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: **FOI2026/00246**

25 March 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 4 March. You wrote:

> *Thank you for your response dated 3 March 2026 and for the guidance regarding the cost limit under Section 12.*
> *To assist the MHRA in providing a response within the appropriate limit, I am refining the scope of my request. Instead of all psychiatric disorders, I request that the MHRA provides the requested information for one of the following two representative SSRI medications.*
> *Please choose the one that is most easily accessible within your records to satisfy the cost limit:*
> • *Option A: Fluoxetine (Prozac) – representing the foundational SSRI approval.*
> • *Option B: Sertraline (Lustral/Zoloft) – representing a widely prescribed modern SSRI.*
> *For the chosen medication, please provide clear YES/NO answers and specific document references for the following:*
> *1. Measurable Biological Cause: Does the MHRA possess any documentation (e.g., from the initial Marketing Authorisation or subsequent reviews) that identifies a specific, measurable biological abnormality or biomarker in patients that the medication is intended to correct?*
> *2. Biological Normalisation: Does the MHRA possess documentation demonstrating that the therapeutic effect of the medication is clinically proven to "normalise" or "balance" a pre-existing and measured neurochemical deficiency (e.g., serotonin levels)?*
> *3. Clinical Thresholds: Does the MHRA possess documents specifying the "normal clinical range" or "threshold values" for serotonin levels used to define the disease state for which the medication is prescribed?*
> *4. Scientific Rationale for Prescription: Does the MHRA possess any document explaining the scientific rationale for why diagnostic biological measurements (e.g., neurotransmitter levels) are not required or performed before the medication is initiated?*
> *If the MHRA maintains that this information is only available within specific Public Assessment Reports (PARs), please provide the direct reference or document title for the specific PAR where the scientific evidence for the biological cause/correction is documented for the chosen drug.*
> *I look forward to your response within the statutory timeframe.*

**MHRA Response**

Under Section 14(1) of the FoI Act, public authorities are not obliged to comply with a request which is deemed vexatious. By way of clarification, it is the request which is treated as vexatious not the person making the request.

A request may be treated as vexatious," if it seeks information of a frivolous nature; if it is likely to cause distress or irritation without justification; or if it is aimed at disrupting the work of an authority or is harassing individuals in it." / "if the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on the organisation."

A vexatious request is assessed with reference to all the circumstances of an individual case. There are four broad themes to consider when looking at whether an FoI request(s) is vexatious. These four themes are:

1. the burden (on the public authority and its staff);
2. the motive (of the requester);
3. the value or serious purpose (of the request); and
4. any harassment or distress (of and to staff).

These four broad themes are not a checklist, and they are not exhaustive they simply emphasise that a range of factors need to be considered when apply Section 14(1).

In this case, the Agency is treating your request as vexatious because of the burden it would place on MHRA and its staff in fulfilling it in its entirety.
The Agency selected Sertraline (Lustral/Zoloft), as representing a widely prescribed SSRI to look for the requested information. The initial UK marketing authorisation approval for Lustral was in 1990 to Pfizer Limited. Subsequently, Lustral underwent several changes of ownership. In order to fulfil your request, staff would have to locate the initial marketing authorisation from the MHRA repository, check all subsequent applications/variations, and specifically review the documents if they are references to diagnostic biological measurements.

We estimate that searching the itemised points of the request would place a disproportionate burden on staff to meet your request. Conducting the required searches would impede staff from other work at MHRA and affect our ability to respond to other queries and publish information on new medicines in a timely manner, which is vital for public and patient safety. Therefore, on this basis, the Agency has decided that Section 14(1) of the FOIA applies on this occasion.

We recommend that you refer to the currently published SmPC here: MHRA Products | Search results. The SmPC reflects the product information. The SmPC sets out the agreed position of the medicinal product, distilled from the information provided during the assessment process, and provides guidance on how to use the medicinal product safely and effectively.

The Public Assessment Report (PAR) for Lustral specifically is not available due to the age of the product; the MHRA publishes the PARs for new marketing authorisations granted after 30 October 2005.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

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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 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**
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/