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

20 December 2023

Dear [redacted]

FOI 23/949

Thank you for your email dated 5 December 2023, where you asked for information on the following:

- I am interested in whether there have been any reports of de novo or exacerbations of nephrotic syndrome in children receiving flu vaccine whether alive or inactivated.

Up to 13 December 2023 the MHRA received 5 adverse drug reaction (ADR) reports of nephrotic syndrome in children, associated with flu vaccines. 4 reports are associated with live flu vaccine and 1 with inactivated flu vaccine.

This information does not represent an overview of the potential side effects associated with these vaccines. A list of the recognised adverse effects of flu 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 these data alone. When considering these data, 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.

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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