Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00644**

7 July 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 12 June. You wrote:

> *Could you advise me where I can find details of reports made to the Yellow Card Scheme regarding side-effects of the Adjuvanted Trivalent Influenza Vaccine, commonly known as TIV, and brand name of Fluad, for 2020, please?*

MHRA Response

We confirm that we hold the information you have requested.

Following a search of our database, with the data lock point of 28/06/2026, we can confirm that the MHRA received a total of 189 UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with Fluad between 01/01/2020 and 31/12/2020.

Please note that this search only included reports where Fluad has been specifically reported as the brand of adjuvanted trivalent influenza vaccine. Brand name information may not always be provided by the reporter; therefore this information may not be representative of all ADR reports received concerning Fluad.

Please find attached a Product Analysis Print (PAP) containing information for all these 189 reports received through the Yellow Card Scheme associated with Fluad in 2020. The attached Drug Analysis Print guidance sheet provides you with further information on how to interpret the print. Please note that many ADR reports contain more than one suspected reaction and the total number of suspected reactions listed on the PAP may be higher than the number of reports received for the product.

Conclusions on the safety and risks of the vaccine cannot be made on the data shown in the PAP. When considering the attached spontaneous data, it is important to be aware of the following points:

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

- The MHRA continuously monitors the safety of medicines and 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 individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

- As spontaneous data do not necessarily refer to proven side effects, you should refer to the product information for the vaccine which can be found here: Fluad | European Medicines Agency (EMA) for details on the possible side effects.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
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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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