Statement from Dr Ronan Glynn on recommencement of the COVID-19 Vaccine AstraZeneca programme

From Department of Health

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On Sunday, 14 March, the National Immunisation Advisory Committee (NIAC) recommended the temporary deferral of the administration of COVID-19 Vaccine AstraZeneca following a report from the Norwegian Medicines Agency of cases of serious, rare thromboembolic (clotting) events, including some complicated by low platelet counts.

To date, no reports of serious clotting events associated with low platelets have been received by the Health Products Regulatory Authority (HPRA) in Ireland. Over 117,000 doses of COVID-19 Vaccine AstraZeneca have been administered in Ireland.

The European Medicines Agency (EMA), through its safety committee conducted and urgent review of all blood clotting events occurring with the COVID-19 Vaccine AstraZeneca to determine if there is a possible safety risk.

The EMA's preliminary report, concluded on 18 March, reported that the benefits of the COVID-19 Vaccine AstraZeneca in combating the threat of COVID-19 continue to outweigh the risk of side effects. The EMA also concluded that the vaccine is not associated with an increase in the overall risk of blood clots in those who receive it.

The NIAC has convened and reviewed the EMA statement in relation to COVID-19 Vaccine AstraZeneca and, following discussion with representatives from the HPRA, the National Coagulation Centre and counterparts across the EU, have recommended that the administration of COVID-19 Vaccine AstraZeneca should be recommenced.

Based on the assessments undertaken by the EMA and the NIAC, and the recommendations of the latter, I have recommended the recommencement of the COVID-19 Vaccine AstraZeneca programme.

The HSE will now work to recommence the administration of COVID-19 Vaccine AstraZeneca.

Notes

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

1. The administration of the AstraZeneca vaccine should be recommenced for use in all those aged 18 and over.

2. Healthcare professionals and vaccine recipients should be informed that very rare, complicated clotting events have been reported in a small number of people who have recently received the AstraZeneca vaccine.

3. Healthcare professionals should be alert to the signs and symptoms of blood clots and/or low platelet count and report any suspected adverse reactions to the Health Products Regulatory Authority (HPRA).

4. Recipients of the AstraZeneca vaccine should be advised to seek immediate medical attention if they develop symptoms such as:

- shortness of breath
- chest pain
- leg swelling and/or persistent abdominal pain within weeks of vaccination

Additionally, anyone with neurological symptoms including severe or persistent headaches (particularly 3 days after vaccination) or blurred vision after vaccination, or who develop skin bruising beyond the site of vaccination, should seek prompt medical attention. These rare events have usually occurred within 14 days of receiving the AstraZeneca vaccine, particularly 3 days or more after.

5. Healthcare professionals should seek early expert advice from the National Coagulation Centre about specialised testing and treatment options for any patients presenting with these events within weeks following the AstraZeneca vaccine.

The NIAC will continue to monitor evidence on COVID-19 vaccines.