Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA

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www.gov.uk/mhra

7th March 2023

Dear

FOI 23/107

Thank you for your email dated 5th February 2023, where you requested information for the following:

- Anonymised Yellow Card data grouped by area, specifically the Buckinghamshire health authority area for all ages.

As you are aware, 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.

Firstly, please accept our apologies; we have noticed an error with the data provided to you in your original request (FOI 22/1227) for patients under 18 years of age. We stated the number of suspected Adverse Drug Reaction (ADR) reports received up to 15 January 2023 was 534; 196 of which were considered serious by the reporter or our medical dictionary, with 5 including a fatal outcome. We would like to confirm that 295 of the suspected ADR reports were considered serious by the reporter or our medical dictionary, and less than 5 reports included a fatal outcome. We are unable to provide data where the number of reports is less than 5 due to patient and reporter confidentiality. Unfortunately, one of the seriousness criteria wasn't included in our previous extraction hence the lower number of reports stated. The number of reports with a fatal outcome is now less than 5 reports due to capturing the total number of adverse reactions, instead of the number of individual reports i.e., a single report can contain multiple adverse reactions. Please accept our apologies for this oversight.

Further to your recent 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. Within your query, you mentioned if there was a link available for the data resources you requested, unfortunately, at this moment we can only provide adverse reaction data by location upon request.

I can confirm that the MHRA have received a total of 8953 spontaneous suspected ADR reports for the NHS Buckinghamshire CCG area up to and including 23 February 2023, with 6230 reports being considered serious by the reporter or our medical dictionary. A total of 104 suspected ADR reports included a fatal outcome. This data is not restricted by age. An ADR report can be classified as serious either if the reporter considers the report to be serious based on pre-selected criteria or if the reaction term reported is considered serious in our medical dictionary*.

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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 23 February 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 as mentioned above that a single Yellow Card report may contain more than one adverse drug reaction or suspect product.

Due to the volume of reports, Table 4 lists the suspect medicines or vaccines with 30 or more reports which we thought would be most helpful to view. The most commonly reported suspect drugs associated with these suspected ADR reports were mainly vaccines which are 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 mandatory fields 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.

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* The seriousness of the report is determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and is defined as 6 possible categories which are documented on the Yellow Card. The 6 pre-selected criteria categories include: death, suspected reactions that are life-threatening, require inpatient hospital admission, significant disability or incapacity, congenital anomaly (birth defect), or suspected reactions that are otherwise "medically significant" based upon medical judgement.

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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

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
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