Medicines & Healthcare products
Regulatory Agency

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[redacted]

13 May 2024

FOI 2024/00080 (follow up to FOI 23/488)

Dear [redacted]

Thank you for your updated information request, dated 2 May 2024, where you requested the following:

1. Adverse drug reaction (ADR) reports per year from 2012 until 2022, excluding MAH.
2. Serious/non serious ADR just from national authorities centre.
3. HCP in detailed information, i.e. how many ADR cases are registered by physicians, nurses, dentist, pharmacologists?
4. Top 15 medicines or systems affected by the ADR reports.

I can confirm the MHRA does hold the information you have requested, as such this has been detailed below for you.

Please find attached excel sheet containing updated Tables 1-4, which includes reports received directly to the Yellow Card scheme and does not include reports received indirectly via pharmaceutical companies. Descriptions of the tables are below:

- Table 1 - the total number of UK direct spontaneous suspected ADR reports received directly to the Yellow Card scheme each year between 2012 and 2022.
- Table 2 - the total number of UK direct spontaneous suspected ADR reports received directly to the Yellow Card scheme 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 six criteria1.
- Table 3 - the total number of UK direct spontaneous suspected ADR reports received directly to the Yellow Card scheme by reporter qualification each year between 2012 and 2022.
- Table 4 - the top fifteen most frequently reported medicines included in the 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.

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 six 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.

Please note, 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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Yours sincerely,

FOI Team

Safety and Surveillance

Yours sincerely,