

FOI 23/669

Dear

Thank you for your request dated September 11th 2023, where you asked:

“We write to make a Freedom Of Information Request regarding Testosterone Undecanoate 1000 mg/4 ml Solution for Injection. We request records of any and all proactive communications received by the MHRA (correspondence, including but not limited to electronically received correspondence, and records of any telephone conversation) in relation to the need to introduce controls for methyl tosylate and ethyl tosylate in the drug substance intermediate or drug substance of Testosterone Undecanoate 1000 mg/4 ml Solution for Injection, and any and all communications by the MHRA sent in response to any said communications. By “proactive communications” we mean any spontaneously received communications, not communications received as a result of a prior request made by the MHRA.”

Our response:

Under Section 17(4) We can neither confirm nor deny whether we hold the information you have requested.

The decision to issue a ‘neither confirm nor deny’ response is not affected by whether we do or do not hold the information but relates to the consequences of confirming or denying the information is held.

We have considered the consequences of confirming or denying that particular type of information is held. The decision to neither confirm nor deny is separate from a decision not to disclose.

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 online via an electronic form: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Or

by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely
MHRA Customer Service Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU