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R.E. FOI 15/184

14th May 2015

Dear Ms Ratajova,

Thank you for your FOI request on the 15th April where you requested Adverse Drug Reaction (ADR) reports in association with a vaccine from the 1st January 2005, including the total number of serious and non-serious ADR reports and the total number of ADR reports in children under the age of 10, between 11 and 18, and in adults aged 19 or over.

As you may already be aware, the Yellow Card Scheme is the UK system for collecting and monitoring information on suspected ADRs in association with medicines and vaccines. The Scheme is run by the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the Commission on Human Medicines (CHM), and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. There is also a legal obligation for pharmaceutical companies to report serious side effects for their products. Spontaneous adverse reaction reporting is the commonest source for identification of drug safety signals, and often provides an early warning of possible hazards.

Further to your request, please may I refer you to table 1 below which summarizes the total number of UK spontaneous suspected ADR reports received by the MHRA in association with a vaccine between 1st January 2005 and 22nd April 2015 including the total number of serious and non-serious reports. The data provided relates to vaccines contained within the routine immunization schedule, a copy of this can be found via the following link: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/315489/PHE-Routine-childhood-imm-July-2014-03.pdf

Table 1: Total number of UK spontaneous suspected ADR reports in association with a vaccine between 1st January 2005 and 22nd April 2015 including serious and non-serious reports

Vaccine 01/01/2005 - 22/04/2015	Total number of ADR reports	Total number of serious reports	Total number of non-serious reports
Diphtheria,tetanus, pertussis, polio and *Haemophilus influenza* type b (DTaP/IPV/Hib)	1309	683	626
Tetanus, diphtheria and polio (Td/IPV)	1076	637	439
Diphtheria,tetanus, pertussis and polio (DTaP/IPV)	1190	469	721

Rotavirus (Rotarix)	412	261	151
Pneumococcal disease (PCV)	1560	840	720
Meningococcal group C disease (Men C)	769	459	310
Hib/Men C	279	150	129
Measles, mumps and rubella (MMR)	1594	1113	481
Pneumococcal disease (PPV)	963	635	328
Fluenz Tetra	872	379	493
Shingles (Zostavax)	626	394	232
Human Papilloma Virus (HPV)	8228	2587	5641
Influenza virus	2944	2380	564

I can confirm that the MHRA has received a total of 21,822 UK spontaneous suspected ADR reports between the 1st January 2005 and 22nd April 2015 in association with the vaccines in the routine immunization schedule, 10,987 of these were serious reports and 10,835 were non-serious. Please be aware that one ADR report may contain more than one vaccine as some vaccinations within the schedule are administered within the same time period. Please also be aware that during this time period many millions of doses of these vaccines have been administered in the UK.

A suspected ADR report is considered 'serious' according to two criteria; firstly whether the original reporter considers the report to be serious. A single case may be deemed serious due to a number of reasons. 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 each ADR has been assigned either serious or non-serious using our medical dictionary (MedDRA), this criteria is specific to the reaction term and not influenced by the individual situation, outcome or severity of the reaction. 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. In cases where the reporter has not indicated the seriousness of the reaction, we will assess the case and select the medically significant criteria if for example the report contains one or more serious ADRs term.

Further to your enquiry, please may I refer you to table 2 which shows the breakdown of total number of ADR reports into the age groups requested in your enquiry. Please note that age is not a mandatory field on a Yellow Card and therefore may not always be reported; only reports where the age of the patient has been stated by the reporter are included in the table below.

Table 2: Total number of ADR reports in association with vaccines between 1st January 2005 and 22nd April 2015 in children under the age of 10, between 11 and 18 and in adults 19 or over

Vaccine 01/01/2005 - 22/04/2015	Total number of reports in children under the age of 10	Total number of reports in children between the age of 11 and 18	Total number of reports in adults 19+
Diphtheria,tetanus, pertussis, polio and *Haemophilus influenza* type b (DtaP/IPV/Hib)	1199	3	1
Tetanus, diphtheria and polio (Td/IPV)	22	703	267
Diphtheria,tetanus, pertussis and polio (DtaP/IPV)	1046	11	86

Rotavirus (Rotarix)	385	0	6
Pneumococcal disease (PCV)	1459	8	14
Meningococcal group C disease (Men C)	503	182	84
Hib/Men C	262	2	4
Measles, mumps and rubella (MMR)	1013	163	306
Pneumococcal disease (PPV)	87	31	794
Fluenz Tetra	665	148	7
Shingles (Zostavax)	0	0	626
Human Papilloma Virus (HPV)	18	7793	83
Influenza virus	169	61	2478

I can confirm that the MHRA has received a total of 6,828 UK spontaneous suspected ADR reports between 1st January 2005 and 22nd April 2015 for children under the age of 10, 9,105 reports for children between the age of 11 and 18, and 4,756 reports for adults 19 or over in association with vaccines in the immunization schedule.

It is important to note that a Yellow Card report is not proof of a side effect occurring, but merely a suspicion by the reporter that the vaccine may have caused the side effect. Yellow Card reports may therefore relate to true side effects of the vaccine, or they may be due to coincidental, underlying medical conditions that would have occurred anyway in the absence of vaccination.

Furthermore the number of reports received via the Yellow Card Scheme does not directly equate to the number of people who suffer adverse reactions to drugs for a number of reasons, as this scheme is associated with an unknown and variable level of under-reporting. ADR reporting rates may be influenced by the seriousness of reactions, their ease of recognition, extent of use of a particular drug and promotion and publicity about a drug.

Please be assured that as with all medicines and vaccines, the MHRA is closely monitoring the safety of all vaccines in the UK. Should any important safety issues be identified, appropriate regulatory action would be taken and communicated to healthcare professionals and patients alike.

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 receipt of the response to your original letter.

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