Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Karen Brunsden
Sent via email: request-301586-b759777e@whatdotheyknow.com

MHRA

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www.gov.uk/mhra

2nd December 2015

Dear Ms Brunsden

FOI 15/568

Thank you for your email dated 10th November 2015, where you requested:

A report listing all serious adverse events for the Diphtheria, Tetanus and Polio vaccination booster given to those aged between 13 and 18 from 2000 to 2007… listing the year, reaction and reaction outcome.

Between 2000 and 2007, the MHRA received 115 serious UK spontaneous suspected Adverse Drug Reaction (ADR) reports in association with the Diphtheria, Tetanus and Polio (DT IPV) vaccination in patients aged between 13 and 18. Please see the table attached for a breakdown of the data as requested.

Please note that the DT IPV vaccination was only introduced in 2004, hence there were no ADR reports received between 2000 and 2003.

A suspected ADR report is considered 'serious' according to two criteria; firstly whether the original reporter considers the report to be serious. The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. We ask reporters to select one of the following criteria by ticking the appropriate box 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, seriousness of reaction terms has also been defined by the MHRA in our medical dictionary. 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 our medical dictionary.

It is important to note that the inclusion of a particular reported reaction in the data provided does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. We encourage such reporting to ensure we can continually appraise the safety of vaccines and medicines. As most vaccines are administered to very large numbers of people every

year, 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. For these reasons, it is very important that the data provided is not interpreted as a list of possible side effects, nor should these data be used to estimate the frequency of side effects or to compare the safety profile of different vaccines.

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

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division