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AGENZIA ITALIANA DEL FARMACO

Seventh AIFA Report on the surveillance of COVID-19 vaccines

The Italian Medicines Agency has published the seventh Pharmacovigilance Report on 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 July 2021 for the four vaccines in use in the current vaccination campaign.

In the period considered, **84,322 reports** were received out of a total of **65,926,591 doses** administered (reporting rate of **128 per 100,000 doses**), of which **87.1% referred to non-serious events**, such as pain at the injection site, fever, asthenia/fatigue, muscle aches.

Serious reports correspond to 12.8% of the total, with a rate of 16 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 80%) on the same day of vaccination or the next day and only more rarely beyond 48 hours after vaccination.

Most of the reports are related to the Comirnaty vaccine (68%), so far the most used in the vaccination campaign (71% of the doses administered) and only to a lesser extent to the Vaxzevria vaccine (25% of the reports and 17% of the doses administered), Spikevax vaccine (6% of reports and 10% of administered doses) and COVID-19 Janssen vaccine (1% of reports and 2% of administered doses).

For all vaccines, the most reported adverse events are fever, fatigue, headache, muscle/joint pain, injection site pain, chills and nausea. The most frequently reported vaccination-related serious adverse events are a flu-like syndrome with severe symptoms, more frequent after the second dose of mRNA vaccines and after the first dose of Vaxzevria.

In relation to the **so-called heterologous vaccinations** to people under 60 who had received Vaxzevria as the first dose, **114 reports** were received, out of a total of 396,952 administrations (the second dose concerned Comirnaty in 82.6% of cases and in 17,4% Spikevax), with a reporting rate of **29 for every 100,000 doses administered**.

In the **age group between 12 and 19 years**, as of 26/07/2021, **530 reports** of suspected adverse events were received out of a total of 1,986,221 doses administered, with a reporting rate of **27 adverse events per 100,000 doses administered**. The distribution by type of adverse events is not substantially different from that observed for all other age groups.

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