Comunicato n. 643 15 aprile 2021

Third AIFA Report on COVID-19 Vaccine Surveillance

The Italian Medicines Agency has published the third COVID-19 Vaccine Surveillance Report. The data collected and analysed concern reports of suspected adverse reactions registered in the National Pharmacovigilance Network between 27 December 2020 and 26 March 2021 for vaccines used in the current vaccination campaign.

Over the period considered, **46.237 reports** were received out of a total of **9.068.349 administered doses** (report rate of 510 per 100,000 doses), of which **92.7% related to non-serious events**, which resolve completely, such as injection site pain, fever, asthenia/fatigue, muscle pain.

Serious reports correspond to 7.1 % of the total, with a rate of 36 serious events per 100,000 administered doses, regardless of the type of vaccine, dose (first or second) and possible causal role of vaccination.

The majority of reports are related to the Comirnaty vaccine (81%), so far the most used in the vaccination campaign (77% of the doses administered), with an increase in reports for Vaxzevria vaccine (17%) as a result of increased use of this vaccine (18% of the administered doses). On the other hand, reports for the Moderna vaccine represent 2 % of the total and are proportional to the most limited number of doses administered (5 %).

The reported events occurred predominantly on the day of vaccination or on the following day (87% of cases). For all vaccines, the most reported adverse events were fever, headache, muscle/joint pain, injection site pain, chills and nausea, in line with known information on vaccines so far used in Italy.

A focus is devoted to thromboembolic events after administration of Vaxzevria. Very rare cases of blod clots associated with low blood platelet levels occurred within 2 weeks of vaccination. Out of a total of 62 cases reported in Eudravigilance in Italy, 7 cases (with two deaths) of cerebral sinus venous thrombosis (CSVT) were reported until 22 March 2021 and 4 cases (with two deaths) of blood clots in multiple blood vessels were reported out of the 24 inserted in the same period in the European surveillance network.The analysis at national level of these reports is conducted with the support of a “Working Group for the evaluation of thrombotic risks from Covid-19 vaccines”, consisting of top national experts in thrombosis and haemostasis. Unknown adverse events are continuously being investigated at national and european level.

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