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Fourth AIFA Report on COVID-19 Vaccine Surveillance

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

Over the period considered, **56.110 reports** were received out of a total of **18.148.394 administered doses** (report rate of 309 per 100,000 doses), of which **91% related to non-serious events**, which resolve completely, such as injection site pain, fever, asthenia/fatigue, muscle pain. As highlighted in the previous Reports, the reported events occurred predominantly on the day of vaccination or on the following day (85% of cases).

Serious reports correspond to 8.6 % of the total, with a rate of 27 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 (75 %), so far the most used in the vaccination campaign (70.9 % of the doses administered), and to a lesser extent to Vaxzevria (22 %) and Moderna (3%) vaccines, while there are no reports related to the Janssen Covid-19 vaccine (0.1% of administered doses) in the period considered.

The assessment of Italian cases of cerebral venous and atypical thrombosis in subjects vaccinated with Vaxzevria is in line with the conclusions of the European Medicines Agency procedure. In Italy, until 26 April 2021, 29 reports of cerebral venous thrombosis and 5 cases of venous thrombosis of atypical location were included in the National Pharmacovigilance Network. Most of these events (22 cases, 65 %) affected women with an average age of about 48 years and affected men only in 1/3 of the cases (12 cases, 35 %) with an average age of about 52 years. The mean time to onset was approximately 8 days after administration of the 1st dose of Vaxzevria vaccine. 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.

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