Master Medicine Protocol for the Administration of Comirnaty 10 micrograms COVID-19 mRNA Vaccine (for children aged 5-11 years)

This medicine protocol is a specific written instruction for the administration of Comirnaty 10 micrograms to children aged 5-11 years included in Statutory Instruments S.I. No.718 of 2021 by healthcare professionals and students in healthcare professions 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 S.I. No. 402 of 2022 on additional and booster doses. This medicine protocol is valid for the 2021/2022/2023 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 10 micrograms to children, 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 Comirnaty 10 micrograms 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://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
- HSE National Immunisation Office (2023) Clinical Guidance for COVID-19 Vaccinations, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf
- Summary of product characteristics (Find this product information from page no. 39 for Comirnaty 10 micrograms /dose concentrate for children aged between 5-11 years) https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-productinformation_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 medicine protocol to facilitate the administration of COVID-19 vaccines to vaccine recipients according to 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, relating 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 10 micrograms COVID-19 mRNA Vaccine to Children 5-11yrs

Document reference number	NIO 001.5
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	December 2021
Date for review of medicine protocol	December 2023
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 vaccination of children aged 5-11 years (see Inclusion Criteria) against COVID19.
Circumstances in which the medicine protocol applies	Targeted vaccination programme for children aged 5-11 years 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 11th March 2020 which is still ongoing.
Inclusion criteria for children using the medicine protocol	**Inclusion Criteria:** ● Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in children aged 5-11 years (i.e. 5 to less than 12 years of age). ● Children who turned 12 years of age after the 1st dose and before the 2nd dose should be given Comirnaty 30 micrograms/dose concentrate or Comirnaty 30 micrograms/dose dispersion for injection i.e. ready to use with the recommended interval of 8 weeks (refer to the relevant medicines protocol) **Precautions** ● Acute severe febrile illness; defer until recovery. ● Previous history of myocarditis or pericarditis after any COVID-19 vaccine - seek specialist advice ● Vaccination should be postponed in children with a previous history of Multisystem Inflammatory Syndrome (MIS-C), until clinical recovery or until 90 days or more since diagnosis, whichever is the longer. ● If vaccination is advised for a child with prior anaphylaxis to an unrelated allergen, observe for 30 minutes after vaccination. ● Children with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used. ● Primary 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 ● Children with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the parent or guardian about this risk. For those with thrombocytopenia (platelet count<$50x10^9$/L), consult the supervising consultant. People with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra) do not require haemostatic cover for vaccination. ● 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 replacement therapy contact the child's supervising consultant

	• COVID-19 vaccines and other vaccines may be administered at the same time or at any interval. Co-administered vaccines should be given in different arms. • There should be an interval of four weeks between monkeypox/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis
Exclusion criteria for vaccine recipient using the medicine protocol	Anaphylaxis following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG) and trometamol).

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. • 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 10 micrograms 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 children who do not wish to receive the vaccine	Advise the parent/legal guardian about the risks of their child not having the vaccine, including risk of possible severe COVID-19 disease. Advice 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 child 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 from the parent/legal guardian for all children who receive the vaccine as per the HSE national consent policy • Vaccine Information Leaflets • Patient held record cards • Health Products Regulatory Authority Adverse Reaction Reporting forms or available 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 10 micrograms COVID-19 mRNA Vaccine which includes the following: • *Medicine Protocol for the Administration of Comirnaty 10 micrograms COVID-19 mRNA Vaccine (for children aged 5-11 years)* • 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 (2023), Immunisation Guidelines for Ireland.* https://rcpi.access.preservica.com/uncategorized/IO_4283f8d0-dcaf-4fae-974e-71421ddcc51f/ • HSE NIO *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) https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
3.0 Name of Medicine	Comirnaty 10 micrograms
Dose & route of administration	• The dose is 0.2ml, 2 doses 8 weeks apart • Minimum interval of three weeks can be applied if there is urgency to achieve protection. • Route of administration: Intramuscular (IM) • Site: The preferred site is the deltoid muscle • If the second dose is given before 17 days (i.e., more than four days before the minimum interval), this is not considered a valid vaccine. A third dose should be given ideally 8 weeks, but at least 21 days after the second (invalid) dose. . Of note: For those immunocompromise due to disease or treatment a third dose should be given ideally 4 weeks after the second (invalid) dose but at least 21 days after the second (invalid) dose. • If the second dose is given between 17 and 21 days after the first dose, it is a valid dose. • If the interval between doses is longer than 8 weeks, the second dose should still be given as soon as possible. The course does not need to be restarted.

	• Children who have received one dose of Comirnaty 10 micrograms should receive a second dose of Comirnaty 10 micrograms to complete the vaccination series (the exception is children who turn 12 years of age after the 1st dose and before the 2nd dose who should be given Comirnaty 30 micrograms/dose concentrate with the recommended interval of 8 weeks as a second dose) • Do not inject the vaccine intravascularly, subcutaneously or intradermally
Children who are immunocompromised due to disease or treatment: (see the NIAC chapter 5a, Table 2)	**Primary course** 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. **Extended primary course** • An additional Comirnaty dose (10 micrograms 0.2ml) should be given to those aged 5-11 years with immunocompromise associated with a suboptimal response to vaccines at the time of vaccination, who have completed their primary course. This is an extended primary vaccination course (total of three vaccine doses). • The additional vaccine should be given after at least 8 weeks following the second dose (28 days in exceptional circumstances). • Serological testing prior to giving an additional dose is not recommended. **First Booster dose** A first booster dose (Comirnaty 10 micrograms 0.2ml) should be given to all those aged 5-11 years with immunocompromise associated with a suboptimal response to vaccines at the time of the primary vaccination course, who have already completed an extended primary vaccination course (three doses). Those who became immunocompromised after their primary course should receive a first booster dose at an interval of four months after their last vaccine dose or SARS-CoV-2 infection (3 months in exceptional circumstances). **Further Booster Dose (i.e., booster dose after the first booster dose) in Spring 2023** - For those aged 5-11 with immunocompromise associated with a suboptimal response to vaccination, a Spring booster in 2023 is recommended after an interval of **6 months** following any previous COVID-19 vaccine dose or SARS-CoV-2 infection.
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/comirnaty-eparproduct-information_en.pdf **Note**: Find this product information from Summary of Product Characteristics page no. 39 for Comirnaty 10 micrograms /dose concentrate for children aged between 5-11 years.

Potential adverse reactions and procedures for treatment of same	Following administration of the vaccine, the child 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 parent/guardian should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the Comirnaty 10 micrograms 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 which is available in a downloadable format from the HPRA website, or on request from the HPRA. The child's General Practitioner should be informed of any clinically significant reported adverse reactions. In the event of an anaphylactic reaction, the incident and all actions taken must be promptly recorded in accordance with *Anaphylaxis*: *Immediate Management in the Community* (NIAC 2023) available 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 child, 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 child 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 parent /legal guardian of the child 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	• Vaccine • Sodium Chloride 0.9% Solution for Injection • 2ml/ 2.5ml / 3ml syringe and 21 gauge green needle for reconstitution • 23 gauge /25g 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 sanitizer, face masks • Access to telephone • Resuscitation equipment and drugs in accordance with *Anaphylaxis*: *Immediate Management in the Community* (NIAC, 2023) 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 child/parent/guardian before vaccination	**Vaccine Information material must be supplied with the consent form to the parent/guardian prior to administration of the vaccine.** **Before Vaccination** Check and confirm that consent has been obtained Discuss with the parent/guardian about the Comirnaty 10 micrograms and the importance of protecting their child's health. Inform the parent/guardian that patient information leaflet is available online at https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf Discuss potential side effects as below Side effects may occur with following frequencies: **Local:** Very common: injection site pain and swelling Common: injection site redness Uncommon: injection site pruritus.

	General: Very common: headache, diarrhoea, arthralgia, myalgia, fatigue, chills and pyrexia Common: nausea, vomiting Uncommon: lymphadenopathy, hypersensitivity reactions (e.g. rash, pruritus, urticaria, angioedema), decreased appetite, insomnia , lethargy, hyperhidrosis (night sweats), extremity pain, asthenia and malaise Rare: acute peripheral facial paralysis Very rare: myocarditis, pericarditis Unknown frequency: anaphylaxis, erythema multiforme, extensive swelling of the vaccinated limb and facial swelling 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/comirnaty-epar-product-information_en.pdf Children may not be protected until at least 7 days after their second dose of the vaccine and the vaccine may not protect all vaccinees. **After Vaccination** Discuss potential side effects with the parent/guardian and give advice how to manage common adverse reactions. Following administration of the vaccine, the child should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction.
Advice to be given to the child/parent/guardian after vaccination	Events of anaphylaxis have been reported therefore NIAC recommends the following monitoring for the post-vaccination period: • Those with no history of anaphylaxis from any cause: 15 minutes • Those with a history of anaphylaxis from any cause: 30 minutes • Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated. The child/parent/guardian 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 child/parent/guardian 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, the parent/guardian 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

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais

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 (2020)* Dublin: Royal College of Physicians Ireland. Online update available at https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

HSE National Immunisation Office (2023) *Clinical Guidance for COVID-19 Vaccinations.* Available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf

Irish Statutory Instruments, Available at https://www.irishstatutebook.ie/eli/statutory.html

Section B Information Specific to Registered Nurses and Registered Midwives for the Administration of Comirnaty 10 micrograms COVID-19 mRNA Vaccine or Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate COVID-19 mRNA Vaccine (for children aged 5-11 years)

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

In order to administer the vaccine, registered nurses and registered midwives must be familiar with the most up to date version of the Comirnaty 10 micrograms COVID-19 mRNA Vaccine or Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate COVID-19 mRNA medicine protocol. Registered nurses and registered midwives must also have completed the Competency Assessment Form included in this section.

Professional Qualifications, Training, Experience and Competence Required

Professional qualifications, training, experience and competence required prior to using this medicine protocol / Professional Qualifications : **Training, Experience, Competence:**	The registered nurse or registered midwife must have completed all of the following: 1. Be a Registered Nurse or Registered Midwife, on the active register maintained by the Nursing and Midwifery Board of Ireland (NMBI) 2. *COVID-19 Vaccination Education Programme for Registered Nurses and Midwives* and Student Nurses and Midwives incorporating *Children Having Vaccinations and Health Care Procedures- Professor Lucy Bray* accessible at www.HSELanD.ie 3. *COVID-19 Vaccination Training Programme – Children aged 5-11 years* accessible at www.hse.land.ie 4. An approved *Basic Life Support for Health Care Providers Course.* (i.e. Irish Heart Foundation (IHF)) Recertification is required every two years 5. Initial *National Anaphylaxis Education Programme for Health Care Professionals* accessible on www.HSELanD.ie followed by a two hour classroom based skills workshop. Recertification is required every two years by completing the on-line *National Anaphylaxis Education Programme for Health Care Professionals* accessible at www.HSELanD.ie 6. *Self-Assessment of Competency Form* to administer the Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate COVID-19 mRNA Vaccine, see below 7. COVAX IBM/Salesforce online programme accessible at https://www.hse.ie/eng/health/immunisation/hcpinfo/hsecovid19vms.html 8. *Immunisation Foundation Programme*, accessible at www.HSELanD.ie **Recommended:** 1. *Storing and Managing Vaccines,* accessible at 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

Government of Ireland (2023) *Statutory Instruments Number 11 of 2023 and S.I. No. 105 of 2023*. Dublin: Stationery Office

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

HSE Policy on the Management of Sharps and Prevention of Sharp Injuries 2022, available at https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management-of-sharps-and-prevention-of-sharp-injuries.pdf

National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community 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://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

National Immunisation Office (2023) Dublin: Clinical Guidance for COVID-19 Vaccination https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf

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

NAME: _____

(PRINT CLEARLY in CAPITALS)

NMBI PIN Number_____

Self-Assessment of Competency to administer Comirnaty 10 micrograms COVID-19 mRNA Vaccine or Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate COVID-19 mRNA vaccine under medicine protocol by registered nurses and registered midwives to children aged 5-11 years. Please complete and discuss with your line manager/clinical lead prior to vaccinating this cohort.

Performance Criteria (Tick/date/initial as applicable)

No	**Critical Element**	**Competent** Date/Initials	**Needs Practice** Date/Initials	**Needs Theory** Date/Initials
1	I practice within my scope of practice (Scope of Nursing and Midwifery Practice Framework, NMBI, 2015) to undertake administration of Comirnaty 10 micrograms COVID-19 mRNA Vaccine or Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate COVID-19 mRNA vaccine			
2	I understand that vaccines are prescription only medicines (POM) and prior to administration require either: 1. a valid prescription for individual vaccines or 2. a medicine protocol for individual vaccines			
3	I understand the role and function of medicine protocols in the context of NMBI and NIAC guidelines in relation to: • The Code of Professional and Ethical Conduct for Registered Nurses and Registered Midwives (NMBI, 2021) • Scope of Nursing and Midwifery Practice Framework (NMBI, 2015) • Guidance for Registered Nurses and Midwives on Medication Administration (NMBI, 2020) (Guiding Principle 2, page 12, 2.8) • Guidance to Nurses and Midwives on Medication Management (An Bord Altranais, 2007) • NIAC Immunisation Guidelines for Ireland available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland			
4	I have read and understood the: • *Immunisation Guidelines for Ireland* (NIAC) • *COVID-19 Guidelines for Vaccinators* (NIO) • *COVID-19 Vaccination Training Programme – Children aged 5-11 years accessible on www.HSELanD.ie* • *5-11 year old Vaccination Pathway Guide for CVCs* • I undertake to review the most current vaccination information from the NIO accessible on: www.immunisation.ie			
5	I have read and understand the NIO (2023) Clinical Guidance for COVID-19 Vaccination Programme Guidelines for Staff			
6	I have read and understood the current Medicine Protocol for this immunisation programme			

7	I have read and understood the documentation required to support implementation of the medicine protocol to ensure safe administration of the vaccine. I can outline the inclusion/exclusion criteria for children aged 5- 11 years under the named medicine protocol			
8	I am competent in safe intramuscular injection technique (Deltoid muscle) for children aged 5-11 years infants (refer to NIAC immunisation guidelines, Chapter 2)			
9	I understand if further education and training is required to deem myself competent in intramuscular injection technique (Deltoid muscle) for children aged 5-11 years I am required to attend a face to face education/training provided by the HSE or HSE contracted providers			
10	I have successfully completed the HSELand education programme; *Covid-19 Vaccination Education Programme for Registered Nurses and Midwives and Student Nurses and Midwives* incorporating *Children Having Vaccinations and Healthcare Procedures – Professor Lucy Bray*			
11	I have the appropriate communication skills to communicate effectively with the child and their parent/legal guardian			
12	I understand if further education and training is required to deem myself competent in preparation of vaccines under medicine protocol utilising Antimicrobial Resistance and Infection Control (AMRIC) aseptic technique, I am required to access an education / training programmes in a Centre for Nurse and Midwifery Education and/or HSELanD			
13	I have successfully completed the following www.hseland.ie programmes: • *HSE Immunisation Foundation Programme* • *AMRIC Aseptic Technique* • *AMRIC Hand Hygiene* • *GDPR* • *National Consent Policy (HSE, 2022) available at:* https://www.hse.ie/eng/about/who/qid/otherquality-improvement-programmes/consent/nationalconsent-policy.html • *Introduction to Children First* accessible on www.HSELanD.ie • COVAX IBM/Salesforce online programme accessible at https://www.hse.ie/eng/health/immunisation/hcpinfo/hsecovid19vms.html			
14	I have attended an approved Basic Life Support for Health Care Providers Course within the last two years (i.e. Irish Heart Foundation (IHF))			
15	I have successfully completed an approved anaphylaxis programme as outlined in section B of the medicine protocol and am familiar with NIAC (2023) Immunisation Guidelines for Ireland Anaphylaxis: Immediate Management in the Community available at: https://rcpi.access.preservica.com/uncategorized/IO_4283f8d0-dcaf-4fae-974e-71421ddcc51f/			
16	In assessing suitability for vaccination I can undertake a clinical assessment of children aged 5 -11years presenting for vaccination within the scope of the medicine protocol			
17	I can refer the child who meet the exclusion criteria to the relevant medical practitioner/clinical lead/lead vaccinator for an individual medical assessment as per medicine protocol			
18	I understand the agreed process, including ICT systems if applicable for the accurate and appropriate documentation in the child's record for vaccine administration			

19	I have sufficient knowledge and understanding of the correct procedure/guideline prior to the administration of the vaccine regarding the following: • Preparation of the vaccine for administration • Documentation of the details of the vaccine to include the vaccine label which has the batch number and use before date/expiry date details • Date and time and site of administration of vaccine • Vaccinator ID (name, signature and NMBI PIN)			
20	I can provide accurate relevant information regarding vaccine consent, benefits, and side effects to the child and their parent/legal guardian			
21	I will utilise documentation procedure for treatment and reporting of adverse drug reactions to the HPRA if required available at: www.hpra.ie			
22	I can demonstrate the procedure for reporting and documentation of medication errors/near misses as per HSE Incident Management Framework (2020)			
23	I dispose of single use equipment and sharps in accordance with guidance on Infection Prevention and Control HSE (2021) available at: https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectionpreventionandcontrolguidanceandframework/Interim%20HSE%20Guidance%20on%20IPC.pdf			
24	In the event of needle stick injury, I agree to follow guidelines as outlined in the 'EMI Tool Kit' available at: https://www.hpsc.ie/a-z/EMIToolkit/			
25	I comply with the guidance on vaccine handling, delivery and storage including the maintenance of the cold chain in accordance with national and local policies, procedures, protocols and guidelines (PPPGs).			

I have sufficient theoretical knowledge and clinical practice to administer COVID – 19 vaccine to children aged 5-11 years independently, and I acknowledge my responsibility to maintain my own competence in line with the Scope of Nursing and Midwifery Practice Framework (NMBI, 2015) and current best evidence.

Registered Nurse/Midwife Name: _____

Registered Nurse/Midwife Signature: _____

NMBI PIN: _____

Date: _____

Support Plan (for use if needed to reach competence outlined)

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

Action necessary to achieve competence:

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……

……

Date to be achieved: ……

Supporting evidence of measures taken to achieve competence:

……

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Registered Nurse/Registered Midwife Signature: _____

Name and Title of Line Manager/Clinical Lead: _____

Line Manager/Clinical Lead Signature: _____

Date: _____