Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA

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London
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www.gov.uk/mhra

31/05/2023

Dear

FOI 23/359

Thank you for your email on 22 May 2023, where you requested **the number of reports the MHRA has received for various drug classes and their associated adverse reaction data**.

- *Selective serotonin reuptake inhibitors (SSRIs)*
- *Serotonin-noradrenaline reuptake inhibitors (SNRIs)*
- *Noradrenaline and specific serotonergic antidepressants (NASSAs)*
- *Tricyclic antidepressants (TCAs)*
- *Serotonin antagonists and reuptake inhibitors (SARIs)*
- *Monoamine oxidase inhibitors (MAOIs)*

1. Could you please provide the total number of reports received by the Agency of side effects from each of these classifications of medication, in each of the following years: 2018-2023

2. In each classification and year, could you please provide the number of reports received from people under the age of 18 years old.

3. Could you please provide the total number of reports received by the Agency of side effects from each of these medications, in each of the following years: 2018-2023

- *Citalopram*
- *Mirtazapine*
- *Fluoxetine*

- *{any others}*

4. For each medication and year, could you please provide the number of reports received from people under the age of 18 years old.

5. For each of these classifications of medication, could you please provide the number of reports received of each of the following side effects in the years 2021 and 2022.

For your enquiry, you may be interested to know that the MHRA has interactive Drug Analysis Profiles (iDAPs) that provide a complete listing of all suspected adverse reactions reported to the MHRA for medicines and COVID-19 vaccines via the Yellow Card scheme. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. Medicines are listed alphabetically by the name of the active ingredient, not by the class or brand name.

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

- A Yellow Card report can include more than one suspect drug or vaccine. Hence, this report will be included in the iDAP of each reported suspect drug or vaccine.

- The inclusion of a particular reaction in our system does not necessarily mean that it has been caused by the suspect drug or vaccine. Many factors must be considered in assessing causal relationships, including temporal association, the possible contribution of concomitant medication, and the underlying disease. We encourage reporters to report suspected ADRs, i.e., the reporter does not have to be sure of a causal association between the drug and the reactions – a mere suspicion will suffice.

- It is 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 to drugs or vaccines and, therefore, cannot be used to determine the incidence of a reaction or compare the safety profile of different drugs or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug, 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 you will notice, some of the information you have asked for is already publicly available in our iDAPs, particularly points 3 and 4 below:

3) Could you please provide the total number of reports received by the Agency of side effects from each of these medications, in each of the following years (2018 – 2023)?
4) For each medication and year, could you please provide the number of reports received from people under the age of 18 years old (2018 – 2023)?

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We understand that the iDAPs are useful when seeking adverse reaction data for an individual drug. Regarding the aspect of your request that concerns drug classes (points 1, 2, 5 and 6), if the information displayed individually by drug does not meet your needs, please can you list the active substances you would like us to include in our data searches for each of the following classes:

- Selective serotonin reuptake inhibitors (SSRIs)
- Serotonin-noradrenaline reuptake inhibitors (SNRIs)
- Noradrenaline and specific serotonergic antidepressants (NASSAs)
- Tricyclic antidepressants (TCAs)
- Serotonin antagonists and reuptake inhibitors (SARIs)
- Monoamine oxidase inhibitors (MAOIs)

We look forward to your response.

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

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
Wycliffe House
Water Lane
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SK9 5AF

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