Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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29 June 2023

Dear [redacted]

FOI 23/395

Thank you for your Freedom of Information (FOI) request dated 31 May 2023 where you asked for the number of Yellow Card reports for the following Adverse Drug Reactions (ADRs):

1. *Total reactions of Administration Site ADR's*
2. *Total reactions of Administration Site ADR's from subcutaneous products*
3. *Total reactions of Therapeutic and non-therapeutic effects – Interactions*
4. *Total reactions of Therapeutic and non-therapeutic effects – Interactions from subcutaneous products*
5. *Total reactions of Therapeutic and non-therapeutic effects - Therapeutic and non-therapeutic responses*
6. *Total reactions of Therapeutic and non-therapeutic effects - Therapeutic and non-therapeutic responses form subcutaneous products*
7. *Total reactions of Product Issues*
8. *Total reactions of Product Issues from subcutaneous products*
9. *Total reactions of skin and subcutaneous tissue disorders*
10. *Total reactions of skin and subcutaneous tissue disorders from subcutaneous products*

All of the data provided in the below table relates to UK spontaneous suspected Yellow Card reports received by the MHRA as of 27 June 2023. To calculate the total number of UK spontaneous ADR reports received for the requested reaction terms listed above we used corresponding MedDRA terms which are listed in the second column of the table.

It may also be helpful if I provide you with further information about the Medical Dictionary for Regulatory Activities (MedDRA), which is the internationally agreed list of terms used for Medicines Regulation. The MHRA uses MedDRA to capture reactions within our ADR reports. MedDRA groups related ADR terms in a hierarchical structure whereby the 'System Organ Classes' (SOCs) is the highest or broadest level. The SOC level terms are further divided into the 'High-Level Group Terms' (HLGTs), 'High-Level Terms' (HLTs), 'Preferred Terms' (PTs) and the 'Lowest Level Terms' (LLTs) which are the most specific terms.

Table 1. Total number of UK spontaneous ADR reports received for the requested reaction terms listed above as of 27 June 2023

Requested Yellow Card data	Corresponding MedDRA Term	Reported Route of Administration	Total number of Yellow Card Reports
Total reactions of Administration Site ADR's	Administration site reactions HLGT	ALL	**56378**
Total reactions of Administration Site ADR's from subcut products	Administration site reactions HLGT	Subcutaneous	**5759**
Total reactions of Therapeutic and non-therapeutic effects – Interactions	Interactions HLT	ALL	**10937**
Total reactions of Therapeutic and non-therapeutic effects – Interactions from subcut products	Interactions HLT	Subcutaneous	**163**
Total reactions of Therapeutic and non-therapeutic effects - Therapeutic and non-therapeutic responses	Therapeutic and nontherapeutic responses HLT	ALL	**30854**
Total reactions of Therapeutic and non-therapeutic effects - Therapeutic	Therapeutic and nontherapeutic responses HLT	Subcutaneous	**1926**

and non-therapeutic responses form subcut products			
Total reactions of Product Issues	Product issues SOC	ALL	**13846**
Total reactions of Product Issues from subcut products	Product issues SOC	Subcutaneous	**2073**
Total reactions of skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders SOC	ALL	**328701**
Total reactions of skin and subcutaneous tissue disorders from subcut products	Skin and subcutaneous tissue disorders SOC	Subcutaneous	**9335**

Numbers of reports have been provided based on the reported route of administration. Therefore, please note that the accuracy of the data relies on the route of administration being provided by the reporter. Where reporters have not specified the route of administration as subcutaneous, reports will not be included in the numbers provided. The data has not been provided based on authorized method of administration listed in product information.

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

- A reported reaction does not necessarily mean it has been caused by the suspect drug or vaccine, only that the reporter had a suspicion it may have been. When any medicine is given to patients, some recipients will inevitably experience illness following its use. The fact that symptoms occur after use of a vaccine or 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular vaccine, and

may be stimulated by promotion and publicity about a vaccine. 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.

I hope the information provided is helpful.

Yours sincerely,

FOI Team,
Safety and Surveillance