Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
www.gov.uk/mhra

12th April 2023

Dear [redacted]

FOI 23/191

Thank you for your Freedom of Information (FOI) request dated 16 March 2023, where you requested adverse reaction data on the most recent HPV vaccine, Gardasil 9.

The MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes, including the Yellow Card scheme. This monitoring process involves the collection of information about **suspected** adverse reactions in patients (through 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 is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

For Gardasil 9, the recognised adverse reactions (side effects) are listed in section 4.8 of Summary of Product Characteristics (SPC) and section 4 of Patient Information leaflets (PIL). You can find links to the SPCs and PILs here: https://www.medicines.org.uk/emc/product/7330

A Vaccine Analysis Profile (VAP) for Gardasil 9 is attached, in which you can see all suspected side effects, known as suspected adverse reactions, that are reported to the MHRA up to and including 30th March 2023. Please refer to the attached information sheet for guidelines on how to interpret the VAPs.

When considering the provided spontaneous Adverse Drug Reaction (ADR) data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the drug or vaccine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a drug or vaccine, and are reported via the Yellow Card scheme, does not in itself mean that

they are proven to have been caused by the drug or vaccine. 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 or vaccine and may be stimulated by promotion and publicity about a drug or vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. During assessment, we take into account of the variable levels of reporting as part of our monitoring procedures.

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,
Patient Safety Monitoring

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