Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

15/05/2023

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

Dear

FOI 23/135

Thank you for your email dated 13th April 2023, where you requested the following information:

> *Is it possible to have information about Yellow Card reports associated with the Shingles vaccine? I specifically would like to know about reports of abnormal liver function tests following Shingles vaccination.*

Further to your request please find attached Vaccine Analysis Print (VAP) for Shingles vaccine, this includes all UK spontaneous reports received up to and including 12.05.2023. As detailed in the report we have received 4 reports of liver function tests abnormal to date.

When considering the 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.

- 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

As the data does not necessarily refer to proven side effects, you should refer to the Patient Information Leaflet for the shingles vaccine: Shingrix powder and suspension for suspension for injection, Herpes zoster vaccine (recombinant, adjuvanted) - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

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
Wilmslow
Cheshire
SK9 5AF