Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

Our Ref: **FOI2026/00164**

15 April 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 15 February. You wrote:

Under the UK Freedom of Information Act 2000, I am writing to request information held by the MHRA regarding the drug retatrutide. Specifically, I would like to request:

1. *Any records of clinical trial approvals for retatrutide in the UK, including trial identifiers and statuses/timeframe of when clinical trials will finish*
2. *Any regulatory correspondence, safety assessments, or inspection reports related to retatrutide submitted to or reviewed by the MHRA.*
3. *Any releasable documents on projected timelines for clinical trial completion, regulatory review, or potential marketing authorisation.*
4. *Any MHRA-held data summarising adverse events, safety signals, or efficacy results submitted as part of UK clinical trials or post-market monitoring if applicable.*
5. *Any email communications held by the MHRA regarding the drug retatrutide between the agency and Eli Lilly or any other parties, including those relating to clinical trial applications, safety assessments, or regulatory approvals. I request that these emails, or non-exempt portions thereof, be released*

MHRA Response

We can confirm that the MHRA holds some of the information you have requested. We have repeated each of your questions and provided our replies beneath.

1. *"Any records of clinical trial approvals for retatrutide in the UK, including trial identifiers and statuses/timeframe of when clinical trials will finish"*

   Our reply: We can confirm that the Agency holds this information. However, the information is exempt under Section 21(1) of the Freedom of Information Act, because the information is reasonably accessible to you, as it is already in the public domain. The requested information about clinical trials for Retatrutide can be found on the Health Research Authority Research summaries website, or the Clinical Trials.gov website at the below links:

   Research summaries - Health Research Authority

Home | ClinicalTrials.gov

To be helpful we have provided the list of NCT numbers which can be searched on the above-mentioned websites. The NCT numbers can be entered into the main search bar on the HRA website or in the 'other terms' field on the .gov search page.

NCT05929066
NCT05931367
NCT05936151
NCT06297603
NCT06383390
NCT06859268
NCT07165028
NCT07232719

2. *"Any regulatory correspondence, safety assessments, or inspection reports related to retatrutide submitted to or reviewed by the MHRA".*

Our reply: We have interpreted correspondence within your request as any communications excluding any submissions as part of the process of an organisation registering a clinical trial within the United Kingdom, as these fall under the definition of reports and registration rather than communications. Considering this definition, we can confirm we do not hold and correspondence with Eli Lilly on Retatrutide.

Safety assessments are carried out by the sponsor while conducting the trial and may be documented and submitted to the MHRA in the form of a Development Safety Update Report (DSUR) - see response to Question 4.

MHRA does not hold any inspection reports related to Retatrutide.

Advice and assistance
Considered separate to your request, but related to inspection activity, we do hold two serious breach notifications relating to a delay in implementation of amendments at two trial sites leading to delayed provision of updated safety information to 12 participants across two sites but no safety events were reported at either site in connection with the delay. Both serious breaches have been closed.

There have been no Urgent Safety Measures notified to MHRA for any trials using Retatrutide.

3. *"Any releasable documents on projected timelines for clinical trial completion, regulatory review, or potential marketing authorisation".*

Our reply: Please refer to our reply to question 1 above.

4. *"Any MHRA-held data summarising adverse events, safety signals, or efficacy results submitted as part of UK clinical trials or post-market monitoring if applicable. (Clarification received that this is for UK metrics only)".*

Our reply: We do not hold this information. In terms of the post-marketing monitoring aspect of your question, Retatrutide has not been placed on the market.

Advice and assistance
The Development Safety Update Report (DSUR) is considered the standard report for informing regulators of the evolving safety profile of drugs under development.

DSURs should take into account all new available safety information received during the reporting period. The DSUR should include**:**

- an analysis of the patients' safety in the concerned clinical trial(s) with an appraisal of its ongoing risk/benefit
- a line listing of all suspected serious adverse reactions (including all SUSARs) that occurred in the trial(s), including all SUSARs from third countries
- an aggregate summary tabulation of SUSARs that occurred in the concerned trial(s)
- region-specific information in accordance with guidelines on how to increase transparency

If it is a DSUR you are seeking, please make a new request for a DSUR for a specific trial (NCT) number. However, please note that because the trial is likely to be on-going, information within the DSUR may be subject to an applicable exemption under the Act. However, any new request will be handled individually based on the specific circumstances and context.

5. *"Any email communications held by the MHRA regarding the drug retatrutide between the agency and Eli Lilly or any other parties, including those relating to clinical trial applications, safety assessments, or regulatory approvals. I request that these emails, or non-exempt portions thereof, be released".*

Our reply:
Please refer to the response to Question 2.

If you have any queries about this letter or if we have interpreted your request incorrectly, 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 Contact Information or telephone 0303 123 1113.

Re-use of our information

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