Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

12th September 2023

Dear [redacted]

FOI 23/619

Thank you for your email dated 15th August 2023 where you enquired about whether the MHRA had received any similar reports concerning the Gardasil vaccine and whether the specific batch numbers received by the patient you reported had resulted in higher levels of Yellow Card reports with similar symptoms.

Please find attached a Vaccine Analysis Print (VAP) for the Gardasil vaccine. The print contains information on all the UK spontaneous Adverse Drug Reaction (ADR) reports received through the Yellow Card scheme up to and including 04/09/23 reporting the Gardasil vaccine. The attached Drug Analysis Print (DAP) guidance sheet 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, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced vaccines during the first one to two years on the market and then falls over time.

Regarding whether the specific batch numbers received by the patient you reported had resulted in higher levels of Yellow Card reports with similar symptoms, we can confirm that no safety concerns have been identified with any of the batches the patient received. Not all batches of the Gardasil vaccine are the same size, and some batches may have had more wastage than other batches or be distributed more widely outside of the UK. Therefore, we would not expect the number of ADR reports for all batches to be the same as they have been administered to different numbers of patients.

Furthermore, different batches would have been used at different stages of the vaccination campaign, and in different patient groups, which could also impact reporting rates. For example, reporting rates were typically higher at the beginning of a vaccination campaign as individuals received their first dose and the likelihood of experiencing a reaction, as well as the propensity to report it, differs across patients.

Please be assured that the MHRA reviews this data regularly and we would communicate any concerns raised with the public and healthcare professionals. If you would like further information on batch usage, please contact the UK Health Security Agency (UKHSA) who hold this information.

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. If appropriate, regulatory action would be taken if any serious risks were confirmed.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: https://products.mhra.gov.uk/ for details on the possible side effects of each vaccine.

We 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
Medicines and Healthcare products Regulatory Agency

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