

FOI 23/312 - opzelura ruxolitinib

MHRA RESPONSE

14 May 2023

Dear

Thank you for your email.

Regarding your request for information on **opzelura ruxolitinib, specifically “any approximate time or news regarding patients in UK can expect about it”**, MHRA neither confirms nor denies that it holds information falling within the description specified in your request. The duty in Section 1(1)(a) of the Freedom of Information (FOI) 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.

Section 41 is an absolute exemption and no consideration of the public interest is required, except to state that we consider its disclosure to constitute an actionable breach of confidence.

Section 43 is a qualified exemption and a consideration of the public interest should be made. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in alerting competitors to whether a rival product is trying to come onto the market or not. Examples of public interest arguments would be a major public health risk or a major procedural failure or irregularity.

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

Kind Regards,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
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