FOI 24/151 - FOI request - Synapse Labs Pvt

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

Tue 12/03/2024 11:59

To [redacted] >

FOI 24/151

Dear [redacted]

Regarding your request for “information about any generic medicines authorised or being evaluated, for supply to any part of the UK, which are based on studies conducted by Synapse Labs Pvt. Ltd, located in Pune, India, and which were not included in the EMA review referred to above,” this information is exempt from disclosure under Section 27, Section 35 and Section 43(2) of the Freedom of Information Act (FOIA).

Section 27(1) covers information that would prejudice or would be likely to prejudice:

(a) Relations between the UK and any other State

(b) Relations between the UK and any international organisation or international court

(c) The interests of the UK abroad

(d) The promotion, or protection, by the UK of its interests aboard

Section 35 sets out four exemptions designed to protect good government and provide a safe space for policymaking:

35 Formulation of government policy, etc.

(1) Information held by a government department or by the Welsh Assembly Government] is exempt information if it relates to—

(a)the formulation or development of government policy,

(b)Ministerial communications,

(c)the provision of advice by any of the Law Officers or any request for the provision of such advice, or

(d)the operation of any Ministerial private office.

Section 43(2) covers information that would, or would be likely to, prejudice the commercial interests of any 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 these class-based exemptions. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in providing this information outweighs the public interest in withholding 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 providing this information. 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 requested

To provide the information requested would be of interest to others following the European Medicines Agency (EMA) review of Synapse Labs Pvt Ltd (https://www.ema.europa.eu/en/medicines/human/referrals/synapse). It would also be of benefit in general to show transparency in MHRA's day-to-day work for the public to see progress with the current investigation.

Considerations in favour of withholding the information

The review of the referral by the EMA concerning Synapse Labs Pvt. Ltd is still ongoing and has not yet concluded. This means that Section 35(1)(a) is engaged and will remain engaged until our review has concluded. To provide information at this point could prejudice this review, by releasing information into the public domain that could be used for persons to try to reach their own conclusions before we have concluded our review. As the referral investigation is being conducted by the EMA, to publish this information would be likely to damage relations between the UK and the EMA, thus also engaging S27. Finally, releasing specific information of the product licences concerned before any investigation has concluded would cause commercial harm to those marketing authorisation holders who hold product licences based on studies conducted by Synapse Labs Pvt. Ltd, which engages Section 43(2).

The public interest favours withholding this 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,

MHRA Customer Experience Centre

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Tuesday, February 13, 2024 3:00 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/151 FOI request - Synapse Labs Pvt

Dear MHRA,