Medicines & Healthcare products
Regulatory Agency

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[redacted]

22/03/2024

Dear [redacted]

RE: FOI 24/202

Thank you for your email dated 28th February 2024 where you requested *"information submitted regarding side effects for Priorix and MMRVaxPro."*

I can confirm the MHRA does hold this information. 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 individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: https://www.medicines.org.uk/emc/ for details on the possible side effects of these vaccines.

I can confirm that up to and including 07/03/2024, the MHRA have received 580 UK spontaneous suspected adverse reaction reports specifically for the Priorix vaccine and 394 UK spontaneous suspected adverse reaction reports for the MMRVaxPro vaccine.

Further to your request, please find attached Vaccine Analysis Prints (VAPs) which contain information on the adverse reactions reported within these reports, received through the Yellow Card scheme up to and including 07/03/2023. The attached guidance sheet provides you with further information on how to interpret the print.

When considering the spontaneous data within this response, 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 vaccinations are given in the UK alone, and when any vaccine is administered

to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. 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 or compare the safety profile of different vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, 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.

We 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
Medicines and Healthcare products Regulatory Agency