Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

16 January 2026

MHRA reference: **FOI2025/01312**

Dear [redacted]

Thank you for your information request, which we received on 16 December 2025. You asked for:

"I am writing to request information under the Freedom of Information Act 2000 relating to the Marketing Authorisation Application (MAA) submitted by Northwest Biotherapeutics, Inc for DCVax-L, an immunotherapy for glioblastoma, which was submitted to the MHRA in December 2023.

Specifically, I request the following information:

1. CHM meeting materials
Please provide:
The agenda, minutes, and any published or unpublished recommendations arising from the Commission on Human Medicines (CHM) meeting held around June 2024 that considered the DCVax-L application.
- *Any formal advice, conclusions, or recommendations issued by CHM to MHRA in relation to this application.*
- *Any action items or follow-up requests communicated to Northwest Biotherapeutics following that CHM meeting.*
- *If any information is withheld under an exemption, please identify the relevant exemption(s) and provide the remainder of the information where possible.*

2. GMP inspection status - Advent Bioservices (Sawston)
Please provide:
- *The date(s) on which MHRA conducted GMP inspections of Advent Bioservices Ltd, Sawston, that were relied upon or referenced in the assessment of the DCVax-L MAA.*

- *Confirmation of whether those inspections have been completed.*
- *Confirmation of whether the outcome of those inspections was considered satisfactory for the purposes of the DCVax-L MAA assessment.*

3. Regulatory status and decision timeline
Please provide:
- *The current assessment status of the DCVax-L Marketing Authorisation Application (eg, under active assessment, clock-stop, final review, or decision-making phase).*
- *Confirmation of whether the MHRA has completed all scientific, clinical, and GMP assessments required to reach a decision.*
- *If available, the expected timeframe for issuance of a regulatory decision on the application.*

4. Reliance on manufacturing authorisations
Please confirm:
- *Whether the Human Medicines Manufacturer's Authorisation (MIA) held by Advent Bioservices Ltd is currently being relied upon for the DCVax-L MAA.*
- *Whether any updates or re-issuance of that MIA were conducted in connection with the DCVax-L assessment.*
- *If any part of this request exceeds cost or scope limits under Section 12 of the Act, I would appreciate advice on how the request may be refined to remain within statutory limits."*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

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.

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Medicines & Healthcare products
Regulatory Agency

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group

Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF