Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Mr Steve Hinks
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MHRA

151 Buckingham Palace Road
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www.gov.uk/mhra

30th August 2017

Dear Mr Hinks,

FOI 17/332

Thank you for your email dated 1st August 2017, where you requested a Drug Analysis Print (DAP) for Gardasil (quadrivalent) vaccine, the 3-in-1 teenage vaccine (tetanus, diphtheria and polio (Td/IPV) vaccine) and the MMR (measles, mumps and rubella) vaccine for the period from September 2012 until present time.

Further to this request, I am pleased to provide you with the DAP for the MMR vaccine and Td/IPV vaccine and a Product Analysis Print (PAP) for Gardasil (brand of quadrivalent Human Papilloma Virus vaccine). Please note that the PAP for Gardasil only includes cases where this brand is specified by the reporter and is for cases concerning the quadrivalent vaccine only and not Gardasil 9. Furthermore, I would also like to highlight that, though the Td/IPV vaccine is given to 14 year olds as part of the current routine immunisation schedule, it is indicated for active immunisation against diphtheria, tetanus and poliomyelitis in children from six years of age, adolescents and adults as a booster following primary vaccination therefore its use is not limited to teenagers. These DAPs list all spontaneously reported UK suspected reactions and displays the total number of reports that we have received for each of the vaccines from 01/09/2012 up to, and including, 07/08/2017. Please refer to the information sheet for guidelines on how to interpret the DAP.

It is important to note that the inclusion of a reported reaction in the print 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 vaccines are given in the UK alone, 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. We keep all reports of suspected side effects under continual review to ensure that any new risks are quickly identified.

For these reasons, it is very important that the information on the printout is not interpreted as a list of possible side effects, nor should these data to be used to estimate the frequency of side effects or to compare the safety profile of different vaccines. For a list of the known, possible side effects and the frequency please refer to the Patient Information Leaflet (PIL) or the Summary of medicinal Products

Characteristics (SmPC) for healthcare professionals. These documents can be accessed on the Electronic Medicines Compendium (eMC) website (http://emc.medicines.org.uk).

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

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