Master Medicine Protocol for the Administration of Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA Vaccine to Vaccine Recipients Aged 12 years and older (Ready to use – Grey cap- Do not dilute)

This medicine protocol is a specific written instruction for the administration of Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA Vaccine to vaccine recipients included in the Statutory Instruments S.I. No. 105 of 2023 and S.I. No. 467 of 2022 for primary and booster doses by healthcare professionals who are registered with their respective regulatory body and students in healthcare professions included in S.I. No. 698 of 2020, S.I. No. 81 of 2021 S.I. No. 245 of 2021. This medicine protocol is valid for the 2022/2023 HSE COVID-19 Vaccination Programme. This medicine protocol enables the healthcare professionals and students described above who are employed in the voluntary and statutory services of the Health Service Executive (HSE) who have undertaken the required education and training programmes to administer Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA Vaccine to vaccine recipients, with reference to guidelines and guidance from National Immunisation Advisory Committee (NIAC), HSE National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA 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/

- HSE 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/comirnaty-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 Comirnaty Original / Omicron BA.4-5 COVID-19 mRNA Vaccine to vaccine recipients aged 12 years and older (Ready to use - Grey cap - Do not dilute)

Document reference number	NIO 001.8
1.0 Critical elements	
Name of organisation where medicine protocol applies	Health Service Providers across the voluntary and statutory services of the HSE, non-HSE healthcare facilities and central vaccination centres. This Medicine Protocol applies to: Registered healthcare professionals included in S.I. No. 698 of 2020, S.I. No.81 of 2021 and S.I. No. 245 of 2021 employed in the voluntary and statutory services of the 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	September 2022
Date for review of medicine protocol	September 2023 (Regularly updated as per the NIAC recommendations & DoH policy)
Document prepared by	HSE 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 Organization declared COVID-19 outbreak as a pandemic on 11 March 2020 which is still ongoing.
Inclusion criteria for vaccine recipient using the medicine protocol	**Inclusion Criteria:** ● Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older ● Note: This vaccine is primarily recommended as a booster vaccine, but can be used as a primary course if necessary **Precautions** ● Acute severe febrile illness: defer until recovery ● Consider non mRNA vaccination for those aged 18 years and older, including pregnant women, with: • Anaphylaxis after multiple, different drug classes, with no identified allergen (may indicate polyethylene glycol (PEG) allergy) • Anaphylaxis after a vaccine, or a medicine which contained PEG • Idiopathic anaphylaxis (may indicate PEG allergy) ● Previous history of myocarditis or pericarditis after any COVID-19 vaccine - seek specialist advice ● There should be an interval of four weeks between mpox(formerly known as monkeypox)/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis ● For those receiving a **first booster** dose of vaccine, who have had breakthrough COVID-19 infection (laboratory-confirmed/antigen-positive with symptoms) since completion of the primary vaccination, the booster dose should be deferred until at least 4 months following diagnosis (3 months in exceptional circumstances) ● For those aged 50 years and older receiving a **further booster** dose of vaccine (i.e., any booster vaccine dose after the first booster vaccine), who have had breakthrough COVID-19 infection (laboratory-confirmed/antigen-positive with symptoms) following the last COVID-19 vaccine dose, **the further booster** dose should be deferred until at least 6 months following diagnosis. For those aged under 50 years, the **further booster** dose should be deferred for 9 months from COVID-19 infection (except those with immunocompromised where the interval is 6 months). ● Vaccination is not contraindicated for those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration ● 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 thrombocytopoenia (platelet count <50 x 10^9/L) 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 (except mpox (formerly known as monkeypox)/ smallpox) may be administered at the same time or at any

interval. As it is not known if COVID-19 vaccine reactogenicity is increased with coadministration, vaccines should preferably be given in different limbs.

Patients with planned immunosuppressive therapy should ideally receive the booster dose two weeks before treatment. The recommended minimum interval may be used.

Pregnancy:

Primary vaccination during pregnancy:

- For those aged 12-29 years, 2 doses 8 weeks apart is recommended. A minimum interval of three weeks may be used if there is urgency to achieve protection.
- For those aged 30 years and older, 2 doses 4 weeks apart is recommended. A minimum interval of three weeks may be used if there is urgency to achieve protection.

Booster vaccination during pregnancy:

First booster

For pregnant adolescents and adults a **first COVID-19 booster vaccine** (for those who have not already received a first booster COVID-19 vaccine) is recommended at least **4 months** since the last COVID-19 vaccine dose or confirmed SARS-CoV-2 infection.

- This first booster vaccine can be given at any stage in pregnancy

Further boosters (for those who received their first booster vaccine before pregnancy)

For pregnant adolescents and adults a COVID-19 booster vaccine once in pregnancy is recommended if it is more than **six months** since their previous COVID-19 vaccine or infection.

- COVID-19 vaccine can be given at any stage in pregnancy
- the booster is ideally given between 20-34 weeks gestation
- if it is more than 12 months since their previous COVID-19 vaccine or infection administration earlier in pregnancy should be considered.

(Of note: If an individual is immunocompromised and eligible for a further booster in pregnancy, then a 6 month interval since their previous COVID-19 vaccine dose or infection is recommended (irrespective of the number of weeks gestation and they may get two booster vaccine doses in pregnancy).

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	Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA Vaccine should not be given under this medicine protocol if the vaccine recipient has: ● Anaphylaxis (serious systemic allergic reaction requiring medical intervention following a previous dose of the vaccine or any of its constituents including polyethylene glycol (PEG) and trometamol). ● Anaphylaxis following another mRNA vaccine. ● Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine.
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. Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine. Consideration may be given to a non-mRNA vaccine for people aged 12 years and older ● The Medical Practitioner/clinical lead/lead vaccinator can consider referring the individual to an allergist/Immunologist for a further assessment ● Document action in clinical record or IT system ● Where Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA 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. Advice regarding minimization 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 (HPRA) Adverse Reaction Reporting forms or availability on-line ● 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 Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA Vaccine which includes the following: ● *Medicine Protocol for the Administration of Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA Vaccine to vaccine recipients (Ready to use - Grey cap - Do not dilute)* ● 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 (2023)*. 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	Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA Vaccine (Ready to use -Grey cap - Do not dilute)
Dose & Route of administration	• The dose is 0.3ml • Route of administration: Intramuscular (IM) • Site: The preferred site is the deltoid muscle • Do not inject the vaccine intravascularly, subcutaneously or intradermally
Primary course	For primary course the dose is 0.3ml, 2 doses 4 weeks apart • For those aged **12-29** years, an interval of **eight weeks** between the first and second doses of an mRNA vaccine is now recommended, with a minimum interval of three weeks if there is urgency to achieve protection. • For those aged 30 years and older, 2 doses **four weeks** apart is recommended, with a minimum interval of three weeks may be used if there is urgency to achieve protection. • If the second dose is given before 17 days, this is not considered a valid vaccine. • A third dose should be given at least four weeks after the second (invalid) dose for those aged 30 years and older, or at least eight weeks after the second (invalid) dose for those aged 12-29 years. • Exceptionally the minimum interval may be used between the invalid second dose and the third dose. Of note: For those immunocompromise due to disease or treatment a third dose should be given at least four weeks after the second (invalid) dose irrespective of their age. • If the second dose is given between 17 and 20 days after the first dose, it is a valid dose. • If the interval between doses is longer than 28 days, the second dose should still be given as soon as possible. The course does not need to be restarted. • Those who have received one dose of Comirnaty 30 micrograms can receive a second dose of Comirnaty Original/Omicron BA.4-5 to complete the vaccination series
Individuals who are immunocompromised due to disease or treatment: (see the NIAC chapter 5a, Table 2)	**Primary course** For those aged 12yrs and above 2 doses to be given with an interval of 4 weeks. Minimum interval of three weeks can be applied if there is urgency to achieve protection. • An additional mRNA vaccine dose should be given to those aged 12 and older with immunocompromise due to disease or treatment who have completed their primary course, regardless of whether the primary course was of an mRNA or an adenoviral vector vaccine. This is an extended primary vaccination course. • The additional vaccine should be given after an interval of 8 weeks following the last dose of an authorised COVID-19 vaccine or infection. (a minimum interval of 28 days may be used in exceptional circumstances)

<table>
<tr>
<td>Booster dose of COVID-19 Vaccine
See the NIAC chapter 5a</td>
<td>
<u>First booster dose</u>
People aged 12 years and older who have completed their primary course with any COVID-19 vaccine type are recommended a single dose (0.3ml) of an Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA vaccine as a first booster dose
The booster dose can be given at the same time or at any interval before or after seasonal influenza vaccine. This applies whether the primary course was an mRNA or viral vector vaccine or a protein subunit vaccine.

Recommended intervals:
First booster
• A four month interval from last vaccine dose or confirmed COVID-19 infection (laboratory-confirmed/antigen-positive with symptoms) is recommended for all aged 12 years and older receiving a first booster dose of vaccine, in exceptional circumstances a minimum interval of three months may be used.

Recommended intervals for further booster vaccination in Spring 2023
• A six month interval from previous COVID-19 booster vaccine or infection is recommended for those aged 50 years and older receiving a further booster as part of the Spring vaccination programme 2023.
• A nine month interval from previous COVID-19 booster vaccine or infection is recommended for those aged 12 - 49 years receiving a further booster as part of the Spring vaccination programme 2023 (except in the case of those with immunocompromise associated with a suboptimal response to vaccination, where an interval of six months following any previous COVID-19 vaccine dose or infection is recommended)
• A minimum interval of three months is permissible from last booster or COVID-19 infection in exceptional circumstances e.g. heightened epidemiologic risk or for operational reasons

• <u>Of note:</u> Those aged 18 - 49 years not in other groups who did not choose to receive a second COVID-19 booster vaccine when it was previously offered to them may still receive a second booster vaccine if there is at least a nine month interval after their first COVID-19 booster vaccine or SARS-CoV-2 infection.
</td>
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<tr>
<td>Booster vaccination in Spring 2023
(irrespective of the number of prior booster doses)</td>
<td>
<table>
<tr><th>Age group</th><th>Booster vaccination in Spring (2023) is recommended irrespective of the number of prior booster doses</th></tr>
<tr><td colspan="2">A six month interval from previous booster vaccine or infection is recommended for those aged 50 years and older.
A nine month interval from previous booster vaccine or infection is recommended for those aged under 50 years except those immunocompromise associated with a suboptimal response to vaccination with an interval of six months</td></tr>
<tr><td>70yrs and older</td><td>A booster vaccine is recommended in spring</td></tr>
<tr><td>50-69yrs</td><td>A booster vaccine is recommended in spring for
-those living in long term care facilities for older adults
-those with immunocompromise associated with a suboptimal response</td></tr>
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<tr><td></td><td>
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<tr><td></td><td>to vaccination with an interval of six months.</td></tr>
<tr><td>12-49yrs</td><td>A booster vaccine is recommended in spring for
-those with immunocompromise associated with a suboptimal response to vaccination with an interval of six months
-aged 18+ years living in long term care facilities for older adults</td></tr>
</table>
</td></tr>
<tr><td>Link to medicine details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA)</td><td>Link to SmPC and Patient Information Leaflet available at:
https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf</td></tr>
<tr><td>Potential adverse reactions and procedures for treatment of same</td><td>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
Vaccine recipients should be advised to seek urgent medical attention if they have symptoms suggestive of an allergic reaction such as difficulty breathing, feeling faint, rapid heartbeat or a skin rash.
NIAC will continue to closely monitor relevant data and will update this advice as necessary.

The vaccine recipient should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the Comirnaty© Original/Omicron BA.4-5 COVID-19 mRNA Vaccine after the above period of observation.</td></tr>
<tr><td>Procedure for reporting adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)</td><td>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 which 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 reactions.

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: Immediate Management in the Community (NIAC 2023), available online at https://rcpi.access.preservica.com/uncategorized/IO_4283f8d0-dcaf-4fae-974e-71421ddcc51f/</td></tr>
</table>

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. Vital signs should be recorded and the vaccine recipient should be reviewed by the relevant medical practitioner/ clinical lead/lead vaccinator and. 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 https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.
Resources and equipment required	• Vaccine (Ready to use - Grey cap - Do not dilute) • Syringe and 23 gauge/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 the 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* (NIAC 2022) available at https://rcpi.access.preservica.com/uncategorized/IO_4283f8d0-dcaf-4fae-974e-71421ddcc51f/ • Safe storage areas for medicines and equipment • Current 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 Comirnaty Original/Omicron BA.4-5 COVID-19 mRNA 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/comirnaty-epar-product-information_en.pdf

Advice to be given to the recipient after treatment	Discuss potential side effects as below. Side effects may occur with following frequencies: **Local:** *Very common*: injection site pain and swelling *Common*: injection site erythema *Uncommon*: injection site pruritus **General:** *Very common:* arthralgia, diarrhoea, fatigue, fever, headache, myalgia *Common:* nausea, vomiting *Uncommon:* insomnia, hypersensitivity reactions (e.g. rash, pruritus, angioedema),lymphadenopathy, malaise, extremity pain, Hyperhidrosis (night sweats), decreased appetite, asthenia and lethargy *Rare:* acute peripheral facial paralysis *Very rare:* myocarditis and pericarditis *Frequency unknown:* Anaphylaxis, Paraesthesia, Hypoaesthesia, Erythema Multiforme, Extensive swelling of vaccinated limb, Facial swelling As per the EMA latest advice, cases of myocarditis and pericarditis have been reported very rarely following vaccination with the COVID-19 mRNA Vaccines including Comirnaty. Healthcare professionals should advise vaccinated individuals to seek immediate medical attention should they experience chest pain, shortness of breath, or palpitations. The cases primarily occurred within 14 days after vaccination, more often after the second dose and in younger men. Details of adverse reactions may be found in the SmPC, available at https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf **After Treatment** Discuss potential side effects and give advice how to manage common adverse reactions. 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: ● 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. Ibuprofen is not recommended in pregnancy. 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 (2023)* Dublin: Royal College of Physicians Ireland. Online update available at https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/

HSE 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. 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

S.I. No. 245/2021 - 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

S.I. No. 467/2022 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2022. Available at http://www.irishstatutebook.ie/eli/2022/si/467/made/en/pdf

Health Service Executive (2021) Induction, Supervision, and Competency Assessment and Practice Protocol for Students as Vaccinators. Available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/induction-supervision-and-competency-assessment-and-practice-protocol-for-students-as-vaccinators.pdf

Section B Information Specific to Registered Nurses and Registered Midwives for the administration of the COVID-19 vaccines

Statement of Support from Dr Geraldine Shaw, Nursing and Midwifery Services Director, Office of the Nursing and Midwifery Services, HSE

I am delighted to support Registered Nurses and Registered Midwives to administer COVID-19 vaccines under medicine protocol.

Nurses and midwives have a long tradition of supporting vaccination programmes, for example Schools Immunisation Programme, Seasonal Influenza Peer Vaccination Programme and Primary Childhood Immunisation Programme.

The national COVID-19 vaccination programme commenced in December 2020. Statutory Instruments No. 698 of 2020, No. 8 of 2021 and No. 43 of 2021 identify nurses and midwives as professions that can administer named COVID-19 vaccines, subject to approval of an education programme by the regulatory body concerned.

In order to administer the vaccines, registered nurses and registered midwives must be familiar with the most up to date version of the medicine protocols including the content of this section and have completed the *COVID-19 Vaccination Programme for Nurses and Midwives* on HSeLanD. Nurses and midwives must also have completed the Competency Assessment Form, also included in this section.

I would like to acknowledge the contribution of the nursing and midwifery professions to this very important national initiative.

Signature

30th March 2021
Date

Professional Qualifications, Training, Experience and Competence Required

Professional qualifications, training, experience and competence required prior to using this medicine protocol / Professional Qualifications:	Registered nurse or registered midwife, maintained on the active register maintained by The Nursing and Midwifery Board of Ireland. HSeLanD education programme titled *COVID-19 Vaccination Programme for Nurses and Midwives* Basic Life Support for Health Care Providers within the last two years.
Training, Experience, Competence:	Initial anaphylaxis programme *(National Anaphylaxis Education Programme for Health Care Professionals)* via HSeLanD followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSeLanD Anaphylaxis e-learning programme available at www.hse.ie. The nurse/midwife must complete the *Competency Assessment Form* to administer the COVID-19 Vaccines. COVAX IBM/Salesforce online programme https://www.hse.ie/eng/health/immunisation/hcpinfo/hsecovid19vms.html **Recommended:** *Storing and Managing Vaccines* www.hseland.ie

Supporting Documents for Registered Nurses and Registered Midwives

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais Health Service Executive (2019) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or Suspected Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis.* Dublin: Health Service Executive

Government of Ireland (2020) *Statutory Instruments Number 698 of 2020*. Dublin: Stationery

Office Government of Ireland (2021) *Statutory Instruments Number 8 of 2021*. Dublin:

Stationery Office Government of Ireland (2021) *Statutory Instruments Number 43 of 2021*.

Dublin: Stationery Office

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

Nursing and Midwifery Board of Ireland (2021) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/Code.

Nursing and Midwifery Board of Ireland (2022) *Practice Standards for Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/Midwives-Standards.

Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Guidance to Nurses and Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/More- Standards-Guidance/Recording-Clinical-Practice

Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework.* Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/Scope-of- Practice/Nursing-Practise-Scope-Definition

Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland, available at: http://www.nmbi.ie

Competency Assessment Form

NAME:

Self-Assessment of Competency to Administer COVID-19 Vaccine under Medicine Protocol

Domain of Practice	**Critical Element**	**Competent** Date/ Initials	**Needs Practice** Date/ Initials	**Needs Theory** Date/ Initials
1	I understand the role and function of medicine protocols in the context of NMBI guidelines in relation to: ● The Code of Professional & Ethical Conduct ● Scope of Nursing and Midwifery Practice ● Guidance to Nurses and Midwives on Medication Management ● NIAC Immunisation Guidelines for Ireland.			
2	I practice within my scope of practice to undertake administration of COVID-19 Vaccines under medicine protocol.			
3	I have undertaken the *COVID-19 Vaccination Programme for Nurses and Midwives* on HSeLanD.			
4	I have attended Basic Life Support for Health Care Providers within the last two years.			
5	I am competent in safe injection technique.			
6	I have attended an approved Anaphylaxis education programme and I am familiar with the current medicine protocol on the administration of Epinephrine by RNs/RMs.			
7	I can outline the inclusion/ exclusion criteria for administering COVID-19 Vaccine under the named medicine protocol.			
8	I can refer to/discuss those that are meeting the exclusion criteria to the relevant medical practitioner for an individual medical assessment as per medicine protocol.			
9	I am familiar with the documentation required to support implementation of the medicine protocol to ensure safe administration of COVID-19 Vaccine.			
10	In assessing suitability for vaccination I can undertake a clinical assessment of individuals within the scope of the medicine protocol.			
11	I can provide information regarding COVID-19 Vaccine, benefits and side effects to vaccine recipients.			
12	I am aware of the procedure for treatment and reporting of potential adverse reactions.			
13	I understand the procedure for reporting and documentation of medicine errors/ near misses.			
14	I dispose of all equipment and sharps in accordance with guidance for Healthcare Risk Waste (HSE, 2010).			

15	I am aware of and comply with the guidance on vaccine storage and handling including the maintenance of the cold chain in accordance with national and local policies.			

16	I have undertaken the following HSeLanD/online programmes: ● AMRIC Aseptic Technique www.hseland.ie ● AMRIC Hand Hygiene www.hseland.ie ● GDPR guidelines www.hseland.ie ● COVAX IBM/Salesforce online programme https://www.hse.ie/eng/health/immunisation/hcpinfo/hseco vid19vms.html			

I have sufficient theoretical knowledge and practice to undertake vaccination under this medicine protocol independently, and I acknowledge my responsibility to maintain my own competence in line with the Scope of Nursing and Midwifery Practice and current best evidence.

Registered Nurse/Midwife Signature:_____ Date:_____

If any deficits in theory and/or clinical practice are identified, the nurse/midwife must discuss with relevant Line Manager and implement appropriate action plan to achieve competency within an agreed time frame.

Action Plan (for use if needed to reach competencies

outlined) Action necessary to achieve competency:

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.. Date to be achieved:…….

Supporting evidence of measures taken to achieve competency:

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Nurse/Midwife signature:

Date:___

Line Manager signature

Date:____

Nursing and Midwifery Board of Ireland Statement of Support 2021