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: **FOI2026/00493**

13 May 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 30 April. You wrote:

> *Under the Freedom of Information Act 2000, I request confirmation of the following for Sertraline 100mg film-coated tablets, batch V2500425, marketed by Amarox Limited under recall EL(26)A/22:*
>
> *1)The country and address of the licensed manufacturing site for this batch.*
>
> *2)The country and address of the licensed site where secondary packaging was carried out.*
>
> *This is for patient safety purposes following the packaging error reported on 28 April 2026.*

MHRA Response

We can confirm that the Agency holds the information you are seeking.

However, we are engaging an exemption from disclosure under Section 41(1) of the FoI Act, which protects information provided in confidence. Additionally, the information you have requested is commercially sensitive and is therefore exempt from release under Section 43(2) of the FoI Act.

Section 41(1)

The information you have requested relates to both 'the country and address of the licensed manufacturing site for this batch,' and 'the country and address of the licensed site where secondary packaging was carried out,' which was obtained by the Agency from the Marketing Authorisation Holder (MAH) directly during the licensing procedure and the Agency believes that if this information would be released it would breach the confidence of the person(s) the information pertains to, actionable by them or any other person. Therefore, we are not going to be releasing the requested information.

Section 43(2)

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.

In this instance we feel that the release of this information could inadvertently expose sensitive business data to competitors and damage reputations for the company and the MHRA.

As required by the FoI Act the use of this exemption requires the public interest for and against disclosure to be assessed.

We recognise that there is a public interest in the disclosure of commercial information relating to manufacturing information for the Marketing Authorisation Holder (MAH) based on ensuring transparency and accountability.

However, when considering arguments against disclosure transparency and accountability, the MHRA considers that the release of the information could result in harm to relationships with private contractors, disclosure could cause commercial, reputational, or operational damage to a contractor and protection of this commercial sensitive information is important to avoid competitive disadvantages, if disclosed could harm the authority or third party their ability to compete or conduct business.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

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