

Minister for Health welcomes European approval for Oxford AstraZeneca COVID-19 vaccine for all over 18s

From [Department of Health](#)

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- **first doses expected to arrive in Ireland on the week beginning February 8**
- **Ireland now expects 1.1 million doses of the three approved vaccines before end of March**
- **public Information campaign for over 85s to begin in the coming days**

The Minister for Health, Stephen Donnelly, has welcomed today's announcement from the European Commission that the AstraZeneca vaccine has been authorised for use across Member States, including Ireland. The roll-out of these vaccines will get underway after the arrival of the first supplies in early February. The stated vaccination programme is to use vaccines as they arrive, subject to the supplier guaranteeing the second dose.

Minister Donnelly said:

"Ireland now has access to three vaccines approved by the European Commission which will allow us to accelerate the roll-out of our vaccine programme in the coming weeks. The first delivery of the AstraZeneca vaccine to Ireland is expected in early February and can be part of the vaccine programme shortly afterwards.

"Despite a reduction in the amount of vaccines initially available from AstraZeneca, Ireland should still receive 1.1 million doses of the three approved vaccines in total by the end of March. This 1.1 million figure includes vaccines that have already been delivered, as well as those currently scheduled to be delivered before March 31. Our priority has always been to ensure that any COVID vaccine administered here would meet all of the rigorous safety and efficacy requirements of the EMA."

Following the recommendation for use of vaccines against COVID-19 by the European Medicines Agency (EMA) and authorisation for use by the European Commission this evening (Friday), the National Immunisation Advisory Committee (NIAC) develops guidance for their use in Ireland which is contained in the Immunisation Guidelines for Ireland. These guidelines are continuously updated and includes guidance on all new vaccines as they are approved for use in Ireland.

Ireland's National Vaccine Programme

Minister Donnelly said:

"The National COVID-19 Vaccination Strategy has targeted the most vulnerable and ensured they have been prioritised. As of Wednesday, January 27 we have administered 161,500 doses of COVID-19 vaccines. 71,600 of these were first doses to residents and staff of our long-term residential care facilities and a further 76,100 first doses to frontline healthcare workers.

"A further 13,800 people have received both doses. The completion of vaccinations in these cohorts will be carried out over the coming weeks. Receiving supplies of the AstraZeneca vaccine, alongside the two other previously approved vaccines, will allow us to begin the programme with Cohort 3 – those over the age of 70, beginning with those aged over 85 years."

Ireland's expected receipt of a total of 1.1 million vaccine doses between January and March will allow:

- completed vaccination of those eligible in the first priority group – people aged 65 and over living in long term care, and the staff who care for them
- the continuation and completion of vaccination for the second priority group – frontline health care workers
- roll out of community vaccinations to people aged over 70 years, starting in February with those aged over 85 years

The third group will be vaccinated according to age, starting with those aged 85+, then 80-84, 75-79 and 70-74. The HSE public information campaign for this group will begin this weekend across radio, print and television.

For this third group, which is based entirely on age, the estimated population numbers are:

Aged 85+ 81,000

Aged 80-84 90,000

Aged 75-79 134,000

Aged 70-74 191,000

Minister Donnelly said:

"Ireland is also part of the European contract for two further vaccines in development, and an option on a third vaccine subject to trial data. Negotiations continue at the European level with other suppliers. Over time, it is hoped supply lines will become more robust and established.

"We appreciate the high demand for this vaccine in Ireland, and the frustration of supply constraints in these early stages of the programme. We will continue to adjust the programme in accordance with supply and the prioritisation and allocation strategy. The roll out to people aged over 70 will begin in February and every effort is being made to deliver this programme as rapidly, and safely, as possible."

ENDS

Notes

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

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.

For more information on safety monitoring, [There's more information on safety monitoring on the HPRA's site here.](#)

More information on Astra Zeneca

- combined results from 4 clinical trials in the United Kingdom, Brazil and South Africa showed that COVID-19 Vaccine AstraZeneca was safe and effective at

preventing COVID-19 in people from 18 years of age. These studies involved around 24,000 people altogether. Half received the vaccine and half were given a control injection, either a dummy injection or another non-COVID vaccine. People did not know if they had been given the test vaccine or the control injection. Importantly, only two of these trials were used to estimate efficacy, as too few cases were reported in two trials to allow for robust efficacy calculations

- based on two clinical trials, in the UK and Brazil respectively, the vaccine demonstrated around a 60% efficacy in reducing symptomatic cases
- most of the participants in these studies were between 18 and 55 years old
- there are not yet enough data in older participants (over 55 years old) to provide a figure for how well the vaccine will work in this group. However, protection is expected, given that an immune response is seen in this age group and based on experience with other vaccines; as there is reliable information on safety in this population, EMA's scientific experts considered that the vaccine can be used in older adults. More information is expected from ongoing studies, which include a higher proportion of elderly participants
- COVID-19 Vaccine AstraZeneca is given as two injections into the arm, the second between 4 to 12 weeks after the first