Medicines & Healthcare products Regulatory Agency

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gov.uk/mhra

[redacted]
[redacted]
By email: [redacted]

14 February 2024

FOI **24/050**

Dear [redacted]

Thank you for your request under the Freedom of Information Act which we received on 17 January 2024.

Your request

> *"1 Freedom of Information Request: Carbamyl Glutamic Acid Powder for Oral Liquid*
>
> *1.1 As brought to our attention in your Email, please note that in our previous FOI Requests in relation to this product we provided an incorrect WDA(H) number.*
>
> *1.2 Please can the MHRA provide us with copies of all correspondence between December 2021 and March 2022 held by the MHRA's Defective Medicines Report Centre (DMRC) relating to Carbamyl Glutamic Acid Powder for Oral Liquid, with Wholesaler Distribution Licence number WDA(H) 16786*
>
> *2 Freedom of Information Request: Epistatus (licence PL 16786/0003; and unlicenced)*
>
> *2.1 Further to your Email we have further narrowed our request in line with your advice. The documents we have requested are now within a time frame of five months. We hope that you are now able to provide us with the information requested below.*
>
> *2.2 Please can the MHRA provide us with copies of all correspondence dated between 1 October 2021 and 16 May 2022 held by the MHRA's DMRC relating to:*
>
> *2.2.1 Epistatus (10mg in 1ml) maleate base (licenced)*

Name on MHRA website: Epistatus 10mg Oromusosal Solution (Midazolam (as maleate))

Product type: Single dose pack (one-pre filled syringe)

Licence Number: PL 16786/0003

2.2.2 Epistatus (10mg in 1ml) maleate base (unlicensed)

Product Type:

a) Multi-dose 5ml bottle (Bottle Product); and

b) Products containing a pre-filled syringe or multiple pre-filled syringes - available in

2.5mg, 5mg, 7.5mg and 10mg (Lower Dose Syringes)."

Our Response:

I confirm that the MHRA does hold information in relation to correspondence between December 2021 and March 2022 held by the MHRA's Defective Medicines Report Centre (DMRC) relating to Carbamyl Glutamic Acid Powder for Oral Liquid, with Wholesaler Distribution Licence number WDA(H) 16786 and also correspondence dated between 1 October 2021 and 16 May 2022 held by the MHRA's DMRC relating to Epistatus (10mg in 1ml) maleate base (licenced)

The MHRA has assessed the information currently held in relation to Freedom of Information request 1 and 2.

We have concluded that the MHRA does hold some of this information, however we have determined that is exempt based on following exemptions:

Section 41 – Information provided in confidence:

1. *Section 41 FOIA: 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.*

   "Section 41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence".

   Freedom of Information Act 2000 (legislation.gov.uk)

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Section 43(1) FOIA: The information constitutes a trade secret.

Section 43(2) FOIA: the disclosure would, or would be likely to, prejudice the commercial interests of Veriton Pharma Limited.

Section 43(1) Freedom of Information Act 2000 (legislation.gov.uk)

"Section 43 is a qualified exemption, and a consideration of the public interest is required. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in releasing information. This information can be used by competitors for their commercial advantage.

In considering section 43, we sought the views of the company Veriton Pharma Limited to ask for their opinion on the release of the information requested. The company confirmed that they consider this information to be "confidential and proprietary intended only to be shared with the Health Authority". They have identified how disclosure would be likely to cause prejudice to their commercial interests, and that this would "cause significant harm both financially as well as an unfair competitive advantage so that competitors would not need to develop their own product or testing or acceptance criteria significantly shortening their time to market." This engages the section 43(1) and 43(2) exemptions.

The ICO guidance also advises that a trade secret is the property of its owner, and gives the following example of the type of information that may be a 'trade secret':

The First-tier Tribunal discussed the 'trade secret' definition in the case of the Department for Work and Pensions v IC EA/2010/0073, (20 September 2010). It quoted from previous court and Tribunal decisions which reviewed the nature of a trade secret.

> *"The Tribunal noted that a trade secret was information, which, if disclosed to a competitor, would be liable to cause real (or significant) harm to the secret's owner. This assumed that the owner used the information in a trade or business and that they either limited the dissemination of the information or at least didn't encourage or permit its widespread publication."*

The Tribunal also noted that the concept of a 'trade secret' related to a particular kind and quality of information. In terms of 'kind', it considered this suggested "something technical, unique and achieved with a degree of difficulty and investment". In terms of 'quality', the Tribunal indicated that the term 'trade secret' suggested the "highest level of secrecy".

We consider that this example is relevant in this case, and that the information requested in this case therefore falls within section 43(1) and is exempt from disclosure.

S43(2) Commercial sensitive information

S43(2) applies where disclosure of the information would be likely to, prejudice the commercial interests of any legal person (an individual, a company, the public authority itself or any other legal entity).

The ICO explains that this is a prejudice-based exemption, which means that information is exempt if its disclosure under FOIA if disclosure would be likely to, prejudice the commercial interests of any legal person (including the public authority holding it). A 'commercial interest' relates to a legal person's ability to participate competitively in a commercial activity.

The ICO's guidance lists a range of circumstances in which a public authority may hold commercial information. Most relevant here is:

- If you undertake regulatory activity (for example, if you issue licences or accreditations), you may hold commercially sensitive information obtained in the course of your investigations or related to your functions.

For information to be exempt from disclosure under section 43(2), a public authority must be able to demonstrate that the disclosure of the information would be likely to, prejudice or harm commercial interests of an individual, a company, the public authority or any other legal entity. This is known as 'the prejudice test'. In conducting this test, we need to identify what the harm is and why it may occur because of disclosure.

The risk of prejudice occurring must be "real and significant, more than hypothetical or remote", and we must be able to demonstrate a causal relationship between the disclosure of the information in question and the prejudice we believe will occur. It is not sufficient to simply argue that because information is 'commercially sensitive', its disclosure would be likely to prejudice commercial interests.

As noted above, to evidence the prejudice in this case we sought views from the company. Having gained their views on this, we consider that the disclosure of the information would be likely to prejudice their commercial interests.

S43(1) and S43(2) of the FOIA are conditional exemptions and require consideration of the public interest. In favour of disclosure, we consider that there is a general public benefit where releasing the information demonstrates openness and transparency, and where this could inform the public and contribute to public scrutiny and debate. However, this must be balanced against the greater public interest in ensuring that such release is not harmful, under the stipulations of S43 of the FOIA.

We cannot see a public interest argument in this instance that outweighs the commercial harm in publishing trade secrets on the manufacture/control of the finished product, which engages S43(1). We also cannot see a public interest

argument in this instance that outweighs the commercial harm in publishing details of the manufacture and control of the product, which can be used by competitors to overcome regulatory hurdles in the development of their own rival products. Finally, we cannot see a public interest argument in this instance that outweighs the commercial harm in publishing details of the manufacture and control of the finished product, which would prejudice the Agency's commercial interests in this case and in future.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

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
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