5 (3 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	GRANTED
PLGB 53632/0038	COMIRNATY OMICRON XBB.1.5 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION, 3-DOSE VIAL	GRANTED
PLGB 53632/0040	COMIRNATY OMICRON XBB.1.5 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED
PLGB 53632/0042	COMIRNATY JN.1 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION	GRANTED
PLGB 53632/0044	COMIRNATY JN.1 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	GRANTED
PLGB 53632/0046	COMIRNATY JN.1 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED
PLGB 53632/0048	COMIRNATY JN.1 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	GRANTED
PLGB 53632/0050	COMIRNATY JN.1 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION	GRANTED
PLGB 53632/0052	COMIRNATY JN.1 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	GRANTED
PLGB 53632/0054	COMIRNATY JN.1 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	GRANTED
PLGB 53632/0056	COMIRNATY JN.1 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION, 3-DOSE VIAL	GRANTED
PLGB 53632/0058	COMIRNATY KP.2 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION	GRANTED
PLGB 53632/0060	COMIRNATY KP.2 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	GRANTED
PLGB 53632/0062	COMIRNATY KP.2 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED
PLGB 53632/0064	COMIRNATY KP.2 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION	GRANTED
PLGB 53632/0066	COMIRNATY KP.2 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	GRANTED
PLGB 53632/0068	COMIRNATY KP.2 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION, 3-DOSE VIAL	GRANTED

Moderna's Covid-19 vaccines registered with MHRA		
PL number	Product name	Status
PLGB 53720/0002	SPIKEVAX DISPERSION FOR INJECTION	CANCELLED
PLGB 53720/0003	COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED)	CANCELLED
PLGB 53720/0004	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.1 (50 MICROGRAMS/50 MICROGRAMS)/ML DISPERSION FOR INJECTION	CANCELLED
PLGB 53720/0005	SPIKEVAX 0.1 MG/ML DISPERSION FOR INJECTION	CANCELLED
PLGB 53720/0006	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 (50 MICROGRAMS/50 MICROGRAMS)/ML DISPERSION FOR INJECTION	CANCELLED
PLGB 53720/0006	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 (50 MICROGRAMS/50 MICROGRAMS)/ML DISPERSION FOR INJECTION	CANCELLED
PLGB 53720/0007	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 25 MICROGRAMS/25 MICROGRAMS DISPERSION FOR INJECTION	CANCELLED
PLGB 53720/0008	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 25 MCG/25 MCG DISPERSION FOR INJECTION IN PFS	CANCELLED
PLGB 53720/0009	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.1 25 MICROGRAMS/25 MICROGRAMS DISPERSION FOR INJECTION IN PFS	CANCELLED
PLGB 53720/0010	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.1 25 MICROGRAMS/25 MICROGRAMS DISPERSION FOR INJECTION	CANCELLED
PLGB 53720/0011	SPIKEVAX XBB.1.5 0.1 MG/ML DISPERSION FOR INJECTION	GRANTED
PLGB 53720/0012	SPIKEVAX XBB.1.5 50 MICROGRAMS DISPERSION FOR INJECTION IN PRE-FILLED SYRINGE	GRANTED
PLGB 53720/0015	SPIKEVAX JN.1 0.1 MG/ML DISPERSION FOR INJECTION	GRANTED
PLGB 53720/0016	SPIKEVAX JN.1 50 MICROGRAMS DISPERSION FOR INJECTION IN PRE-FILLED SYRINGE MRNA-1273.167	GRANTED
PLGB 53720/0017	SPIKEVAX JN.1 50 MICROGRAMS DISPERSION FOR INJECTION	GRANTED

PL number	Product name	status
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PL 53632/0001	COVID-19 MRNA VACCINE BIONTECH	WITHDRAWN
PL 53720/0001	MRNA-1273 SARS-COV-2 VACCINE SUSPENSION FOR INJECTION	WITHDRAWN