Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

30 November 2023

Dear [redacted]

FOI 23/925

Thank you for your email dated 27 November 2023, where you asked for information on the following:

- All Yellow Card adverse reaction reports for the Fluenz Tetra Influenza nasal vaccine used by the NHS for children in the UK.

Please find attached a Product Analysis Print (PAP) for Fluenz Tetra. This report contains a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme up to and including 28 November 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 report.

This information does not represent an overview of the potential side effects associated with this vaccine. A list of the recognised adverse effects of Fluenz Tetra vaccine 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