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AGENZIA ITALIANA DEL FARMACO

Eleventh AIFA Report on the surveillance of anti-COVID-19 vaccines

The Italian Medicines Agency has published the eleventh Pharmacovigilance Report on anti-COVID-19 vaccines. The data collected and analysed concern the reports of suspected adverse reactions registered in the National Pharmacovigilance Network between 27 December 2020 and 26 March 2022 for the five vaccines in use in the current vaccination campaign.

In the period considered, **134,361 reports** were received out of a total of **135,849,988 doses** administered (reporting rate of **99 per 100,000 doses**), of which **82.1% referred to non-serious events**, such as pain at the injection site, fever, asthenia/fatigue, muscle pain.

Reporting rates for the 2nd dose are lower than for the 1st and even lower for the 3rd dose. The population exposed to the 4th dose is still limited.

Serious reports correspond to 17.8% of the total, with a rate of 18 serious events per 100,000 doses administered. As reported in previous Reports, regardless of the vaccine, dose and type of event, the reaction occurred in most cases (about 72%) on the same day as vaccination or the next day and only more rarely beyond 48 hours.

Comirnaty is currently the most used vaccine in the Italian vaccination campaign (65.2%), followed by Spikevax (24.7%), Vaxzevria (9.0%), COVID-19 Vaccine Janssen (1.1%) and Nuvaxovid (0.02%), in use since 28 February 2022. The distribution of reports by type of vaccine follows that highlighted in previous Reports: Comirnaty 66.5%, Vaxzevria 17.7%, Spikevax 14.5%, COVID-19 vaccine Janssen 1.3%, Nuvaxovid 0.03%.

For all vaccines, the most reported adverse events are fever, fatigue, headache, muscle/joint pain, chills, gastrointestinal upset, vegetative reactions, fatigue, local reaction or pain at the injection site.

In the age group 5-11 years, as of 26/03/2022 a total of 439 reports (about 0.3% of total reports) were entered for the Comirnaty vaccine, the only one currently used in this age group, with a rate reporting of about 21 cases per 100,000 doses. The most frequently reported adverse events were injection site pain, headache, fever and fatigue. Almost all of these reports are attributed to the first dose.

The Report is available on the AIFA website at the page:
https://www.aifa.gov.it/farmacovigilanza-vaccini-covid-19