Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/01154**

26 October 2026

Dea[redacted]

Thank you for your Freedom of Information (FOI) request received on 29 September 2026. You wrote:

I would like to make a Freedom of Information request regarding the marketing authorisation application for DCVax-L submitted by Northwest Biotherapeutics.

I have followed the previous MHRA FOI responses concerning this application, including FOI 24/094, in which MHRA confirmed that it held an MAA for DCVax-L and that the applicant had requested the 150-day assessment route.

I am not seeking any confidential clinical, scientific or commercially sensitive information. I am mainly interested in the administrative and procedural history of the application.

Could you please provide, if this information is held and can be disclosed:

1. *The date on which the DCVax-L MAA was formally validated by MHRA.*
2. *The date on which the substantive assessment of the application began, if this is recorded separately from the validation date.*
3. *The number of formal requests for further information that MHRA has sent to Northwest Biotherapeutics in relation to the application, together with the dates of those requests.*
4. *The dates on which responses to those formal requests were received by MHRA. I am not asking for the contents of the requests or responses.*
5. *Whether there have been any formal pauses, clock-stops, extensions or other changes to the review timetable, and, if so, the dates and general reason/category recorded for each.*
6. *Whether the application has been referred to, or scheduled for consideration by, the Commission on Human Medicines (CHM).*
7. *If a CHM referral has taken place, the date of the referral and, if applicable, the date of the CHM meeting. I am not requesting the substance of any CHM deliberations.*
8. *Whether MHRA has recorded a final regulatory decision on the DCVax-L MAA. If a decision has been made, I would like the date and nature of the decision, to the extent this can be disclosed.*
9. *If there has not yet been a final decision, whether MHRA records the application as being under assessment and, if so, the current procedural stage using MHRA's own terminology.*

I appreciate that some of this information may be exempt from disclosure. If that is the case, I would be grateful if you could provide whatever non-exempt information can be released and identify the relevant exemption for anything withheld.

I am specifically requesting information already held by MHRA and am not asking MHRA to create new information, conduct an analysis, or provide an opinion.

Thank you for your assistance.

Kind regards,

[redacted]

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 FOI Act 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 FOI Act.

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 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/