



Medicines & Healthcare products
Regulatory Agency

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Our Ref: **FOI2026/01086**

15 October 2026

Dea [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 17 September. You wrote:

I would like to see the full review of MHRA's request for Eli Lilly to investigate post marketing reports of persistent sexual dysfunction following discontinuation of fluoxetine and other SSRIs. All reviews of published literature, case reports, consumer internet reports, and incidental research findings discussing persistent sexual dysfunction following SSRI discontinuation. Lilly identified six published articles containing 14 case reports involving prolonged or persistent sexual dysfunction after discontinuation of SSRIs, including three reports involving fluoxetine. After this review, Lilly proceeded to update Prozac labels in the United States to warn of the risk of persistent sexual dysfunction

The text is included here, and the FDA document is attached.

"

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Regulatory Response

6. Persistent Sexual Dysfunction

6.1. Overview

This addendum is provided to support a labeling supplement for Prozac (fluoxetine). The purpose of this labeling supplement is to update Section 6.1 Clinical Trial Experience of the Prozac USPI arising from a review requested by the MHRA in August 2010. The review was completed and submitted to the MHRA by Lilly in November 2010, and the CDS was updated in November 2010.

6.2. Background

Lilly received a request from the MHRA on 31 August 2010 for a cumulative review of adverse reactions related to sexual dysfunction suspected to be associated with fluoxetine use, with a particular focus on those cases that have persisted long term after treatment with fluoxetine has been discontinued. This was to aid the MHRA's evaluation

of the potential signal of sexual dysfunction which may persist after treatment with an SSRI has been stopped. Following clarification with the MHRA, Lilly defined the term "persistent" to mean at least 3 months after discontinuation of fluoxetine treatment, which is based on the half-life of fluoxetine and its active metabolite, norfluoxetine.

There is a high incidence of sexual dysfunction in the general population, and the occurrence of sexual dysfunction is consistently higher in patients with depression than in the general population (Kennedy and Rizvi 2009). Most antidepressants have side effects related to sexual functioning, and it has been estimated that up to 60% of patients receiving SSRIs report some form of treatment-emergent sexual dysfunction (Kennedy and Rizvi 2009).

In recent years there have been several publications (reviews, commentaries, case reports, consumer-provided internet-based information, and incidental research findings) that discussed persistent sexual dysfunction following SSRI discontinuation. Six articles reported 14 case reports of patients experiencing prolonged or persistent sexual dysfunction following discontinuation of several SSRIs, including fluoxetine (3 reports), paroxetine, citalopram, and sertraline. The exact mechanisms for persistent sexual side effects after SSRI discontinuation discussed in the literature are unclear, and only mechanistic hypotheses have been suggested."

Please include Eli Lilly's discussion of clinical trial evidence for persistent sexual dysfunction and the MHRA's identification of persistent sexual dysfunction as a long-term risk.

MHRA Response

We confirm that we hold the information you have requested and provide in the following attachments

- a) the MHRA's assessment was presented to the Pharmacovigilance Expert Advisory Group in February 2011, the committee paper is provided
- b) the minutes of the committee meeting dated February 2011

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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