Statement on the approval of the AstraZeneca COVID-19 vaccine in the Irish vaccination programme

From Department of Health

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The National Immunisation Advisory Committee (NIAC) has recommended that, in line with the approvals granted by the European Medicines Agency (EMA), all currently authorised COVID-19 vaccines can be used in adults of all ages, including those aged 70 years and older.

NIAC has also recommended that mRNA vaccines (Pfizer BioNTech and Moderna approved in Ireland) should be used for the over 70’s where practicable and timely.

The Chief Medical Officer has reviewed the NIAC’s recommendations and has advised the Minister for Health who has accepted the recommendations provided.

The High-Level Taskforce on COVID-19 Vaccination and the HSE have been informed of the decisions and are working through the operational implications. The Minister for Health has asked the HSE and the Taskforce to advise him on the immediate implications for the vaccination programme.

A number of other EU countries have made similar decisions with regard to the provision of mRNA vaccines to older people.

The expert advice to the Minister recognised that currently there is limited data on the AstraZeneca vaccine in relation to older age groups. Those aged over 70 are a key priority group for protection because of their greater risk of severe illness, hospitalisation and death from COVID-19.

Supplies of AstraZeneca will begin arriving in Ireland from next week and deliveries of Pfizer and Moderna will continue as scheduled.

Minister Stephen Donnelly said:

"It has been a remarkable achievement by science to have developed, rigorously tested, gained regulatory approval and distributed three safe and effective vaccines in little over a year since SARS-CoV-2 was first identified. The addition of a third COVID-19 vaccine from AstraZeneca will significantly enhance the implementation of our vaccination programme and, together with those from Pfizer and Moderna, will play a very important role in protecting our population from COVID-19 and helping us to overcome the challenges which
we have faced over the last year. The roll-out of community vaccinations to our over 70s will begin as planned this month starting with those aged 85 and over."

Chief Medical Officer Dr Tony Holohan said:

"The main objective of the vaccination strategy is to prevent morbidity and mortality. International and national data indicate that those aged 70 years and older are at significantly higher risk of hospitalisation and mortality. Due to the demonstrated efficacy of mRNA vaccines in older persons and in recognition of their particular vulnerability in terms of their increased risk of death and serious disease if they contract COVID-19, it has been recommended that mRNA vaccines be administered to all those over 70 years in order to provide the highest level of protection available to this population."

ENDS

Notes

COVID-19 Vaccine AstraZeneca

- on 29 January the European Commission granted a conditional marketing authorisation for COVID-19 Vaccine AstraZeneca for use in people from 18 years of age, based on a recommendation from the European Medicines Agency (EMA)
- COVID-19 Vaccine AstraZeneca is a viral vector vaccine. It is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein from SARS-CoV-2 COVID-19. Vaccine AstraZeneca does not contain the virus itself and cannot cause COVID-19
- 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
- the Agency based its calculation of how well the vaccine worked on the results from study COV002 (conducted in the UK) and study COV003 (conducted in Brazil)
- these showed a 59.5% reduction in the number of symptomatic COVID-19 cases in people given the vaccine (64 of 5,258 got COVID-19 with symptoms) compared with people given control injections (154 of 5,210 got COVID-19 with symptoms). This means that the vaccine demonstrated around a 60% efficacy in the clinical trials
- most of the participants in these studies were between 18 and 55 years old. There were not enough results 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

National Immunisation Advisory Committee
Advice from the National Immunisation Advisory Committee (NIAC) recommends that in line with the conditional marketing authorisation granted by the EMA:

- all currently authorised COVID-19 vaccines can be used in adults of all ages, including those aged 70 years and older
- NIAC stated that given the high rates of community transmission, the best vaccine to administer to the older population is the one which can be soonest administered
- where practicable and timely, those aged 70 years and older should be given mRNA vaccines, as these vaccines have a higher reported overall efficacy which makes them preferable for use in those at highest risk of adverse outcomes

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CMO Advice to Minister

- the main objective of the vaccination strategy is to prevent morbidity and mortality. International and national data indicate that those aged 70 and older are at significantly higher risk of hospitalisation and mortality
- due to the superior efficacy demonstrated by mRNA vaccines, including in older persons (albeit the data is limited), and in recognition of their particular vulnerability in terms of their increased risk of death and serious disease if they contract SARS-CoV-2, it is recommended that mRNA vaccines be administered to all those over 70 years in order to provide the highest level of protection available to this population
- the policy advice in relation to vaccination of those older than 70 years with mRNA vaccines will be updated as required, based on any further NIAC advice

Read the CMO's latest letter to the Minister for Health.

What an mRNA vaccine is

mRNA vaccines are a new type of vaccine to protect against infectious diseases. However, researchers have been studying and working with them for decades.

- once an mRNA vaccine is injected into muscle cells, it gives them instructions for how to make a harmless protein called a spike protein that is unique to the COVID virus
• next, cells display the spike protein on its surface
• the body recognises that the spike protein should not be there and builds defensive white cells that will remember how to fight the virus if exposed to it in the future
• after the spike protein is made, cells break down the mRNA instructions so they do not stay in the body
• there are currently two mRNA vaccines licensed for use in Ireland - the Pfizer/BioNTech, and Moderna vaccines