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

3rd October 2023

Dear [redacted]

FOI 23/700

Thank you for your email dated 25th September 2023, where you asked:

- Please can you send us a copy of the reports for the side-effects for the flu nasal vaccine 2023

I can confirm that the MHRA has received 3094 UK spontaneous suspected adverse reaction reports associated with the Influenza nasal vaccine Fluenz Tetra up to and including the 2nd October 2023. Please find attached a Vaccine Analysis Print (VAP) which lists all the reactions reported to the MHRA in association with the Fluenz Tetra vaccine. Also attached is a guidance sheet which provides you with further information on how to interpret the print.

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 vaccine, only that the reporter had a suspicion it may have. Each year, millions of doses of routine vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine or medicine, 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.

- 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. 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.

As these data do not necessarily refer to proven side effects, you should refer to the product information leaflet (PIL) and the Summary of Product Characteristics (SPC) which can be found here: https://www.medicines.org.uk/emc/product/3296 for details on the known possible side effects of the Fluenz Tetra vaccine.

The Medicines and Healthcare products Regulatory Agency (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 individually assessed

and cumulative information 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

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
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