Medicine Protocol for the Administration of Jcovden COVID-19 vaccine (previously COVID-19 Vaccine Janssen) to Vaccine Recipients

This medicine protocol is a specific written instruction for the administration of Jcovden COVID-19 vaccine to vaccine recipients included in S.I. No. 155 of 2021 by healthcare professionals included in Statutory Instruments S.I. No. 698 of 2020, S.I. No. 81 of 2021 and S.I. No. 245 of 2021 who are registered with their respective regulatory body and students in healthcare professions included in S.I. No. 245 of 2021. This medicine protocol is valid for the 2021/2022 HSE COVID-19 Vaccination Programme. This medicine protocol enables the healthcare professionals and students described above employed in the voluntary and statutory services of the Health Service Executive (HSE) who have undertaken the required education and training programmes to administer Jcovden COVID-19 vaccine to vaccine recipients, with reference to guidelines and guidance from the National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics for Jcovden COVID-19 vaccine as detailed by the European Medicines Agency (EMA).

- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Dublin: Royal College of Physicians Ireland *, Online Update available at* https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/
- National Immunisation Office (2020) Clinical Guidance for COVID-19 Vaccinations, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf
- Summary of Product Characteristics https://www.ema.europa.eu/en/documents/product-information/jcovden-previously-covid-19-vaccine-janssen-epar-product-information_en.pdf

The Nursing and Midwifery Board of Ireland (NMBI) defines medicine protocols as "written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect" (An Bord Altranais, 2007).

The HSE has developed this medicines protocol to facilitate the delivery of COVID-19 immunisation in line with NIAC recommendations, Department of Health (DoH) and HSE policy.

The professional groups and students using this protocol must ensure that the protocol is organisationally authorised by an appropriate authorising person, related to the professional or student cohort of vaccinators by whom the vaccine is to be administered, including requirements of registration, education, training and assessment of competency.

Medicine Protocol for the Administration of Jcovden COVID-19 vaccine to vaccine recipients

Document reference number	NIO 001.4
1.0 Critical elements	
Name of Organisation where medicine protocol applies	Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE), non-HSE healthcare facilities and central vaccination centres. This Medicine Protocol applies to: Registered healthcare professionals included in S.I. 698, S.I. 81 and S.I. No. 245 employed in the voluntary and statutory services of the Health Service Executive (HSE) and students in healthcare professions included in S.I. No. 245 of 2021 who have undertaken the required education and training programmes.
Date the medicine protocol comes into effect	April 2021
Date for review of medicine protocol	April 2024 (Regularly updated as per the NIAC recommendations & DoH policy)
Document prepared by	The National Immunisation Office (NIO)
Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol ***"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"***	Name: **Dr. Éamonn O' Moore,** Director of National Health Protection, HSE Signature:  Name: **Dr Colm Henry**, Chief Clinical Officer, HSE Signature: 

2.0 Clinical criteria	
Clinical condition for use of the medicine protocol	The clinical condition for which this medicine protocol has been developed is for the immunisation of vaccine recipients against COVID-19 (see Inclusion Criteria) .
Circumstances in which the medicine protocol applies	Targeted immunisation programme for vaccine recipients against COVID-19 as identified in the DoH policy based on the NIAC recommendations. The World Health Organisation declared COVID-19 outbreak as a pandemic on 11th March 2020 which is still ongoing.
Inclusion criteria for vaccine recipient using the medicine protocol	**Inclusion Criteria:** Individuals aged 18 years and older who have a contraindication or clinical precaution to a non-mRNA vaccine and to Nuvaxovid if they have made an informed decision based on their understanding of the risk of developing thrombosis with thrombocytopenia syndrome (TTS) compared with the consequences of COVID-19 infection. **Precautions:** ● Acute severe febrile illness defer until recovery ● Advice from a relevant specialist should be sought for a person with a history of an immediate severe allergic reaction to multiple drug classes with no identified allergen, any other vaccine injected antibody preparation or medicine likely to contain polysorbate 80 or idiopathic anaphylaxis and the risks should be weighed against the benefits of vaccination. ● Vaccination should be deferred until clinical recovery from COVID-19 at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic ● Vaccination is not contraindicated for those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration ● Immune Thrombocytopenia (ITP) with Jcovden COVID-19 vaccine ITP is a condition in which the immune system mistakenly targets blood cells called platelets that are needed for normal blood clotting. It can cause bleeding and can sometimes be fatal. Very few cases of ITP have occurred after Jcovden COVID-19 vaccine. It has usually occurred within 4 weeks of vaccination and will be added as a side effect for Jcovden COVID-19 vaccine (frequency unknown). If an individual has a history of thrombocytopenic disorder, the risk of developing low platelet levels such as ITP should be considered before vaccination, and platelet monitoring is recommended after vaccination with Jcovden COVID-19 vaccine for an individual who has a history of ITP. ● Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM (intramuscular) injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopenia (platelet count <50 x 10^9/ml) consult the supervising consultant

	● Those with inherited coagulopathies who require factor replacement therapy should receive it on the day of vaccination, prior to the IM vaccination. If there is uncertainty about the need for cover, contact the patient's Comprehensive Care Centre ● COVID-19 vaccines and other vaccines may be administered at the same time or at any interval. As it is not known if COVID-19 vaccine reactogenicity is increased with co-administration, vaccines should preferably be given in different limbs. ● Patients with planned immunosuppressive therapy should ideally receive the vaccine two weeks before treatment **Pregnancy:** ● Pregnant women should be offered an mRNA vaccine **Breastfeeding:** ● There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping.
Exclusion criteria for vaccine recipient using the medicine protocol	Jcovden COVID-19 vaccine should not be given under this medicine protocol if the vaccine recipient has: ● Past anaphylaxis (serious systemic allergic reaction requiring medical intervention) to any of its constituents (including polysorbate 80). ● Anaphylaxis following another viral vector vaccine. ● Thrombosis with Thrombocytopenia Syndrome (TTS) after the first dose of another viral vector COVID-19 vaccine ● A history of capillary leak syndrome
Actions to be taken for those who are excluded from the medicine protocol	● Refer to/discuss with the relevant Medical Practitioner/Clinical lead/Lead vaccinator for an individual medical assessment ● Document action in clinical record or IT System ● Where Jcovden COVID-19 vaccine is prescribed following medical assessment, the vaccinator may administer the vaccine within his/her scope of practice. **Note:** In determining their scope of practice, vaccinators must make judgements about their competency to carry out a role or activity in accordance with the guidance from their regulator.
Action to be followed for vaccine recipients who do not wish to receive the vaccine	Advise of the risks of not having the vaccine, including risk of possible severe COVID-19 disease. Advise regarding minimisation of risk
Description of circumstances and referral arrangements when further advice or consultation is required	Refer to/discuss with relevant Medical Practitioner/Clinical lead/lead vaccinator if the vaccine recipient had previous adverse reaction or other clinical concerns as outlined in exclusion criteria.

Documentation required to support implementation of the medicine protocol	• Check for and ensure consent has been obtained • Vaccine Information Leaflets • Patient held record cards • Health Products Regulatory Authority Adverse Reaction Reporting forms • National Incident Management System Form NIRF-01-v12 available at: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf
	It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of Jcovden COVID-19 vaccine which includes the following: • *Medicine Protocol for the Administration of Jcovden COVID-19 vaccine to vaccine recipients* • Please refer to Section B for registered nurses / midwives and *Self-Assessment of Competency Form* • *Health Service Executive (2021) Induction, Supervision, and Competency Assessment and Practice Protocol for Students as Vaccinators*. • *Anaphylaxis: Immediate Management in the community*. NIAC, Immunisation Guidelines for Ireland https://rcpi.access.preservica.com/uncategorized/IO_4283f8d0-dcaf-4fae-974e-71421ddcc51f/ • HSE *Clinical Guidance for Covid-19 Vaccination* https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf • COVID-19 chapter from *NIAC Immunisation Guidelines for Ireland* (2023) available at https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/

3.0 Name of Medicine	Jcovden COVID-19 vaccine
Dose & Route of administration	• The dose is 0.5ml • Route of administration: Intramuscular (IM) • Site: The preferred site is the deltoid muscle • Number of doses: One dose ONLY • Do not inject the vaccine intravascularly, subcutaneously or intradermally • Jcovden COVID-19 vaccine may be given to those with a contraindication to a 2nd dose of an mRNA COVID-19 vaccine and to Nuvaxovid, to complete the course. One dose of Jcovden COVID-19 vaccine should be given after an interval of at least 28 days.
Link to Medicine, details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA)	**Link to Summary of Product Characteristics and Patient Information Leaflet** Available at: https://www.ema.europa.eu/en/documents/product-information/jcovden-previously-covid-19-vaccine-janssen-epar-product-information_en.pdf
Potential adverse reactions and procedures for treatment of same	Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction • Vaccine recipients: 15 minutes • Those with a history of mastocytosis: 30 minutes • Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated The vaccine recipient should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the Jcovden COVID-19 vaccine after the above period of observation.
Procedure for reporting adverse drug reactions to the Health Products Regulatory Authority (HPRA)	The vaccinator should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out on line at http://www.hpra.ie or through use of the yellow card system that is available in a downloadable format from the HPRA website, or on request from the HPRA. The vaccine recipient's General Practitioner (GP) should be informed of any clinically significant reported adverse reaction. In the event of anaphylaxis, the incident and all actions taken must be promptly recorded in accordance with the Management of a Patient with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee 2023), available online at https://rcpi.access.preservica.com/uncategorized/IO_4283f8d0-dcaf-4fae-974e-71421ddcc51f/

Procedure for the reporting and documentation of errors and near misses involving the medicine	In the case of medicine errors that directly involve the vaccine recipient, i.e. wrong medicine/dose/route being administered or another medicine error, the vaccinator must remain with the person and closely monitor them for any adverse reactions. The vaccine recipient should be reviewed by the relevant medical practitioner/clinical lead/lead vaccinator and vital signs should be recorded. The incident must be reported to the relevant line manager/person in charge as soon as possible. The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day. (National Incident Report Form (NIRF 01 – V12) available at: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf The vaccine recipient and/or significant others should be informed of the incident. Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.
Resources and equipment required	• A multidose vial of Jcovden COVID-19 vaccine • 1 ml/2ml/2.5ml syringe, 23/25 gauge needle for IM administration • Fridge/cooler box with data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8°C • Disposable kidney dishes/trays • 70% alcohol swabs (for sterilizing vials) • Gauze swabs, tape/plasters • Sharps bins, and bins for disposal of healthcare risk and non-risk waste • Alcohol hand sanitiser • Access to telephone • Resuscitation equipment and drugs in accordance with *Anaphylaxis*: *Immediate management in the Community* (National Immunisation Advisory Committee, 2023) available at • Safe storage areas for medicines and equipment • Current Jcovden COVID-19 vaccine medicine protocol
Audit process to identify appropriate use of the medicine protocol or unexpected outcomes	All documentation will be held for review and audit purposes as per local/national agreement.

4.0 Information for vaccine recipient	
Advice to be given to the vaccine recipient before treatment	**Vaccine Information material must be supplied to the vaccine recipient prior to administration of the vaccine.** **Before Treatment** Check and confirm that consent has been obtained Discuss the Jcovden COVID-19 vaccine and the importance of protecting their health. Inform vaccine recipient that patient information leaflet is available online at https://www.ema.europa.eu/en/documents/product-information/jcovden-previously-covid-19-vaccine-janssen-epar-product-information_en.pdf Discuss potential side effects as below. Side effects may occur with following frequencies: **Local:** Very common: injection site pain Common: injection site erythema, swelling **General**: Very common: fatigue, headache, myalgia, nausea Common: arthralgia, chills, cough, pyrexia Uncommon: asthenia, back pain, hyperhidrosis, malaise, muscular weakness, oropharyngeal pain, pain in extremity, rash, sneezing, tremor, diarrhoea and paraesthesia Rare: hypersensitivity, urticaria, hypoesthesia, lymphadenopathy, vomiting, tinnitus and Venous Thromboembolism (VTE) Very rare: Thrombosis in combination with thrombocytopenia, Guillain-Barre syndrome Frequency unknown: Transverse Myelitis A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with Jcovden COVID-19 vaccine. This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of these cases occurred within the first fourteen days following vaccination. Recipients of Jcovden COVID-19 vaccine should be instructed to seek prompt medical assistance and mention recent vaccination if they have any of the following in the weeks after receiving Jcovden COVID-19 vaccine® ● breathlessness, ● pain in the chest or stomach, ● swelling or coldness in leg, ● severe or worsening headache or blurred vision after vaccination,

	• persistent bleeding, • multiple small bruises, reddish or purplish spots, or blood blisters under the skin Additionally, anyone with neurological symptoms including severe or persistent headaches (particularly 3 or more days after vaccination) blurred vision, seizures or mental status changes or who develops petechiae or ecchymoses beyond the site of vaccination, should seek prompt medical attention. Capillary leak syndrome is now listed as a very rare side effect of Jcovden COVID-19 vaccine. Recipients should be advised so seek medical attention if they have the following symptoms in the days after vaccination, which may be associated with feeling faint (due to low blood pressure): • oedema in the extremities • sudden weight gain. Guillain-Barré syndrome (GBS) has been reported as a very rare side effect following vaccination with Jcovden COVID-19 vaccine. Recipients should be advised to seek medical attention if they develop symptoms including : • double vision or difficulty moving eyes • difficulty swallowing, speaking, or chewing • coordination problems and unsteadiness • difficulty walking • tingling sensations in the hands and feet • weakness in the limbs, chest or face • problems with bladder control and bowel function. Healthcare professionals should be alert of GBS signs and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment, and to rule out other causes. Rare cases of Venous Thromboembolism (VTE) VTE (which is different from TTS or Thrombosis with Thrombocytopenia syndrome) was added as a rare (frequency >1/10,000 to <1/1,000) side effect of Jcovden COVID-19 vaccine based on data from clinical trials and post marketing surveillance. Healthcare professionals and individual receiving the vaccine should be aware of this risk, especially in those who may have an increased risk of VTE. A full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC), available at https://www.ema.europa.eu/en/documents/product-information/jcovden-previously-covid-19-vaccine-janssen-epar-product-information_en.pdf

Advice to be given to the recipient after treatment	**After Treatment** Discuss potential side effects Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction. Events of anaphylaxis have been reported therefore NIAC recommends the following monitoring for the post-vaccination period: ● Post vaccination observation period ● Vaccine recipients: 15 minutes ● Those with a history of mastocytosis: 30 minutes ● Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated The vaccine recipient should not leave the healthcare facility if they are feeling unwell and must report any side effects to a member of the vaccination team. The vaccine recipient should be advised to report any side effects to the relevant medical practitioner. If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol or ibuprofen-containing products) may be used. If more serious adverse or persistent effects occur, vaccine recipient should be advised to contact their GP/out of hours service.
Details of any necessary follow-up, action and referral arrangements	In the event of an adverse reaction the vaccination team must ensure that all procedures are adhered to as outlined in Section 3.

References

- Health Service Executive (2010) *Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste.* Dublin: Health Service Executive.

- National Immunisation Advisory Committee (2023) *Anaphylaxis: Immediate Management in the Community*. Available at https://rcpi.access.preservica.com/uncategorized/IO_4283f8d0-dcaf-4fae-974e-71421ddcc51f/

- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland,* Dublin: Royal College of Physicians Ireland. Online update available at https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/

- National Immunisation Office (2020) *Clinical Guidance for COVID-19 Vaccinations.* Available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf

- S.I. No. 155 of 2021 Medicinal Products (Prescription and Control of Supply) (Amendment) (No.4) Regulations 2021. Available at https://www.irishstatutebook.ie/eli/2021/si/155/made/en/pdf

- S.I. No. 81/2021 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No.4) Regulations 2021. Available at http://www.irishstatutebook.ie/eli/2021/si/81/made/en/pdf

- S.I. No. 698/2020 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. Available at http://www.irishstatutebook.ie/eli/2020/si/698/made/en/pdf