



Medicines & Healthcare products
Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00913**

15 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 17 August. You wrote:

I am requesting information relating specifically to Oestrogel/Estrogel, PL 28397/0002. In response to my previous FOI request, the MHRA advised that an electronic clinical overview addendum is available for Oestrogel/Estrogel (PL 28397/0002) and suggested submitting a new request limited to this specific PL reference.

Please provide a copy of that electronic clinical overview addendum.

I am particularly interested in any sections relating to the authorised dosage in Section 4.2, including the evidence or rationale supporting the highest authorised dose and any discussion or assessment of higher doses, where contained within the document.

If any information is exempt from disclosure, please provide the remaining non-exempt sections or relevant redacted extracts. Electronic PDF format is preferred.

MHRA Response

The Agency has completed its search for the information you have requested, and we are able to confirm that we do hold the information you have requested.

Please note that some of the information in the attached documents has been redacted. We consider that the information is exempt under sections 40 and 43 of the Fol Act. Furthermore, some of the information falls outside the scope of the Fol request.

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 Fol 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.

Section 43(2) exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties but also the commercial interests of the Agency. It is intended to protect the ability of a public authority like MHRA to obtain goods or services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category. We have considered the balance of the public interest when applying this exemption.

The exemption is to safeguard the commercially sensitive information / industrial secrets of a third party / commercial enterprise (which can include a Government Department). This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity).

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

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