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AGENZIA ITALIANA DEL FARMACO

AIFA APPROVES VACCINE MIX IN SUBJECTS UNDER 60 YEARS OF AGE WHO HAVE RECEIVED THE FIRST DOSE OF VAXZEVRIA

During its 13 June 2021 meeting, AIFA's Technical Scientific Commission (CTS) issued an opinion on the vaccine mix in subjects under 60 years of age who have received the first dose of Vaxzevria, also in light of the changed epidemiological scenario characterised by a reduced viral circulation.

Based on the clinical studies published over the last few weeks, the CTS considered it appropriate to approve the vaccine mix (first dose of Vaxzevria and second dose of Comirnaty or, by analogy, Moderna vaccine) in light of a significant enhancement of the antibody response and the good reactogenicity.

Considering the evidence that has just become available, the current absence of specific indications in the Summary of Product Characteristics (SmPC) of the medicines in question and the need to allow a smooth roll-out of the vaccination campaign, AIFA issued a favourable opinion to include Comirnaty and COVID-19 Vaccine Moderna in the list of medicinal products under Italian Law 648/1996, as a second dose to complete the mixed vaccination cycle in subjects under 60 years of age who have already had their first dose of Vaxzevria.

The CTS considered that the administration of a second dose with an mRNA vaccine could take place 8 to 12 weeks after the administration of the first dose of Vaxzevria.

The implementing decision will be published shortly in the Italian Official Journal.