Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: **FOI2026/00774**

12 August 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 16 July. You wrote:

> *Under the Freedom of Information Act I would like the following:*
>
> *1. All information - paper, reports, research, minutes of meetings and electronic documents including emails an letters, regarding the symptoms of Protracted Antidepressant Withdrawal Syndrome (PSSD, PAWS etc).*
>
> *2. All information - paper, reports, research, minutes of meetings and electronic documents including emails an letters, related to changes in brain function following the long term use of antidepressants.*
>
> *3. All information - paper, reports, research, minutes of meetings and electronic documents including emails an letters, related to Emotional Blunting following the long term use of antidepressants.*

MHRA Response

We are unable to deal with your FoI request without clarification of the information you seek. Specific responses regarding the 3 points are outlined but some additional background information highlighting what is already in the public domain may help you to refine your request.

Although papers presented to MHRA's independent advisory committees are not published, summary minutes are published here: https://www.gov.uk/government/organisations/commission-on-human-medicines/about/membership#summary-minutes.

Regulatory action that requires a change in clinical practice are communicated to healthcare professionals via out safety bulletin Drug Safety Update which is available here: https://www.gov.uk/drug-safety-update. Drug Safety Update is published each month and also includes detail of Direct Healthcare Professional Communications that have been issued.

In relation to reports suspected side effects, MHRA and other regulators use a medical dictionary for regulatory activities (MedDRA). This is used within the Yellow Card scheme

and signal detection and assessment processes. Unfortunately, although SNOMED codes for Protracted Antidepressant Withdrawal Syndrome and Persistent sexual dysfunction following withdrawal of an SSRI, these terms are not included in MedDRA and neither is emotional blunting. Post SSRI sexual dysfunction is a lower level term of sexual dysfunction in MedDRA.

The MHRA publishes details of reported side effects for medicines and vaccines in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed here: https://yellowcard.mhra.gov.uk/idaps. You can view profiles for the relevant drug of interest and find data relating to the number of reports received by year, suspected adverse reactions reported, and breakdowns by age, sex and other variables.

To view adverse reactions of interest, please refer to the Total Reaction Profile tab , specifically under General disorders, Nervous system disorders and Reproductive system and breast disorders where you can drill down to find more granular reactions via the table. Please note you can right click on each of the categories and select expand all if helpful.

Terms available to view which may be of interest include, but are not limited to, antidepressant discontinuation syndrome, withdrawal syndrome and drug withdrawal syndrome. Post SSRI sexual dysfunction is categorised under sexual dysfunction and found in the Reproductive system and breast disorders class.

It is important to note that the information presented in the iDAPs does not represent an overview of the potential side effects associated with the product, and the information should be view with the essential context provided on the webpage in mind. A list of the recognised suspected adverse reactions is provided in the information for healthcare professionals and the patient information leaflets which can be found here: Find product information about medicines - GOV.UK.

The MHRA is a paperless office and all documents have been electronically stored for many years. The MHRA has some paper archives that are stored off site and if those documents are needed we may need to request an extension in order to retrieve and review those documents.

Under Section 16 of the FoI Act we should assist you in helping you focus your request. To help us do so, we would like to know:

- For question 1 whether you consider the iDAP findings for the specific antidepressants under the MedDRA terms antidepressant discontinuation syndrome, withdrawal syndrome and drug withdrawal syndrome to adequately address the data request on “protracted antidepressant withdrawal syndrome.”

There is already some information on the regulatory assessment of the term “post SSRI Sexual Dysfunction” in the public domain and I include a link to the minutes of the EU meeting in 2019 where this issue was discussed and regulatory action taken at an EU level PRAC recommendations on signals adopted at the 13-16 May 2019 PRAC_en

As you may be aware the MHRA convened an expert working group (EWG) to review the effectiveness of the communication of the risk of “PSSD” in the currently approved patient information leaflets. Please see Patient and family experiences inform antidepressant safety information review - GOV.UK. The MHRA will be issuing updated warnings on the risk of sexual dysfunction which may continue after stopping treatment in the Autumn on the regulatory position is finalised following recommendations of the EWG and advice of the Commission on Human Medicines.

- For question 2 it would be helpful to understand what exact changes in brain function you are interested in – physical/ structural, biochemical/ neurotransmitter and your definition of “long term.”

As you may be aware studies are submitted at the time of licensing medicines and the data included is standardised to include non- clinical (animal) data and human data. Other studies may be published at any time in the products life cycle and are generally in the public domain. It would be helpful if you could please define the exact nature of brain changes you are interested in. Please also clarify the definition of “long term” e.g. more than 3 months of treatment. Please also clarify whether you are looking for human or non-clinical data.

The available data on long term effects can be found on individual antidepressant Summary of Product Characteristics and Patient Information Leaflets available at MHRA Products | Home

- For question 3 please be aware that although the term “Emotional Blunting” is not a term in the regulatory dictionary. Some antidepressants such as paroxetine are associated with “emotional instability” as part of a withdrawal syndrome. We request you define “long term” and what you mean by the term “emotional blunting” to assist with our search.

We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

We recommend that you familiarise yourself with the Information Commissioners Office guidance on how to submit an FOI to a public authority. We have provided these links below to aid in future requests:

https://ico.org.uk/for-the-public/official-information/preparing-and-submitting-your-information-request/

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

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/