FOI 23/202 – Yellow card data for the 6 in 1 childhood vaccinations

MHRA RESPONSE
14 April 2023

Thank you for your recent FOI request from 20th March 2023, where you asked for information on the following:

"Please can you supply the link the Yellow Card data for the 6 in 1 baby vaccination adverse reactions."

As you may already be aware the recognised side effects of medicines and vaccines are described in the product information. This consists of the Summary of Product Characteristics or 'SPC' for healthcare professionals and for patients a Patient Information Leaflet or 'PIL'. There are currently two 6 in 1 childhood vaccination (DTPA HepB HIB IPV vaccine) products available in the UK, Infanrix Hexa and Vaxelis. The product information for these vaccines can be found at:

Infanrix Hexa: https://www.medicines.org.uk/emc/product/2586
Vaxelis: https://www.medicines.org.uk/emc/product/12264

Further to your request, please find attached Vaccine Analysis Prints (VAPs) for the 6 in 1 childhood vaccination (DTPA HepB HIB IPV vaccine). This VAP contains complete data for all UK spontaneous suspected adverse reactions, or side effects, since the start of the Yellow Card Scheme, 01/07/1963 until 20/03/2023. Please refer to the attached information sheet for guidelines on how to interpret these VAPs.

When considering the attached spontaneous ADR data, 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 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. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- Additionally, 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.

I 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,
Vigilance and Risk Management of Medicines Division

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF