Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
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MHRA Website

Our Ref: **FOI2026/00525**

11 June 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 14 May. You wrote:

> *can you please send me the Clinical Study Report of the study with the identifier A0501093 including all its appendices, serious adverse events, discontinuations, protocol deviations, narratives of serious adverse events?*
>
> *This study must have been done by Pfizer/Viatris using the active substance Sertraline. Other identifiers for the same study are NCT01302080 or SPRITES.*
>
> *I am a mother whose son died after he has been prescribed Lustral. In the study A0501093, there must have been higher levels of lifetime suicidal behavior in the sertraline-treated patients. Please provide me the details of these events in the clinical study.*

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 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 that would be placed on MHRA and its staff in fulfilling your request in its entirety. In order to fulfil this request, we would need to extract the following documentation for:

- a0501093-report-body **-** 1123 pages
- Appendix1 - a0501093 - sponsor signatures - 3 pages
- Appendix 2 - Protocol A0501093 – 47 pages
- Appendix 3 - Investigators and corresponding Independent Ethics Committees (IECS) or Institutional Review Boards (IRBS) - 17 pages
- Appendix 4 - Statistical Analysis Plan - 49 pages
- Appendix 5 - Sample Case Report Form (Crf) / Data Collection Tool (Dct)- 84 pages
- Appendix 6 - Sample Standard Subject Information Sheet and Informed Consent Document (ICD) - 17 pages
- Appendix 7.1a (Final analysis) - Withdrawn-subjects - 29 pages
- Appendix 7.2 (Final analysis) - Protocol-deviations - 11 pages
- Appendix 7.7) (Final analysis) - Adverse-events - 520 pages

These documents would then need to be checked page by page to see if there is any information that should be redacted under one or more sections of the FOI Act. This would need to be assessed by a subject matter expert; doing so would remove them from their day-to-day duties to respond to other queries, and to prepare and publish Public Assessment Reports of granted Marketing Authorisations. This in turn would have an impact on public and patient safety as well as an impact on the Agency obligation and commitment to transparency through established publication schemes. We would then need to consult with third parties on these documents to see if there are any objections to their release or any additional redactions that need to be made on their behalf.

We estimate that the work itemised above would place a disproportionate burden on staff in order to meet your request. Therefore, on this basis, the Agency has decided that Section 14(1) of the FOI Act applies on this occasion. We recommend that you restrict any future request to, for example, the main body of the clinical study report (CSR), identified as ‘a0501093-report-body’.

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