MANDATORY VACCINATION IN SICILY: ADVERSE EVENTS IN CHILDREN BEFORE AND AFTER THE LAW 119/2017

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Introduction: The decrease of vaccination coverages, particularly in children, in the last years has been largely confirmed. For this reason, the National Plan for Vaccine Prevention (NPVP) 2017-2019approved in Italy, was followed by the extensively discussed Law 119/2017. In addition to already mandatory vaccinations against diphtheria, tetanus, hepatitis B and poliomyelitis, those against measles, mumps, rubella (MMR), varicella, pertussis and Haemophilus influenzae type b (Hib) were added to the list, for children aged 0-16.

Materials and methods: We analyzed all suspected adverse events following immunization (AEFIs) reports, sent to Sicilian Regional Pharmacovigilance Centre from August 2016to July 2018. In particular, we evaluated the reported AEFIs related to mandatory vaccines, 12months before the approval of the Law 119/2017(August 2016to July 2017) and 12months after (August 2017to July 2018). Additionally, during the same period, we carried out a retroprospective observational analysis of AEFIs that led children (age 0-16) to the Pediatric Emergency Department (ED) of Azienda Ospedaliera Universitaria (AOU) "G. Martino" of Messina. We included in the study only AEFI with a probable or possible causality assessment, according to the World Health Organization criteria

Results: Throughout the study period, 598reports covering AEFIs, related to mandatory vaccines were sent to the Sicilian Pharmacovigilance Regional Centre of them 61.9% during the first period and 38.1% after the approval of Law. This result has been confirmed by data reported in the Vaccine Report 2017edited by AIFA (Italian Medicines Agency), in which ADR reporting rate for mandatory vaccines in Sicily was higher (40.5%) than the Italian rate (34.3%) during 2017. In particular, diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b (Hib) vaccine was the most representative ones before the approval of the Law, due to the presence of active pharmacovigilance projects. On the other hand, regarding the obligatory measles, mumps, rubella, and varicella vaccine, a considerable increase in AEFIs reporting (26vs 53) was observed after the adoption of Law 119/2017. Moreover, we wanted to compare the results obtained in a single center study, during the same period. 12reports, covering 19AEFIs, were described in AOU of Messina. Among them, 8AEFIs' reports were related to mandatory vaccines, and we did not see any difference before and after the adoption of the Law. The median (Q1-Q3) age was 27.8(3.5–41.2) months with a slight predominance in females. The most commonly suspected vaccines were diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, and H. influenzae B vaccine (n=6), diphtheria, tetanus, pertussis, and inactivated poliomyelitis vaccine (n=1) and measles, mumps, rubella, and varicella vaccine (n=1). Six reports were serious and led to hospitalization, complete recovery occurred in all cases. According to MedDra (Medical Dictionary for Regulatory Activities) reported adverse reactions were: dermatological manifestations (4cases), neurological disorders (3cases) and various symptoms affecting different organs or systems (4cases). Furthermore, the adoption of the new Law increased also, the administered number of all mandatory and recommended vaccines (79,045vs 96,700) in the area of Messina, as reported by the local health authority (ASP Messina).

Discussion and conclusions: To prevent the reappearance of diseases that have been eradicated, it's necessary to have high vaccination rate, mainly for vulnerable population, as children, and immunosuppressed subjects. In this context, a key role is played by the active pharmacovigilance system, through the continuous monitoring of vaccines in order to obtain an uniform and optimal vaccination coverage.