FOI 24/251 - [redacted] (Case Ref: GM26494/OC)

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Wed 13/03/2024 11:49
To [redacted]
Our ref: FOI 24/251

Dear [redacted]

Lumateperone/Caplyta by Intra Cellular Therapies

Thank you for your email of 24 May 2022 on behalf of your constituent regarding the licensing and benefits of lumateperone/Caplyta by Intra Cellular Therapies. We apologise for the considerable delay in reply.

We can confirm that no product named “Caplyta” or containing the active ingredient “lumateperone” has been authorised by MHRA.

Unfortunately, we cannot provide information on whether there may or may not be an application in progress for any particular product.

When we need to refuse a written request for information in this way, we need to do this under the provisions of the Freedom of Information Act 2000 (FOIA), so that we include the relevant exemptions and the reasons why we are applying them. This means that for your enquiry about “Caplyta”, we need to refuse to confirm or deny whether we hold this information under Section 41(2) (S41 – information provided in confidence) and Section 43(3) (S43 – prejudice to commercial interests) of the FOIA.

We will explain these exemptions below.

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.

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

Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

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: 24 May 2022 11:47

To: Chief Executive <Chief.Executive@mhra.gov.uk>
Subject: [redacted] [redacted] (Case Ref: GM26494/OC)

Good Morning,

I hope this email finds you well. I am a Caseworker for [redacted] or South West Hertfordshire, and I am contacting you regarding a constituent's case. [redacted] has been contacted by his constituent regarding the licensing and benefits of the drug Lumateperone/Caplyta by Intra Cellular Therapies.

[redacted] has contacted the National Institute for Health Care and Excellence regarding this who have informed him that whilst they are aware of the drug, the Medicines and Healthcare Regulatory Agency is the body responsible for the licensing of medicines in the UK, and they would be best placed to advise on regulatory timelines for this drug.

[redacted] would be most grateful if you would review the matter and provide him with a response that he can then share with his constituent. When responding, we would be grateful if you could use the case reference number GM26494/OC. If you require any further information, please do not hesitate to ask. Thank you very much in advance for your co-operation on this issue.

[redacted] forward to hearing from you.

Kindest Regards,

[redacted]