

ABSTRACT

Analysis of Spontaneous Adverse Events Reports of Measles, Mumps, and Rubella Vaccine

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Introduction: The MMR vaccine is a combined vaccine used to vaccinate children against measles, mumps and rubella. Spontaneous reporting of adverse reactions is an important source of information to identify potential risks of medicinal products.

Objective: The aim of this diploma thesis is the analytical evaluation of spontaneous reports of suspected adverse reactions after vaccination with MMR vaccine registered in the database of the State Institute for Drug Control during the period 2004 to 2017.

Methods: The data were analyzed in Microsoft Excel spreadsheet software using descriptive statistics methods. The reported adverse reactions were classified into appropriate organ system classes according to the MedDRA Glossary of Medical Terminology. The expectability and severity of adverse reactions were assessed.

Results: A total of 805 cases of suspected adverse reactions were reported between 2004 and 2007, which included 2,812 adverse reactions. Most suspected adverse reactions were associated with Priorix. The majority (70%) of the reported reports came from physicians. The majority of reports (92%) were suspected of having a serious adverse reaction. The highest number of reported reactions came from the Application Site and General Disorders (22%), Subcutaneous Tissue and Skin Disorders (17%) and Psychiatric Disorders (13%) classes. In 37% of the reported reports, the side effects disappeared. For one patient, the side effects were fatal.

Conclusion: Analytical evaluation of spontaneous reports of suspected adverse reactions following MMR vaccination has largely informed us of the number of reported reactions

related to this vaccine, their severity, and especially the occurrence of unexpected adverse reactions.

