Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA

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Mrs K Hunter
request-271409-930d1365@whatdotheyknow.com

25th June 2015

Dear Mrs Hunter,

FOI 15/262

Thank you for your FOI request on the 2nd June where you request Yellow card data in association with the Human Papillomavirus vaccine.

The Yellow Card Scheme allows health professionals and patients to report suspected adverse reactions (ADRs) to vaccines and medicines. It is important to note that a Yellow Card report is not proof of a side effect occurring, but a suspicion by the reporter that the vaccine/medicine may have caused the reported event. The MHRA continually analyses Yellow Card data in order to detect any previously unrecognised adverse reactions or changes in the safety profile of products. As Yellow Card reports do not necessarily related to proven side effects, the data cannot therefore be used to derive a frequency of side effects nor to compare the safety of different vaccines.

Further to your request, I can confirm that the MHRA has received a total of 2617 Yellow Card reports in association with the HPV vaccine that were considered serious (either by the reporter or the nature of the event reported) up to 24/06/2015. Every report is taken seriously and the reports remain under review. The vast majority of suspected side effects reported so far relate to those we would expect with most types of vaccine, and the expected benefits of HPV vaccine far outweigh any known risks. The possible side effects of Cervarix and Gardasil are listed in the SmPC and PIL, which are part of their licence. More than 8 million doses of HPV vaccine have been given in the UK since 2008, with close to 90% of eligible teenagers vaccinated.

Please note that when we acknowledge the receipt of an Adverse Drug Reaction (ADR) report we always ask that any changes or new information be reported to us. Not every Yellow Card report requires follow up, which depends on the information contained in the report. In addition, for reports received indirectly from pharmaceutical companies, follow-up is conducted by the Marketing Authorisation Holder for that product as part of their Pharmacovigilance responsibilities. Therefore, the MHRA determines whether to request further information on a suspected ADR report on a case by case basis.

Of these 2617 reports, 440 reports have been followed up for further information. The Yellow Card Scheme is voluntary and while we follow up reports for missing and updated information such as outcome of reactions, the reporter may or may not respond to our request for additional information.

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You have also asked whether the girls who reported 'Serious Adverse Events' following vaccination are now well. Such information is not always provided in a Yellow Card report. Some reports may contain more than one adverse event. The 2617 reports contain 9251 adverse events, of which 5523 were reported as recovered or recovering. A further 1972 reports did not include an outcome.

The HPV vaccine has a very good safety record, and surveillance shows it has contributed to a significant decrease in rates of infection with the two main cancer-causing human papillomaviruses. The UK programme is expected to eventually prevent hundreds of deaths from cervical cancer every year.

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.

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision.

The Information Commissioner can be contacted at:
Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF
If you have a query about this letter, please contact me.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division