

11. Adverse Vaccine Reactions Reported in Italy After the Introduction of New Reporting Modalities

C. Santuccio, L. Sottosanti, Cinzia Cupani, L. Tartaglia, M. Venegoni

Italian Medicines Agency, Pharmacovigilance Office, Italy

Background: In Italy it is mandatory to report every suspected adverse reaction to vaccines, including listed and not serious ones. Until 2003 these reports had to send at Pharmacovigilance and at Prevention General Direction of Ministry of Health by two different ADRs forms with confusion among reporters. From the 2003 a new unique reporting form and a unique transmission were established to national pharmacovigilance network, whilst the Prevention General Direction has access to loaded data. The new provisions together with an extraordinary immunisation campaign against measles and congenital rubella, has considerably increased the attention on spontaneous reporting.

Objective: To describe Italian experience in vaccine ADRs spontaneous reporting after the introduction of the new reporting modalities.

Methods: Suspected ADRs reports are sent to local pharmacovigilance responsible, that after checking reports quality, coded information and input data in pharmacovigilance national network. ADRs are coded with MedDRA.

The suspected ADRs to vaccines, present in national PV network with onset date since 1 January 2003 to 26 May 2006, have been analysed.

Results: Vaccine ADRs spontaneous reports have notably increased during 2004 in quantity and in quality; during 2003 such reports were 918 without a defined seriousness in about 50%; in 2004 and 2005 reports were respectively 1986 and 1776 and 2005 the percentage of reports without defined seriousness was about 5.3%.

Conclusion: Spontaneous reporting is an important source of information on drug safety, but need to be always stimulated and facilitate. Our experience shows the increase of quantity and quality reports, after sensitisation action due to new provisions and the extraordinary immunisation campaign against measles and congenital rubella. Anyway, the experience shows also that when the tone of used means is not more considered a novelty, the acquired attitude seems to disperse and the number of report begins to decrease again.

It is important to keep a constant action of information and training of health-care professionals about the spontaneous reporting as instrument able to identify signals that can not be discovered with other means. An example is the experience with Morupar: this vaccine has been recalled by Italian authority after several reports of serious allergic reactions. Without the spontaneous reporting, no other modality could show these cases.