Medicines & Healthcare products Regulatory Agency



MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom

www.gov.uk/mhra

31<sup>st</sup> January 2024

Dear

FOI 24/016

Thank you of your email dated 3<sup>rd</sup> January 2024, where you requested:

"I write to you to ask for information regarding the sexual side effects of SSRIs that persist after or emerge upon discontinuation, also known as post-SSRI sexual dysfunction (PSSD).

Can I be provided with all internal emails regarding this matter."

Your request asks for "all internal emails" regarding the "matter" which you have identified as "information regarding the sexual side effects of SSRIs that persist after or emerge upon discontinuation, also known as post-SSRI sexual dysfunction (PSSD)"

We should first explain that a request for 'all internal emails' on a given subject is going to generate large numbers of results based on the keyword searches used; while a search would locate all emails containing the particular combination of keywords we have searched for, we would need to conduct a number of differently combined keyword searches to ensure that all information of possible relevance to your request, we would then need to manually review each of the emails to identify those that do contain information relevant for your request. As it can take an average two minutes to check each email (and longer when the results contain one or more attachment, which would also need to be checked for relevance) we estimate that the time needed for review of these results would exceed the 24 hour appropriate limit set out in Section 12(1) of the FOI Act.

Section 12 of the FOI Act specifies that a public authority may refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information. In accordance with Section 16 of the FOI Act, concerning the provision of advice and assistance to those requesting information under FOI, you are advised to narrow the scope of your request. For example define the time period and the specific products you are interested.





- SSRIs is the term given to a large class of medicines but does not include all antidepressants. SSRIs include citalopram, dapoxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline and vortioxetine. Are there specific medicines that you are interested in?
- Please be aware that internal emails are retained for a period of 3 years and therefore your search request should fall within the last 3 years.
- We hold information about possible adverse reactions received through the Yellow Card scheme. Summary details about the suspected adverse reactions received are published on our <u>website</u> and referred to as interactive Drug Analysis Profiles (iDAP). These are available for each active substance. You can expand fields and use key word searches within the iDAP to explore the reported side effects.
- Please note that the medical dictionary used internationally by regulatory authorities does not include post-SSRI sexual dysfunction (PSSD) as a specific term and may not specifically be used within MHRA internal communications. The general term sexual dysfunction is more likely to be used but after reviewing the iDAPs you may wish to narrow your search to specific terms related to sexual dysfunction.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

## FOI Team,

Vigilance and Risk Management of Medicines Division

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If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF

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