Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00499**

20 May 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 7 May 2026. You wrote:

> *Dear MHRA FOI Team,*
> *Thank you for your response of 6 May 2026, stating that the MHRA does not hold information regarding the scientific evidence review or rationale that justifies Levothyroxine monotherapy as the UK's 'first choice' or the standard treatment.*
> *I find this admission concerning from a statutory perspective. Under the Human Medicines Regulations, the MHRA is the designated body responsible for the safety, quality, and efficacy of medicines in the UK.*
> *If the MHRA does not hold the scientific rationale for the efficacy of the UK's third most-prescribed drug, I request a formal clarification on the following:*
> *1. Statutory: How does the MHRA fulfil its duty to ensure the ongoing efficacy of Levothyroxine monotherapy if it holds no internal scientific review of the biological mechanisms (specifically deiodination/conversion) that justify its licence?*
> *2. Regulatory: In a concurrent response (Ref: CEO 20584), the MHRA CEO's office states that the product's efficacy is predicated on conversion to the active ligand. If the FOI team holds no records of this rationale, does this indicate that the MHRA is relying entirely on third-party guidelines (e.g., NICE, BTA, and SfE)—none of which account for the mechanisms of deiodinases or conversion—rather than conducting its own independent regulatory due diligence?*
> *3. Information Not Held: If the MHRA enforces manufacturing standards for this drug but does not hold the scientific rationale for its biological 'Action and Use,' at what point did the MHRA decouple manufacturing oversight from biological efficacy?*
> *I wish to register this as a formal challenge to the adequacy of the search. It is implausible that a statutory regulator holds no record of the scientific basis for the primary treatment of a condition affecting millions.*

MHRA Response

It may be helpful if we explain the role of the FOI Act. It provides a legal right of access to recorded information held by a public authority like the MHRA, subject to certain exemptions that may apply. The Act does not oblige a public authority to create new information to answer questions; nor does it require a public authority to give an opinion or explanation, generate answers to questions, or create or obtain information it does not hold.

If you ask a question, rather than requesting recorded information, we will provide you with the recorded information that best answers the question. Once we have provided the recorded information, we have met our obligations under the Act; interpreting the information provided is up to you.

Your request asks questions and makes statements that seeks to engage us in debate which you want us to respond to. This would need new information to be created.

We do not hold any recorded information to answer your request and will therefore not be progressing your request any further.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU
Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

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