



Guidance for Obtaining Consent for COVID 19 Vaccination in Community/ Retail Pharmacy Setting – 2 July 2021

Note that the guidance here is specific to the context of the provision of COVID-19 Vaccine Janssen® in community or retail pharmacy settings

What are the key considerations when obtaining consent for the COVID 19 vaccine?

Consent is the giving of permission or agreement for an intervention such as a vaccination following a process of communication about the proposed intervention.

It should be presumed that most people 18 years of age and over (including those who have mild cognitive impairment) will be able to give their own informed consent to receiving the COVID-19 vaccine.

A three-tier approach to the provision of information is as follows:

1. Essential information required for informed consent on vaccine options for 18-35 year olds, including benefits and risks: <https://www.hse.ie/eng/services/news/newsfeatures/covid19-updates/covid-19-vaccine-materials/important-information-about-the-covid-19-vaccine-janssen.pdf>.
2. Product information leaflet available on-line: <https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-janssen> and in hard copy.
3. Opportunity for more detailed information or discussion for those people presenting for vaccination who may have questions. There are also links on the HSE website with accessible information available in other formats.

For informed consent to be valid, the person must:

- Have received sufficient information in a comprehensible manner about the nature, potential risks and benefits of the proposed intervention, of any alternative intervention and of not receiving the intervention,
- Not be acting under duress; and,
- Have the decision-making capacity to make the decision (even if requiring support to do so).

If there are concerns that a person who presents for vaccination does not appear to understand the vaccine information including the potential risks of receiving the **COVID-19 Vaccine Janssen®** then vaccination should be deferred and the person can be advised to seek medical advice.

Recording the process of consent

The process for recording the consent of a person receiving vaccination includes the completion of the **COVID-19 Vaccine Janssen® Vaccination Consent Form for people aged 18-34 years** (Pharmacy use only) for every person who receives vaccination. Completed forms must be retained as a record by the participating pharmacy:

<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/janssen-consent-form.pdf>

Further information for vaccinators is available under the following link:

<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/>