Minister for Health welcomes European approval of COVID-19 vaccine made by Janssen

From Department of Health

Published on 11 March 2021

Last updated on 12 March 2021

The Minister for Health, Stephen Donnelly, has welcomed today's announcement from the European Commission that the COVID-19 vaccine made by Janssen, a subsidiary of Johnson & Johnson, has been authorised for use across Member States, including Ireland.

Minister Donnelly said:

"Today is another significant and positive day in our country's response to COVID-19 as we see the addition of a fourth COVID-19 vaccine from Johnson & Johnson.

"This single-dose vaccine will significantly enhance the implementation of our vaccination programme and, together with those from Pfizer, Moderna and AstraZeneca, it will play a very important role in protecting our population from COVID-19.

"Ireland has an advance purchase agreement for 600,000 doses of the Janssen vaccine between April and June. Since our vaccination programme began late last year, I have always said that Ireland's programme is only limited by supply. Our rollout plans are flexible and are designed to accommodate unforeseen events such as changes to supplies from manufacturers."

The roll-out of these vaccines will get underway after the expected arrival of the first supplies in late April.

Notes

After a vaccine is licensed for use, several more steps are needed before the vaccine can be administered.

The steps include:

- the National Immunisation Advisory Committee must complete and publish its advice on the use of COVID-19 vaccines in Ireland
- the HSE National Immunisation Office works to finalise training and education materials for vaccinators
- public information materials are prepared so they can be provided to the people due to be vaccinated

- rollout plans are finalised
- vaccination teams visit and delivery of vaccines to certain locations are scheduled

Role of the Health Products Regulatory Authority (HPRA)

The HPRA is the national regulator for medicines in Ireland. They work closely with the European Medicines Agency (EMA). Applications for authorisation of COVID-19 vaccines are made to the EMA and if approved, they can be used in all EU Member States. Ireland, through the HPRA, is an active participant in all European reviews. The HPRA contributes directly to the assessment of all new medicines and the monitoring of their safety once in use. This is also the case for COVID-19 vaccines and treatments.

Since the beginning of the pandemic, regulators across the world, including the HPRA, have collaborated in an unprecedented manner to offer rapid expert advice and guidance on the best methods and design of clinical trials. This global co-operation is fully focussed on safely accelerating access to new vaccines once they are shown to be safe and effective.

The HPRA is also an expert member of NPHET, advising on the regulatory aspects of medicines, including vaccines, and medical devices.

The HPRA, together with the EMA and other EU medicines agencies, will continuously assess safety data emerging in relation to COVID-19 vaccine use, through well-established safety monitoring systems. Any potential safety concerns identified will be addressed by taking appropriate regulatory action to safeguard individual and public health and communicating with the public in a transparent and timely manner.

The HPRA strongly encourages healthcare professionals and members of the public, to report suspected adverse reactions (side effects) to COVID-19 vaccines to the HPRA.

You can find more information on safety monitoring on the HRPA's site.