Medicines & Healthcare products Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]

3rd July 2023

FOI 23/401

Dear [redacted]

Thank you for your information request, dated 7 June 2023, where you request "*the Yellow card report on MMR vaccines in 1 year olds*".

I can confirm that we have received 3,641 UK spontaneous suspected ADR reports for the MMR vaccine in 1-year olds up to and including 29/06/2023. To note, patient age is not a mandatory field on a Yellow Card report and therefore is not always provided. Consequently, an reports where age has not been reported to us, will not be included in this data.

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. Any emerging evidence relating to possible risks associated with vaccines and medicines, is carefully reviewed and, if appropriate, regulatory action would be taken if any serious risks were confirmed.

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

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. Each year, millions of doses of routine vaccines are given in the UK alone, and when any vaccine is administered to very large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the 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 vaccines 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.

We hope you find this information useful.

Yours sincerely,

FOI Team,
Safety and Surveillance

If you have a query about the information provided, please reply to this email

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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