

**FOI 23/145**

5<sup>th</sup> March 2023

Dear

Thank you for your email.

Regarding whether MHRA has “any plans to licence Apo Varenicline in the UK” 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.

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

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10 South Colonnade, Canary Wharf, London E14 4PU  
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