Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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www.gov.uk/mhra

29th June 2023

Dear [redacted]

FOI 23/398

Thank you for your FOI request dated 3rd June 2023, where you requested the following information:

"I would like to see copies of all reports made via Yellow Card Scheme by either doctors or patients relating to side-effects from a medication called Mirtazapine (Remeron), including any reports that were not officially published or released to the general public, and all details concerned.

I am particularly interested in all reports relating to adverse effects or side effects from the medication, with more specific interest in side-effects/adverse effects that may include cochlear hair cell damage in the ear, tinnitus, hearing loss, balance problems or symptoms related to ototoxicity, particularly in the ear.

I would like to have specific reports related to the tests that produced above side effects provided if possible too."

Unfortunately, we are unable to provide copies of all the reports made via the Yellow Card scheme, as this information is exempt from release under section under Section 40 (personal data) and Section 41 (information provided in confidence) of the Freedom of Information (FOI) Act 2000. Section 40 protects personal data, the disclosure of which would breach one or more of the data protection principles. Section 41 is an absolute exemption and no consideration of the public interest is required, except to state that we consider its disclosure to constitute an actionable breach of confidence.

Currently the MHRA publishes interactive charts and tables displaying data for all medicines. Interactive Drug Analysis Profiles (iDAPs) contain complete listings for all medicines of all UK spontaneous suspected adverse drug reactions received by the MHRA and are available to view on our website: https://yellowcard.mhra.gov.uk/iDAP/. It is important to note that there is an iDAP for each licensed medicine by drug substance, not by drug brand.

However, please find attached a Drug Analysis Print (DAP) for Remeron, which contains information on all the UK spontaneous Adverse Drug Reaction (ADR) reports received through the Yellow Card scheme up to and including 12/06/2023. Following a search of our database up to and including 12th

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June 2023, I can confirm that the MHRA have received 41 spontaneous suspected ADR reports associated with Remeron. The attached Drug Analysis Print (DAP) guidance sheet provides you with further information on how to interpret the print.

As requested, please see Table 1 below of the number of ADR reports relating to adverse reactions as specified in your email, received up to and including 12/06/2023, these can also be seen on pages 4 and 14 of the print provided.

Table 1 – UK spontaneous suspected ADR reports for Remeron and specified reactions reported (up to and including 12/06/2023)*

Adverse reaction	Number of ADR reports
Deafness neurosensory	0
Tinnitus	1
Hearing loss	0
Ototoxicity	0
Ataxia	1

*Please note that the sum of reports in the table will not be equal to the total number of unique reports as one report may contain more than one of these reactions.

When considering the attached spontaneous data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: https://www.medicines.org.uk/emc/ for details on the possible side effects.

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,
Safety and Surveillance

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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
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