Press release no. 649 10 June 2021

AGENZIA ITALIANA DEL FARMACO

Fifth AIFA report on surveillance of COVID-19 vaccines

The Italian Medicines Agency has published the fifth 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 May 2021 relating to the four vaccines used in the current vaccination campaign.

In the period considered, **66,258 reports** were submitted out of a total of **32,429,611 administered doses** (reporting rate of 204 per 100,000 doses), of which around **90% refer to non-serious events**, such as pain at injection site, fever, asthenia/fatigue, muscle aches. As previously reported, the events mostly occur on the same day as vaccination or on the following day (83% of cases).

Serious reports are 10.4% of the total, with a rate of 21 serious events per 100,000 administered doses, regardless of the type of vaccine, the dose (first or second) and the possible causal role of the vaccination.

Most reports are related to the Comirnaty vaccine (71.8%), which so far has been the most widely used in the vaccination campaign (68.7% of administered doses), and only to a lesser extent to the Vaxzevria vaccine (24% of reports and 20.8% of administered doses), to the Moderna vaccine (3.9% of reports and 9% of administered doses) and to the COVID-19 Janssen vaccine (0.3% of reports and 1.5% 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 refer to an influenza-like syndrome with severe symptoms, more frequent after the second dose of mRNA vaccines and after the first dose of Vaxzevria.

The reporting rate of cerebral venous sinus thrombosis in subjects vaccinated with Vaxzevria is in line with the European reports (1 case per 100,000 first doses administered, no cases after the second dose), mainly occurring in people under 60 years of age.

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