Medicines & Healthcare products
Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]

07/02/2024

Dear [redacted]

FOI 24/049

Thank you for your email dated 16th January 2024 where you requested *data specifically surrounding vaccine related side effects on the following vaccines: 6 in 1 vaccine (diphtheria, hepatitis B, Hib (Haemophilus influenzae type b), polio, tetanus, whooping cough) rotavirus, men B & pneumococcal vaccination*.

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.

I can confirm that up to and including 08/01/2024, the MHRA have received the following number of UK spontaneous suspected adverse reaction reports for each of the requested vaccines:

Vaccine	Total number of UK spontaneous adverse reaction reports
6 in one (DTaP/IPV/Hib/HepB)	690
Rotavirus	1547
Meningitis B	3071
Pneumococcal (PCV) vaccine	3045

Please find attached Vaccine Analysis Prints (VAPs) which contain information on the reported adverse reactions for each vaccine. The attached guidance sheet provides you with further information on how to interpret the print. As these data do not necessarily refer to proven side effects, you should refer to the product information for details on the possible side effects of these vaccines.

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