Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
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London
E14 4PU

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MHRA Website

Our Ref: **FOI2026/00551**

17 June 2026

Dear [redacted]

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

For Question 1, please treat the request as applying first to the Pfizer/BioNTech COVID-19 mRNA vaccine marketing authorisation/product lifecycle only, not Moderna at this stage.

To keep the request within the appropriate limit, I am content for the search to be confined to the principal Pfizer/BioNTech adult COVID-19 mRNA vaccine authorisation/product lifecycle, being the authorisation most directly connected to BNT162b2/Comirnaty. If MHRA requires the exact PL number to process the request, please identify the relevant principal Pfizer/BioNTech adult product PL number under your section 16 duty to advise and assist, or confirm which PL number MHRA considers to be the correct principal authorisation for this narrowed request.

For Question 1, please confine the search to non-clinical/pre-clinical and pharmaceutical-quality assessment records within Healthcare Quality and Access, including any relevant assessment reports or post-authorisation assessment records dated between 1 January 2021 and 31 December 2024. I am not asking for a wider Safety and Surveillance pharmacovigilance search under Question 1 unless the named Aldén et al. paper was specifically escalated into such records from HQA/non-clinical review.

For Question 2, please apply the request first to the principal Pfizer/BioNTech adult COVID-19 mRNA vaccine authorisation/product lifecycle only. Again, if the exact PL number is required, please identify the relevant PL number under section 16 or confirm which PL number MHRA considers to be the correct principal authorisation for this narrowed request.

For Question 2, the search should be limited to pharmaceutical-quality, residual-DNA, process-related impurity, or post-authorisation quality assessment records dated between 1 January 2023 and 31 December 2024 which cite, reference, or respond to the residual-plasmid-DNA quantification work published by Kevin McKernan and co-authors in 2023 concerning BNT162b2 and/or mRNA-1273 lots, including any internal comparison against the 10 ng per dose regulatory threshold.

For Question 3, please read the request narrowly. I am asking for the accountable officer, role-holder, team lead, or equivalent responsible within HQA and/or the relevant MHRA post-authorisation assessment function for deciding whether the above named published literature

required post-authorisation reassessment, regulatory action, further questions to the MAH, or no action.

If MHRA's position is that no such accountable officer, role-holder, team lead, or equivalent exists for this literature-triggered post-authorisation assessment function, please confirm that fact.

For avoidance of doubt, I am not asking for the full assessment file, the MAH's underlying submissions, commercially confidential material, or the full text of internal reports. I am asking only whether the named studies are cited, referenced, or responded to in the narrowed assessment records, and for the relevant accountable role-holder information requested in Question 3.

MHRA Response

Thank you for clarifying your request, while we have confined the search to what you have recently specified, unfortunately, the cost limit was estimated to be crossed. Therefore, we can confirm neither confirm nor deny that we hold the information requested, but it is exempt from disclosure under section 12(2) of the Freedom of Information Act.

This is because we estimate the cost of searching for and identifying the requested information would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. 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(1) of the FoI Act the Agency is not therefore obliged to comply with your request and we will not be processing it further.

Factors contributing to the time estimate
There were a number of factors which contributed to the cost limit being estimated to be exceeded by the request. The marketing authorisation deemed most likely to be relevant to the request was PLGB 53632/0002, as with many medicinal products, the lifecycle of this vaccine has a great number of entries and we expect the majority of these relate to pharmaceutical or non-clinical aspects.

To search for the information, we established that each lifecycle entry would need to be opened & the assessment report accessed and then searched for the information. Initially, the intention was to search using Ctrl+F for two key terms: 'Alden' and 'McKernan' but it was later noted that the name of the first author includes an accent; Ald**é**n, meaning that preliminary searches would need to restarted using both forms of the name. Further, it was also noted that some assessment reports were embedded files within over-arching assessment file. To access the embedded files, each over-arching file needed to be saved locally and then accessed, adding steps to the search process. While for many examples, it was clear where an assessment file was embedded, other overarching reports gave in-text references to an accompanying assessment report, this undermined the use of Ctrl + F based searches, as it meant that the contents of some of the files would need to be read.

Under Section 16 of the FoI Act we should help you narrow your request so that it may fall beneath the cost limit. We have noted that question 2 has a narrower date range: "dated between 1 January 2023 and 31 December 2024" while this range still captures a fairly large number of lifecycle entries, we expect that we would be able to check these for the McKernan reference within the cost limit. We should also be able to provide a straight-forward answer to Question 3, but we cannot part answer FoI requests. If you wish for a swift answer to

Question 3, on this occasion we would suggest submitting this question separately and we handle both requests, a refined request related to the McKernan paper, and Q.3 in its present form, in parallel.

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 Contact Information 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:
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