



INFORMED CONSENT ADDENDUM

COVID-19 VACCINATION WITH J&J'S JANSSEN VIRAL VECTOR VACCINE FOR PEOPLE UNDER 60

Given the guidelines produced by the Scientific and Technical Committee of the Italian Medicines Agency (AIFA) on June 11, 2021, according to which:

- a) the COVID-19 vaccine recommended for people aged under 60 years is either Comirnaty (Pfizer-BioNTech) or Moderna (viral mRNA vaccine);
- b) the administration of the Janssen vaccine (authorized for people over the age of 18) is recommended for people aged over 60 years;
- c) if **specific situations** arise in which **the benefits of a single administration** are patent (*homeless people, asylum seekers, or people experiencing social problems which significantly reduce their chances of sticking to vaccine schedules*), and in the absence of other options, the Janssen vaccine can be administered, after obtaining the opinion of the locally competent Ethics Committee;

Given that, following the request for an urgent opinion submitted on July 6, 2021 by Parma Local Health Authority (AUSL), the locally competent Ethics Committee stated that the single-dose vaccination seems to be a **valuable option** in order to reach effective vaccine coverage, **in the abovementioned circumstances** (636/2021/PARERE/AUSLPR);

I was informed by Dr.

that, based on the medical history I provided, the risk/benefit ratio, in relation to my specific situation and the difficulty of receiving a second dose, makes the single-dose vaccine a valuable and convenient option. Therefore

I, THE UNDERSIGNED..... BORN ON

HEREBY GIVE MY CONSENT FOR the administration of JOHNSON & JOHNSON's JANSSEN vaccine.

I ALSO AGREE TO REPORT ANY SYMPTOMS OR SIGNS CONSISTENT WITH DEEP VEIN THROMBOSIS or THROMBOCYTOPENIA THAT MAY APPEAR OVER THE NEXT 21 DAYS (shortness of breath, chest pain, leg swelling, leg pain, persistent abdominal pain after vaccination, severe or persistent headache, blurred vision, confusion or seizures after vaccination, or ecchymoses-petechiae outside the injection site a few days later) TURNING TO THE GENERAL PRACTITIONER, THE OUT-OF-HOURS HEALTHCARE SERVICE OR THE EMERGENCY ROOM FOR A HEALTH EVALUATION.

DATE AND PLACE

SIGNATURE

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