



Medicines & Healthcare products Regulatory Agency

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

Our Ref: **FOI2026/00832**

14 August 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 28 July. You wrote:

Please provide the recorded clinical and regulatory basis for the highest authorised doses of:

Estradot 100 micrograms/24 hours — PL 04416/1723

Evorel 100 — PL 49105/0008

Oestrogel Pump-Pack — PL 28397/0002

For each product, please provide the relevant redacted clinical assessment/expert report, the studies supporting the current Section 4.2 dosage, any recorded rationale for selecting the highest dose, and whether higher doses were submitted or assessed.

If complete documents cannot be disclosed, please provide relevant non-exempt extracts and study identifiers. Electronic PDF format is preferred.

MHRA Response

We can neither confirm nor deny we hold information falling within the description specified in your request under section 12(2) of the Freedom of Information Act, as to do so would exceed the cost limit.

This is because we estimate the cost of checking if we hold the requested information or not would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(2) of the FoI Act the Agency is not therefore obliged to comply with your request and we will not be processing it further. The reason being the information requested for the above product is not currently available electronically due to the current marketing authorisations changing ownership, and the clinical information is stored in our repository under different MA numbers. Having searched our repository records under the three product names, we have found a total of 34 Boxes that reflect the MA for the above products.

Under Section 16 of the FOI Act, we should assist you in focusing your request.

We suggest requesting one specific PL reference. We have an electronic clinical overview addendum available for Oestrogel/Estrogel (PL 28397/0002).

We will consider any further request as a new FOI 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 Contact Information](#) 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/>