Master Medicine Protocol for the Administration of Comirnaty KP.2 30 micrograms/dose COVID-19 mRNA Vaccine to Vaccine Recipients aged 12 years and older *(Ready to use - Do not dilute)*

This medicine protocol is a specific written instruction for the administration of Comirnaty KP.2 30 micrograms/dose COVID-19 mRNA Vaccine to vaccine recipients included in the Statutory Instruments S.I. No.582 of 2024 by 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 S.I. No. 245 of 2021. This medicine protocol is valid for the 2024/2025 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) who have undertaken the required education and training programmes to administer Comirnaty KP.2 30 micrograms/dose COVID-19 mRNA Vaccine to vaccine recipients, with reference to guidelines and guidance from National Immunisation Advisory Committee (NIAC), HSE National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Comirnaty KP.2 30 micrograms/dose COVID-19 mRNA Vaccine 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 (2024) Clinical Guidance for COVID-19 Vaccinations, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf

- Summary of Product Characteristics https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf (from page 346)

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 medicines protocol to facilitate the delivery of COVID-19 immunisation in line with NIAC recommendations endorsed by the Department of Health (DoH).

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

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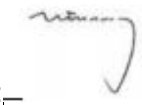
Document reference number	NIO November 2024 Version 1
1.0 Critical elements	
Name of organisation and settings where medicine protocol applies	Health Service Providers across the voluntary and statutory services of the HSE, non-HSE healthcare facilities, HSE mobile vaccination clinics and central vaccination 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	November 2024
Date for review of medicine protocol	November 2025 (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: 

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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 immunisation of vaccine recipients against COVID-19 (see Inclusion Criteria).
Circumstances in which the medicine protocol applies	Targeted immunisation programme for vaccine recipients against COVID-19 based on the NIAC recommendations endorsed by the DoH.
Exclusion criteria for vaccine recipient using the medicine protocol	Comirnaty KP.2 30 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, (Contained in all presentations of Comirnaty currently use in Ireland) ● Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine.
Inclusion criteria for vaccine recipient using the medicine protocol	**Inclusion Criteria:** ● Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older in line with NIAC Chapter 5a. **Note:** This vaccine is recommended for **primary and booster doses** **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 ● 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 COVID-19 vaccine - Observe for 30 minutes ● Previous history of myocarditis or pericarditis after any COVID-19 vaccine: Consult with cardiologist ● Mastocytosis: Vaccinate as scheduled and observe for 30 minutes ● Idiopathic anaphylaxis or Anaphylaxis after food, venom or medication: Vaccinate a scheduled and observe for 15 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 ● 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 cover, contact the patient's Comprehensive Care Centre ● 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. If administration in separate limbs is not feasible or desired, administration in the same limb, separated by at least 2.5 cm, is appropriate ● Patients with planned immunosuppressive therapy should ideally receive the booster dose two weeks before treatment. The recommended minimum interval may be used.
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. 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 following an individual benefit risk 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 30 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
Action to be followed for vaccine recipients who do not wish to receive the vaccine	Advise of the risks of not having the vaccine, including risk of possible severe COVID-19 disease. Advice regarding minimization 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 vaccine recipient 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 ● Vaccine Information Leaflets ● Patient held record cards ● Health Products Regulatory Authority (HPRA) Adverse Reaction Reporting forms or availability 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 KP.2 30 micrograms/dose COVID-19 mRNA Vaccine which includes the following: ● *Medicine Protocol for the Administration of Comirnaty KP.2 30 micrograms/dose COVID-19 mRNA Vaccine to vaccine recipients (Ready to use - Do not dilute)* ● Please refer to the relevant Section B for your healthcare profession and *Self-Assessment of Competency Form*

Master Medicine Protocol for the Administration of Comirnaty KP.2 30 micrograms/dose COVID-19 mRNA Vaccine to Vaccine Recipients aged 12 years and older *(Ready to use - Do not dilute)*

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

- *Anaphylaxis: Immediate Management in the community*. NIAC, *Immunisation Guidelines for Ireland (2023)*. https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
- HSE National Immunisation Office (2024) *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* (2024) https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

</td></tr>
<tr><td>3.0 Name of Medicine</td><td>Comirnaty KP.2 30 micrograms/dose COVID-19 mRNA Vaccine (Ready to use - Do not dilute)</td></tr>
<tr><td>Dose & Route of administration</td><td>

- The dose is 0.3ml
- Recommended for **primary and booster dose**
- Route of administration: Intramuscular (IM)
- Site: The preferred site is the deltoid muscle
- Do not inject the vaccine intravascularly, subcutaneously or intradermally

</td></tr>
<tr><td>Primary schedule & Booster dose in Autumn 2024</td><td>
<table>
<tr><th>Age</th><th>Primary schedule</th><th>Booster dose in Autumn 2024 (*six months interval is required)</th></tr>
<tr><td>60 years and older</td><td>single dose</td><td>single dose</td></tr>
<tr><td>18 years - 59 years
•those living in long term care facilities for older adults.</td><td>single dose</td><td>Single dose</td></tr>
<tr><td>12 years – 59 years
•those with medical conditions (see the NIAC chapter 5a) associated with a higher risk of COVID-19 hospitalisation, severe disease or death.</td><td>single dose</td><td>single dose</td></tr>
<tr><td>12 years - 59 years
•those with immunocompromise associated with a suboptimal response to vaccination.</td><td>2 to 3 doses (see further details in the immunocompromised section below)</td><td>single dose (an interval of three months may be used e.g., schedule to commence chemotherapy)</td></tr>
<tr><td>Health and care workers</td><td>single dose</td><td>single dose</td></tr>
<tr><td>Pregnant adolescents and adults</td><td>single dose</td><td>single dose (see further details in the pregnancy section below)</td></tr>
<tr><td colspan="3">Access to the primary schedule for those aged 12yrs - 59yrs should be available who are not listed above, following discussion with a health care provider (e.g., GP, pharmacist or HSE vaccinator), request vaccination
For those aged 12yrs - 59 yrs, who are not listed above, a dose of a COVID-19</td></tr>
</table>
</td></tr>
</table>

	booster vaccine in Autumn 2024 is **not** routinely recommended. However, access to a COVID-19 booster vaccine in Autumn 2024 should be available for those aged 18-59 years who, following discussion of their reasons with a health care provider (e.g., GP, pharmacist or HSE vaccinator), request vaccination. **Of Note: ***A booster dose of a COVID-19 vaccine is recommended in Autumn 2024 **six** months following the last COVID-19 vaccine or SARS-CoV-2 infection irrespective of the number of previous doses or types of COVID-19 vaccine received. In certain circumstances a minimum interval of three months may be used (e.g., in a person scheduled to commence chemotherapy or operational reasons).
Immunocompromised due to disease or treatment: (see the NIAC chapter 5a)	Primary schedule: For those who are immunocompromised **two** doses are recommended with a **four** week interval 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. 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.
Pregnancy	Primary schedule: Single dose is recommended Booster vaccination during pregnancy is recommended all year and not seasonal. For pregnant adolescents and adults, a **COVID-19 booster vaccine in autumn 2024** once in pregnancy is recommended, if it is more than six months since their previous COVID-19 vaccine or infection. • this recommendation is not seasonal and applies all year. • COVID-19 vaccine can be given at any stage in pregnancy • the booster dose ideally given between 20-34 weeks gestation. (Of note: *For those who are pregnant and are immunocompromised, a second booster dose within the same pregnancy may be considered if six months has elapsed since their last booster dose or SARS-CoV-2 infection*). **Breastfeeding:** There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping.
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-epar-product-information_en.pdf

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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 ● 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 Vaccine recipients should be advised to seek urgent medical attention if they have symptoms suggestive of an allergic reaction such as difficulty breathing, feeling faint, rapid heartbeat or a skin rash. NIAC will continue to closely monitor relevant data and will update this advice as necessary. The vaccine recipient should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the Comirnaty KP.2 30 micrograms/dose COVID-19 mRNA 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 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 the medicine	In the case of medication errors that directly involve the vaccine recipient, 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. Vital signs should be recorded and the vaccine recipient should be reviewed by the relevant medical practitioner/ clinical lead/lead vaccinator. 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 https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.

Resources and equipment required	• Vaccine (Ready to use - Do not dilute) • Syringe and 23 gauge/25 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 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 the vaccine recipient before treatment	**Vaccine Information material must be supplied to the vaccine recipient prior to administration of the vaccine.** **Before Treatment** Check and confirm that consent has been obtained. Discuss the Comirnaty KP.2 30 micrograms/dose COVID-19 mRNA Vaccine and the importance of protecting their health. Inform vaccine recipient that 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 are listed below.: **Local:** Very common: injection site pain and swelling Common: injection site redness **General:** Very common: arthralgia, diarrhoea, fatigue, fever, chills, headache, myalgia, pyrexia Common: nausea, vomiting Myocarditis and pericarditis are very rare side effects of mRNA vaccines and Nuvaxovid, occurring predominantly after the second dose and in males under 30 years of age. Higher rates are reported following Spikevax compared with Comirnaty. The risk is lower following booster vaccination. The risk of vaccine associated myocarditis can be reduced by extending the interval between the first and second mRNA COVID-19 vaccine dose in the primary schedule for immunocompromised. These conditions can develop within a few days after vaccination and have primarily occurred within 14 days. Available data suggest

Advice to be given to the recipient after treatment	that the course of myocarditis or pericarditis following vaccination is not different from myocarditis or pericarditis in general. Details 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 Treatment** 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. 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. Ibuprofen is not recommended in pregnancy. If more serious adverse or persistent effects occur, vaccine recipient 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
- HSE National Immunisation Office (2024) *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 (2024)* 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