Medicine Protocol for the administration of the

Comirnaty Omicron XBB.1.5 (10 micrograms)/dose concentrate COVID-19 mRNA Vaccine (for children aged 5-11 years)

by

General Practice Nurse(s) employed at

Medigroup, Cathedral Road, Cork

- This medicine protocol is a specific written instruction for the administration of **Comirnaty Omicron XBB.1.5 (10 micrograms)/dose concentrate COVID-19 mRNA Vaccine to children aged 5-11 years** by the General Practice Nurse(s) to persons attending Medigroup Medical Centre who are included in the target population to receive COVID-19 booster vaccination.

- This medicine protocol is valid for the 2023/2024 COVID-19 Vaccination Programme and is guided by the National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics for **Comirnaty Omicron XBB.1.5 10 micrograms/dose COVID-19 mRNA Vaccine** as detailed by the European Medicines Agency (EMA).

- 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 medication 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 medicine protocol is in effect" (An Bord Altranais, 2007, p35).

This sample medicine protocol is based on the HSE template for this medication in the current season https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/comirnatyxbb15for511yrs.pdf

It is important to be familiar with the professional guidance on Medication Management and Medication Administration from NMBI www.nmbi.ie and HSE National Immunisation Office (NIO) https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/ for information specific to the vaccine respectively.

The following is a minimum recommended list of professional guidance documents relating to the use of Medicine protocols:

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais https://www.nmbi.ie/nmbi/media/NMBI/Publications/Guidance-Medicines-Management.pdf?ext=.pdf
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*. Royal College of Physicians Ireland (RCSI) online update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/
- National Immunisation Office (2018) *Supporting Documentation for Vaccinations in General Practice* https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf
- Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration*: Dublin. NMBI https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020.pdf?ext=.pdf
- Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice*. *Professional Guidance* Dublin: NMBI https://www.nmbi.ie/nmbi/media/NMBI/Publications/recording-clinical-practice-professional-guidance.pdf?ext=.pdf
- Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework*. Dublin: NMBI https://www.nmbi.ie/nmbi/media/NMBI/Publications/Scope-of-Nursing-Midwifery-Practice-Framework.pdf?ext=.pdf
- Nursing and Midwifery Board of Ireland (2014) *The Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: NMBI https://www.nmbi.ie/NMBI/media/NMBI/Code-of-Professional-Conduct-and-Ethics.pdf?ext=.pdf

Learning resources:

The National Immunisation Office

- COVID-19 information for HCPs - https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/

- eLearning Programmes available on HSeLanD for all HSeLanD learners including :

    - **Immunisation Foundation Programme**
    - **Storing and Managing Vaccines**
    - **COVID-19 Vaccination Programme for competent Vaccinators**

MEDICINE PROTOCOL FOR THE ADMINISTRATION OF Comirnaty Omicron XBB.1.5 10 micrograms/dose COVID-19 mRNA Vaccine TO VACCINE RECIPIENTS (READY TO USE – GREY CAP- DO NOT DILUTE)

1.0 Critical Elements	
1.1 Name of Organisation where protocol applies	Medigroup Medical Centre, Cathedral Road, Cork
1.2 Date the protocol comes into effect	From September 2023
1.3 Date for review of protocol	To April 2024 (regular updates as per NIAC/NIO direction)
1.4 Document adapted from the HSE 2022/2023 Medicine Protocol	Medicine Protocol for the Administration of Comirnaty Omicron XBB.1.5 10 micrograms/dose COVID-19 mRNA Vaccine to vaccine recipients to nurses, midwives, healthcare workers, agency staff, contract workers and volunteers by registered nurses and registered midwives https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/comirnatyxbb15for511yrs.pdf
1.5 Name and signature of the employing authority who is authorising the implementation of the protocol **Document prepared in collaboration with**	"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medication protocol and authorise its implementation" Name: _____(Employer/Principal GP) Title: _____ Signature: _____ MCRN: _____ Name: _____(GP Nurse) Title: _____ Signature: _____ NMBI: _____

1.6.1 Names and signatures of general practice nurses agreeing to work within the protocol	"I have read the medicine protocol and I am competent under my Scope of Nursing and Midwifery Practice Framework (NMBI, 2015) to administer vaccines using this protocol" Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____
	Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____
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	Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____

2.0 Clinical Criteria	
2.1 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 (see Inclusion Criteria) against COVID-19.
2.2 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 11th March 2020 which is still ongoing
2.3 Inclusion criteria for patient treatment 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) Note: This vaccine is recommended as a booster vaccine only.
2.3a Precautions	• Acute severe illness; defer until recovery • Recent mpox vaccine: Allow at least a 4 week interval between mpox vaccine and subsequent COVID-19 vaccine. No interval is required between COVID-19 and subsequent mpox vaccine • Previous history of myocarditis or pericarditis after any COVID-19 vaccine – consult Cardiologist • Anaphylaxis after multiple different drug classes, with no identified allergen (may indicate PEG allergy). Anaphylaxis after a vaccine or a medicine known to contain PEG Unexplained anaphylaxis (may indicate PEG allergy) ○ Clarify if PEG is tolerated (see the below link for FAQs) https://www.rcpi.ie/Healthcare-Leadership/NIAC/Hot-topics-and-resources/Hot-topicsand-general-resources ○ Discuss with allergist/ immunologist ○ Consider vaccination with non mRNA COVID-19 vaccine ○ Observe for 30 minutes • Anaphylaxis after food, venom or medication: Vaccinate as scheduled and observe for 15 minutes • Mastocytosis: Vaccinate as scheduled and observe for 30 minutes • 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 thrombocytopenia (platelet count <50 x 10^9/L consult the supervising consultant • 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 • Children with planned immunosuppressive therapy should ideally receive the booster dose two weeks before treatment. The recommended minimum interval may be used • 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 • Vaccination should be postponed in children with a previous history of Multisystem Inflammatory Syndrome (MIS-C), until clinical recovery or until at least 3 months since

	diagnosis, whichever is longer • For those who are immunocompromised and receiving a further booster dose of vaccine (i.e., the next booster after the first booster vaccine) as part of the Autumn booster 2023 campaign, this can be given 6 months after their last COVID-19 vaccine or COVID-19 infection (3 months in exceptional circumstances).
2.4 Exclusion criteria for patient treatment using the medicine protocol	**Comirnaty Omicron XBB.1.5 10 micrograms/dose COVID-19 mRNA Vaccine should not be given under this medicine protocol if the vaccine recipient has:** • Anaphylaxis after an mRNA vaccine • Anaphylaxis after polyethylene glycol (PEG, e.g., some bowel preparations for • endoscopy, certain laxatives such as Movicol) • Anaphylaxis after trometamol • Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine.
2.5 Actions to be taken for those who are excluded from the medicine protocol	• Refer to/discuss with the relevant GP 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 GP can consider referring the individual to an allergist/Immunologist for a further assessment • Document action in clinical record or IT system • Where Comirnaty Omicron XBB.1.5 10 micrograms/dose 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
2.6 Actions to be followed for eligible persons who do <u>not</u> wish to receive vaccination	1. Advise parent/guardian on the risks of not having the vaccine, including risk of possible severe COVID-19 disease 2. Advice regarding the minimisation of risk 3. Document in clinical notes

2.7 Documentation required to support implementation of the medicine protocol	1. Evidence/record that consent has been received 2. Vaccine Information Leaflets 3. Patient-held record cards 4. Practice clinical record- electronic or paper patient file 5. Health Products Regulatory Authority Adverse Reaction Reporting Forms https://www.hpra.ie/homepage/about-us/report-an-issue It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of Comirnaty Omicron XBB.1.5 10 micrograms/dose COVID-19 mRNA Vaccine which includes the following: • Medicine Protocol for the Administration of Comirnaty Omicron XBB.1.5 10 micrograms/dose COVID-19 mRNA Vaccine to vaccine recipients (Ready to use – Grey cap- Do not dilute) • Anaphylaxis: Immediate Management in the community. National Immunisation Advisory Committee, Immunisation Guidelines for Ireland. https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf • HSE Clinical Guidance for Covid-19 Vaccination https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pd • COVID-19 chapter from NIAC immunisation Guidelines for Ireland (2020) (available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/) • Immunisation Bulletins from national Immunisation Office https://www.hse.ie/eng/health/immunisation/infomaterials/newsletter/

3.0 Details of Medication to be supplied	
3.1 Name of Medication	**Comirnaty Omicron XBB.1.5 10 micrograms/dose COVID-19 mRNA Vaccine** *Note – this vaccine needs to be diluted*
3.2 Dose and Route of administration	• The dose is 0.2ml Note: Currently recommended for booster dose only • Route of administration: Intramuscular (IM) • Site: The preferred site is the deltoid muscle • Do not inject the vaccine intravascularly, subcutaneously or intradermally
3.2a Booster dose of COVID-19 Vaccine See the NIAC chapter Table 5a.1	Booster vaccines are not routinely recommended in the 5-11years age group. Irrespective of the number of prior booster doses: A booster vaccine is recommended in autumn for: • those with immunocompromised associated with a suboptimal response to vaccination • those with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death.
3.3 Link to Medicine **Details of product information and other data including instructions for supply and administration is available on the Health Product Regulatory Authority at www.hpra.ie**	**Link to Summary of Product Characteristics and Patient Information Leaflet** available at: https://www.ema.europa.eu/en/documents/product%20information/comirnaty-epar-product-information_en.pdf **Legal Classification:** POM (Prescription Only Medication) (includes prescription under this medicine protocol)

3.4 Possible Side Effects	See SPC and information provided in Patient Information leaflet (PIL) for this specific vaccine in respect of possible side effects. https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf *(Note: The patient / parent / guardian should be reassured there may be no side effects following the vaccination)*
3.5 Potential adverse reactions and procedures for treatment of same	Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction 1. Vaccine recipients: 15 minutes 2. Those with a history of mastocytosis: 30 minutes 3. 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 Omicron XBB.1.5 (10 micrograms)/dose concentrate after the above period of observation. The vaccine recipient's General Practitioner (GP) should be informed of any clinically significant reported adverse reactions.
3.6 Procedure for	All adverse drug reactions or suspected adverse drug reactions following administration of the

reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)	vaccine must be reported as soon as possible in accordance with criteria outlined by the HPRA. Adverse Reaction Reporting Forms can be accessed at the following link: https://www.hpra.ie/homepage/about-us/report-an-issue The incident and all actions taken must be promptly recorded in accordance with Anaphylaxis: Treatment in the Community (NIAC, 2016) available on line at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf Record actions in patient file
3.7 Procedure for the reporting and documentation of errors and near misses involving the vaccine	In the case of medication errors that directly involve the patient, i.e. wrong medication/patient/dose/route being administered or another medication error, the general practice nurse/general practitioner must remain with the patient and closely monitor the patient for any adverse reactions (if the reaction has occurred while the patient is still on the premises). Vital signs should be recorded and the patient should be reviewed by the general practice nurse and general practitioner. 1. The incident must be reported to the general practitioner as soon as possible. 2. The incident and all actions taken must be promptly recorded 3. The parent or guardian should be informed of the nature of the incident 4. Incident Report Form must be completed by the practice and held by the authorising general practitioner 5. Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.
3.8 Mechanisms for storage of vaccines and for obtaining supply	Storage and ordering of vaccines in accordance with guidance included in Guidelines for Vaccinations in General Practice (see section 8, pages 22-27)
3.9 Resources and equipment required	1. Vaccine Fridge with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C) 2. Vaccine 23 gauge / 25g gauge needle for IM administration 3. Sharps bins, and bins for disposal of other hazardous materials 4. Disposable kidney dishes/trays 5. Cotton wool balls/tape/plasters 6. Alcohol hand sanitiser 7. Surgical face masks 8. Access to telephone 9. Resuscitation equipment and drugs in accordance with National Immunisation Advisory Committee (2022) Anaphylaxis: Immediate Management in the Community available online: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264- 546089359925/ 10. Safe storage areas for medicines and equipment 11. Current medicine protocol
3.10 Audit process to identify appropriate use of the protocol or unexpected outcomes	1. All documentation to be held for review and audit purposes 2. Regular team meetings are advisable to review the use of the medication protocol

4.0 Information for Vaccine Recipients/Carers	
4.1 Advice to be given to the patient/parent/guardian before and/or after treatment* ** literature for patients whose first language is not English is available on the National Immunisations Office website and should be made available to patients if required*	**Before vaccination:** • The patient information leaflet (PIL) should be supplied in advance of obtaining informed consent. • Discuss the Comirnaty Omicron XBB.1.5 10 micrograms/dose COVID-19 mRNA Vaccine and the importance of protecting the child's health. Inform 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. Details 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 • Inquire if they have any questions before proceeding. • Obtain informed consent and a signed consent form (as per local policy) **After vaccination:** Discuss potential side effects 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. 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. If more serious adverse or persistent effects occur, vaccine recipient should be advised to contact their GP/out of hours service.
4.2 Details of any necessary follow-up, action and referral arrangements	1. Inform patient/parent/guardian if and when a subsequent vaccine is due. 2. Document all advice/details in patients records 3. In the event of an adverse reaction, the general practice nurse must ensure that all procedures are adhered to as outlined in section 3.0 of this protocol.

5.0 Staff authorised to use medicine protocol	**** all nurses working under medicine protocol should do so guided by their scope of practice and should be supported and encouraged to achieve and maintain competence in all areas noted by the authorising general practitioner.***
5.1 Professional qualifications, training, experience and competence required prior to using this medicine protocol	Registered nurse or registered midwife, maintained on the active register of the Nursing and Midwifery Board of Ireland. **Required Training** • Basic Life Support for Health Care Workers within the last two years • 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.hseland.ie **Recommended Training** Having successfully completed the following programmes: • Immunisation Foundation Programme (available on www.hseland.ie) • eLearning Medication Management Programme (available from www.nmbi.ie) **Required Experience** Currently employed as a general practice nurse and have had an opportunity to shadow experienced vaccinator in gaining experience. **Required Competence** Competence in injection technique Self-assessment of competency assessed as per Supporting Information for Vaccinations in General Practice https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf