Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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

9th June 2023

Dear [redacted]

RE: FOI 23/320

Thank you for your email dated 2nd May 2023, where you asked for clarity on the data provided in FOI 23/238 and requested further breakdown of this data.

To clarify I can confirm that the number of reports stated previously as 13,848 UK spontaneous Yellow Card reports in association with the Higher Level Term (HLT) 'renal failure and impairment', is correct and is the number of unique reports received up to and including 25th April 2023. The sum of reports the spreadsheet will not equal the number of unique reports above, as some reports will contain multiple reactions and multiple suspect drugs. Therefore, reports will be counted once against each suspect drug present in a single case, and if a single case contains multiple reactions within the HLT 'renal failure and impairment' it will also be counted more than once.

Please find attached tables 1-3 which display the data provided previously split by number of reports received per year, age, and sex.

Further to your additional request for the number of reports displayed with corresponding ROR value, unfortunately we are unable to disclose data where there are less than 5 reports as these are exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI act. Supplying you with this information could lead to patient identification. As outlined in our Privacy Policy Privacy Policy | Making medicines and medical devices safer (mhra.gov.uk), The Policy states that we may receive requests for Yellow Card report data under the Freedom of Information Act. While we are legally obliged to provide some of the requested information, we only provide high-level summary information with all person-identifiable data excluded.

In your most recent email dated 5th June 2023 you have requested data at the Preferred Term (PT) level to aid your research. We therefore recommend that you complete a Type II data request application. Within this application form you can detail the research proposals / aims and specify the exact data required. Your application will then be reviewed by the Pharmacovigilance Expert Advisory Group (PEAG), there may also be a cost involved, further information and the application form can be found here: Membership - Commission on Human Medicines - GOV.UK (www.gov.uk).

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

When considering the attached 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.

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