



## COVID-19: AIFA authorizes Moderna vaccine

The Italian Medicines Agency has authorized the Moderna Covid-19 Vaccine for prevention of the 2019 coronavirus disease (COVID-19) in subjects aged 18 or over.

Director General Nicola Magrini is very satisfied: "We welcome with enthusiasm the possibility of making a second tool available for this vaccination campaign which is achieving excellent results in Italy. It is a substantially equivalent vaccine compared to the first, with very convincing data relating to all populations at risk".

"Science has provided us in a very short time with another powerful and effective weapon which is sure to have an immediate impact on the health of those most at risk, but also limit the circulation of the virus if, as is desirable and as has indeed been happening, the 'participation in the vaccination campaign is fast and wholehearted", AIFA's President Giorgio Palù said.

In the meeting held on 7 January 2021, AIFA's Scientific-technical Committee gave a positive opinion to the dossier, underlining the particularly favourable risk/benefit ratio of the vaccine in the population at greater risk and also established the supply regime for marketing.

This is the second COVID-19 vaccine approved by the Agency, after Comirnaty, the vaccine developed by BioNTech and Pfizer and authorized on 22 December 2020.

Compared to the Comirnaty vaccine, on the basis of currently available data, the safety and efficacy profile of the Moderna vaccine appears substantially overlapping. Some different characteristics are reported as follows:

- The Moderna vaccine is indicated from 18 years of age, instead of 16;
- The vaccination schedule provides for two administrations 28 days apart, instead of at least 21 days;
- Immunity is considered fully acquired starting 2 weeks after the second administration, instead of one;
- The vaccine is stored at temperatures between -15°C and -25°C, but is stable between +2°C and +8°C for 30 days if unopened;
- The multidose vial contains 6.3 ml and does not require dilution, therefore it is ready for use.