Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

05/01/2024

Dear [redacted]

RE: FOI 23/947

Thank you for your email dated 5th December 2023 where you requested *"a list of reported adverse events from 2017 to 2023 for the 6:1 vaccine given to babies"*.

I can confirm that between 01/01/2017 and 31/12/2023 the MHRA have received 688 UK spontaneous suspected adverse reaction reports for the 6-in-1 vaccine.

Please find attached a Vaccine Analysis Print (VAP) which contains information on the reported adverse reactions and the corresponding number of reports for the 6-in-1 vaccine. The attached guidance sheet provides you with further information on how to interpret the print.

Please note that based on the routine immunisation schedule, the 6-in-1 vaccine is usually administered to children at 8, 12 and 16 weeks old, however children may still receive this vaccine up to the age of 10. As such, the data provided to you contains all adverse drug reaction reports received for this vaccine and is not limited to just those given to babies.

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 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

If you have a query about the information provided, please reply to this email

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire