FOI 23/135

10th March 2023

Dear

Thank you for your email dated 10th February 2023, where you requested information about.

- Adverse reactions of the child 6 in 1 vaccine and MMR vaccine reported from 2020-2023

Further to your request I can confirm the number of UK spontaneous Yellow Card reports received between 01/01/2020 and 03/03/2023 is 828 reports for the MMR vaccine and 284 reports for the child 6 in 1 vaccine.

Please find attached Vaccine Analysis Prints (VAP) for both vaccines which lists all the adverse reactions that have been reported to the Yellow Card scheme during this time period. Please note, as it is possible for one report to contain multiple ADRs, the number of ADRs is greater than the number of individual cases. Please find attached a DAP guidance sheet which provides you with further information on how to interpret the print.

When considering the 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 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

As the data does not necessarily refer to proven side effects, you should refer to the NHS website for details on the possible side effects of each vaccine here MMR (measles, mumps and rubella) vaccine - NHS (www.nhs.uk) and 6-in-1-vaccine-overview - NHS (www.nhs.uk)

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