

FOI 23/022

3rd February 2023

Dear

Thank you for your email dated 9th January 2023, where you requested information on the following:

- I was wondering how I could go about accessing data on MHRA Yellow Card reactions for an entire drug class (e.g., the selective serotonin reuptake inhibitors), including a subdivision by the MedDRA system-organ-class categories

Further to your request I can confirm up to and including 27/01/2023 we have received a total of 40,554 UK spontaneous Adverse Drug Reaction (ADR) reports where either citalopram, escitalopram, sertraline, fluoxetine, fluvoxamine, paroxetine, dapoxetine or vortioxetine have been reported. As requested, the attached Drug Analysis Print (DAP) lists all the ADRs which have been reported for the SSRIs as listed above. Please also find attached a DAP guidance sheet which provides you with further information on how to interpret the print.

When considering the 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 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.

Please note if you do plan to publish anything based on this data, please submit your paper for review beforehand so we can ensure that the data has been interpreted accurately.

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,

Vigilance and Risk Management of Medicines Division