



MHRA

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www.gov.uk/mhra

14 February 2024

Dear

FOI 24/116

Thank you for your email dated 31 January 2024, where you asked for information on the following:

Yellow Card reports for any batch of MMR Vax Pro for the last 5 years

Please find attached a Product Analysis Print (PAP) for M-M-R vaxPro. This report contains a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme between 1 January 2019 and 6 February 2024. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. Please refer to the attached information sheet for guidelines on how to interpret the report.

This information does not represent an overview of the potential side effects associated with this vaccine. A list of the recognised adverse effects of M-M-R vaxPro can be viewed in the information for healthcare professionals and recipients here.

Conclusions on the safety and risks of the vaccines cannot be made on the data shown in the report alone. When viewing the report, you should remember that:

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the
 vaccine may have caused the adverse reaction. The existence of an adverse reaction report
 does not necessarily mean that the vaccine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse reaction. Sometimes reactions can be part of the condition being treated rather than being caused by the vaccine.
- Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different vaccines using Yellow Card data. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.





The MHRA continuously monitors the safety of 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 assessed, and cumulative information is reviewed at regular intervals. 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,

Vigilance and Risk Management of Medicines Division

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

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