FW: FOI 24/104 - Freedom of Information request - Comments to Swedish regulator regarding effects of fluoxetine

Pharmacovigilanceser <vigilanceservice@mhra.gov.uk>

Tue 27/02/2024 18:48

To:MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>; [redacted]

4 attachments (676 KB)

Annex 4.pdf; Annex 7.pdf; Annex 8.pdf; Annex 9.pdf;

From: Pharmacovigilanceser <vigilanceservice@mhra.gov.uk>
Sent: Tuesday, February 27, 2024 6:47 PM
To: [redacted]
Subject: RE: FOI 24/104 - Freedom of Information request - Comments to Swedish regulator regarding effects of fluoxetine

Dear [redacted],

Thank you for your FOI request dated 31st January, 2024 where you asked us to provide you with any further correspondence sent to or received from the Swedish Medical Products Agency (Läkemedelsverket) pertaining to the issue addressed in your previous request, ie. the sexual side effects of fluoxetine in rats.

We can confirm that the MHRA does hold this information and a copy has been attached (see annexes 4 to 9). Information that has been redacted is exempt under Section 40 (Personal Information) of the Freedom of Information (FOI) Act and is therefore withheld.

Section 40 provides that personal information may be exempt from release where to do so would contravene data protection principles.

We 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.

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

Annex 4 - email containing the Final Assessment Report (AR) on the non-clinical studies on effects on sexual development, jointly prepared by UK and France which addressed Sweden's comments. This was circulated by France to the MAH and the concerned member states (including Sweden).
Annex 7 – email asking for an update on the non-clinical FUMs on sexual development studies.
Annex 8 – email responding with the Joint Final AR on the non-clinical AR studies.
Annex 9 – email querying the Final AR on a procedure assessing the clinical data on effects on sexual development.

Kind regards,

FOI Team
Safety & Surveillance Group
Medicines and Healthcare Products Regulatory Agency
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