Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: **FOI2024/00653**

November 2024

Dear [redacted],

Thank you for your Freedom of Information (FoI) request received on 26 October. You wrote:

> *Can you please tell me how many Yellow Card reports you have filed with the MedDRA code 10086208 (post-SSRI sexual dysfunction) broken down by medication?*

MHRA Response

We confirm that we hold the information you have requested and provide it in the format you requested below.

As you will know from FOI 2024/00428, the MHRA codes suspected Adverse Drug Reactions (ADRs) within Yellow Card reports using the MedDRA. There are five levels to the MedDRA hierarchy, arranged from very specific to very general. At the most specific level, called "Lowest Level Terms" (LLTs), there are more than 80,000 terms which parallel how information is communicated. The MedDRA code 1008620 relates to the MedDRA LLT, post-SSRI sexual dysfunction.

When submitting ADR reports via the Yellow Card website, reporters are asked to select the symptoms they have experienced from a drop-down list which includes all the LLTs available in MedDRA. If a reporter reports a symptom that doesn't directly correspond to a MedDRA term, our team of trained assessors work code the reported symptoms to a MedDRA term based on the information available to them. The term post-SSRI sexual dysfunction was added to the Medical Dictionary for regulatory purposes in 2021.

Following a search of our ADR database, we can confirm that the MHRA has received 33 UK spontaneous suspected ADR reports which have reported the MedDRA LLT, post-SSRI sexual dysfunction up until 10th November 2024. Please find below table 1 which specifies the suspected medications reported within these reports.

Table 1: UK Spontaneous suspected ADR reports for which have reported the MedDRA LLT post-SSRI sexual dysfunction broken down by drug substance until 10/11/2024 inclusive.

Substance Name	Number of Reports
SERTRALINE	11
CITALOPRAM	7

FLUOXETINE	5
ESCITALOPRAM	4
VORTIOXETINE	3
DULOXETINE	2
AMITRIPTYLINE	1
LITHIUM	1
MIRTAZAPINE	1
NORTRIPTYLINE	1
OLANZAPINE	1
VENLAFAXINE	1

Please note that a single Yellow Card report may contain multiple suspect drugs. As such the total number of reports for these drugs cannot be calculated from the information available for each individual drug.

You can view suspected adverse reactions reported to the MHRA via the Yellow Card scheme on our website as interactive Drug Analysis Profiles (iDAPs). Within these iDAPs reports of post-SSRI sexual dysfunction are captured under the term Sexual dysfunction.

When considering the spontaneous adverse reaction data detailed above, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine or vaccine, only that the reporter had a suspicion it may have. The fact that symptoms or events occur after use of a medicine or vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the medicine or vaccines. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is important to note that the number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the drug is known. Many factors influence the number of reports that we receive in the UK and we are aware that there is considerable ‘under-reporting’ of reactions to the Scheme. Reporting rates are influenced by the seriousness of the adverse drug reactions, their ease of recognition, the extent of use of a particular product, and may also be stimulated by promotion and publicity about a product. Reporting rates tend to be highest when a product is first put on the market.

Since 2019, the product information available to healthcare professionals and patients has contained information that SSRIs may cause symptoms of sexual dysfunction and that there have been reports of long-lasting sexual dysfunction where the symptoms have continued despite discontinuation of SSRIs. This information is available to healthcare professionals in the Summary of Product Characteristics (SmPC) and to patients in the patient information leaflets (PIL). Both documents can be accessed electronically at https://products.mhra.gov.uk/.

The MHRA continuously monitors the safety of all medicines, including SSRI’s through a variety of pharmacovigilance processes including the Yellow Card scheme. We conduct careful analysis using all available sources of evidence in pharmacovigilance, including regular review of suspected adverse reactions submitted through the Yellow Card scheme via our signal detection procedures, data from clinical and epidemiological studies, the medical literature and information from pharmaceutical companies and other worldwide regulatory authorities. Please be assured that the MHRA will take appropriate regulatory action should this be required.

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.

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