Master Medicine Protocol for the Administration of Comirnaty KP.2 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 KP.2 3 micrograms/dose concentrate COVID-19 mRNA vaccine to children aged 6 months to 4 years included in Statutory Instruments S.I. No. 582 of 2024 by healthcare professionals 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.This medicine protocol is valid for the 2025 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) and who have undertaken the required education and training programmes to administer Comirnaty KP.2 3 micrograms/dose concentrate 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 (SmPC) for Comirnaty KP.2 3 micrograms/dose concentrate as detailed by the European Medicines Agency (EMA).

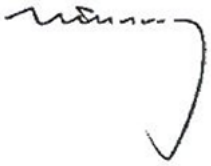
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Dublin: Royal College of Physicians Ireland , Online Update available at https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
- HSE National Immunisation Office *Clinical Guidance for COVID-19 Vaccinations*, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf
- Summary of Product Characteristics available at https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf (From page 249)

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 endorsed by the Department of Health.

The professional groups using this medicine protocol must ensure that it 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.

Master Medicine Protocol for the Administration of Comirnaty KP.2 3 micrograms/dose concentrate COVID-19 mRNA Vaccine (for infants and children aged 6 months - 4 years)

Document reference number	Version 2-NIO - Comirnaty KP.2 3 micrograms/dose- March 2025
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. 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.
Date the medicine protocol comes into effect	April 2025
Date for review of medicine protocol	April 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
Exclusion criteria for vaccine recipient under this medicine protocol	Comirnaty KP.2 3 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.
Inclusion criteria for children using this medicine protocol for administration of Comirnaty KP2 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 **Primary schedule and booster** doses. **Note:** Booster vaccination is recommended for those aged 6 months to 4 years with certain health care conditions only. Refer to the booster dose section of this protocol. ● If a child, who requires more than one dose of Comirnaty KP.2 3 micrograms to complete their primary vaccination course, becomes five years of age before completion of the recommended schedule for those aged 6 months-4 years, the schedule should be completed with the age appropriate dose of Comirnaty KP.2 10 micrograms as follows: ○ If they have received one dose of Comirnaty 3 micrograms give a single dose of Comirnaty KP.2 10 micrograms with an interval of four weeks between dose one and dose two ○ If they have received two doses of Comirnaty 3 micrograms and a third dose is recommended by a relevant specialist physician: leave an interval of eight weeks, then give one dose of Comirnaty KP.2 10 micrograms. ● 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. **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 vaccine and subsequent mpox vaccine. ● Previous history of myocarditis or pericarditis after any COVID-19

	vaccine: ○ Consult with 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-topics-and-general-resources ○ Discuss with allergist/immunologist ○ Consider vaccination with non mRNA vaccine ○ Observe for 30 minutes ● Idiopathic Anaphylaxis or Anaphylaxis after food, venom or medication: ○ Vaccinate as scheduled and observe for 15 minutes ● Mastocytosis: ○ Vaccinate as scheduled and observe for 30 minutes ● Children with a previous history of Multisystem Inflammatory Syndrome (MIS-C): ○ Vaccination should be postponed until clinical recovery or until at least 3 months since diagnosis, whichever is the longer. ● Vaccination is not contraindicated for those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration ● Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM (intramuscular) injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopoenia (platelet count <50 x 10^9/L) consult the supervising consultant ● Those with inherited coagulopathies who require factor replacement therapy should receive it on the day of vaccination, prior to the IM vaccination. If there is uncertainty about the need for replacement therapy contact the child's supervising consultant Priority should be given to other routine childhood immunisations. **Coadministration** • No interaction studies in young children have been performed on coadministration of COVID-19 vaccines with childhood vaccines. • 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
Actions to be taken for those who are excluded from this 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 KP.2 3 micrograms/dose concentrate 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	Advise the parent/legal guardian about the risks of their child not having the vaccine, including risk of possible severe COVID-19, particularly if their child has an underlying medical condition.

wish to receive the vaccine	
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.
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 (HPRA) Adverse Reaction Reporting forms or available on-line at http://www.hpra.ie • 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 KP.2 3 micrograms/dose concentrate which includes the following: • *Medicine Protocol for the Administration of Comirnaty KP.2 3 micrograms/dose concentrate 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.* https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ • 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* https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
3.0 Name of Medicine	
3.0 Name of Medicine	Comirnaty KP.2 3 micrograms/dose concentrate COVID-19 mRNA vaccine **(Yellow cap)** 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 (From page 249)
Dose & Route of administration	• The dose is 0.3ml • Route of administration: Intramuscular (IM) • Do not inject the vaccine intravascularly, subcutaneously or intradermally

Vaccine recipient Age	Site	Needle length & Size
Birth to <12 months	Vastus lateralis muscle of anterolateral thigh	25 mm 23-25 gauge
12 to <36 months	Vastus lateralis or deltoid muscle (depending on muscle mass)	25mm 23-25 gauge
3 years and older	Deltoid muscle of upper arm*	25 mm 23-25 gauge

*The anterolateral thigh may be also be used.

Primary schedule of COVID-19 Vaccine

Age	Primary Schedule
6 months- 4 years	Recommended for: 1.Those with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death (as outlined in NIAC Chapter 5a) 2. Those with immunocompromise associated with a suboptimal response to vaccination (see further details in the immunocompromised section below) **Note:** Access to the primary schedule should be available for those aged 6 months- 4 years who, following discussion with a health care provider (e.g., GP, pharmacist or HSE vaccinator), request vaccination. **Primary schedule for those aged 6 months to 4 years (without immunocompromise):** a. **Two doses** for those with no prior history* of SARS-CoV-2 infection (four weeks interval). Or b. **Single dose** for those with a prior history* of SARS-CoV-2 infection. * Prior history of COVID-19 can be confirmed by any of: positive PCR test, antigen test or clinical diagnosis. For example, a single dose primary series could be considered in a child who had symptoms consistent with COVID-19 at a time when household contacts tested positive.

Primary Course for those with

<u>Primary course for those with immunocompromising conditions</u>

immunocompromising conditions	Children with planned immunosuppressing therapy should ideally complete primary vaccination two weeks before treatment. The recommended minimum interval may be used. For those aged 6 months to 4 years with immunocompromise, a **two dose** primary course is recommended with a **four week interval** (i.e., 28 days) between dose one and dose two. A **third dose** may be administered, **eight weeks** (i.e., 56 days) after the second dose, following instruction from a relevant specialist physician. For immunocompromised a relevant specialist physician may recommend a minimum interval of **three weeks** (i.e., 21 days) between dose one and dose two or **four weeks** (i.e., 28 days) between dose two and dose three, if there is urgency to achieve protection. • If the second dose is given between 17 and 20 days after the first dose (i.e., not more than 4 days before the minimum interval of 21 days), it is a valid dose. • If the interval between doses is longer than 28 days (i.e., the recommended interval), the second dose should be given as soon as possible. The course does not need to be restarted. • If a third dose is required and is given between 24 and 27 days after the second dose (i.e., not more than 4 days before the minimum interval of 28 days), it is a valid dose. • If the interval between doses is longer than 56 days (i.e., the recommended interval), the third dose should be given as soon as possible. The course does not need to be restarted.
Booster dose of COVID-19 vaccine in Spring 2025 (see the NIAC chapter 5a)	A booster dose of COVID-19 vaccine in Spring 2025 is recommended for those aged 6 months-4 years with: • immunocompromise associated with a suboptimal response to vaccination A booster dose of COVID-19 vaccine if indicated should be given **six months** following the last COVID-19 vaccine or SARS-CoV-2 infection (In certain circumstances an interval of **three months** may be used (e.g., planned immunosuppressive therapy or operational reasons, see the NIAC chapter 5a). For those aged 6 months- 4 years who are healthy, a booster dose of a COVID-19 vaccine in Spring 2025 is **not routinely** recommended For eligible children aged 6 months to 4 years, the recommended COVID 19 booster vaccine for Spring 2025 is Comirnaty KP.2 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 and Patient Information Leaflet available at https://www.ema.europa.eu/en/documents/product information/comirnaty-eparproduct-information_en.pdf
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 KP.2 3 micrograms/dose concentrate 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 vaccine recipient's General Practitioner (GP) should be informed of any clinically significant reported adverse reactions. In the event of anaphylaxis, the incident and all actions taken must be promptly recorded in accordance with the *Management of a Patient with Anaphylaxis*: *Immediate Management in the Community* (NIAC 2023), available online at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
Procedure for the reporting and documentation of errors and near misses involving this medication	In the case of medication errors that directly involve the child, i.e. wrong medication/dose/route being administered or another medication error, the vaccinator must remain with the child 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	● Comirnaty KP.2 3 micrograms/dose concentrate 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) available at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ • 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 child/ parent/legal guardian before vaccination	**Vaccine information material must be supplied prior to administration of the vaccine.** **Before Vaccination** • Check and confirm that informed consent has been obtained • Explain the procedure • Answer questions • Inform the parent/legal guardian that the patient information leaflet is available online at https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf Discuss common adverse events as listed below **Local:** *Very common:* tenderness injection site, injection site redness (6-23 months); injection site pain and redness (age 2-4 years), *Common:* injection site redness **General:** *Very common:* irritability, drowsiness, decreased appetite, fever*, (6-23 months), fatigue, headache, irritability myalgia, fever (2 -4 years), *Common:* nausea, vomiting **A higher rate of fever/pyrexia has been reported after the second dose*. A full list of adverse reactions may be found in the SmPC, available at https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf **After 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.
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
- HSE National Immunisation Office, *Clinical Guidance for COVID-19 Vaccinations.* Available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf
- National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/.
- National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community. Available at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
- 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
- Irish Statutory Instruments, Available at https://www.irishstatutebook.ie/eli/statutory.html