Press release no. 661 10 September 2021

AGENZIA ITALIANA DEL FARMACO

Eighth AIFA Report on the surveillance of COVID-19 vaccines

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

In the period considered, **91,360 reports** were received out of a total of **76,509,846** administered **doses** (reporting rate of **119 in every 100,000 doses**), of which **86.1% referred to non-serious events**, such as injection site pain, fever, asthenia/fatigue, muscle pain.

Serious reports account for 13.8% of the total, with a reporting rate of 13 serious events in every 100,000 administered doses. As previously indicated, regardless of vaccine, dose and type of event, most reactions (about 80%) 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%), followed by Vaxzevria (16%), Spikevax (11%) and COVID-19 Vaccine Janssen (2%). In line with the previous publications, the distribution of reporting by type of vaccine is similar to the distribution of administered doses (Comirnaty 67%, Vaxzevria 24%, Spikevax 8% 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, **248 reports** were received out of a total of 604,865 administered doses (the second dose was Comirnaty in 76% of cases and Spikevax in 24% of cases), with a reporting rate of **41 in every 100,000 administered doses**.

As at 26 August 2021, in the **12-19 age group**, **838 reports** of suspected adverse had been received out of a total of 3,798,938 administered doses, with a reporting rate of **22 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.

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