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Ireland: Weekly Vaccine Target Reduced by 30,000 Doses Due to Precautionary Pause in AstraZeneca Use

The NIAC is due to meet again today and a further statement is expected to follow.

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The number of doses to be administered in Ireland this week has been reduced by more than a third of the original plan due to the pause in the use of the AstraZeneca vaccine.

The National Immunisation Advisory Committee (NIAC) has recommended that the administration of the Covid-19 AstraZeneca vaccine be temporarily deferred, pending the outcome of an investigation at EU level.

In a statement this morning, Deputy Chief Medical Officer Dr Ronan Glynn said the recommendation has been made following a report from the Norwegian Medicines Agency of four new reports of serious blood clotting events in adults after receiving the AstraZeneca vaccine.

> "It has not been concluded that there is any link between the Covid-19 vaccine AstraZeneca and these cases," Dr Glynn said.
>
> "However, acting on the precautionary principal, and pending receipt of further information, the NIAC has recommended the temporary deferral of the Covid-19 vaccine AstraZeneca vaccination programme in Ireland."

80,000 vaccines were due to be administered in Ireland this week, the HSE told *TheJournal.ie*.

> "We now expect to administer approximately 50,000," the HSE said.
>
> "While we are expecting to administer about 30,000 less than planned they would not all be 'cancelled appointments' as specific appointments would not have been made for many later in the week."

The Health Products Regulatory Authority (HPRA) is in a continued dialogue with the EMA

and national medicines regulators across Europe in respect of the ongoing European review.

> The decision to temporarily suspend use of the AstraZeneca Covid-19 vaccine was based on new information from Norway that emerged late last night. This is a precautionary step. The National Immunisation Advisory Comm meets again this morning and we'll provide an update after that
>
> — Stephen Donnelly (@DonnellyStephen) March 14, 2021

Norwegian health officials yesterday reported a number of further cases of blood clots or brain haemorrhages in younger people who received the AstraZeneca Covid-19 jab, but said they could not yet say they were vaccine-related.

The Norwegian Medicines Agency said similar incidents had been reported in other European countries. While there was no proof of a link to the vaccine, anyone under 50 who felt unwell and developed large blue patches after vaccination should seek medical attention.

Yesterday, the Norwegian Medicines Agency said it had "received several adverse event reports about younger vaccinated people with bleeding under the skin (tiny dots and /or larger blue patches) after coronavirus vaccination.

> "This is serious and can be a sign of reduced blood platelet counts," it said.
>
> "Today, we received three more reports of severe cases of blood clots or brain haemorrhages in younger people who have received the AstraZeneca vaccine. These are now receiving hospital treatment," it added.

Geir Bukholm, director of Infection Control and Environmental Health at the Norwegian Institute of Public Health, said that following the decision to suspend the jab, it was now "the Norwegian Medicines Agency's role to follow up on these suspected side effects and take the necessary measures".

Explaining the concern regarding the latest clotting reports from Norway, Dr Glynn told RTÉ Radio One's This Week that there had been a number of disparate reports during the week from a number of different places, and that "the majority of those reports were to do with clots in the leg or cloths in the lung,"

However, he added that:

> "The four reports that have come through from Norway are specific to clotting events involving the brain, and again they're clotting events in younger people in their 30s and 40s, which is unusual.

To date, the HPRA has received a small number of reports associated with blood clots following vaccination with the AstraZeneca vaccine. However, it has not received any reports of the nature of those described by the Norwegian Medicines Agency.

The HRPA said it will continue to monitor national reports "very closely".

Speaking to RTÉ Radio One's Brendan O'Connor this morning, NIAC chairperson Professor Karina Butler said the question currently is whether the newly reported clots are "totally coincidental, random events" or if "there could be a casual relationship that the vaccine may have triggered" the symptoms.

> "We, above all, want to ensure that what we're recommending is safe and that we can maintain confidence in the vaccine programme, we felt that we had to pause, just pause, until we get the additional information that could possibly, hopefully, give us the reassurance that this is fine," Professor Butler said.
>
> "We did this out of abundance of caution," she said.

She added that she hopes if the roll-out of the AstraZeneca vaccine can resume, the public will have "even greater confidence that this has been looked at absolutely rigorously, absolutely thoroughly and there was no need to worry".

Professor Butler said that it is hoped there will be a "conclusion" to this situation by "the end of the week".

The World Health Organization has said no causal link had been established between the vaccine and blood clotting after Denmark, Norway and Iceland on Thursday temporarily suspended the use of the vaccine over concerns about patients developing post-jab blood clots.

The HPRA said in a statement this afternoon that "there is currently no indication that the vaccine was the cause of these events and there may be alternative explanations for their occurrence that are unrelated to the vaccine".

> "However, the safety of the public is of the utmost importance, and it is essential that reports of potential safety concerns, even if very rare, are rigorously and swiftly investigated so that the public can be reassured and if required, appropriate action can be taken," it said.

Roll-out impact

It's currently unclear how long the AstraZeneca vaccine roll-out will be suspended for.

Speaking on RTÉ Radio One's This Week, Dr Ronan Glynn said the EMA is due to meet again on Wednesday or Thursday to discuss data collected regarding the situation.

With regards to the roll-out of the Pfizer/Moderna vaccine, HSE's Chief Clinical Officer Dr Colm Henry told the programme that the distribution of those will continue "without disruption".

The people affected by the suspension of the AstraZeneca vaccine will be the remaining healthcare workers and, to some extent, the category of people aged 16-69 who have high risk conditions, according to Dr Henry.

> "They are the group that for whom the vaccination appointments are suspended pending the outcome of the EMA [investigation]," Dr Henry said.

AstraZeneca response

AstraZeneca, an Anglo-Swedish company which developed the vaccine with Oxford University, has defended the safety of its product.

In a statement released this morning, a spokesperson for the company said an analysis of its safety data that covers reported cases from more than 17 million doses of vaccine administered "has shown no evidence of an increased risk of pulmonary embolism, deep vein thrombosis or thrombocytopenia with Covid-19 vaccine AstraZeneca".

> "In fact, the reported numbers of these types of events for Covid-19 vaccine AstraZeneca are not greater than the number that would have occurred naturally in the unvaccinated population," the spokesperson said.
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> "In clinical trials, no trends or patterns were observed with regard to pulmonary embolism, deep vein thrombosis, or events possibly related to thrombocytopenia," they said.
>
> "A careful review of all available safety data including these events is ongoing and AstraZeneca is committed to sharing information without delay. We also note that the European Medicine Agency (EMA) has asked for an assessment of events related to thrombocytopenia from other COVID-19 vaccine manufacturers (per communication 11 March)."

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