

**FOI 23/654**

Dear

Thank you for your email.

*“Do you have any public information regarding progress of reviews of new drugs – I can see that you have something for PIP but I can’t seem to find anything for adults.*

*If there isn’t anything available is there anyway that I would be able to get an update on Zuranolone by Biogen? (which I can see on PIP).”*

Thank you for your enquiry, however, we can’t confirm whether there may or may not be an application for any particular product. This means that for your enquiry about whether any applications have been received by MHRA for the product Zuranolone by Biogen, we need to refuse the request and neither confirm or deny whether we hold any information about this under Section 41 (S41) and Section 43 (S43) of the FOI Act (FOIA).

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.

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**

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

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