FOI 23/959 - RE: Enquiry Regarding the Approval Status of Zuranolone (ZURZUVAE™) in the UK

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

Fri 05/01/2024 14:49

To [redacted]

FOI 23/959

Dear [redacted],

Thank you for your request for information dated December 4th 2023, where you asked:

"Could you please provide information on the following:

- The current status of Zuranolone's regulatory review by the MHRA.
- Any anticipated timelines for its approval and availability in the UK.
- Additional relevant information or guidance documents related to Zuranolone that might be available to the public.

Understanding the availability and approval status of new medications is crucial for patients, healthcare professionals, and individuals following advancements in mental health treatment options. Your assistance in providing this information would be greatly appreciated."

Our response:
we neither confirm nor deny that we hold information falling within the description specified in the request. The duty in Section 1(1)(a) of the Freedom of Information Act 2000 does not apply, by virtue of Section 41 (Information provided in confidence) and Section 43 (Commercial interests) of that Act. This should not be taken as an indication that the information you requested is or is not held by the department.

S41 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. S43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in alerting competitors to whether a competitor is close to obtaining a marketing authorisation or not.

However, we would like to make you aware that you could contact the pharmaceutical company directly to ask of their intentions for marketing / regulatory approaches with regard to Zuranolone in GB/UK, but please note, it would be Biogen's decision to share this information.
https://www.biogen.com/company/contact-us.html?accKey=6

If you have a query about the information provided, please reply to this email.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 0203 080 6000

From: [redacted]
Sent: Monday, December 4, 2023 6:40 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: Enquiry Regarding the Approval Status of Zuranolone (ZURZUVAE™) in the UK

[redacted]

Dear MHRA,

I am writing to inquire about the current status of Zuranolone (marketed as ZURZUVAE™ in the US), in the United Kingdom. As an individual interested in the latest developments in mental health treatments for myself, I am keen to understand whether Zuranolone has or will be approved for use in the UK, specifically for the treatment of postpartum depression or any other conditions such as MDD.

Zuranolone has recently garnered attention following its approval by the U.S. Food and Drug Administration (FDA) for the treatment of postpartum depression. Given its novel approach as an oral medication for this condition, I am eager to know if similar regulatory steps have been taken or are anticipated in the UK.

Could you please provide information on the following:

- The current status of Zuranolone's regulatory review by the MHRA.
- Any anticipated timelines for its approval and availability in the UK.
- Additional relevant information or guidance documents related to Zuranolone that might be available to the public.

Understanding the availability and approval status of new medications is crucial for patients, healthcare professionals, and individuals following advancements in mental health treatment options. Your assistance in providing this information would be greatly appreciated.

Thank you for your time and attention to this matter. I look forward to your response.

Sincerely,

[redacted]