Medicines & Healthcare products Regulatory Agency

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[redacted]

02 August 2023

FOI 23/488

Dear [redacted]

Thank you for your information request dated 4th July, where you requested the below:

1. How many adverse drug reaction (ADR) reports do you have per year from 2012 until 2022?

2. How many of them are serious/ not serious per year?

3. How many were reported by patients and how many by physicians per year?

4. What are the main top 5 medicines or systems affected by the ADR reports?

Further to your request, please find attached excel sheet containing Tables 1-4, descriptions of which are below:

- Table 1 - the total number of UK spontaneous suspected ADR reports received each year between 2012 and 2022.
- Table 2 - the total number of UK spontaneous suspected ADR reports received by seriousness each year between 2012 and 2022. An ADR report is considered serious according to two criteria; firstly, a reported reaction can be considered serious according to our medical dictionary. Secondly, whether the original reporter considers the report to be serious whereby they can select based on 6 criteria[1].
- Table 3 - the total number of UK spontaneous suspected ADR reports received from members of the public or healthcare professionals each year between 2012 and 2022. Please note, this table only includes reports

1 *The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant.*

received directly to the Yellow Card scheme and does not include reports received indirectly via pharmaceutical companies.

- Table 4 - The five most frequently reported medicines included in UK spontaneous ADR reports received each year between 2012 and 2022. Please be aware that the MHRA does not use ATC groups across all medicinal products, therefore this information has been provided by drug substance.

Please note, Yellow Card data for clozapine is subject to reporting bias which results in an unusually high number of reports compared to other medicines. This is because people treated with clozapine in the UK are required to undergo weekly, 2-weekly or monthly blood monitoring and are monitored more closely in clinical practice than patients receiving most other medicines. This in turn increases the likelihood that adverse reactions, as well as co-incidental medical events, are detected and reported to us.

Similarly, COVID-19 vaccines are subject to unusually high number of reports compared to other medicines or vaccines, due to high public awareness of the Yellow Card scheme and encouragement of reporting of all events relating to COVID-19 vaccines. Usage of the vaccines increased over the course of the campaigns and as such, so has reporting of adverse events with a temporal association with vaccination. However, this does not mean that there is a link between vaccination and the adverse events reported.

When considering the attached provided spontaneous ADR data, it is also 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 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.

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Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

FOI Team

Safety and Surveillance