Statement from Acting Chief Medical Officer Dr Ronan Glynn - Monday 12 April 2021

From Department of Health

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On 7 April 2021, the European Medicine Agency (EMA) announced that they had concluded an investigation into a number of very rare, unusual blood clots occurring with low platelets in people following vaccination with Vaxzevria (formerly COVID-19 Vaccine AstraZeneca). The EMA's safety committee (PRAC) concluded that unusual blood clots with low blood platelets should be listed as very rare side effects of Vaxzevria/AstraZeneca but that the benefits of this vaccine continue to outweigh the risks.

The National Immunisation Advisory Committee (NIAC) have today revised recommendations for the use of Vaxzevria/AstraZeneca. In line with these recommendations:

- all of those aged 60 years and older can get any authorised COVID-19 vaccine, including Vaxzevria/AstraZeneca
- Vaxzevria/AstraZeneca is not recommended for those aged under 60 years including those with medical conditions with very high or high risk of severe COVID-19 disease

For people who have already received Vaxzevria/AstraZeneca:

- those aged 60 years and older should continue to receive their second dose 12 weeks later as scheduled
- those aged under 60 years with an underlying condition (those identified in cohort 4 and cohort 7) should continue to receive their second dose 12 weeks later as scheduled
- those aged under 60 years with no underlying condition (therefore not identified in cohort 4 and cohort 7) should have the scheduled interval between their first and second doses extended to 16 weeks to allow for further assessment of the benefits and risks as more evidence becomes available
- those who have developed unusual blood clots with low platelets after the first dose of Vaxzevria/AstraZeneca should not be given a second dose

As of 7 April, the Health Products Regulatory Authority (HPRA) has been notified of approximately 2,800 reports of suspected side effects associated with Vaxzevria/AstraZeneca, in the context of 204,270 doses administered. The HPRA confirms it has received notice of a case of special interest and is continuing to follow up on this to see if it fits the profile of the very rare blood clots which were the subject of the EMA review. An

additional small number of cases describing low platelet counts have been received and follow up is ongoing to rule out the presence of blood clots.

We will continue to monitor the roll-out of Vaxzevria/AstraZeneca in Ireland and internationally in collaboration with the HPRA and the NIAC. The Department of Health, the HSE and the High-Level Taskforce will now work together to ensure that these updated recommendations are incorporated into the ongoing implementation of the vaccination programme.

Notes

ACMO slides for press conference on 12 April 2021

Download

Read the recommendation from NIAC.

The NIAC has made the following recommendations to the Department of Health:

The benefits versus the risks of this vaccine may vary by age and as alternative COVID-19 vaccines are available in Ireland, NIAC has revised the recommendations for the use of the of AstraZeneca vaccine (known as Vaxzevria).

- any authorised COVID-19 vaccine, including Vaxzevria COVID-19 vaccine AstraZeneca, is recommended for those aged 60 years and older including those with medical conditions with very high or high risk of severe COVID-19 disease
- Vaxzevria COVID-19 vaccine AstraZeneca is not recommended for those aged under 60 years including those with medical conditions with very high or high risk of severe COVID-19 disease
- a second dose of Vaxzevria COVID-19 vaccine AstraZeneca should not be given to anyone who developed unusual blood clots with low platelets after the first dose

Advice for those who have received a first dose of Vaxzevria COVID-19 vaccine AstraZeneca is:

- those aged 60 and older should receive their second dose 12 weeks later as scheduled
- those aged under 60 years with a very high risk or high-risk medical condition should receive their second dose 12 weeks later as scheduled

- those aged under 60 years without a very high risk or high-risk medical condition should have the scheduled interval between doses extended to 16 weeks to allow further assessment of the benefits and risks as more evidence becomes available

The Allocation Strategy was approved by Cabinet, based on public health and ethical guidance. It is a living document, subject to review where necessary and on new evidence, but any modification would follow the same process. Following approval by Cabinet (30 March 2021), the following is the updated COVID-19 Allocation Strategy:

1 People aged 65 years and older who are residents of long-term care facilities (likely to include all staff and residents on site)

2 Frontline healthcare workers

3 People aged 70 and older

4 People aged 16-69 with a medical condition that puts them at very high risk of severe disease and death

5 People aged 65-69 whose underlying condition puts them at a high risk of severe disease and death

6 Other people aged 65-69 and key workers essential to the vaccine programme

7 People aged 16-64 who have an underlying condition that puts them at high risk of severe disease and death

8 Residents of long-term care facilities aged 16-64

9 People aged 64 years and younger, and people aged 16-64 living or working in crowded settings