FOI 23/290 - reports received on Repevax (pertussis, Polio, diphtheria and tetanus) and on first vaccines administered to new-borns in the first year

MHRA RESPONSE
16 May 2023

Thank you for your email dated 17 April 2023, where you asked for information on the following:

- **Reports you have received on Repevax (pertussis, Polio, diphtheria and tetanus)**
- **Reports you have received on first vaccines that are administered to new-borns in the first year**

Please find attached a Vaccine Analysis Print (VAP) for Repevax (DTaP IPV vaccine), plus a VAP for each of the vaccines given in the first year according to the current routine childhood vaccination schedule (from February 2022). These reports contain a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme up to and including 14 May 2023. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. Please refer to the attached information sheet for guidelines on how to interpret the VAPs.

This information does not represent an overview of the potential side effects associated with the vaccines. A list of the recognised adverse effects of these vaccines can be viewed in the information for healthcare professionals and recipients here.

Conclusions on the safety and risks of the vaccines cannot be made on the data shown in the report alone. When viewing the report, you should remember that:

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the vaccine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse reaction. Sometimes reactions can be part of the condition being treated rather than being caused by the vaccine.
- Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different vaccines by comparing the numbers presented in the vaccine reports. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.

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 assessed, and cumulative information is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

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