Medicines & Healthcare products Regulatory Agency

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[redacted]

20th December 2023

Dear [redacted]

RE: FOI 23/945

Thank you for your email dated 4th December 2023 where you requested "*any reports of adverse effects from either of the two measles, mumps and rubella (MMR) vaccines (Priorix or MMRVaxPro) in children at either the first or second dose"* and information regarding the 4-in-1 preschool booster vaccination, also known as the DTaP/IPV vaccine.

I can confirm that up to and including 07/12/2023, the MHRA has received:

- 570 UK spontaneous suspected adverse reaction reports associated with the Priorix vaccine.
- 387 UK spontaneous suspected adverse reaction reports associated with the MMRVaxPro vaccine.
- 2215 UK spontaneous suspected adverse reaction reports associated with the DTaP/IPV vaccine.

Further to your request, please find attached the Vaccine Analysis Prints (VAP) for details of the reported reactions to the above-mentioned vaccines, received through the Yellow Card scheme up to and including 07/12/2023. The attached Drug Analysis Print (DAP) guidance sheet provides you with further information on how to interpret the print. It is important to note that the total number of reactions in the table will not be equal to the total number of unique reports, as one report may contain more than one reaction.

Please note, these vaccines may also be used outside of the routine schedule and so the reports within these VAPs may not all relate to children.

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.

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.

Finally, please be aware that the VAPs provided should not be used as a list of side effects to these vaccines. All established adverse reactions for Priorix, MMRVaxPro and the currently available DTaP/IPV vaccine Boostrix-IPV can be found within section 4 of the Patient Information Leaflet (PIL), available on the MHRA products website.

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

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