Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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Canary Wharf
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United Kingdom

www.gov.uk/mhra

26th January 2023

Dear [redacted]

FOI 22/1227

Thank you for your email dated 26th December 2022, where you requested information for the following:

- Anonymised Yellow Card data grouped by area and age group, specifically the Buckinghamshire health authority area for under 18's.

For this data request, we searched for cases that fell under the NHS Buckinghamshire Clinical Commissioning Group (CCG) area. The Buckinghamshire CCG is a 50 member group of GP practices and their associated branches across the entire Buckinghamshire County, details of all the practices the CCG covers can be found on this website here.

Further to your request we have provided you with tables which display information similar to what is represented in our interactive Drug Analysis Profiles (iDAPs) and the COVID-19 vaccine reports published for all reports across the UK.

I can confirm that the Medicines and Healthcare products Regulatory Agency (MHRA) received a total of 534 spontaneous suspected Adverse Drug Reaction (ADR) reports for patients under 18 years old for the NHS Buckinghamshire CCG area up to and including 15/01/2023. I can confirm that there are a total of 196 Yellow Card reports that are reported as serious and a total of 5 suspected ADR reports with a fatal outcome. An ADR report can be classified as serious either if the reporter considers the reaction to be serious or if the reaction term itself is considered serious in our medical dictionary.

Please see the tables attached for the total number of Yellow Card reports for all medicines and vaccines reported within the NHS Buckinghamshire CCG area up to and including 15/01/2023, broken down by age (Table 1), sex (Table 2), the number of adverse reactions within each System Organ Class (SOC) (Table 3) and the number of reports received for each suspect drug/vaccine (Table 4). For Tables 3 and 4, please note that a single Yellow Card report may contain more than one adverse drug reaction or suspect product.

Where results include less than 5 reports, we are unable to provide further details to ensure patient and reporter confidentiality. With this in mind, we have not listed the suspect drug or vaccine brand names with 5 or fewer reports for table 4 as there were over 100 entries.

The most commonly reported suspect drugs associated with these suspected ADR reports were mainly vaccines which is not unexpected given that these are administered in wide scale campaigns or as part of the routine national immunisation schedule.

It is important to note that this search was conducted based on the reporter's postal address. Therefore, if this is not provided or if the reporter has only provided their email address, the report will not be included in these data. Postal addresses, age and sex are not a mandatory field when submitting a Yellow Card report for a medicine or vaccine. Therefore, the data provided may not be a true reflection of the number of Yellow Card reports submitted within the NHS Buckinghamshire CCG area.

When considering the spontaneous Adverse Drug Reaction (ADR) data provided within this response, it is important to be aware of the following points:

- The fact that symptoms or events occur after use of a medicine or vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the medicine or vaccine. 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.

The MHRA continuously monitors the safety of medicines and vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are individually assessed and cumulative information reviewed at regular intervals, and if appropriate, regulatory action would be taken if any serious risks were confirmed.

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

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If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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