



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2026/01039**

22 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 14 September 2026.
You wrote:

I am requesting recorded information concerning the assessment of national marketing authorisation applications, particularly innovative/biological medicinal products submitted before 3 April 2025 and remaining under assessment after that date.

I am not requesting the contents of any applicant's regulatory dossier, RFI questions or responses, confidential clinical/manufacturing information, assessor opinions, or commercially confidential information. Where a question below is phrased as a question, please treat it as a request for any recorded guidance, policy, SOP, work instruction, data, correspondence template, or other information held by MHRA that answers it.

1. Procedure applicable to legacy applications

Please provide any recorded guidance, SOP, transitional instruction or policy explaining which assessment procedure applies to a national MAA that:

*was submitted and validated before 3 April 2025; and
remained under active MHRA assessment after 3 April 2025.*

In particular, did such applications remain under the former 150-day national assessment procedure, transition to the National Assessment Procedure published on 3 April 2025, or follow another transitional procedure?

2. Meaning of second and subsequent RFIs under the procedure applicable to those legacy applications

Please provide any recorded information explaining:

a. the circumstances in which a second RFI would be issued;

b. whether a second RFI could contain unresolved major objections which, if unresolved, would preclude marketing authorisation, or whether second RFIs were ordinarily/reserved for minor or otherwise resolvable outstanding matters;

c. the circumstances in which a third or subsequent RFI could be issued;

- d. whether there was any maximum or usual number of RFIs;*
- e. when unresolved issues would instead result in consultation with the Commission on Human Medicines and/or a CHM letter concerning possible non-approvability; and*
- f. whether satisfactory resolution of a second/subsequent RFI would ordinarily be followed by final compliance checks before grant.*

3. Historical outcome data by number of RFIs

For completed national MAAs for innovative medicines, new active substances, biological products, ATMPs or vaccines assessed under the former national/150-day procedure, preferably covering 1 January 2021 through 2 April 2025, please provide, if held in readily retrievable form:

*number receiving zero RFIs and final outcome: grant / refusal / withdrawal;
number receiving one RFI and final outcome: grant / refusal / withdrawal;
number receiving two RFIs and final outcome: grant / refusal / withdrawal;
number receiving three or more RFIs and final outcome: grant / refusal / withdrawal.
If MHRA does not hold this exact table but holds an existing dataset from which these fields can readily be extracted, please provide that dataset or the closest existing aggregate information rather than creating new analysis.*

4. Historical outcome data for unusually prolonged reviews

For the same class of completed applications, if readily held, please provide counts by final outcome (grant / refusal / withdrawal) for applications whose elapsed time from validation/procedure start to final disposition exceeded:

*12 months;
18 months;
24 months.*

If MHRA instead records duration in clock-on assessment days, clock-stop periods, or another measure, please provide the closest existing information. I am particularly interested in whether very prolonged reviews historically have materially different grant/refusal/withdrawal outcomes.

5. Historical outcome following CHM concern

If readily available, for the same period please provide the number of national innovative/biological MAAs that received a CHM letter indicating a provisional view that authorisation might not be granted, broken down by eventual outcome:

*subsequently granted;
refused;
withdrawn.*

6. Meaning of MHRA terminology

Please provide any recorded definition or guidance concerning the phrases:

*“initial regulatory review”
“first regulatory decision”
when used in relation to a pending MAA.*

In particular, does “first regulatory decision” ordinarily refer to the ultimate initial decision to grant or refuse an application, rather than an RFI, clock stop, CHM consultation, provisional CHM opinion, or other intermediate review step?

7. Limited procedural metadata concerning DCVax-L / murcidencel

Finally, insofar as the following can be disclosed without revealing confidential scientific or commercial information, please provide the following limited procedural metadata concerning the publicly acknowledged DCVax-L (murcidencel) MAA submitted by Northwest Biotherapeutics in December 2023:

- a. Which procedural framework currently governs this application: the former 150-day procedure, the post-April-2025 National Assessment Procedure, or another/transitional procedure?*
- b. How many RFIs have been issued to date?*
- c. The month and year only in which each RFI was issued.*
- d. The month and year only in which MHRA received a complete response to each RFI.*
- e. Whether any CHM letter communicating a provisional view that the application might not be approvable has been issued.*
- f. Whether MHRA has notified the applicant that the application has entered final compliance checks.*

I expressly do not request the substance of any RFI, applicant response, assessment report, CHM deliberation, clinical or CMC issue, regulatory recommendation, or other confidential dossier material.

If any portion of question 7 is considered exempt under sections 41, 43 or another provision of FOIA, please disclose any separable non-exempt procedural metadata and identify the exemption relied upon for each withheld item rather than withholding question 7 in its entirety.

Similarly, if fulfilling all of questions 3–5 would exceed the Section 12 cost limit, please prioritize the request in the following order:

- (1) Question 1*
- (2) Question 2*
- (3) Question 3*
- (4) Question 7*
- (5) Question 5*
- (6) Question 4*
- (7) Question 6*

If any requested statistical breakdown is not held in exactly the form requested, I would be grateful for the closest existing aggregate data, management information or underlying readily extractable data rather than requiring MHRA to create new information.

Please also provide advice and assistance under Section 16 of FOIA if narrowing any element would permit disclosure that otherwise could not be provided.

MHRA Response

We can confirm that no product named “DCVax-L” has been authorised by MHRA.

Unfortunately, we cannot provide information on whether there may or may not be an application in progress for any particular product. When we need to refuse a written request for information in this way, we need to do this under the provisions of the FOIA so that we include the relevant exemptions and the reasons why we are applying them. This means that for your enquiry about “DC-Vax” we need to refuse to confirm or deny whether we hold this information under Section 41(2) (S41 –information provided in confidence) and Section 43(3) (S43 – prejudice to commercial interests) of the FOIA.

We will explain these exemptions below.

Section 41 –

(2) The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with Section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence.

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).
- (3) The duty to confirm or deny does not arise if, or to the extent that, compliance with Section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).

Public interest test

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering the neither confirm nor deny provision 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 neither confirming nor denying that the information is held outweighs the public interest in confirming or denying whether the MHRA holds the information you have requested. 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 saying whether information is held or not. 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 confirming whether or not we hold the information

To confirm or deny whether or not an application has been received by MHRA would be of interest to patient groups and healthcare professionals in knowing and understanding whether a relevant treatment could soon be available to patients. It would also be of benefit in general to show transparency in MHRA’s day-to-day work for the public to see what applications are currently being considered by MHRA.

Considerations in favour of neither confirming nor denying whether we hold the information

To confirm or deny whether we are currently considering an application for a particular medicine would be of great interest to rival companies who are marketing or looking to market their own products. Knowledge of whether an application is being considered by MHRA can be used as market intelligence in order to gauge when a new product is likely to come onto the market so strategies can be employed to prevent that product getting a foothold in the market. Further, to confirm or deny that we may hold any information on

applications that are not yet authorised in the UK can make companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

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](https://ico.org.uk/for-the-public/foi/) 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/>