

FOI 23/327 - applications for mirvetuximab

REQUEST

1 May 2023

Would you be able to advise whether MHRA are looking to approve mirvetuximab for use in platinum resistant ovarian cancer and, if so, when this is likely to be?

This was approved by FDA in November last

year: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-mirvetuximab-soravtansine-gynx-fra-positive-platinum-resistant>

MHRA RESPONSE

18 May 2023

Dear

Thank you for your email.

Regarding whether MHRA is looking to approve or has received any applications for mirvetuximab for the use in platinum resistant ovarian cancer have been received by MHRA, we would refuse to confirm or deny 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 product 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