Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA

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Dear

FOI 23/048 –

Freedom of Information request - Vaccine Analysis Print (VAP) for shingles vaccines

Thank you for your email dated 20th January 2023, where you asked for information on the following:

> *Vaccine Analysis Print (VAP) for the following shingles vaccines:*
> *1. Zostavax*
> *2. Shingrix*

As per your request, I would like to kindly direct you to the enclosed Vaccine Analysis Prints (VAPs) for the Zostavax and Shingrix brand of shingles vaccines, where the brand name has been specified by the reporter. The prints contain information on all UK spontaneous suspected Adverse Drug Reaction (ADR) reports received through the Yellow Card scheme up to and including the 20th January 2023. While we encourage reporters to give as much information as possible, it is not mandatory for the brand name to be reported as only the active substance is needed. It is important to note that it is possible for one report to contain multiple ADRs, the number of ADRs is greater than the number of individual cases. Please also find attached a VAP 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.

• 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 or vaccine, and may be stimulated by promotion and publicity.

Furthermore, information regarding a vaccine, including all ingredients within the vaccine, the indication, the mechanism (i.e. way a medicine works), and all the side effects can be found in the product information, which can be accessed on the Electronic Medicines Compendium (eMC) website (http://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
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