Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

23 May 2024

MHRA reference **FOI2024/00076**

Dear [redacted]

Thank you for your information request, which we received on 30th April 2024. You asked for:

> ***"I would like to receive copies of correspondence with FDA / Eli Lilly regarding changes to fluoxetine labeling. Particularly changes in labeling that involves persistent sexual dysfunction."***

We confirm that we do not hold all of the information you have asked for and suggest that you refine your request to define the time period and nature of the correspondence you are interested in.

A search of emails for the staff members involved in monitoring the safety of fluoxetine has not identified any correspondence with the FDA on the labelling change to the fluoxetine licence that involves persistent sexual dysfunction. Please note that it is not routine practice for the MHRA to have correspondence with the FDA on specific labelling changes beyond notifications which are also published on the FDA website.

A search of emails for the staff members involved in monitoring the safety of fluoxetine has not identified any correspondence between specific staff at the MHRA and Eli Lilly on changes to the fluoxetine product information.

However, our Sentinel database holds all of the documentation and associated letters shared between the MHRA and marketing authorisations for each variation to amend the product information for each medicine. For fluoxetine, this includes the variations between its approval in 1988 until Eli Lilly cancelled their licence in 2020.

As an example of the type of correspondence that we hold, annex 1 contains a copy of the letter to Eli Lilly approving the changes to the fluoxetine product information that involves persistent sexual dysfunction.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Safety and Surveillance Group
Healthcare, Quality and Access Group
Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/

If you re-use our information, you should include the following attribution, including a link to the OGL v3.0:

Annex 1

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MHRA

MHRA
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E14 4PU
United Kingdom

gov.uk/mhra

Head Of Regulatory Affairs
ELI LILLY & COMPANY LIMITED
LILLY HOUSE
PRIESTLEY ROAD
BASINGSTOKE
HAMPSHIRE
RG24 9NL
UNITED KINGDOM

28/11/2019

Dear Head Of Regulatory Affairs,

APPROVAL

Our Reference:	PL 00006/0195 - 0113
Your Reference:	00006
Product:	PROZAC 20mg hard capsules
Type of Procedure:	Mutual Recognition
Submission Type:	Variation
Submission Category:	Type II
Submission Complexity:	Standard
EU Procedure Number (if applicable):	FR/H/0242/002/WS/051
Reason:	To update SmPC 1-0, 2-0, 4-2, 4-4, 4-8, 6-5, label and PIL (other than 4-4 and 4-8, all SmPC sections updated in PL 0006/0272 only) to include a statement on persistent sexual dysfunction, following PSUR assessment report PSUSA/00001442/201709. QRD and excipients guideline changes are also made.

The Licensing Authority agrees to the above submission(s), including any replacement and amendment pages of the original that were provided with your written request.

The approval date is 26/06/2019.

Please retain this letter with the formal documents relating to the Marketing Authorisation/Registration as evidence of approval.

All Marketing Authorisations/Registrations are subject to standard provisions contained in current medicines regulations, full details of which are published on the MHRA website:
http://medicines.mhra.gov.uk/ourwork/licensingmeds/licensingmeds.htm

Yours sincerely,