FW: FOI 24/225

FOILicensing <FOILicensing@mhra.gov.uk>
Tue 02/04/2024 12:04

To:MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>;FOILicensing <FOILicensing@mhra.gov.uk>;
[redacted]

Hi all,

This one has gone out.

Thanks,
[redacted]

From: FOILicensing <FOILicensing@mhra.gov.uk>
Sent: Tuesday, April 2, 2024 12:03 PM
To: [redacted]
Subject: FOI 24/225

Dear [redacted]

Regarding your email of 05 March 2024, where you have asked the following:

"I was wondering if you could please update me regarding approval of the DC Vax vaccination for brain tumour from Northwest Biotherapeutics, please?"

We are aware of the following post that has been made by Northwest Biotherapeutics:

https://nwbio.com/northwest-biotherapeutics-announces-marketing-authorization-applications-submitted-uk-mhra-dcvax-l-glioblastoma/

Any further information on this application would be exempt under Section 41(1) and Section 43(2) of the Freedom of Information (FOI) Act.

41.—(1) Information is exempt information if —
(a) it was obtained by the public authority from any other person (including another public authority), and,
(b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.

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 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 refusing outweighs the public interest in providing any information we hold. 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 releasing further information on this issue. 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 providing information
To provide information on an application 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 refusing to provide information
To provide further information on 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 and how it is being assessed/where it is in the assessment process 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 provide information on applications that are not yet authorised in the UK 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.

We consider that the public interest favours withholding any further information.

If you have a query about the information provided, please reply to this email.

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

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would 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 your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,
FOI Team

Department of Health's policy on the use of electronic communications. For more information on the Department of Health's email policy, click **DHTermsAndConditions**