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: **FOI2026/00390**

24 April 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 13 April 2026. You wrote:

> *This is an indirect FOI request, done on behalf of the Swedish Medical Products Agency, MPA. I am in no way impersonating an official at the Agency, and this private initiative should only be construed as an effort to help the MPA to finally get the missing information in this important matter.*
> *In the year 2011 Sweden, as Co-rapporteur regarding the approval av Prozac/Fontex for children, should have received the Non-Clinical Assessment Report of Prozac from the MHRA, so that the MPA could give its comments to it before finalization.*
> *The MPA never got this AR, from September 2011, and did not then get the opportunity to comment on it.*
> *The MPA has informed me that now, 15 years later, they got the attached redacted version of the report.*
>
> *And we come to this: I now request that the MHRA releases the unredacted AR to the MPA (the report that should have arrived 15 years ago). Even if the MPA doesn't have a chance to now give its comments and fulfil its obligations as Co-rapporteur, the Agency finally will gain access to the original unredacted report.*
> *I would appreciate a confirmation that the report has been sent to the MPA.*

MHRA Response

We are unable to provide you with the information requested, as a disclosure under FOI is a disclosure into the public domain. Therefore, any release of the assessment report requested under FOI would require redactions of some information, in line with the relevant sections of the FOI Act.

Advice and assistance
We advise that the Swedish Medical Products Agency (MPA) contact the MHRA directly for the assessment report, so that it can be considered further as an information request from another regulator. Here is a link to various contact points: Contact the MHRA - GOV.UK
Alternatively, the international recognition team can assist you with the request Recognition@mhra.gov.uk

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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