Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: **FOI2026/00468**

19 May 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 29 April. You wrote:

> *Please can I have confirmation of the number of recorded reactions/adverse effects raised in connection to the vaccination programme in primary schools within Northern Ireland since the implementation of the flu mist programme.*

MHRA Response

We can confirm that, from the inception of the Yellow Card Scheme up to 30 April 2026, there have been 141 suspected adverse drug reaction (ADR) reports associated with the nasal influenza vaccine used in children in Northern Ireland. These reports include a total of 390 individual reactions. Please note that a single Yellow Card report may contain more than one adverse drug reaction. This information is provided in the attached annex in PDF format.

Please note that reporting of suspected adverse drug reactions via the Yellow Card Scheme is voluntary, and the information provided does not necessarily indicate that the vaccine caused the reported reaction.

The reporter's address is not a mandatory field within Yellow Card reports. The data provided in this response has therefore been derived using postcode and/or reporter country information, where this has been supplied. If a postcode has been entered incorrectly, omitted, or if the reporter has provided an email address in place of a postal address, the report will not have been captured within this dataset.

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 reviewed at regular intervals.

When considering the spontaneous data provided, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the vaccine, medicine, or device only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine, medicine, or device, 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, medicines, or devices. ADR and Device incident reporting rates are influenced by the seriousness of adverse reactions, their ease of recognition, the extent of use of a particular medicine or device, and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

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