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 November 2023

Dear [redacted]

FOI 23/749

Thank you for your Freedom of Information request dated 6th October 2023 where you requested:

1. *Are any of your mental health medications listed on your website being currently investigated and any due to be and if you can disclose to myself which medications?*
2. *Can you provide me with the information for if antipsychotics and mental health medications listed on your website have been reported to have memory loss side effects and long term memory loss side effects?*
3. *I would also like to request if Yellow Card can create the reporting option of reporting side effects completely anonymously without providing any personal details?*

All medications prescribed for mental health conditions are subject to ongoing safety monitoring from the time of licensing.
At the time of licensing, safety data from the clinical trial population are available and inform the content of information available for the healthcare professionals and patients in the format of the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL).
Safety information evolves over time as wider populations of people are prescribed the medications. These safety data are collected and reported systematically in periodic safety update reports (PSURs) compiled by the marketing authorisation holders of individual medications and submitted to the regulatory authorities for assessment.
Side effects associated with medications prescribed for mental health conditions cases reported in the post marketing setting can also be reported directly to the MHRA via the Yellow Card Scheme.
Newly available safety data for each medication are assessed on a regular basis and any new safety signals identified from a range of sources including the PSURs and Yellow Cards are discussed by a multidisciplinary team at MHRA at weekly signal meetings and taken forward as appropriate through risk proportionate regulatory action to amend product information and issue wider communications through Drug Safety Update articles, updates to associated clinical guidance and via National Patient Safety Alerts.

Regulatory decisions taken by the MHRA are informed by advice from the independent Commission on Human Medicines (CHM). In relation to medications prescribed for mental health conditions, most recently the Commission endorsed a proposal from MHRA to convene an Expert Working Group to consider the risk minimisation for suicide and suicidal behaviours associated with antidepressants and this group will meet for the first time next year.

In response to your second question, you can view all our adverse drug reaction (ADR) data for antipsychotic and other medicines on our Yellow Card website. You can do this by following this link:

https://yellowcard.mhra.gov.uk/idaps and scrolling to the bottom of the page. Here, you can use the alphabetical tool to select the drug of interest, which will open an interactive Drug Analysis Profile (iDAP) for this drug. The iDAP displays the data in a variety of tables and graphs. The table at the bottom of the page includes the reactions that have been reported for the drug of interest. You can expand each category of reactions to see the number of reports for individual reactions and also whether any resulted in a fatal outcome. Specifically for memory loss, please go to **Nervous system disorders> Mental impairment disorders > Memory loss (excl dementia)> amnesia**, to view the number of reports related to your enquiry. There are also filters down the left-hand side of the webpage that allow you to filter the data by age, sex, seriousness etc, if you wish.

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

- A reported reaction does not necessarily mean it has been caused by the drug, 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. We continuously review Yellow Card reports, alongside all other sources of safety data, to monitor safety and identify any new risks.

- 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 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.

You may also find it helpful to view the online Summary of Products Characteristics (SPC) and Patient Information Leaflet (PIL) resources. These resources are freely available to the public and provide details on the known side effects of medicinal products and vaccines, with their associated frequencies. You can access these resources using this website and searching for the name of the specific products in question: https://www.medicines.org.uk/emc . I hope that this is helpful.

Regarding your final question relating to anonymous yellow card reports, as mentioned previously, in order to submit a Yellow Card report, we ask for the reporter's name and contact details.. We also require one non-identifiable information (such as initials, age, sex, or ethnicity) of the person affected by the incident to understand the impact on different populations. Please see the link to our privacy policy for further information: Privacy Policy | Making medicines and medical devices safer (mhra.gov.uk).

I hope the information provided is helpful; however, 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,
Vigilance and Risk Management of Medicines Division

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