FOI 24/096 - RE: CEO 19796: ACK - Re: Dr Rod Adams - Licensing of Neomel (Andrew Jones MP)

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Fri 02/02/2024 16:16

To [redacted] >

1 attachments (65 KB)

1511_001.pdf;

FOI 24/096

Dear [redacted]

Thank you for your letter of 29 August 2023 and we apologise for the delay in responding. Regarding the current status of an application received by MHRA, Unfortunately, we cannot provide information on whether there may or may not be an application for any particular product. This means that for your enquiry about whether any applications have been received by MHRA for Neomel we neither confirm nor deny we hold information relevant to your request. Section 41(2) and Section 43(3) of the Freedom of Information Act (FOIA) absolves us from the requirement to say whether or not we hold information:

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.

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 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.
Your constituent Dr Rod Adams has said he has correspondence from MHRA and has been working with Neoceuticals Ltd, who he has said is the applicant. We suggest, if this is the case, that he contacts either Neoceuticals Ltd or MHRA directly (and not through the FOIA) for further updates.
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,
MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000

From: Executive Office <Executive.Office@mhra.gov.uk>
Sent: Friday, September 15, 2023 11:32 AM
To: [redacted]
Cc: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: CEO 19796: ACK - Re: Dr Rod Adams - Licensing of Neomel [redacted]
Dear [redacted],
Thank you for your letter of 29 August 2023 to Dr Raine.
This email is to acknowledge your letter. You will receive a response in due course.
Kind Regards
[redacted]
Diary Officer to Dame June Raine DBE
Executive Office – Office of the Chief Executive and Chair
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
[redacted]