Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Ms [redacted]
[redacted]

MHRA

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11th January 2024

Dear [redacted]

FOI 23/979

Thank you for your FOI request dated 14th December 2023, where you requested the following information:

"I am looking for yellow card reporting data on the 6in1 vaccine? DTaP/Hib/HepB/IPV."

I can confirm that up to and including 03/01/2024, the MHRA have received 690 UK spontaneous suspected adverse reaction reports associated with the DTaP/IPV/Hib/HepB vaccine.

Please find attached Vaccine Analysis Prints (VAP) which contain information on the reported adverse reactions and the number of reports with a fatal outcome. 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. Reporting rates are influenced by the seriousness of the reaction, their ease of recognition, the extent of use and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines, vaccines during the first one to two years on the market and then falls over time.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: https://products.mhra.gov.uk/ for details on the possible side effects of the vaccine.

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