FW: Re: FOI 24/205 - Testosterone Undecanoate 1000 mg/4 ml Solution for Injection (PL 00289/2540)

Afzal, Ajmal <Ajmal.Afzal@mhra.gov.uk>
Wed 27/03/2024 17:03
To [redacted]
<FOILicensing@mhra.gov.uk>;MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

1 attachments (248 KB)
2024.02.28 - FOI Request to MHRA.pdf;
Please see the below which was sent out from the FOILicensing mailbox this afternoon.

Aj

From: FOILicensing
Sent: Wednesday, March 27, 2024 5:00 PM
To: [redacted]
Subject: Re: FOI 24/205 - Testosterone Undecanoate 1000 mg/4 ml Solution for Injection (PL 00289/2540)
Importance: High

Dear [redacted]

Many thanks for your communication dated 28 February 2024, where you requested the following:
"We write to make a Freedom of Information Request regarding Teva UK Limited's marketing authorisation for Testosterone Undecanoate 1000 mg/4 ml Solution for Injection (PL 00289/2540).
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 the above-mentioned Teva UK Limited's marketing authorisation for Testosterone Undecanoate 1000 mg/4 ml Solution for Injection. We also request 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."

We can confirm that a Marketing Authorisation was granted for Testosterone Undecanoate 1000 mg/4 ml Solution for Injection (PL 00289/2540) on 13 February 2024.

Regarding whether we have received any proactive communications in relation to the need to introduce controls for methyl tosylate and ethyl tosylate in the drug substance intermediate or drug substance, we neither confirm nor deny we hold information relevant to your request. Section 41(2) and Section 43(3) of the Freedom of Information Act (FOIA) absolves us from the requirement to say whether or not we hold information:

41.—(2) The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence.

43.
(1)Information is exempt information if it constitutes a trade secret.
(2)Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

(3)The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).

Public interest test

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering the neither confirm nor deny provision of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in neither confirming nor denying that the information is held outweighs the public interest in confirming or denying whether the MHRA holds the information you have requested. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in saying whether information is held or not. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of confirming whether or not we hold the information

To confirm or deny whether or not we have received communication regarding the introduction of particular controls in the drug substance specification could be of interest to patients and healthcare professionals in knowing and understanding whether or not particular quality aspects had been discussed prior to granting the licence. There is a general public benefit where releasing the information demonstrates openness and transparency, and where this could inform the public and contribute to public scrutiny and debate.

Considerations in favour of neither confirming nor denying whether we hold the information

To confirm or deny whether we have received communication from the MAH regarding aspects relating to controls within the drug substance specification may be of interest to rival companies who are developing their own products. Revealing whether or not discussions have taken place concerning details of the drug substance specification could cause prejudice to the commercial interests of the company, causing an unfair competitive advantage so that competitors would have information to use to develop their own testing or acceptance criteria, shortening their time to market. Further, to confirm or deny that we hold this information would create a chilling effect, with companies reluctant or unwilling to approach MHRA (or vice versa) for advice on the development of their products, which would increase the time taken to develop new medicines. This would not be beneficial to patients in general.

In addition to the above, it should be noted that detailed information on the test methods used and the specification and quantitative acceptance criteria established for the active substance is considered commercially confidential, in line with the Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) guidance on transparency – see the below-linked document, where it states that this information is commercially confidential information (CCI): Microsoft Word - HMA_EMA_Guidance_Document_20120309_adopted_clean.doc

We trust that you will understand this position and the response. However, if you disagree with how we have interpreted the FOIA in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 in writing to:
Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF

Yours sincerely

FOI Team

Please find attached.

Thank you and best regards

[redacted]

[redacted]
Partner
[redacted]

[redacted]

[redacted]

bristows.com

[redacted]

received. Incoming and outgoing email messages are routinely monitored for compliance with the Department of Health's policy on the use of electronic communications. For more information on the Department of Health's email policy, click **DHTermsAndConditions**