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AGENZIA ITALIANA DEL FARMACO

Thirteenth AIFA Report on the surveillance of anti-COVID-19 vaccines

The Italian Medicines Agency has published the thirteenth Pharmacovigilance Report on anti-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 2022 for the four vaccines used in the current vaccination campaign.

In the period considered, **139,548 reports** were received out of a total of **140,689,690 doses** administered (reporting rate of **99 per 100,000 doses**), of which **81.5% referred to non-serious events**, such as pain at the injection site, fever, asthenia/fatigue, muscle pain.

In the third quarter of 2022, the reporting rates for the 1st dose remain higher than subsequent doses and are significantly lower after the 4th dose (2nd booster dose).

Serious reports correspond to 18.5% of the total, with a rate of 18 serious events per 100,000 doses administered, in line with the previous Reports. The reports are classified as serious or non-serious based on internationally standardised criteria that do not always coincide with the real clinical seriousness of the reported event.

For all vaccines, the most reported adverse events are fever, fatigue, headache, muscle/joint pain, chills, gastrointestinal upset, vegetative reactions, fatigue, local reaction or pain at the injection site.

As of 26/09/2022, vaccinations with bivalent formulations updated to the new Omicron variants had already begun, but there were no reports of suspected adverse reactions.

The data contained in this periodic Report are consistent with those published to date and in line with the safety information already discussed at the EU level.

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