Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
www.gov.uk/mhra

[redacted]

06 February 2024

FOI 24/061

Dear [redacted]

Thank you for your information request, dated 19 January 2024, where you asked for the ethnicity data for all reports concerning clozapine. As previously mentioned, we can provide this as aggregated data in a separate table to the data for clozapine available on the Yellow Card website.

As requested, I am pleased to confirm that up to and including 2 February 2024 we have received a total of 517 UK spontaneous suspected adverse drug reaction (ADR) reports for clozapine where the reporter provided the patient's ethnicity. A breakdown of these reports by ethnicity can be found in Table 1 below. Please note that ethnicity is an optional field when filling out a Yellow Card report, and as such is not always provided by the reporter. The Yellow Card scheme relies on voluntary reporting to monitor the safety of all healthcare products in the UK and by not making all report fields mandatory, we aim to maximise the number of reports we receive.

Table 1: All UK spontaneous suspected ADR reports for clozapine broken down patient ethnicity.

Patient Ethnicity	Count
African	14
Any other Asian background	10
Any other black background	4
Any other ethnic group	2
Any other mixed background	5
Any other white background	36
Bangladeshi	2
British	408
Caribbean	9
Chinese	4
Indian	3
Irish	9

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Pakistani	6
White & Asian	1
White & Black African	1
White & Black Caribbean	3
Sum:	517

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

- The likelihood of experiencing an adverse drug reaction when taking clozapine cannot be estimated from the data alone. This is because we have limited information about how many people have taken these medicines without experiencing a reaction.

- 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 drug, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the drug. 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 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. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

Please be assured that all reports are continually reviewed to detect possible new side effects that may require regulatory action, and to differentiate these from things that would have happened regardless of the vaccine or medicine being administered, for instance due to underlying or undiagnosed illness. This review takes into account all factors, including whether any ethnic groups may be disproportionately affected by suspected adverse reactions to medicines.

I hope the information provided is helpful however please do not hesitate to contact me if I can be of further assistance.

Yours sincerely,

FOI Team,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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