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AGENZIA ITALIANA DEL FARMACO

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

The Italian Medicines Agency has published the twelfth 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 June 2022 for the five vaccines in use in the current vaccination campaign.

In the period considered, **137,899 reports** were received out of a total of **138,199,076 doses** administered (reporting rate of **100 per 100,000 doses**), of which **81.8% referred to non-serious events**, such as pain at the injection site, fever, asthenia/fatigue, muscle aches.

In the second quarter of 2022, reporting rates for the 1st dose remain higher than for subsequent doses and are lower after the 4th dose for all vaccines.

Serious reports correspond to 18.1% of the total, with a rate of 18 serious events per 100,000 doses administered, in line with previous reports. Please note that the severity of the reports is defined on the basis of standardised criteria that do not always coincide with the actual clinical severity of the event.

The adverse reaction occurred in most cases (approximately 71%) on the same day of vaccination or the day after and only more rarely beyond 48 hours, regardless of the vaccine, dose and type of event.

Comirnaty is the currently most used vaccine (65.4%), followed by Spikevax (24.7%), Vaxzevria (8.8%), Jcovden (ex-COVID-19 Vaccine Janssen) (1.1%) and Nuvaxovid (0.03%), in use since 28 February 2022. In line with previous Reports, the distribution of reports by type of vaccine follows that of administrations, with the exception of Vaxzevria and Spikevax which appear to be reversed in this trend (Comirnaty 66, 3%, Vaxzevria 17.4%, Spikevax 14.9%, Jcovden 1.3%, Nuvaxovid 0.1%).

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

In the age group 5-11 years, as of 26/06/2022 a total of 471 reports (about 0.5% of the total) were entered for the Comirnaty vaccine, the only one currently authorised for this age group, with a reporting rate of about 18 cases per 100,000 doses. Approximately 95% of these reports are attributed to the 1st dose and approximately 5% to the 2nd. The most frequently reported adverse events, regardless of severity and causation, were injection site pain, headache, fever and fatigue.

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

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