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

7th November 2023

Dear [redacted]

FOI 23/779

Thank you for your email dated 14th October 2023, where you requested information for the following:

- A summary of Yellow Card reports for the Flublok Quadrivalent vaccine

As per your request, I can confirm that there have been a total of 177 UK suspected spontaneous Yellow Card adverse drug reaction (ADR) reports for Flublok quadrivalent vaccine received through the Yellow Card scheme, up to and including 27/10/2023.

Unfortunately, we do not currently publish iDAPs for influenza vaccines. The MHRA have begun implementing a new enhanced format of data visualisations. This enables us to provide improvements in format, accessibility and data protection whilst allowing access to more data than has been published previously. The initial phase of this development involved the provision of COVID-19 vaccine data with further plans to include all routine vaccination data and replace existing iDAPs for medicines in 2023.

However, further to your request, we have extracted this data and are pleased to provide it to you in the form of the attached Vaccine Analysis Print (VAP). The attached Drug Analysis Print (DAP) guidance sheet provides you with further information on how to interpret the prints. It is important to note that the total number of reactions in the table will not be equal to the total number of unique reports, as one report may contain more than one reaction.

When considering the spontaneous Adverse Drug Reaction (ADR) data provided within this response, 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 been. 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.

- 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 drug, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines and vaccines during the first one to two years on the market and then falls over time.

Please be aware that the VAP provided should not be used as a list of side effects to Flublok, as many factors have to be taken into account. Established undesirable effects are reflected in section 4 of the Patient Information Leaflet (PIL). Please see the following link for your reference: flublokv1 (windows.net).

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, and 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,
Safety and Surveillance

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
Wilmslow
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SK9 5AF

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