



## Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of  
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Our Ref: **FOI2025/00218**

28 March 2025

Dear [REDACTED],

Thank you for your Freedom of Information (FoI) request received on 2 March. You wrote:

*We are a group of doctors from the Royal London Hospital carrying out a systematic review on adverse mental health side effects from hormones and hormone blockers used for management of endometriosis pain.*

*We are contacting you at the Medicines and Healthcare Products Regulatory Agency because many of our endometriosis patients in clinic report depression and anxiety from these medications, but this is not borne out by the body of research. We are exploring why this may be. Please can you help us by answering these questions:*

*- does your reporting scheme invite the report of side effects of medications that are used for indications outside their license (such as combined pill for endometriosis)*

*- do you have a body of reports of adverse mental health side effects from hormones and hormone blockers that you can share with us?*

### **MHRA Response**

Regarding your first query, I can confirm that Yellow card reports can be received for off-label indications, and these are entered onto our database.

Members of the public and healthcare professionals voluntarily submit reports of suspected side effects to the MHRA through the Yellow Card Scheme. The MHRA assesses the balance of risks and benefits of all medicines and vaccines at the time of initial licensing and throughout their use in clinical practice. While a significant proportion of the population will gain benefit from taking a medicine or vaccine and experience no serious adverse effects, there will always be a proportion of individuals who will suffer a side effect as a direct result of taking a medicine or vaccine. The MHRA endeavours to minimize risk where possible through measures such as restricting use in particular patient populations and under specific clinical circumstances as well as providing information on the possible side effects so that healthcare professionals and patients can make informed choices and manage possible side effects when they do occur. The MHRA continuously monitors the safety of medicinal products through a variety of pharmacovigilance approaches including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by

the Yellow Card scheme are assessed and cumulative information reviewed at regular intervals.

Regarding your second query, we are unable to deal with your FoI request without clarification of the information you seek. The reason for this is to enable us to identify and locate the specific information requested.

Under Section 16 of the FoI Act we should assist you in helping you focus your request. To help us do so, we would like to know:

- The term “hormones and hormone blockers” is broad term, therefore please would you be able to provide particular ATC codes or classification from BNF treatment summaries, to identify the drugs of interest.

We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

We recommend that you familiarise yourself with the Information Commissioners Office guidance on how to submit an FOI to a public authority. We have provided these links below to aid in future requests:

<https://ico.org.uk/for-the-public/official-information/preparing-and-submitting-your-information-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

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## **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](mailto: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**

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>