Medicines & Healthcare products Regulatory Agency

[redacted]

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13th June 2023

Our Ref: FOI 23/397

Dear [redacted]

Thank you for your email dated 2nd June 2023 where you requested Yellow Card data for routine childhood vaccines. Please find attached a Vaccine Analysis Print (VAP) for the following vaccine substances. The current routine childhood vaccination schedule (as per February 2022), can be found here, https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule

1. Diphtheria, tetanus, pertussis (whooping cough), polio, Haemophilus influenzae type b (Hib) and hepatitis B (DTaP/IPV/Hib/HepB) vaccine
2. Meningitis B (MenB) vaccine
3. Rotavirus vaccine
4. Measles, mumps and rubella (MMR) vaccine
5. Pneumococcal conjugate vaccine (PCV)
6. Hib and Meningococcal group C (MenC) vaccine
7. Diphtheria, tetanus, pertussis and polio (DTAP/ IPV) vaccine
8. Human papillomavirus (HPV) vaccine
9. Tetanus, diphtheria and polio (Td/IPV) vaccine
10. Meningococcal groups A, C, W and Y (MenACWY) vaccine

The Vaccine Analysis Prints (VAPs) contain details of the reported reactions to the above-mentioned vaccines, up to and including 17th April 2023. The attached Drug Analysis Print (DAP) guidance sheet provides you with further information on how to interpret the prints. 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.

When considering the attached spontaneous adverse drug reaction (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 been. 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular vaccine, and may be stimulated by promotion and publicity about a vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

Please be aware that the VAPs provided should not be used as a list of side effects to these vaccines. All established undesirable effects for the vaccines can be found at the Electronic Medicines Compendium (EMC) website. These are listed in section 4.8 of the Summary of Product Characteristics (SmPC) and section 4 of the Patient Information Leaflet (PIL). Please see the following link for your reference: Home - electronic medicines compendium (emc).

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.

I hope the information provided is helpful. 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 Group