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: **FOI2026/00196**

27 April 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 24 February. You wrote:

> *I am writing to request information under the Freedom of Information Act 2000.*
> *Please provide a copy of the MHRA letter dated 7 November 2025 that is referenced in correspondence with the sponsor of the PATHWAYS clinical trial (relating to puberty blockers / GnRH analogues in children and young people).*
> *If the full letter cannot be disclosed, I request that you provide:*
> *1. The full text with any personal data appropriately redacted; or*
> *2. If any exemptions are applied, a copy of the letter with exempted material redacted, together with a clear explanation of which exemptions have been relied upon and why; and*
> *3. Any covering note or summary document produced by MHRA that describes the content, purpose, or regulatory concerns raised in the letter.*
> *I am seeking this information in the public interest, as the PATHWAYS trial is a matter of significant public, clinical, and ethical interest.*
> *Please provide the information electronically by email.*
> *If my request is too broad or would exceed the cost limit, I would be grateful if you could advise how it might be refined so that some or all of the information can be disclosed.*

MHRA Response

We can confirm that we hold some of the information you have requested, however some is exempt from disclosure. We will address each request individually below.

1. The full text with any personal data appropriately redacted; or

We have provided a copy of the 7 November 2026 letter as part of this response, however we are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure

would breach one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018

2. ***If any exemptions are applied, a copy of the letter with exempted material redacted, together with a clear explanation of which exemptions have been relied upon and why; and***

Please refer to our response for question 1.

3. Any covering note or summary document produced by MHRA that describes the content, purpose, or regulatory concerns raised in the letter.

We can confirm we do not hold this information. There are no concerns raised within the provided information as it is a letter of notice of acceptance of amended request.

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.

Re-use of our information