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AGENZIA ITALIANA DEL FARMACO

Ninth AIFA Report on the surveillance of COVID-19 vaccines

The Italian Medicines Agency has published its ninth 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 September 2021 for the four vaccines used in the current vaccination campaign.

In the period considered, **101,110 reports** were received out of a total of **84,010,605 administered doses** (reporting rate of **120 in every 100,000 doses**), of which **85.4% referred to non-serious events**, such as injection site pain, fever, asthenia/fatigue, muscle pain.

Serious reports account for 14.4% of the total, with a reporting rate of 17 serious events in every 100,000 administered doses. As previously indicated, regardless of vaccine, dose and type of event, most reactions (about 76%) occurred on the day of vaccination or on the following day, and more rarely beyond the 48 hours following vaccination.

Comirnaty is currently the most widely used vaccine in the Italian vaccination campaign (71.2%), followed by Vaxzevria (14.5%), Spikevax (12.5%) and COVID-19 Vaccine Janssen (1.8%). In line with the previous publications, the distribution of reporting by type of vaccine is similar to the distribution of administered doses (Comirnaty 68%, Vaxzevria 22%, Spikevax 9% and COVID-19 Vaccine Janssen 1%).

For all vaccines, the most reported adverse events are fever, fatigue, headache, muscle/joint pain, injection site pain or local reaction, chills and nausea.

In relation to the **so-called heterologous vaccination** for people under 60 who had received Vaxzevria as first dose, **262 reports** were received out of a total of 644,428 administered doses (the second dose was Comirnaty in 76% of cases and Spikevax in 24% of cases), with a reporting rate of **40 in every 100,000 administered doses**.

As at 26 September 2021, in the **12-19 age group**, **1,358 reports** of suspected adverse event had been received out of **5,623,932 administered doses**, with a reporting rate of **24 adverse events in every 100,000 administered doses.** The distribution by type of adverse event is not substantially different from that observed in any other age group.

With regard to the administration of the third dose, which began in September, only **one report** was received, compared to approximately **46,000 administered doses**.

Considering the stability of the reporting trend for the various COVID-19 vaccines, the **Surveillance Report will no longer be published monthly but quarterly**. The update of the interactive graphs will continue to be available monthly on the AIFA website.

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