

FOI 24/095 - Freedom of Information request

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

Fri 22/03/2024 20:11

To

Dear

Further to your discussion with our FOI Manager last week, we are writing to advise that after completing our considerations for your request, we are sorry to advise that we are refusing the information you have requested at this time under section 41(1) and 43(2) of the FOI Act. The DSUR is marked as being provided in confidence; and we are concerned disclosure under the FOI Act would therefore be considered a breach of this confidence, and risk prejudice to the commercial interests of a party.

To explain, we have not received written permission for disclosure of the DSURs; this is an explicit condition set out in the documents. While we appreciate the difficulties of UCLB's situation, as a public disclosure under the FOIA, we are not able to take the identity and motives of the requester into account when we reach a decision, and we must consider the wider impact of disclosure (which includes publication of disclosures on our own website).

Section 41(1) applies when the information has been provided in confidence, and disclosure would be an actionable breach of that confidence; section 43(2) applies when disclosure would be likely to prejudice the commercial interests of any party. The ICO's guidance lists a range of circumstances in which a public authority may hold commercial information, and 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.

S43(2) of the FOIA is a qualified exemption and so requires consideration of the public interest in disclosure and in maintaining the exemption. We consider that there is a 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 public interest in ensuring that such release does not cause the prejudice identified in the exemption and in this case, we consider that the factors in favour of public disclosure do not clearly outweigh the concerns regarding possible prejudice likely to result from breach of confidence, and therefore consider that section 43(2) continues to apply alongside section 41(1).

We appreciate that you have a purpose and interest in requesting this information, and we have also considered whether it may be possible to take your enquiry forward outside the FOI Act. However, we would note in the first instance that you do have the option to appeal this decision under the FOIA and ask for an internal review to be conducted, in accordance with the complaints process for all FOI requests. If you were able to provide any further details of the return of IPR to UCLB, and the extent to which this would cover the DSUR that you are interested in, then we would be happy to consider this aspect further.

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

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: info@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

From: [REDACTED]
Sent: Friday, January 26, 2024 4:20 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Cc: [REDACTED]
Subject: FOI 24/095 - Freedom of Information request

Dear MHRA,

Further to the below email response provided by [REDACTED] I write on behalf of [REDACTED] the wholly owned subsidiary commercialisation company of [REDACTED] to confirm that the information requested under the freedom of information request relates to data submitted in support of a Phase II clinical trial of VSN16R, an orally bioavailable compound based on anandamide, conducted by Canbex Therapeutics Ltd for the treatment of multiple sclerosis related spasticity (ClinicalTrials.gov number NCT02542787. EU trials register Number: 2014-004412-11).

As a spin-out company of [REDACTED], IP assets including those relating to VSN16R and compound analogues, were initially licensed and subsequently assigned from [REDACTED]. Similarly, the necessary confidentiality measures were established between both organisations.

Despite demonstration of an excellent safety profile, unfortunately VSN16R did not meet the primary efficacy endpoints specified in the CTA authorized for the aforementioned clinical trial. The associated IPR has subsequently since been assigned back to [REDACTED] who have resumed their position of legal owner.

[REDACTED] consents to the provision of the DSUR information sought under the freedom of information request and would be happy to assist where required in securing its acquisition.

With thanks and kind regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] is a wholly owned subsidiary of [REDACTED]. This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this email in error, you should not use or disclose the contents and you should immediately notify the sender and delete the email. Any personal data in this email must be handled in accordance with the Data Protection Act 2018. This email may contain files which are subject to third party copyright. If you open, store, copy, distribute, communicate or adapt such a file, you are presumed to have the necessary permissions from the copyright owner to do so.