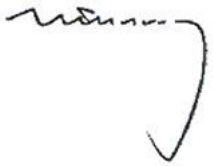
Master medicine protocol for the administration of Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA vaccine (for children aged 6 months-4 years)

This medicine protocol is a specific written instruction for the administration of Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection, COVID-19 mRNA vaccine to children aged 6 months to 4 years included in Statutory Instruments S.I. No 418 of 2025 by healthcare professionals in healthcare professions included in Statutory Instruments S.I. No. 245 of 2021 who are registered with their respective regulatory body.This medicine protocol is valid for the 2025/2026 HSE Winter 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) and who have undertaken the required education and training programmes to administer Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection, COVID-19 mRNA vaccine to children aged 6 months to 4 years, 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 (SPC) for Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection as detailed by the European Medicines Agency (EMA).

- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Online Update available at: www.higa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland
- HSE National Immunisation Office *Clinical Guidance for COVID-19 Vaccinations*, available at: www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/cgc19.html
- Summary of Product Characteristics available at: www.medicines.ie/medicines/comirnaty-lp-8-1-3-micrograms-dose-concentrate-for-dispersion-for-injection-mdv-36531/spc

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, page 35).

A medicine protocol is a nationally approved prescription for the supply and administration of a medicine as per above definition. The HSE Chief Clinical Officer and Director of National Health Protection have approved the use of medicine protocols by healthcare professionals listed in S.I. No. 245 of 2021 and S.I. No 418 of 2025. This medicine protocol is developed to facilitate the delivery of HSE winter vaccination programme 2025/2026 in line with NIAC recommendations endorsed by the Department of Health (DoH).

Document reference number	Version 3-NIO - Comirnaty LP.8.1 3 micrograms - August2025
1.0 Critical elements	
Name of organisation/settings where medicine protocol applies	Health Service Providers across the voluntary and statutory services of the HSE, non-HSE healthcare facilities, HSE mobile vaccination clinics and central vaccination centres. This Medicine Protocol applies to: Healthcare professionals who are registered with their respective regulatory body in healthcare professions included in S.I. No. 245 of 2021 and S.I. No 418 of 2025 who are registered with their regulatory body ad have undertaken the required education and training programmes relevant to their professions.
Date the medicine protocol comes into effect	September 2025
Date for review of medicine protocol	September 2026 (Regularly updated in line with the NIAC recommendations & DoH policy)
Document prepared by	HSE National Immunisation Office (NIO)
Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol ***"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"***	Name: **Dr. Éamonn O' Moore**, Director of National Health Protection, HSE  Signature: Name: **Dr Colm Henry**, Chief Clinical Officer, HSE Signature: 

2.0 Clinical criteria	
Clinical condition for use of the medicine protocol	The clinical condition for which this medicine protocol has been developed is for the vaccination of children aged 6 months to 4 years against COVID-19 (see Inclusion Criteria).
Circumstances in which the medicine protocol applies	Targeted vaccination programme for children aged 6 months to 4 years against COVID-19 based on NIAC recommendations endorsed by the DoH
Inclusion criteria for children using this medicine protocol for administration of Comirnaty® LP.8.1 3 micrograms	**Inclusion Criteria:** Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in children aged 6 months to 4 years in line with NIAC Chapter 5a This vaccine is recommended: • For those aged 6 months to 4 years with medical conditions associated with a higher risk of severe COVID-19 as listed in Table 5a.1 of Chapter 5a. For those who have been vaccinated previously, a dose of a COVID-19 vaccine is recommended once a year. • For those aged 6 months to 4 years with immunocompromise associated with suboptimal response to vaccination. For those who have been vaccinated previously, a dose of COVID-19 vaccine is recommended twice a year. • For those aged 6 months to 4 years who have never been vaccinated against SARS-CoV-2 infection, vaccination is recommended for those who have a medical condition associated with a higher risk of COVID-19 hospitalisation, severe disease or death or who have immunocompromise associated with a suboptimal response to vaccination. As per the NIAC guidelines access to a COVID-19 vaccine should be available to those aged 6 months to 4 years **who have never been vaccinated** against SARS-CoV-2 infection regardless of their risk of COVID-19 who, following discussion with a healthcare professional request vaccination.
Precautions for children using this medicine protocol for administration of Comirnaty® LP.8.1 3 micrograms	**Precautions:** • Acute severe illness: o Defer until recovery. • Recent mpox vaccine: o Allow at least a 4 week interval between mpox vaccine and subsequent COVID-19 vaccine. No interval is required between COVID-19 vaccine and subsequent mpox vaccine. • 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): o Clarify if PEG is tolerated (see the Allergies FAQs) o Discuss with allergist/immunologist o Consider vaccination with non mRNA vaccine o Observe for 30 minutes • Previous history of myocarditis or pericarditis after any COVID-19 vaccine: o Consult with Cardiologist • Children with a previous history of Multisystem Inflammatory Syndrome (MIS-C): o Vaccination should be postponed until clinical recovery or until at least 3 months since diagnosis, whichever is the longer. • Idiopathic Anaphylaxis or Anaphylaxis after food, venom or medication: o Vaccinate as scheduled and observe for 15 minutes

	• Mastocytosis: o 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 thrombocytopoenia (platelet count <50 x 10^9/L) consult the supervising consultant. See Chapter 2 of the Immunisation Guidelines of Ireland sections 2.4.6 and 2.4.7 for information, including the technique for IM injection, in this patient group. • Those with inherited coagulopathies receiving factor replacement therapy should be given IM vaccination within a few days after treatment See Chapter 2 of the Immunisation Guidelines of Ireland, sections 2.4.6 and 2.4.7 for information, including the technique for IM injection, in this patient group. **Coadministration** • No interaction studies in young children have been performed on coadministration of COVID-19 vaccines with childhood vaccines. • Priority should be given to other routine childhood immunisations. • Until there is more evidence it is prudent to separate COVID-19 vaccination in children aged 6 months-4 years from other vaccines for a period of 14 days
Exclusion criteria for vaccine recipient under this medicine protocol	Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection 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 mRNA vaccine. •
Actions to be taken for those who are excluded from this medicine protocol or who have a precaution	• All individuals with precautions should be assessed by the vaccinator for suitability and if required referred to a specialist medical team for advice. • All individuals meeting exclusion criteria must be referred to the relevant medical professional for an individual medical assessment. • Document assessment in clinical notes/on NIIS system. • Where ComirnatyLP.8.1 3 micrograms/dose concentrate for dispersion for injection 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 in children for whom the vaccine is recommended by NIAC.
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 a previous adverse reaction or other clinical concerns as outlined in exclusion criteria or precautions.

<table>
<tr><td>Documentation required to support implementation of the medicine protocol</td><td>

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
NIIS record/ Patient held record cards

It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection which includes the following:

Medicine Protocol for the Administration of Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection, COVID-19 mRNA vaccine (for children aged 6 months to 4 years)
Please refer to Section B for registered nurses / midwives and Self-Assessment of Competency Form
Anaphylaxis: Immediate Management in the Community. NIAC (2023), Immunisation Guidelines for Ireland.
Chapter 5a COVID-19 from NIAC Immunisation Guidelines for Ireland
HSE NIO Clinical Guidance for COVID-19 Vaccination

</td></tr>
<tr><td colspan="2">3.0 Name of Medicine and recommendations in line with the Immunisation Guidelines of Ireland</td></tr>
<tr><td>Name of Medicine</td><td>Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection
COVID−19 mRNA Vaccine
Note: This vaccine needs to be diluted with 1.1 mL sodium chloride 9 mg/mL (0.9%) solution for injection
Please check the SPC for this vaccine preparation and administration available at: www.medicines.ie/medicines/comirnaty-lp-8-1-3-micrograms-dose-concentrate-for-dispersion-for-injection-mdv-36531/spc</td></tr>
<tr><td>Dose & Route of administration</td><td>

Dose: The dose is 0.3 ml (after dilution)
Route of administration: Intramuscular (IM)
Do not inject the vaccine intravascularly, subcutaneously or intradermally

Site of vaccination
<table>
<tr><th>Vaccine recipient age</th><th>Site</th><th>Needle length & Size</th></tr>
<tr><td>Birth to <12 months</td><td>Vastus lateralis muscle of anterolateral thigh</td><td>25 mm
23-25 gauge</td></tr>
<tr><td>12 to <36 months</td><td>Vastus lateralis or deltoid muscle (depending on muscle mass)</td><td>25mm
23-25 gauge</td></tr>
<tr><td>3 years and older</td><td>Deltoid muscle of upper arm*</td><td>25 mm
23-25 gauge</td></tr>
</table>
*The anterolateral thigh may be also be used.
</td></tr>
<tr><td>Those who have never been vaccinated against SARS-CoV-2 infection</td><td>
For those aged 6 months to 4 years who have never been vaccinated and in whom COVID-19 vaccine is indicated::

Two doses of an mRNA COVID-19 vaccine are recommended in those who have no prior history* of a SARS-2 infection. There should be an interval of four weeks between dose one and dose two.
One dose of an mRNA COVID-19 vaccine is recommended in those who have a prior history* of a SARS-CoV-2 infection.

*Prior history of SARS-CoV-2 infection can be confirmed by either a positive PCR test, a positive antigen test or clinical diagnosis.
</td></tr>
</table>

Special considerations for those with immunocompromised aged six month to 4 years who have never been vaccinated against SARS-CoV-2 infection	For those aged 6 months to 4 years with immunocompromise who have never been vaccinated against SARS-CoV2 infection: • Two doses of an mRNA COVID-19 vaccine are recommended. There should be an interval of four weeks between dose one and dose two. A third dose may be administered, eight weeks after the second dose, following instruction from a relevant specialist physician. A minimum interval of four weeks between the second and third dose may be used if there is urgency to achieve protection. **Additional Considerations:** • If a child with immunocompromise who has received an mRNA vaccine becomes five years of age before completion of the recommended schedule for six months to four year olds, the schedule should be completed with the age-appropriate dose of the currently available mRNA vaccine. • If the second dose is given more than four days before the minimum interval to a person with immunocompromise, this is not considered a valid dose. A further dose should be given at least eight weeks after the invalid dose. If a third dose (recommended for a person with immunocompromise), is given before the minimum interval, then this is not considered a valid dose, and a further dose should be given eight weeks after the invalid dose • Those who have never been vaccinated against SARS-Co-V-2 infection, with planned immunosuppressing therapy should ideally complete COVID-19 vaccination (one to three doses as indicated by their underlying condition), two weeks before beginning treatment, adhering to minimum intervals. • Those with immunocompromise, who have never been vaccinated against SARS-CoV-2 infection, who develop SARS-CoV-2 infection should receive a first dose of a COVID-19 vaccine at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who were asymptomatic. Those with persisting symptoms following COVID-19 infection may be vaccinated, unless there is evidence of recent clinical deterioration. • Those with immunocompromise who develop SARS-CoV-2 infection after their first dose of COVID-19 vaccine should be given the subsequent dose at least four to eight weeks after diagnosis or onset of symptoms, followed by a third dose if recommended by a relevant specialist physician. • Those with immunocompromise who develop SARS-CoV-2 infection more than seven days after the second vaccine dose, do not require a third dose. Those who have SARS-CoV-2 infection within seven days of their second dose should have a third dose after an interval of four to eight weeks, if a third dose is recommended by a relevant specialist physician. . • If a previously vaccinated person with planned immunosuppressant therapy has not received a COVID-19 vaccine in the six months prior to starting therapy, they should be offered a vaccine dose regardless of the time of year.
Recommendations for those previously having received a vaccine against SARS-CoV-2 infection **For individuals aged 6 months to 4 years with immunocompromise:**	A dose of COVID-19 vaccine is recommended **once a year** for those aged 6 months-4 years with: • Medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death (See table5a.1 in chapter 5a of the Immunisation Guidelines of Ireland) A dose of COVID-19 vaccine is recommended **twice a year** for those aged 6 months-4 years with: • Immunocompromise associated with a suboptimal response to vaccination For eligible children aged 6 months to 4 years, the recommended antigenically updated mRNA COVID 19 vaccine is Comirnaty LP.8.1 3 micrograms

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 SmPC https://www.medicines.ie/medicines/comirnaty-lp-8-1-3-micrograms-dose-concentrate-for-dispersion-for-injection-mdv-36531/spc and Patient Information Leaflet https://www.medicines.ie/medicines/comirnaty-lp-8-1-3-micrograms-dose-concentrate-for-dispersion-for-injection-mdv-36531/patient-info#tabs
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 for at least 15 minutes to allow monitoring of any immediate reaction including suspected anaphylactic reaction. The vaccine recipient /Parent/Legal Guardian should be advised to contact the relevant medical personnel in the event of an adverse reaction occurring following administration of the vaccine (General Practitioner (GP) /out of hours/Emergency Department) after the above period of observation. **Reporting side effects** The vaccine recipient's parent/legal guardian should be advised that they can report any side effects to the Health Products Regulatory Authority (HPRA) at www.hpra.ie .
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 online at https://www.hpra.ie The vaccine recipients parent/legal guardian should be advised that they can also report any side effects to the Health Products Regulatory Authority (HPRA) at https://www.hpra.ie The vaccine recipient's GP should be informed if there is a reported adverse reaction. In the event of anaphylactic reaction, the incident and all actions taken must be promptly recorded in accordance with the National Immunisation Advisory Committee (2023) *Anaphylaxis: Immediate Management in the Community* available online
Procedure for the reporting and documentation of errors and near misses involving this medication	In the case of medicine errors that directly involve the child, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the vaccinator must remain with the child and closely monitor them for any adverse reactions. Vital signs should be recorded and the child should be reviewed by the vaccinator. The incident must be reported to the relevant line manager as soon as possible. The incident and all actions taken must be promptly recorded and the relevant National Incident Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day, available online The child's parent and/or legal guardian must be informed of the incident. Further information can be found in the HSE Open Disclosure Policy 2025 Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below and as per local policy. Any errors and near misses not involving medications (i.e. needle stick injuries etc.) the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report form and forwarded to the relevant line manager. Refer to 'EMI Tool Kit' available at https: //www.hpsc.ie/a-z/EMIToolkit/.

Resources and equipment required	• Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection, COVID-19 mRNA vaccine • Syringe and 21 gauge green needle for reconstitution • 1ml syringe and 23 gauge /25g gauge needle for IM injection • Fridge/cooler box with data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8˚C. • Disposable kidney dishes/trays • 70% alcohol swabs (for sterilizing vials) • Gauze swabs, tape/plasters • Sharps bins, and bins for the disposal of healthcare risk and non-risk waste • Alcohol hand sanitiser • Access to telephone • Resuscitation equipment and drugs in accordance with *Anaphylaxis*: *Immediate Management in the Community* (NIAC 2023) online • Safe storage areas for medicines and equipment • Current medicine protocol for the administration of Comirnaty LP.8.1 3 micrograms
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 child/ parent/legal guardian before vaccination	**Vaccine information material must be supplied prior to administration of the vaccine.** **Before Treatment** 1. Review consent in line with the HSE National Consent Policy and confirm that there are no contraindications or precautions to vaccination. 2. Discuss the Comirnaty LP.8.1 vaccine 3. Discuss potential side effects as listed below The following side effects may be experienced: **Local:** ***Very common:*** injection site pain, swelling. ***Common***: injection site redness. **General:** ***Very common***: irritability, drowsiness, arthralgia, chills, diarrhoea, fatigue, headache, myalgia, pyrexia. ***Common:*** nausea, vomiting. For additional information on side effects, see Summary of Product Characteristics
Advice to be given to the child//parent/legal guardianafter treatment	**After Vaccination** • Discuss potential side effects and give advice how to manage common adverse reactions. • Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction. 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. Ensure the post vaccination advice is given
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.
5.0 Staff authorised to use this medicine protocol	
Professional qualifications, training and competence required prior to using this medicine protocol	1) Be a registered healthcare professional, on the active register maintained by the relevant professional regulatory body in Ireland 2) An approved *Basic Life Support for Health Care Providers Course* within the last two years (For e.g. Irish Heart Foundation (IHF), American Heart Association (AHA) 3) 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 or the relevant anaphylaxis management programme approved by their professional organisation. 4) *mRNA COVID-19 Vaccine Formulations for children aged 6 months -11 years*(recommendations and clinical considerations video for children aged 6 months to 11 years and pharmacy storage and handling modules for the vaccine formulations, for 6 months to 4 years) accessible on www.HSELanD.ie 5) *Storing and Managing Vaccines* accessible on www.HSELanD.ie **Note:** In addition to the above, the vaccinator must complete the education, training, and self-assessment of competence requirements as recommended by their professional organisation /regulatory authority. Registered Nurses and Registered Midwives, Registered Physiotherapists, Radiographers, Radiation Therapists, Optometrists and Vaccinators registered with Pre-Hospital Emergency Care Council (PHECC) must read their Section B document specific to this medicine protocol and complete the Self-Assessment of Competency Form relevant to their profession.

References

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

Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Registered Midwives on Medication Administration*. Dublin: Nursing and Midwifery Board of Ireland available at:

https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020

Health Service Executive (2022) Revised National Consent Policy 2022 V1

www.hse.ie/nationalconsentpolicy

Health Service Executive (2025) Open Disclosure Policy
https://www2.healthservice.hse.ie/files/220/

National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community. Available at https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC)
https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/.

Chapter 5a National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*: *available at https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland*

S.I. No. 245/2021 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. Available at
https://www.irishstatutebook.ie/eli/2021/si/245/made/en/print

S.I. No. - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. Available at https://www.irishstatutebook.ie

Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection COVID−19 mRNA Vaccine SUMMARY OF PRODUCT CHARACTERISTICS available at www.medicines.ie/medicines/comirnaty-lp-8-1-3-micrograms-dose-concentrate-for-dispersion-for-injection-mdv-36531/spc