



Medicines & Healthcare products
Regulatory Agency



MHRA

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1st March 2021

Dear [REDACTED]

Our Ref: FOI 21/112

Thank you for your email dated 1st February 2021, where you asked for information on:

- Adverse reactions pertaining to the human papillomavirus (HPV) vaccination reported under the yellow card scheme specifically for the area of Sefton, Merseyside, PR8.

The 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. Vaccines encompass a wide variety of products with different indications, different ingredients and different mechanisms of action and as such safety for each vaccine is considered individually rather than as a group.

Please find attached a Drug Analysis Print (DAP) for the HPV vaccines. The print contains information on all the UK spontaneous Adverse Drug Reaction (ADR) reports received through the Yellow Card Scheme up until the 15/02/2021 that mention one or both of Merseyside or Sefton in the address and/or include a postcode beginning PR8. Please note, the reporter's address is not a mandatory field in a Yellow Card form; reporters can submit a Yellow Card without providing this information. Therefore, this result may not be a true reflection of reporting within the Merseyside/Sefton/PR8 area. Please also find attached a DAP 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



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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.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: <https://www.medicines.org.uk/emc/> for details on the possible side effects of each vaccine.

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

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