Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00412**

6 May 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 16 April 2026. You wrote:

> *1. Failure to Address Current Statutory Duties. While the MHRA may not hold the historical 1963 files, the Agency assumed statutory responsibility for the safety, efficacy, and quality of medicines in 2003. Regulation is a continuous act, not a historical event. I therefore request a review of why the following current information was not disclosed:*
> • *The Scientific Evidence Review or Rationale held by the MHRA post-2003 that justifies the continued regulatory "gold standard" status of T4-monotherapy, despite published evidence regarding deiodinase (DIO2) polymorphism and T3-conversion failure.*
> • *The Marketing Authorisations (Product Licences) currently held by the MHRA for Levothyroxine products, specifically the sections outlining the clinical trials or grandfathered data used to validate T4-monotherapy as an exclusive first-line treatment.*

MHRA Response
A thorough search of our records has established that the information you requested is not held by the MHRA

I will address each of your points individually.

- *The Scientific Evidence Review or Rationale held by the MHRA post-2003 that justifies the continued regulatory "gold standard" status of T4-monotherapy, despite published evidence regarding deiodinase (DIO2) polymorphism and T3-conversion failure.*

The MHRA has not been involved with any assessments, Scientific Evidence Review or Rationale that justifies the use of Levothyroxine as the 'gold standard' for T4 monotherapy. It is not within MHRA's remit to conduct independent scientific evidence reviews of established clinical practice within the UK. NHS clinical practice guidelines are informed by clinical expert opinion and guide practitioners in their prescribing decisions. The MHRA holds no background information on NHS guidelines, therefore we recommend you contact NHS England or the Department of Health and Social Care (DHSC) for the information you seek.

- *The Marketing Authorisations (Product Licences) currently held by the MHRA for Levothyroxine products, specifically the sections outlining the clinical trials or grandfathered data used to validate T4-monotherapy as an exclusive first-line treatment.*

Levothyroxine is indicated for the treatment of hypothyroidism (congenital or acquired), diffuse non-toxic goitre, goitre associated with Hashimoto's thyroiditis, suppression therapy in thyroid carcinoma, juvenile myxoedema. Levothyroxine is not recommended exclusively as first line treatment. In some clinical situations, liothyronine may be the first line treatment of choice in severe and acute hypothyroid states because of its rapid and more potent effect.

For your reference, the Summary of Product Characteristics (SmPC) for Liothyronine published on the MHRA website can be found using the link below:
Microsoft Word - 29524620797893092_spc-doc.doc

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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