Master Medicine Protocol for the Administration of Comirnaty 3 micrograms / dose concentrate COVID-19 mRNA Vaccine (for infants and children aged 6 months - 4 years)

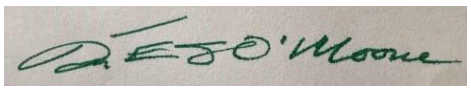
This medicine protocol is a specific written instruction for the administration of Comirnaty 3 micrograms to infants and children aged 6 months - 4 years included in Statutory Instruments S.I. No.11 of 2023 by healthcare professionals included in Statutory Instruments S.I. No. 698 of 2020, S.I. No. 81 of 2021 and S.I. No. 245 of 2021 who are registered with their respective regulatory body. This medicine protocol is valid for the 2023/2024 HSE COVID-19 Vaccination Programme. This medicine protocol enables the healthcare professionals 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 3 micrograms to infants and 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 (SmPC) for Comirnaty 3 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. 72 for Comirnaty 3 micrograms /dose concentrate for children aged between 6months-4 years) https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

The Nursing and Midwifery Board of Ireland 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) policy.

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

Document reference number	NIO 2023
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, S.I. No. 81 and S. I. No. 245 employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes.
Date the medicine protocol comes into effect	January 2023
Date for review of medicine protocol	January 2024
Document prepared by	HSE National Immunisation Office
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 infants and children aged 6 months-4 years (see Inclusion Criteria) against COVID19.
Circumstances in which the medicine protocol applies	Targeted vaccination programme for infants and children aged 6 months-4 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 infants and children using the medicine protocol	**Inclusion Criteria:** ● Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in infants and children aged 6 months-4 years. ● A 4-year-old child who received the initial dose (or doses) of Comirnaty 3 micrograms and who is 5 years of age at the time of their second or third dose should receive the next dose(s) of Comirnaty 10 micrograms. If a child becomes five years of age before completion of the recommended course, the schedule should be completed with the age appropriate dose, Comirnaty 10 microgram as follows: • If they have received one dose of Comirnaty 3 micrograms: leave an interval of three weeks, then give two doses of Comirnaty 10 micrograms eight weeks apart • If they have received two doses of Comirnaty 3 micrograms: leave an interval of eight weeks, then give one dose of Comirnaty 10 micrograms. **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 infants/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. ● Anaphylaxis after multiple different drug classes, with no identified allergen (may indicate Polyethylene Glycol (PEG) allergy), anaphylaxis after a vaccine or a medicine known to contain PEG or unexplained anaphylaxis (may indicate PEG allergy) referral to allergist/Immunologist is recommended before consideration for vaccination. ● Infants/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 ● Infants/children with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the parent or legal 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 infant's/child's supervising consultant ● Until there is evidence for safe co-administration in this age group, Comirnaty 3micrograms should be separated from other vaccines by **14 days**.
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 3 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 infant/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 infant/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 infants/children who receive the vaccine as per the HSE national consent policy ● Vaccine Information Leaflets ● Patient held record cards ● Health Products Regulatory Authority (HPRA) 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 3 micrograms which includes the following:

<table>
<tr><td></td><td>

Medicine Protocol for the Administration of Comirnaty 3 micrograms / dose concentrate COVID-19 mRNA Vaccine (for infants and children aged 6 months - 4 years).
Please refer to Section B for registered nurses & midwives & Competency Assessment Form
Critically examining the evidence and practice of holding children for clinical procedures (Masterclass Recording - 6th Dec 2022) accessible on www.HSELanD.ie
COVAX IBM/Salesforce online programme accessible at https://www.hse.ie/eng/health/immunisation/hcpinfo/hsecovid19vms.html
Anaphylaxis: Immediate Management in the Community. NIAC, 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) (available at https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

</td></tr>
<tr><td>3.0 Name of Medicine</td><td>Comirnaty 3 micrograms / dose concentrate COVID-19 mRNA Vaccine

Note: This vaccine needs to be diluted. Please check the SmPC for this vaccine preparation and administration available at https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf</td></tr>
<tr><td>Dose & Route of administration</td><td>

Primary Course: The dose is 0.2ml, 3 doses with an interval of 3 weeks between dose one and two and 8 weeks between dose two and three.
Route of administration: Intramuscular (IM)

<table>
<tr><th>Vaccine recipient Age</th><th>Site</th><th>Needle length & Size</th></tr>
<tr><td>6 months to <12 months</td><td>Vastus lateralis muscle of anterolateral thigh</td><td>25 mm
23-25 gauge</td></tr>
<tr><td>1 year – 4 years</td><td>Vastus lateralis muscle of anterolateral thigh or deltoid muscle of upper arm (depending on muscle mass)</td><td>25 mm
23-25 gauge</td></tr>
</table>

If the interval between doses is longer than the recommended interval, the next dose should be given as soon as possible. The course does not need to be restarted.
If the second dose is given more than four days before the minimum interval this is not a valid dose. A further dose should be given at least three weeks after the invalid dose.

</td></tr>
</table>

	• If the third dose is given more than four days before the minimum interval this is not a valid dose. A further dose should be given at least eight weeks after the invalid dose. • Do not inject the vaccine intravascularly, subcutaneously or intradermally

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-epar-product-information_en.pdf **Note**: Find this product information from Summary of Product Characteristics page no. 72 for Comirnaty 3 micrograms /dose concentrate for infants and children aged between 6 months-4 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/legal guardian should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the Comirnaty 3 micrograms 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, which is available in a downloadable format from the HPRA website, or on request from the HPRA. The Infant/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 infant/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 infant/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. An incident report form must be completed by the vaccinator and forwarded to local or regional Risk Manager as per local policy. 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 • 2.5ml / 3ml syringe and 21 gauge green needle for reconstitution • 1ml syringe and 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 • 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 to the parent/legal guardian prior to administration of the vaccine.** **Before Vaccination** Check and confirm that consent has been obtained Discuss with the parent/ legal guardian about the Comirnaty 3 micrograms and the importance of protecting their infant/child's health. Inform the parent/guardian that a 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, injection site tenderness (6-23 months) Common: injection site redness Uncommon: injection site pruritus **General:** Very common: arthralgia, chills, decreased appetite (6-23 months), diarrhoea, drowsiness (6-23 months), fatigue, headache, irritability (6-23 months), myalgia, pyrexia Common: nausea, rash (6-23 months), vomiting Uncommon*: asthenia, decreased appetite, extremity pain, insomnia, hyperhidrosis, hypersensitivity reactions(e.g., angioedema, pruritus, rash, urticaria), lethargy, lymphadenopathy in the same arm as vaccination, malaise, night sweats Rare*: acute peripheral facial paralysis Very rare*: myocarditis, pericarditis (see NIAC chapter 5a, section 5a.4.2) Unknown frequency*: anaphylaxis, erythema multiforme, extensive swelling of the vaccinated limb, facial swelling, hypoaesthesia, paraesthesia * from six months of age and older A higher rate of pyrexia was seen after the second dose. The most frequent adverse reactions in those that received any primary course dose included: • in infants 6-23 months of age, irritability (> 60%), drowsiness (> 40%), decreased appetite (>30%), tenderness at the injection site (> 20%), injection site redness and fever (> 10%) • in children 2-4 years of age, pain at injection site and fatigue (> 40%), injection site redness and fever (> 10%). 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 Infants and children may not be protected until at least 7 days after their second dose of the vaccine and the vaccine may not protect all vaccine recipients.

	After Vaccination Discuss potential side effects with the parent/legal 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/legal 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 infant/child/parent/legal 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 parent/legal 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/legal 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* (2023) 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 3 micograms/dose concentrate COVID-19 mRNA vaccine to infants and children aged 6 months – 4 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 3 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. The medicine protocol and Competency Assessment Form are available at www.immunisation.ie. Registered nurses and registered midwives must have completed the *COVID-19 Vaccination Programme for Nurses and Midwives* (HSE Office of the Nursing and Midwifery Services Director), available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/hseland.pdf. They must also complete the COVID-19 Vaccination Training Programme –Infants and Children aged 6 months-4years accessible on www.HSELand.ie

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 Programme for Nurses and Midwives accessible on www.HSELanD.ie 3. COVID-19 Vaccination Training Programme – Infants and Children aged 6 months-4 years accessible on www.HSELlanD.ie 4. Critically examining the evidence and practice of ***holding children*** for clinical procedures (Masterclass Recording - 6th Dec 2022) accessible on www.HSELanD.ie 5. An approved *Basic Life Support for Health Care Providers Course* within the last two years (i.e. Irish Heart Foundation (IHF)) 6. 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 on www.HSELanD.ie *7.* Self-Assessment of Competency Form to administer the *Comirnaty 3 micrograms /dose concentrate COVID-19 mRNA Vaccine* www.immunisation.ie. 8. COVAX IBM/Salesforce online programme accessible at https://www.hse.ie/eng/health/immunisation/hcpinfo/hsecovid19vms.html 9. *Immunisation Foundation Programme*, available at www.HSELanD.ie **Recommended:** 1. *Storing and Managing Vaccines,* available 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 Health Service Executive

Government of Ireland (2023) *Statutory Instruments Number 11 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.

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 3 micrograms/dose concentrate COVID-19 mRNA vaccine under medicine protocol by registered nurses and registered midwives to infants and children aged 6 months-4 years old.

	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, Nursing and Midwifery Board of Ireland (NMBI, 2015) to undertake administration of Comirnaty 3 micograms/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 – Infants and Children aged 6 months-4 years accessible on www.HSELlanD.ie* I undertake to review the most current vaccination information from the NIO available at: www.immunisation.ie			
5	I have read and understand the NIO (2023) Clinical guidance for COVID-19 Vaccination Programme Guidelines for Staff (section for Infants and Children aged 6 months-4 years)			
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 infants and children aged 6 months to 4 years old under the named medicine protocol			
8	I am competent in safe intramuscular injection technique for infants and children from 6 months -11months of age on Vastus lateralis muscle and 12months – 4years of age on Vastus lateralis muscle or deltoid muscle based on their muscle mass (refer to the NIAC immunisation guidelines, Chapter5)			
8a	I understand if further education and training is required to deem myself competent in intramuscular injection technique for infants and children aged 6 months to 4 years on Vastus lateralis /Deltoid muscle based on their age and muscle mass, I am required i) to attend a face to face education/training provided by the HSE or HSE contracted providers and ii) complete part 2 of this competency assessment form (observation and demonstration of IM injection technique on Vastus lateralis muscle at the vaccination clinic if required after completion of face to face training)			
9	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 programme in a Centre for Nurse and Midwifery Education and /or HSELanD			
10	I have successfully completed the following www.hseland.ie programmes: 1. *Immunisation Foundation Programme* 2. *AMRIC Aseptic Technique* 3. *AMRIC Hand Hygiene* 4. *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 • Critically examining the evidence and practice of ***holding children*** for clinical procedures (Masterclass Recording - 6th Dec 2022) accessible on www.HSELanD.ie			
11	I have attended an approved Basic Life Support for Health Care Providers Course within the last two years (i.e. Irish Heart Foundation (IHF))			
12	I have successfully completed an approved anaphylaxis programme as outlined in section B of the medicine protocol and am familiar with NIAC (2022) Immunisation Guidelines for Ireland Anaphylaxis: Immediate Management in the community available at: https://rcpi.access.preservica.com/uncategorized/IO_3e502bee-8fcb-48e9-97df-1718b69d0540/			
12	In assessing suitability for vaccination I can undertake a clinical assessment of individuals presenting for vaccination within the scope of the medicine protocol			
13	I can refer the infant/child who meet the exclusion criteria to the relevant medical practitioner /clinical lead/lead vaccinator for an individual medical assessment as per medicine protocol			
14	I understand the agreed process, including ICT systems if applicable for the accurate and appropriate documentation in the infant/child record for vaccine administration			
17	I will adhere to 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)			
18	I can provide accurate relevant information regarding vaccine, benefits and side effects to the parent/legal guardian			

19	I will utilise documentation procedure for treatment and reporting of adverse drug reactions to the Health Products Regulatory Authority if required available at: www.hpra.ie			
20	I can demonstrate the procedure for reporting and documentation of medication errors/near misses as per HSE Incident Management Framework (2020)			
21	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			
22	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/			
23	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).			

Part 2
Vaccinators are required to observe and demonstrate the administration of a minimum of 3 intramuscular injections (IM) on the Vastus lateralis muscle site under direct supervision of the competent vaccinator/trainer to be deemed competent to administer Intramuscular injection in the Vastus lateralis muscle of the anterolateral thigh.

Intramuscular injection technique observed on Vastus lateralis muscle of the anterolateral thigh						
Competent vaccinator/Trainer Name:		Date	Date	Date		
Competent vaccinator/Trainer Signature:						
		Supervised Assessments			Competence Demonstrated Yes/NO	Signature of Competent vaccinator/Trainer
	Skills Required	Date	Date	Date		
Competency	Positions vaccine recipient appropriately and chooses appropriate vaccination site i.e. use of Vastus lateralis muscle of anterolateral thigh					
	Demonstrates correct intramuscular injection technique in the Vastus lateralis muscle					

I have been deemed competent to administer COVID-19 vaccine using the Vastus lateralis muscle of the anterolateral thigh in infants and children aged 6 months to 4 years old.

I have sufficient theoretical knowledge and practice to administer COVID – 19 vaccine to infants and children aged 6 months to 4 years old 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: _____

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 action plan to achieve competency within an agreed time frame

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

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: _____