Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

3rd June 2024

Dear [redacted]

FOI 2024/00121

Thank you for your FOI request dated 17th May 2024, where you requested the following information:

> *1. Please provide the number of suspected adverse drug reactions reported in accordance with the Yellow Card Scheme, for the drugs listed below, broken down annually for the following years where available, 2019, 2020, 2021, 2022, 2023:*
>
> *A. Diazepam*
> *B. Zaleplon*
> *C. Zopiclone*
> *D. Citalopram*
> *E. Tramadol*
> *F. Naproxen*
> *G. Sertraline*
>
> *I'd be grateful if this information could include all categories of reporting from serious reaction to unlisted reaction to those reported in the, 'unsure whether to report' category. If patient confidentiality is a barrier to providing this information, please amalgamate the numbers by drug type and year with 'x' number of total reports and I'll view them with that understanding in mind.*
>
> *Please note, I've not requested a breakdown by age group for the same reason. Please also note, I've asked by medication, not brand name, so please include all relevant brands under the relevant medications.*

I can confirm that the MHRA does hold this information; however, it is exempt from release under Section 21 of the FOI Act – information accessible by other means: the information you have requested is already in the public domain.

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/. On this platform, you will be able to search for the specified drugs you listed and find the reported suspected adverse reactions associated with them. You can also refine your search to have reports from the specific years you require (2019, 2020, 2021, 2022, 2023), by updating the 'Year received'. It is important to note that there is an iDAP for each licensed medicine by drug substance, not by drug brand. Please note that the brand names associated with the substance will be provided on "Overview" table at the top of the page. The platform also provides other searches which you can filter by, including "Report Submission", "Age Group" and "Seriousness".

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.

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 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. 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.

The MHRA continuously monitors the safety of medicines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

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
Wilmslow
Cheshire
SK9 5AF