COVID-19 VACCINE BULLETIN 10 UPDATED

Welcome to the updated tenth bulletin from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

Bulletins will be published every week or more frequently, if required.

Bulletin Update

The National Immunisation Advisory Committee (NIAC) has recommended the temporary deferral of the administration of the COVID-19 Vaccine AstraZeneca® as of 14 March 2021.

Questions and answers about the temporary deferral of COVID-19 Vaccine AstraZeneca® - can be found **here**.

The COVID-19 Vaccine Bulletin 10, originally published on Friday March 12th 2021, has been updated following the statement released by the National Immunisation Advisory Committee (NIAC) on March 14th 2021 in relation to COVID-19 vaccine AstraZeneca.

The NIAC statement is summarised below.

Summary of statement from the National Immunisation Advisory Committee (NIAC) – Updated March 14th 2021:

The National Immunisation Advisory Committee (NIAC) has today (Sunday March 14th 2021) recommended the temporary deferral of the administration of the COVID-19 Vaccine AstraZeneca®.

Following a new safety alert from the Norwegian Medicines Agency received late on 13 March 2021, NIAC met with the HPRA and HSE representatives to consider this new information. The alert followed four new reports of serious, rare thromboembolic (clotting) events, including some complicated by thrombocytopenia (low platelet count) in adults under 65 years of age after vaccination with COVID-19 Vaccine AstraZeneca®. To date, no reports of similar events have been received by the HPRA. Over 117,000 doses of COVID-19 Vaccine AstraZeneca® have been given in Ireland.

The European Medicines Agency (EMA) has been investigating a number of reports of clotting events following vaccination with COVID-19 Vaccine AstraZeneca®. Further information is expected from the EMA in the next few days, which will include a review of the additional events. The possible relationship between these events and the COVID-19 Vaccine AstraZeneca® is uncertain and is being investigated. It is very important that all potential rare events are rigorously and swiftly investigated so we can support public confidence.

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In the rare event that someone who has received the COVID-19 Vaccine AstraZeneca® feels increasingly unwell more than three days after vaccination, and/or who notices larger or smaller blue spots in the skin (purpuric, non-blanching rash, skin haemorrhages) they should consult their doctor or out-of-hours medical service.

These rare events that have been reported have usually occurred within 14 days of the COVID-19 Vaccine AstraZeneca®.

Chair of NIAC, Prof Karina Butler said: *"This is a precautionary move. We will continue to monitor the situation and if we can be satisfied that these events are coincidental and not caused by this vaccine we will reassess the situation. The HPRA will keep NIAC fully informed as the EMA investigation progresses and we will keep you updated".*

"This vaccine is proven to be very effective against severe COVID-19 disease, which is associated with a risk of clotting events. We have taken this step out of an abundance of caution."

Read NIAC Statement in full here

Summary of advice relating to the temporary deferral of COVID-19 Vaccine AstraZeneca®

1. Patients with an appointment for COVID-19 AstraZeneca® vaccination in the coming days should not attend their appointment until further contact from the HSE about the resumption of the programme has been received.
    a. In the meantime it is important that all COVID-19 precautions continue to be followed.
2. Any appointments for a first or second dose of Pfizer or Moderna COVID-19 vaccine can still go ahead as they are not included in this safety alert.
3. The recommended dose interval between the first and second dose of COVID-19 Vaccine AstraZeneca® is 12 weeks so no appointments for second doses with COVID-19 AstraZeneca® vaccine have been scheduled at this time. Further information will be provided about second doses as soon as it is available.
4. These events are rare and we do not know if they are caused by the vaccine.
5. As these cases have most commonly been reported within 14 days of the receiving the vaccine, people who have received the COVID-19 Vaccine AstraZeneca® and feel increasingly unwell more than three days after vaccination, and/or who notice larger or smaller blue spots in the skin (purpuric, non-blanching rash, skin haemorrhages) should consult a doctor or out-of-hours medical service.

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From what age are COVID-19 vaccines licensed?

Comirnaty® Pfizer/BioNTech vaccine is the only COVID-19 vaccine used in Ireland that is authorised for people aged **16 years and older.** The other COVID-19 vaccines are authorised for people aged **18 years and older.**

Remember to check the age of the person being vaccinated to ensure they are eligible to receive the vaccine you are giving them.

Vaccine	Comirnaty® (Pfizer/BioNTech)	COVID-19 Vaccine Moderna®	COVID-19 Vaccine AstraZeneca®
Licensed for age:	16 years and older	18 years and older	18 years and older

What does % vaccine efficacy mean?

Efficacy is the degree to which a vaccine prevents disease and possibly also transmission under ideal and controlled circumstances i.e. in a randomised controlled clinical trial. Effectiveness refers to how well the vaccine performs in the real world. Although a vaccine that has a high efficacy would be expected to be highly effective it is unlikely to be the same.

Information on vaccine efficacy comes from the Phase 3 trials of the vaccine. For example, COVID-19 Vaccine Moderna has a 94% efficacy after 2 doses.

This means that the vaccine reduced the risk of COVID-19 by 94%. It does not mean that people vaccinated had a 6% risk of getting COVID-19–their risk of COVID-19 was far lower than this.

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COVID-19 Vaccines in pregnancy

Pregnant women are at a similar risk to non-pregnant women of contracting COVID-19 disease. Most pregnant women who are infected with COVID-19 will experience mild to moderate symptoms, and the risk of passing COVID-19 virus to the baby is low.

However, pregnant women who become ill from COVID-19 are more likely to be admitted to hospital, to need care in an ICU, and to die when compared with non-pregnant women patients. Women from Black, Asian and minority ethnic backgrounds may be more likely than other pregnant women to be admitted to hospital with COVID-19 disease.

The risks of severe COVID-19 disease in pregnant women may be higher in those with certain medical conditions, those aged >35 years, those with a BMI ≥30 and where infection occurs in the third trimester.

Pregnant women can receive any authorised COVID-19 vaccine

The National Immunisation Advisory Committee advises:

Administration of COVID-19 vaccines in pregnancy should be considered when the potential benefits outweigh any potential risks for the mother (e.g. at high risk of severe disease, HCW) and foetus.

Pregnant women who meet the priority criteria for vaccination and their obstetric caregivers should engage in shared decision-making in advance of vaccination. Counselling should balance available data on vaccine safety, risks to pregnant women from SARS-CoV-2 infection, and a woman's individual risk for infection and severe disease.

Where the risk/benefit is favourable the two dose schedule should be given between 14 and 33 completed weeks of gestation.

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EMA decision on COVID-19 Vaccine Janssen®

A fourth COVID-19 vaccine has been approved for use in the EU on 11th March 2021.

COVID-19 Vaccine Janssen® (Johnson and Johnson) was granted conditional marketing authorisation by the EU following approval by the European Medicines Agency.

The vaccine is a viral vector vaccine and is licensed as a single dose regimen for adults aged 18 years and older.

Read The Summary of Product Characteristics Here

The National Immunisation Advisory Committee is developing guidance in relation to this newly authorised vaccine which will be available soon.

Medicines & Healthcare products Regulatory Agency (UK) summary of Coronavirus Vaccines

On March 11 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom published their weekly summary of Coronavirus Vaccines. The report outlines the suspected side effects from COVID-19 vaccines reported in the UK known as the "Yellow Card" scheme. Key findings of the report are listed below:

- Up to February 28 2021, an estimated 10.7 million first doses of the Pfizer/BioNTech vaccine and 9.7 million doses of the Oxford University/AstraZeneca vaccine had been administered, and around 0.8 million second doses, mostly the Pfizer/BioNTech vaccine, had been administered.
- Up to February 28 2021, 33,207 "yellow cards" have been reported for the Pfizer/BioNTech, 54,180 have been reported for the Oxford University/AstraZeneca vaccine, and 251 have been reported where the brand of the vaccine was not specified.
- For both vaccines, the overwhelming majority of reports relate to injection-site reactions (sore arm for example) and generalised symptoms such as 'flu-like' illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally, these happen shortly after the vaccination and are not associated with more serious or lasting illness.

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Medicines & Healthcare products Regulatory Agency (UK) summary of Coronavirus Vaccines

Conclusions of the report are listed below:

- The increases in number of adverse reaction reports reflects the increase in vaccine deployment as new vaccination centres have opened across the UK.
- The number and nature of suspected adverse reactions reported so far are not unusual in comparison to other types of routinely used vaccines.
- The overall safety experience with both vaccines is so far as expected from the clinical trials.
- Based on current experience, the expected benefits of both COVID-19 vaccines in preventing COVID-19 and its serious complications far outweigh any known side effects.
- As with all vaccines and medicines, the safety of COVID-19 vaccines is being continuously monitored.

Our website and our clinical guidance include several frequently asked questions and answers to help guide vaccinators. For example:

Q. Does a woman who wishes to conceive need to leave any interval after getting COVID-19 vaccines before getting pregnant?

A. It is not necessary to leave any interval after having the vaccine and becoming pregnant. If a woman becomes pregnant following the first dose, they should wait until 14 weeks of gestation or after to get the second dose, and should discuss the risks and benefits with their Obstetrician or GP.

Read More Here

Website

Visit our website www.immunisation.ie regularly for the most up to date information to support vaccinators and health professionals responding to queries.

Our dedicated COVID-19 Vaccination section contains

- Information from the National Immunisation Advisory Committee
- Clinical guidelines
- COVID-19 vaccine studies
- IM Injection technique reminders
- Dedicated pages for the licensed COVID-19 vaccines

View Here

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COVID-19 Vaccination Training Programme

This week we passed 10,000 completions for the National Immunisation Office "COVID-19 Vaccination Training Programme" on HSELand.

The programme covers topics like

- Recommendations and contraindications
- Preparing vaccines for administration
- Communications and consent

The programme is updated regularly to include the most up to date information to support vaccinators who are competent in giving vaccinations.

You will be notified by email when new content is available for completion. Follow the instructions in the email to complete the updates. You do not need to redo the entire programme.

Register Here

Do you have queries?

For questions about the COVID-19 Vaccination programme

- COVID-19 vaccine orders or deliveries to GPs, please email gpvaccines@hse.ie
- Health Professionals for your own COVID-19 vaccination appointments, please email Covid19.support@hse.ie
- Legal queries, potential challenges related to vaccination and obtaining a consent, please email lead.integratedcare@hse.ie and dervelagray@rcpi.ie
- For clinical queries and queries relating to cold chain maintenance or breakdown, please email immunisation@hse.ie

The National Immunisation Office is not involved in the allocation or delivery of COVID-19 Vaccines.

*Recommendations about COVID-19 vaccine are changing as more information becomes available so please visit our **website** for the most up to date information.*