Abstract

Analysis of spontaneous adverse events reports of Infanrix hexa vaccine

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Introduction: Infanrix hexa vaccine is used for vaccination of infants and toddlers against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and disease caused by *Haemophilus influenzae* type b. Analysis of spontaneous adverse drug reactions (ADRs) reports is one of the most important sources of information to evaluate drug-related risks.

Objective: The aim of this study was to analyse spontaneous ADRs reports of Infanrix hexa vaccine, which were sent to the State Institute for Drug Control (SÚKL) database in the period from 2004 to 2017.

Methods: The data was analysed using descriptive statistic in MS Excel. ADRs were classified according to the MedDRA. Seriousness and expectedness of ADRs were evaluated.

Results: Overall 1288 reports were obtained containing 4334 ADRs, approximately 3.4 ADRs per report. Infanrix hexa vaccine was the only suspected drug in most of the reports (75.9%). Physicians were the most frequent reporters (70.2%). Serious ADRs were found in 84.3% of reports. The most frequent ADRs were general disorders and administration site conditions (31.4%), nervous system disorders (18.3%), and psychiatric disorders (16.5%). There were 1683 (38.8%) unexpected ADRs, of which the most frequent were impaired psychomotor development, insomnia, apathy. Most of the ADRs resolved (70.0%). One case was fatal.

Conclusion: Analysis of spontaneous ADRs reports of Infanrix hexa vaccine presented the overall number of reports, ways of reporting, seriousness of ADRs, the most frequently reported ADRs and revealed some possibly unexpected ADRs.