Medicines & Healthcare products Regulatory Agency

[redacted]

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19 April 2023

FOI 23/059

Dear [redacted]

Thank you for your information request, dated 24 January 2023. I apologise for the delay in responding.

1. Since 2019, what information has been provided to prescribers of SSRIs about the enduring sexual side effects? Was an alert put out?

MHRA reply:

Since 2019, the product information available to healthcare professionals and patients has contained information that Selective Serotonin Reuptake Inhibitors (SSRIs)/serotonin norepinephrine reuptake inhibitors (SNRIs) 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/SNRI. 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/

A specific alert notifying healthcare professionals about the updated warning was not issued.

2. What is the process for establishing the prevalence of PSSD?

All other side effects of SSRIs have an associated risk, i.e. whether it is 'more than 1 in 10' or 'up to 1 in 100', yet with PSSD we have no idea despite over 3 decades of use and millions of prescriptions issued.

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I note that UK psychiatrists have all but given up on reporting adverse events via the Yellow Card scheme, making fewer than 5 reports in 2021 (FOI 22 1096.pdf). whereas they were making hundreds of reports in the 1990s (FOI 19.473 Table 1.pdf). Given that psychiatrists no longer consider pharmacovigilance part of their job, what other strategies do you have?

MHRA reply:

The term post-SSRI sexual dysfunction (PSSD) is not recognised by the regulatory dictionary – MedDRA. However, the symptoms experienced by patients can be reported as suspected side effects.

The frequency of suspected side effects cannot be estimated using spontaneous data such as the number of reports received through the Yellow Card Scheme. The frequency statements included in the product information are based on study data where the total number of patients receiving the treatment as well as the number experiencing the side effect have been studied. A robust study would be needed in order to establish the prevalence of PSSD, this would require PSSD to be clearly defined and recognised as a specific medical condition.

There is a regular review of new adverse reactions and any change in frequency or severity of established adverse reactions conducted through weekly assessments of Yellow Card reports received by the MHRA as well as through the cumulative reports prepared by the Marketing Authorisation Holders for each individual medicine which are referred to as periodic safety update reports.

The change in the number of reports received now compared to the 1990's when these medicines were first marketed may be associated with reporting requirements. New medicines are intensively monitored to ensure any new safety concern is identified promptly. The MHRA encourages the reporting of all suspected reactions to newer medicines and vaccines, which are denoted by an inverted Black Triangle symbol (▼). Further information about the black triangle scheme is available on the MHRA website. When each SSRI was introduced to the UK market it would have been assigned the black triangle symbol to encourage reporting of all suspected adverse reactions. However, as the medicines became established, the black triangle symbol was removed and although any adverse reaction could continue to be reported, healthcare professionals are encouraged to report all serious suspected adverse reactions, even if the effect is well recognised. The guidance highlights areas of special interest which should be reported. The MHRA regularly conduct activities to encourage reporting of suspected adverse reactions to the Yellow Card scheme.

For rare adverse reactions and for adverse reactions where data are evolving or challenging to collect, such as when they start or persist beyond the half life of the medicine (time the medicine is active in the body), prevalence rates may be difficult to estimate.

Reporting to the Yellow Card scheme is voluntary by prescribers and patients. For healthcare professionals, the General Medical Council Good Medical Practice

guideline section 14i reminds all registered doctors that they must report suspected adverse drug reactions in accordance with the relevant reporting scheme.

3. What plans are there to reduce the harms of PSSD in the future? Are their plans beyond the hint on the PIL? Will it ever be called 'PSSD'?

MHRA reply:

The MHRA is not responsible for the naming or the classification of medical conditions. The MHRA will continue to monitor all suspected adverse reactions, including sexual side effects associated with the prescribing of antidepressant medicines in accordance with pharmacovigilance legislation.

4. How does the MHRA intend to speed up the process of recognising harms cause by drugs? Is it acceptable that it took over 28 years to recognise a life-changing side effect of such a popular class of medicines?

MHRA reply:

The MHRA is committed to identification of side effects associated with medicines and robust data assessments to determine if emerging signals of adverse reactions are related to a medicine or a wide range of other medical confounding factors. The MHRA holds weekly multidisciplinary signal detection meetings and has a number of expert advisory groups to provide input on the evidence available during the life cycle of the medicine and the need for timely regulatory action.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at

Information Commissioner’s Office
Wycliffe House

Medicines & Healthcare products
Regulatory Agency

Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

Safety and Surveillance