Medicines & Healthcare products
Regulatory Agency

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United Kingdom
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[redacted]

31 May 2024

MHRA reference: **FOI2024/00095**

Dear [redacted]

Thank you for your information request, which we received on 6 May. You asked for:

> *"DCvax-L has been under a 150-day MHRA review since 22 Dec 2023. No CHM meeting has yet been scheduled to discuss DCvax-L. I am wondering if any approval would require the latter (CHM meeting), or can MHRA approval happen simply at the conclusion of the 150-day MHRA review?"*

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

Unfortunately, we cannot provide information on whether or not a pending marketing authorisation application for a named product will be put before CHM. This information would be considered to be commercially sensitive and is exempt from release under Section 43(2).

We will explain these exemptions below.

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).

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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 withholding the decision on whether the product will be put to the **Commission on Human Medicines** (CHM), outweighs the public interest in releasing. 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.

Factors considered in the public interest in favour of releasing the information
To provide information on whether or not a pending marketing authorisation application for a named product will be put before CHM, 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 understand if an application is likely to require further steps prior to receiving an assessment outcome.

Factors considering in the public interest for withholding the information
To provide information on whether or not a pending marketing authorisation application for a named product will be put before CHM, 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, release information on whether a product is due to be put to CHM can create a chilling effect, with companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

The status of a marketing authorisation application i.e. 'considered or not considered by CHM' is *not* a reliable indicator for when access to a specific medicine will occur. In the first scenario if an application is not triaged for CHM, MHRA can still request further information from applicants, and significant additional time can be required while applicant's prepare information & data to support a response, and for the assessment or the response to occur. To further illustrate the point, even once a product is authorised, a company may elect to make further changes (variations) prior to marketing their product, and they may also have a significant lead time in which to prepare marketing materials or risk minimisation materials such as

educational materials for healthcare professionals and patients, and mock-ups for patient information leaflets. Dates to market can also be extended, for example due to deliberations with private suppliers and NICE next steps for NHS availability. Overall, these factors lessen the public interest in the information and further tilt the balance in favour of maintaining the commercial sensitivity of the application and maintaining the trust between the pharmaceutical industry and MHRA.

General information about the CHM is available to the public online, this information explains the role of CHM and includes public summary minutes which are published following CHM meetings. In these minutes the indications (use) of a product that was discussed at the meeting is recorded, for example, 'a medicine used to treat cancer', however, the product name is intentionally omitted to protect the commercially sensitive status of the application.

Advice and assistance
The below information on the process by which applications are selected for the CHM agenda may be useful to you.

"The Commission on Human Medicines and Expert Advisory Groups (EAGs) offer advice to the MHRA and the licencing assessment teams on the scientific content of marketing authorisation applications.

In accordance with Medicines Act 1968 and Human Medicines Regulations 2012 (SI 2012/1916) the MHRA is expected to seek advice from the Commission, under certain circumstances including prior to refusal of any marketing authorisation application (MAA). This is particularly relevant to national applications but similar approach is adopted for decentralised procedures to adopt a UK position.

The Commission and EAGs consider all new chemical entities (including combinations), major variations including those seeking new indications and, where necessary, generic applications, to establish their comparability with the originator products, applications for new routes of administration, new pharmaceutical forms and bibliographic applications. They may also consider other issues brought to them either by the Licencing authority or by the company relating to a decision of the licensing authority (MHRA)"

Please also note that the pharmaceutical company may be willing to confirm the status of their application. The contact details for NW Biotherapeutics are below:

Northwest Biotherapeutics Contact Us - Northwest Biotherapeutics (nwbio.com)

In regards, to the outcome of your FOI request we understand that this may be disappointing; however, by providing the above contact point to you, we hope that the company will be able offer you with further support in relation to DC-Vax-L.

This concludes our response to your request.

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

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