FOI 23/046

16th February 2023

Dear

Thank you for your Freedom of Information (FOI) request dated 18th January 2023, where you requested the total number of Yellow Card reports submitted for the MMR vaccine per year broken down by age, seriousness, and number of cases with a fatal outcome.

I can confirm that the MHRA has received a total of 7865 direct, UK, spontaneous suspected adverse drug reaction (ADR) reports for the MMR vaccine up to and including 30/01/2023. Of these 7865 reports, the MHRA has received 4366 serious reports, of which 53 reports have 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. A causal association with the MMR vaccine has not been established for any of the reports with a fatal outcome and overall no safety concern has been identified within these reports.

We have provided a breakdown of the number of reports received per year with additional information on the number of serious reports in Table 1. It is important to note that the number of serious reports also includes reports with a fatal outcome. We are unable to provide the specific breakdown of the number of reports with a fatal outcome per year as there are fewer than 5 reports for most years. This information is exempt under from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI act. Supplying you with this information could lead to patient identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme. Where results include less than 5 reports, we are unable to provide further details to ensure patient and reporter confidentiality.

We have also provided a breakdown of the number of reports received per year by age range in Table 2. Where fewer than 5 reports have been received for a specific year and age range, we have concealed this number to comply with data protection laws and protect reporter confidentiality outlined above.

It is 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 or vaccine and may be stimulated by promotion and publicity about a drug or vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

Furthermore, please note it is important to realise that a report of a suspected ADR does not necessarily mean the reaction has been caused by the drug, only that the reporter had a suspicion it may have. The fact that symptoms occur after a drug is given does not mean that they have been caused by the drug itself, as underlying illnesses and other conditions may be responsible.

When the Yellow Card scheme was established, one of the key principles defined was that it would not be used for audit purposes as health professionals should send Yellow Cards on a voluntary basis. Any data provided should not be used in any way to attempt to identify the original reporter of the Yellow Card nor should the data be used for disciplinary or audit purposes.

I hope this information is useful and would like to thank you for your support of the scheme. Please do not hesitate to contact me if I can be of any further assistance or you would like further data in subsequent quarters.

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,

Patient Safety Monitoring