COVID-19 VACCINE BULLETIN 14

Welcome to Bulletin 14 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.

EMA review of Vaxzevria© (COVID-19 Vaccine AstraZeneca)

On April 7th 2021, the Pharmacoviligance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) finished their review of the safety signal relating to Vaxzevria®, the AstraZeneca COVID-19 vaccine.

The Committee carried out an in-depth review of 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis reported in the EU drug safety database (EudraVigilance) as of 22 March 2021, 18 of which were fatal. The cases came mainly from spontaneous reporting systems of the EEA and the UK, where around 25 million people had received the vaccine.

EMA's safety committee (PRAC) concluded that unusual blood clots with low blood platelets should be listed as very rare side effects of Vaxzevria®. COVID-19 is associated with a risk of hospitalisation and death. The reported combination of blood clots and low blood platelets is very rare, and the overall benefits of the vaccine in preventing COVID-19 outweigh the risks of side effects.

One plausible explanation for the combination of blood clots and low blood platelets is an immune response, leading to a condition similar to one seen sometimes in patients treated with heparin (heparin induced thrombocytopenia, HIT). The PRAC has requested new studies and amendments to ongoing ones to provide more information and will take any further actions necessary.

EMA is reminding healthcare professionals and people receiving the vaccine to remain aware of the possibility of very rare cases of blood clots combined with low levels of blood platelets occurring within 2 weeks of vaccination. So far, most of the cases reported have occurred in women under 60 years of age within 2 weeks of vaccination. Based on the currently available evidence, specific risk factors have not been confirmed.

Patients should seek medical assistance immediately if they have the following symptoms

- shortness of breath
- chest pain
- swelling in your leg
- persistent abdominal (belly) pain
- neurological symptoms, including severe and persistent headaches or blurred vision
- tiny blood spots under the skin beyond the site of injection

Read More on the PRAC statement here

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The National Immunisation Advisory Committee are reviewing the report on Vaxzevria©(COVID-19 Vaccine AstraZeneca) from the European Medicines Agency and their recommendations are expected soon

WHO Global Advisory Committee on Vaccination Statement

On April 7th 2021, the COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) released a statement following their review of reports of very rare cases of blood clots with low platelets following vaccination with the AstraZeneca COVID-19 vaccine.

The subcommittee reviewed latest information from the European Medicines Agency along with information from the United Kingdom's Medicines and healthcare Products Regulatory Agency (MHRA), and other Member States.

Based on the review the subcommittee made the following recommendations:

- Based on current information, a causal relationship between the vaccine and the occurrence of blood clots with low platelets is considered plausible but is not confirmed. Specialised studies are needed to fully understand the potential relationship between vaccination and possible risk factors.
- The events under assessment are very rare, with low numbers reported among the almost 200 million individuals who have received the AstraZeneca COVID-19 vaccine around the world.
- Rare adverse events following immunisation should be assessed against the risk of death from COVID-19 disease and the potential of the vaccines to prevent infections and reduce deaths due to diseases. In this context, it should be noted that as of today, at least 2.86 million people have died of COVID-19 disease worldwide.
- People receiving the vaccine should be aware of the symptoms to look out for following vaccination and to seek medical attention urgently if symptoms develop. Clinicians should be aware of relevant case definitions and clinical guidance for patients presenting with thrombosis and thrombocytopenia following COVID-19 vaccination.
- The GACVS will meet again next week to review additional data and will be issuing further recommendations as relevant

Read More on the GACVS statement here

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The European Medicines Agency has updated the Summary of Product Characteristics and Patient Information Leaflet for Vaxzevria®

Thrombosis in combination with thrombocytopenia is now listed as a very rare adverse reaction.

Of note thrombocytopenia (without thrombosis) is listed as common adverse reaction. Low platelet counts were noted in some participants who underwent blood tests as part of clinical trials. These were asymptomatic, mild and were not associated with clotting events.

Read More Here

Information materials, medicines protocol and other materials will be updated to reflect these changes.

Janssen (Johnson and Johnson) vaccine guidance and training

Clinical guidance for COVID-19 vaccination has been updated to include COVID-19 Vaccine Janssen®. The vaccine is given as a single dose of 0.5mls.

The training programme on HSELand has also been updated to include modules on this vaccine.

The medicines protocol for the vaccine as well as other materials are also available

See More Here

TITLE	DESCRIPTION
Type of vaccine	Adenovirus vector vaccine
Dosage	One dose 0.5ml
Interval between doses	**No interval – single dose schedule**
Presentation	Multidose clear glass vial The vaccine is a colourless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection
Dilution	**NO DILUTION REQUIRED**
Shelf life of an unopened vial at between +2°C to +8°C	3 months (until "use before" time and date)
Shelf life once vial is opened "discard time"	3 hours after first puncture

For more details please see

Guidelines of the National Immunisation Advisory Committee

Clinical Guidance for COVID-19 vaccination

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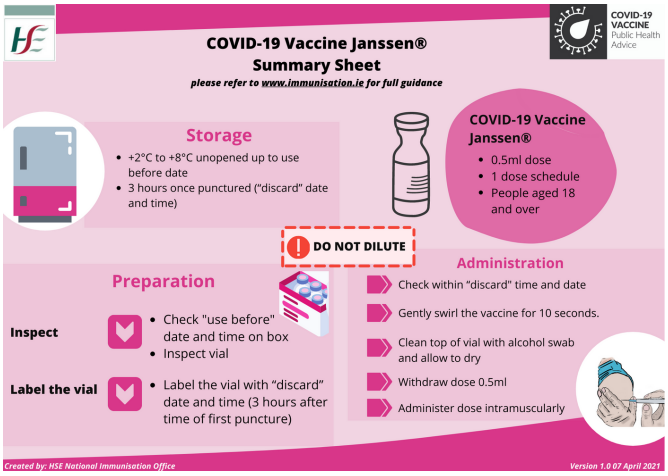
One-page summary and quick reference guide for COVID-19 vaccines

We have developed a one-page summary of each COVID-19 vaccine used in the vaccination programme as well as a quick reference guide.

See More Here

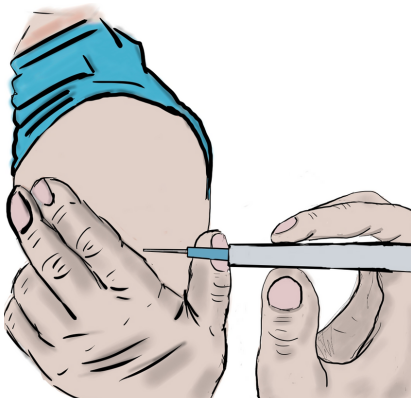


People on treatment for cancer and other conditions

Vaccination of people with underlying medical conditions is underway. This includes people receiving chemotherapy and immunosuppressive therapies.

Chemotherapy and immunosuppressive therapies are not contraindications to any of the COVID-19 vaccines used in the COVID-19 immunisation programme and individuals receiving these treatments should be vaccinated.

Intramuscular Injection of vaccine and the importance of correct IM injection technique



Everyone who administers COVID-19 vaccines must be competent in correct intramuscular injection technique into the deltoid muscle.

Incorrect administration may result in injection of the vaccine into the subcutaneous tissue, which may render if ineffective.

Incorrect administration may also result in injuries, including shoulder injury related to vaccine administration (SIRVA) which is a preventable occurrence caused by the injection of a vaccine into the shoulder capsule rather than the deltoid muscle.

We have developed a video which demonstrates correct injection technique.

This is also included in the vaccination training modules included on HSELand.

Watch Video Here

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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

Visit Here

COVID-19 Vaccination Training Programme

There are now **over 11,700** completions for the National Immunisation Office "COVID-19 Vaccination Training Programme" on HSELand. The programme is being updated today to include information about COVID-19 Vaccine Janssen®.

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

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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

Should vaccines be exposed to temperatures outside of these parameters please contact the National Immunisation Office immediately. Contacts include:

- Achal Gupta: achal.gupta@hse.ie mobile 087 4064810
- Mariangela Toma: mariangela.toma@hse.ie mobile 087 7575679
- Cliona Kiersey: cliona.kiersey@hse.ie mobile 087 9915452
- Email the immunisation inbox: 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.*