



AIFA publishes the 2019 Vaccine Report

In 2019, out of a total of 23 million doses administered in Italy for all types of vaccines, only 22 reports of adverse reactions were found per 100,000 doses, corresponding to approximately 11.2 reports per 100,000 inhabitants, basically in line with the rate observed in 2017 and 2018.

Such data are shown in the 2019 Vaccine Report, published by AIFA on its institutional portal, which describes the vaccine surveillance activities performed in Italy by the Italian Medicines Agency in collaboration with the National Institute of Health (Istituto Superiore di Sanità) and with the Working Group on analysis of vaccine signals. This includes monitoring and evaluating reports of suspected adverse reactions to vaccines, both spontaneous (passive pharmacovigilance) and prompted by independent studies (active pharmacovigilance).

"Post-marketing monitoring of vaccine safety is of the utmost importance not only to continuously evaluate the risk/benefit profile of vaccines and to plan vaccine campaigns for the prevention of infectious diseases, but also to provide transparent and updated information on their safety and on the surveillance activities carried out at a national and global level", DG Nicola Magrini underlined.

Again this year it was possible to calculate the reporting rates (ratio between reports and exposure data), by using data relating to the number of vaccine doses administered in 2019, provided by the Directorate General for Health Prevention of the Ministry of Health in cooperation with the Regions.

From the analysis of national data, no information was brought into light that could change the risk/benefit ratio for the various types of vaccines currently used, thus confirming their safety, consistently with what has been observed also at the European level. The rate of reports which may be deemed serious and correlated to vaccination is 2.9 cases per 100,000 doses, mainly

corresponding to already known events (hyperpyrexia, allergic reactions, etc.). In fact, all suspected adverse reactions observed in 2019 are known and therefore already reported in the product information of the vaccines authorized in Italy.

In addition to the in-depth analysis of suspected adverse reactions for each type of vaccine, as every year, the Report particularly focuses on anti-flu vaccines and in this edition provides insights concerning the 2019/2020 flu season in Italy, the vaccinations in adults and the impact of COVID-19 on routine vaccinations.