



[foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk).

[MHRA Website](#)

Our Ref: **FOI2026/00387**

11 May 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 12 April. You wrote:

*Please treat this as a formal request under the Freedom of Information Act 2000.*

*Please provide copies of SmPC documents for fluoxetine held by the MHRA between 1 January 2011 and 31 December 2019. Please include all versions, including historical versions.*

*This request does not seek any information that could expose patient identity. Where information is exempt, I request that related, non-exempt material be disclosed.*

## **MHRA Response**

We confirm that we hold the information you have requested.

The medicinal products Prozac (fluoxetine hydrochloride) 20 mg, 30 mg, 40 mg and 60 mg hard capsules (PL 00006/0195-0198) were first authorised in the United Kingdom (UK) to the Marketing Authorisation Holder (MAH) Eli Lilly and Company Limited on 25 November 1988 and were full dossier applications.

The medicinal product Prozac 20 mg per 5 ml oral solution (initially known as Prozac 20 mg per 5 ml oral liquid; PL 00006/0272) was first authorised on 28 October 1992 in the UK to the MAH Eli Lilly and Company Limited, cross-referring to Prozac 20 mg capsules (PL 00006/0195). The answers to your requests for information on the active substance fluoxetine are based on data available for Prozac 20 mg capsules (PL 00006/0195) and Prozac 20 mg per 5 ml oral solution (PL 00006/0272).

Please find attached the approved Summaries of Product Characteristics (SmPCs) we hold for the Prozac (fluoxetine hydrochloride) products over the period 1 January 2011 to 31 December 2019.

In addition, please find attached Annex A, which provides details of the reason the documentation provided for the Prozac products were approved.

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

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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](mailto: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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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>