Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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16 April 2019

Dear Hayley,

FOI 19/151

Thank you for your Freedom of Information request dated 25th March 2019 where you requested:

- all information on safety studies /trials of the HPV vaccine (Gardasil)
- all independent information on safety studies/trials of the HPV vaccine (Gardasil)
- statistics of the HPV vaccine efficacy against cervical cancer cases and deaths.
- safety studies/ tests on Amorphous Aluminium Hydroxyphosphate Sulfate [AAHS] in the use of vaccines.
- information on the total of HPV adverse reactions reported from vaccines to date (25-03-19). Can this be categorised from mild to severe and death.

The MHRA does not hold information on the safety studies/trials and efficacy studies for Gardasil vaccine. Gardasil was authorised for use in the European Union under the centralised procedure and was approved by the European Medicines Agency. Further information regarding the authorisation details can be found on the EMA website. https://www.ema.europa.eu/en/medicines/human/EPAR/gardasil. You may wish to contact the EMA directly to request any data they hold.

The MHRA does not hold specific safety study/test data on aluminium in vaccines. When vaccines are authorised for the use, the safety of the product as a whole, including any ingredients such as aluminium adjuvants, are evaluated for safety. More information on the safety of aluminium in vaccines can be found via the following link for the World Health Organisation's Global Advisory Committee on Vaccine Safety (GACVS): https://www.who.int/vaccine_safety/committee/topics/adjuvants/en/

Further to your request, for adverse reaction data received by the UK I have enclosed the Drug Analysis Print (DAP) for Human Papillomavirus (HPV). The DAP lists all UK spontaneously reported adverse reactions (ADRs) on the MHRA database associated with HPV vaccines up to and including 25th March 2019.

Please refer to table 1 below for a breakdown of the total number of reports received in report categories non-serious, serious and fatal. Please note: the fatal reports fall within the serious category and are not additional to the stated total.

Table 1. UK spontaneous ADR reports for HPV vaccines received up to and including 25/03/2019

Report Category	Number of Reports
Non-serious	5972
Serious	3396
Fatal	9
Total	9368

*Data Extraction date: 02/04/2019

When considering the number of serious reports stated above it is important to note, the seriousness criteria for ADR reporting are defined as 6 possible categories which are documented on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant. In addition to this, reaction terms are also defined as serious or non-serious in the Medical Dictionary for regulatory Activities (MedDRA) which we use to code ADRs in our database. Therefore, an ADR report can be serious because the reporter considers the reaction to be serious or because the reaction term itself is considered serious in MedDRA.

When assessing the data within this response, it is important to note that the inclusion of a report on our database does not necessarily mean that the events described were caused by the vaccination, only that the reporter had a suspicion it may have, or it had a close temporal relationship to the administration of the vaccine. More than 10 million doses of HPV vaccine have been administered in the UK since 2008, and when any vaccine is administered to very large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine, and are reported via the Yellow Card Scheme, does not in itself mean that they are proven to have been caused by the vaccine. Underlying or concurrent illnesses may be responsible and such events can also be coincidental. Ongoing safety reviews by EU and international regulatory and health authorities, as well as numerous published epidemiological studies from independent academics, have found no evidence of chronic illness or serious harms from HPV vaccines.

Furthermore, the number of reports received should not be used as a basis for determining incidence of a reaction as neither the total number of reactions occurring, nor the number of patients receiving the vaccination is known. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular vaccination, and may be stimulated by promotion and publicity about a vaccination.

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,

Medicines & Healthcare products Regulatory Agency

MHRA
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Vigilance and Risk Management of Medicines Division

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