FOI 23/900 Current Status of Tianeptine Sodium in UK Psychiatric Medicines

Dear

Thank you for your Freedom of Information (FOI) request dated 21 November 2023, where you asked the following:

> *"I am writing to request information under the Freedom of Information Act 2000 regarding the current status of tianeptine sodium, an antidepressant drug, among UK psychiatric medicines. I am particularly interested in understanding why tianeptine sodium is not currently marketed or available for prescription in the UK.*
>
> *Tianeptine sodium, a tricyclic antidepressant with a unique pharmacologic profile, has demonstrated efficacy in treating major depressive disorder (MDD) and anxiety disorders. It is currently marketed in several countries around the world, including France, Spain, Italy, and Russia. However, it is not currently available for prescription in the UK.*
>
> *I would appreciate it if you could provide me with the following information:*
>
> *1. The current regulatory status of tianeptine sodium in the UK, including any decisions made by the Medicines and Healthcare products Regulatory Agency (MHRA) regarding its approval or marketing authorization.*
>
> *2. If tianeptine sodium has been evaluated by the MHRA, the specific reasons for its rejection or non-approval, including any concerns regarding its safety or efficacy.*
>
> *3. Any ongoing or planned reviews or evaluations of tianeptine sodium by the MHRA or other relevant UK authorities.*
>
> *4. If there are any specific factors or regulatory challenges that have prevented tianeptine sodium from being marketed or available for prescription in the UK.*
>
> *5. Any available information on the potential benefits and risks associated with the use of tianeptine sodium, considering its clinical effectiveness and safety profile in other countries.*
>
> *6. Any plans or initiatives by the UK government or healthcare authorities to reassess the regulatory status of tianeptine sodium and potentially make it available for prescription in the UK.*
>
> *I would prefer the information to be provided in the following formats:*

- *Excel spreadsheets*
- *Research papers*
- *Charts and graphs*

I would also be interested in receiving any relevant documents or reports related to the evaluation or consideration of tianeptine sodium in the UK regulatory context."

Our response

After a reasonable search of our records, we can confirm that there are no active Marketing Authorisation/s for Tianeptine Sodium in GB/UK.

In relation to the questions 2-5 and the additional question our response is that of information not held. However, to elaborate on your additional question marked in italics, we have located a previous scientific advice meeting for Tianeptine Sodium—but this meeting was in relation to an indication separate from MDD and anxiety. We considered this information out-of-scope of your request.

Further, if you were to request information about a scientific advice meeting, we would like to provide the advice and assistance under s16 FOIA, that it is unlikely that to be released publicly, because advice meetings are often taken in confidence.

Our response to Q.6. MHRA does not hold this information. Please be advised that MHRA does not solicit applications for new medicines.

We trust that you will find this response of some assistance, even if it is simply confirming the negative. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 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,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU