Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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United Kingdom

www.gov.uk/mhra

14th July 2023

Dear [redacted]

FOI 23/426 – trend of reporting to Yellow Card Scheme

Thank you for your email dated 17th June 2023, where you asked for information on the following:

- *The statistics of the number of reports you have received to the yellow card scheme per year (ideally split by patients and medical professionals), going back as far as you're able.*

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[1]. Through continued activities to simplify reporting and increase awareness[2] we hope to continue increasing the trend in patient engagement.

Please find the requested data in the attached spreadsheet. 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

[1] https://yellowcard.mhra.gov.uk/idaps
[2] Campaigns | Making medicines and medical devices safer (mhra.gov.uk)

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.

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,
Safety and Surveillance