Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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www.gov.uk/mhra

12th September 2023

Dear [redacted]

RE: FOI 23/605

Thank you for your recent FOI request from 14th August 2023, where you asked for information on the following:

"Statistics for ADR reporting for the years 2019, 2020, 2021, and 2022? I do not require detailed information by drug, etc, but would like to know general information such as:

- *Total number of ADRs reported in each year (preferably broken down by month - if possible)*
- *Percentage of ADRs reported by newly qualified doctors (i.e. Foundation Programme year 1) each year*
- *Percentage of ADRs reported by patients and/or parents/carers each year*
- *Percentage of ADRs reported by other healthcare professionals each year*
- *Percentage of each class of ADR reported (i.e. A -E) each year*"

It may be helpful to provide firstly some background information to allow interpretation of this data. The Yellow Card Scheme is the UK system for collecting and monitoring information on suspected adverse drug reactions (ADRs). The Scheme is run by the MHRA and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. There is also a legal obligation for pharmaceutical companies to report serious ADR reports to their drugs. The purpose of the Scheme is to provide an early warning that the safety of a product may require further investigation. The Yellow Card Scheme began in 1964 to enable reporting of suspected side effects and was initially limited to healthcare professionals. Following a successful pilot in 2005, patient reporting was formally launched in 2008 and patients now account for the largest reporting group and make a significant contribution to the Scheme. All reports, including from patients, are reviewed through a signal detection process to identify previously unrecognised concerns about medicines and consider if further action is necessary.

Our Yellow Card strategy aims to publicise the importance of reporting to the Scheme and raise awareness amongst healthcare professionals and patients. Alongside this we are improving the ease of reporting, for example with mobile apps, and increasing transparency through publishing our data. Through continued activities to simplify reporting and increase awareness we hope to continue increasing the trend in patient engagement.

Further to your request, please see below the breakdown for the total number of ADRs reported in each month between 2019 and 2022 and the percentage of reports from patients/parents/carers

and healthcare professionals per year. Please note that this includes ADR reports directly received by the MHRA by healthcare professionals and patients only and does not include ADR reports received by the MHRA from the pharmaceutical industry. There is a large increase in the total number of Yellow Card reports received by both patients and healthcare professionals in 2021. This coincides with the rollout of the COVID-19 vaccinations and our targeted work to raise awareness of the scheme with recipients of the 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.

This information cannot be used to estimate the frequency of potential side effects associated with medicines and vaccines occurring in the UK. This is because we have limited information about how many people have taken a medicine or vaccine without experiencing a reaction.

A list of the recognised adverse effects to a medicine is provided in the information for healthcare professionals and the recipient information. Directions on how to report any adverse reactions to a medicine to the Yellow Card scheme is also included in the recipient information.

Table 1: Total number of UK Spontaneous direct ADR reports received 2019-2022

	Total number of ADR reports per year			
Month	**2019**	**2020**	**2021**	**2022**
January	2440	2931	31505	16513
February	2332	2805	57314	7307
March	2727	2262	82505	6042
April	3006	1760	51973	5641
May	2755	1774	46839	5310
June	2491	2112	44560	4281
July	2739	2245	29930	3959
August	2369	1931	19533	3727
September	2613	2410	14935	5770
October	3007	2780	13555	9862
November	3026	2432	19016	7054
December	2540	5255	30717	4778
Total	**32045**	**30697**	**442382**	**80244**

Table 2: Percentage of ADRs reported directly to the MHRA by patients and/or parents/carers and healthcare professionals 2019-2022

	Percentage of ADRs reported per year			
	2019	**2020**	**2021**	**2022**
Patients/parents /carers	27.60%	30.06%	81.36%	66.49%
Healthcare professionals	72.40%	69.94%	18.64%	33.51%

I can confirm that the MHRA does not hold information regarding ADRs specifically reported by newly qualified doctors. While reporter qualification is a required field for Yellow Cards from healthcare

professionals this includes more generalised reporter groups only such as GP, Hospital Doctor and Pharmacist.

In addition, the MHRA does not classify each Yellow Card into a specific class of ADR reported (i.e. A -E). We conduct signal detection activities based on the information in our database, in which specific drug/vaccine-reaction combinations which meet defined criteria are assessed to determine if risk-minimisation measures need to be implemented. Additional information regarding ADR reports received by the MHRA is published online at https://yellowcard.mhra.gov.uk/idaps.

I hope the information provided is helpful. The MHRA encourages the use of Yellow Card data. However, we seek to ensure that the data is studied and applied appropriately, and any conclusions/interpretations consider the above information. For this reason, if you wish to use this information for a publication, we request that you engage with the MHRA during this process and provide a copy of the report. 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