AGENZIA ITALIANA DEL FARMACO

Second AIFA Report on the surveillance of COVID-19 vaccines

Data confirm safety profiles

The Italian Medicines Agency has published the second Pharmacovigilance Report on COVID-19 vaccines, concerning the data recorded in the National Pharmacovigilance Network (RNF) until 26 February 2021.

The reports mainly concern the Pfizer/BioNTech Comirnaty vaccine (96%), which was the most used vaccine, and only to a lesser extent the Moderna vaccine (1%) and the AstraZeneca vaccine (3%).

Overall, as of 26 February 2021, **30,015 reports have been assessed** in the RNF **out of a total of 4,118,277 doses** administered for all vaccines, with a **reporting rate of 729 per 100,000 doses**. A higher rate than that which is usually observed for other vaccinations, such as influenza vaccination, but consistent with the results of clinical studies and indicative of the special attention paid to this vaccination. **The average age is 46 years, consistent with the average age of the vaccinated**, mostly health professionals. 93.6% of the reports refer to non-serious events and are in line with the information already present in the Summary of Product Characteristics of the vaccines.

For all three vaccines, **the most reported adverse events** were fever, headache, muscle/joint pain, injection site pain, chills and nausea (93% of reports). The cumulative frequency of reporting did not differ between first and second doses for the Pfizer and Moderna vaccines, while for the AstraZeneca vaccine there are still no second dose injections, scheduled after 12 weeks.

The reported events mainly occurred on the same day of vaccination or the day after (87% of cases).

The serious reports, for which the causal link with vaccinations is being assessed, correspond to 6.1% of the total, with a rate of 44 serious events per 100,000 doses administered, regardless of the type of vaccine and dose administered.

The data processed and presented in the Report should be considered as descriptive of a dynamic process in continuous evolution given the current transition towards a substantial increase in daily vaccinations. Please note that a large number of reports does not imply that the vaccine is more dangerous, but is an indication of the **high capacity** of the pharmacovigilance system to **monitor safety**.