

Minister for Health welcomes green light for Pfizer/BioNTech COVID-19 vaccine

From [Department of Health](#)

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Minister for Health, Stephen Donnelly TD has welcomed the announcement by the European Commission that it has authorised the use of the Pfizer/BioNTech COVID-19 vaccine. This means that roll-out of the vaccines can begin across the European Union.

Minister Donnelly said:

"After a very difficult year, it is great to be moving into 2021 with the wonderful news that the first COVID-19 vaccine has been approved for use in the European Union. Our priority was to ensure that any COVID vaccine administered in Ireland meets all of the rigorous safety and efficacy requirements of the EMA, and so this is a huge achievement by our medical and scientific communities.

"Within the coming days, we will begin administering this vaccine in Ireland. We have detailed plans in place for this roll-out through the National COVID-19 Vaccination Strategy. The most vulnerable will be prioritised first and over time, these vaccines will allow us to re-open our society and economy.

"In the meantime, I am asking everyone to continue to follow the public health guidance. COVID-19 is still with us, and it is still deadly. We all know the right actions - wash your hands, wear a face covering, maintain a two-metre social distance and remember that every contact counts."

The European Medicines Agency's human medicines committee (CHMP) and its experts have been working intensively to evaluate data submitted by BioNTech and Pfizer. Following that work, today the EMA has recommended granting a conditional marketing authorisation for the Pfizer BioNTech vaccine. This was granted by the European Commission this evening.

The vaccines will be made available free of charge in Ireland and have been authorised for use for those above the age 16. Comirnaty is given as two injections into the arm, at least 21 days apart.

The vaccines will be rolled out in three phases - the initial roll out is expected to begin before the end of the year. This will be followed by a mass ramp-up as more vaccines become available, and then open access.

The highest priority groups, those over the age of 65 living in long-term care facilities and frontline healthcare workers in direct patient contact, will receive the vaccine first.

Vaccines will be administered from long-term care facilities, hospitals, mass vaccination clinics, GP surgeries and community pharmacies. This will be done by qualified and trained healthcare workers, including hospital doctors, community medical officers, nurses, GPs and pharmacists.

Minister Donnelly said:

"I would like to take a moment to thank the healthcare professionals who will now move to administer this vaccine safely. They have worked selflessly all year to protect us from the worst impacts of COVID-19 and will continue to do so as the vaccine becomes available. We all have a role to play in supporting their heroic efforts by trying our best to avoid catching and transmitting this virus over the coming festive period."

ENDS

Notes

- after clean water, vaccination is the most effective intervention for saving lives and promoting good health
- COVID-19 vaccines are being developed following the same legal requirements for pharmaceutical quality, safety and effectiveness as other medicines
- COVID-19 vaccines can only be approved and used if they comply with all the requirements of quality, safety and efficacy set out in the EU pharmaceutical legislation. No vaccine will be used until market authorisation is received from the European Commission based on the recommendations of the European Medicines Agency (EMA)
- any authorised vaccine will be subject to ongoing monitoring in Ireland by the Health Product Regulatory Authority (HPRA)
- a conditional marketing authorisation is one of EU's regulatory mechanisms for facilitating early access to medicines that fulfil an unmet medical need, including in emergency situations such as the current pandemic. It is a formal authorisation of the vaccine, covering all batches produced for the EU and providing a robust assessment to underpin vaccination campaigns
- Comirnaty works by preparing the body to defend itself against COVID-19. It contains a molecule called messenger RNA (mRNA) which has instructions for making the spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells
- when a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein. The person's immune system will then recognise this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it
- if, later on, the person comes into contact with SARS-CoV-2 virus, their immune system will recognise it and be ready to defend the body against it
- the mRNA from the vaccine does not stay in the body but is broken down shortly after vaccination

- Ireland is currently involved in an EU Procurement Exercise being operated by the European Commission on behalf of member states to procure a portfolio of suitable, safe and effective vaccines, in sufficient quantities, to combat COVID-19
- the government established a cross-Government High-Level Taskforce to support and oversee the development and implementation of the vaccination programme
- the National COVID-19 Vaccination Strategy prepared by the Taskforce was launched on Tuesday 15 December following sign-off from Cabinet. It outlines Ireland's high-level plan for safe, effective and efficient vaccination of the population, while safeguarding continued provision of health and social care services. [The strategy is available to read here](#)
- the COVID-19 vaccine programme will be rolled out nationally and vaccines will be available free of charge to everyone in Ireland
- as initial supplies of the vaccine will be limited the government has agreed to a provisional priority list of groups for vaccination
- the COVID-19 Vaccine Allocation Strategy was approved by Government on 8 December 2020. [Further information on priority groups is available to read here](#)
- the vaccine will be administered by qualified and registered healthcare professionals. They will receive comprehensive and specialist training on COVID-19 vaccines