Master Medicine Protocol for the Administration of Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL COVID-19 mRNA Vaccine to Vaccine Recipients

This medicine protocol is a specific written instruction for the administration of Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL COVID-19 mRNA Vaccine to vaccine recipients included in the Statutory Instruments S.I. No.11 of 2023 for booster doses by healthcare professionals who are registered with their respective regulatory body and students in healthcare professions included in S.I. No. 698 of 2020, S.I. No. 81 of 2021 and S.I. No. 245 of 2022. This medicine protocol is valid for the 2023/2024 HSE COVID-19 Vaccination Programme. This medicine protocol enables the healthcare professionals and students 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 Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL 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 Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL COVID-19 mRNA Vaccine as detailed by the European Medicines Agency (EMA).

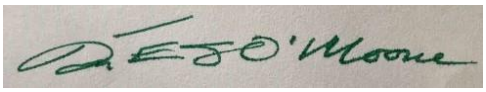
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Dublin: Royal College of Physicians Ireland, online update available at https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/
- HSE National Immunisation Office (2020) *Clinical Guidance 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/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf

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, Department of Health (DoH) and HSE policy.

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

Medicine Protocol for the Administration of Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL COVID-19 mRNA Vaccine to vaccine recipients

Document reference number	NIO 2023
1.0 Critical Elements	
Name of Organisation where medicine protocol applies	Health Service Providers across the voluntary and statutory services of the HSE, non-HSE healthcare facilities and Central Vaccination Centres. This Medicine Protocol applies to: Registered healthcare professionals included in S.I. No. 698 of 2020, S.I. No. 81 of the 2021, S. I. No. 245 and employed in the voluntary and statutory services of the HSE and students in healthcare professions included in S.I. No. 245 of 2021 who have undertaken the required education and training programmes
Date the medicine protocol comes into effect	February 2023
Date for review of medicine protocol	February 2024 (Regularly updated as per 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 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 as identified in the DoH policy based on the NIAC recommendations. The World Health Organization declared COVID-19 outbreak as a pandemic on 11 March 2020 which is still ongoing.

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 30 years of age and older for booster vaccination only.
	● Note: This vaccine is not currently recommended for primary course or additional dose of COVID-19 mRNA vaccine.
	
	Precautions:
	● Acute severe illness defer until recovery
	● Those with the following history should receive a viral vector vaccine:
	  ● Anaphylaxis after multiple, different drug classes, with no identified allergen (may indicate Polyethylene Glycol (PEG) allergy)
	  ● Anaphylaxis after a vaccine, or a medicine which contained PEG
	  ● Idiopathic anaphylaxis (may indicate PEG allergy)
	● Previous history of myocarditis or pericarditis after any COVID-19 vaccine - seek specialist advice
	● There should be an interval of four weeks between Mpox/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis
	● For those receiving a **first booster** dose of vaccine, who have had breakthrough COVID-19 infection (laboratory-confirmed/antigen-positive with symptoms) since completion of the primary vaccination, the booster dose should be deferred until at least 4 months following diagnosis (3 months in exceptional circumstances)
	● For those aged 50 years and older receiving a **further booster** dose of vaccine (i.e., any booster vaccine dose after the first booster vaccine), who have had breakthrough COVID-19 infection (laboratory-confirmed/antigen-positive with symptoms) following the last COVID-19 vaccine dose, **the further booster** dose should be deferred until at least 6 months following diagnosis. For those aged 30-49 years, the **further booster** dose should be deferred for 9 months from COVID-19 infection (except those with immunocompromised where the interval is 6 months).
	● 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 intramuscular (IM) 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 may be administered at the same time or at any interval (except Mpox /smallpox vaccine). As it is not known if COVID-19 vaccine reactogenicity is increased with coadministration, vaccines should preferably be given in different limbs. ● Patients with planned immunosuppressive therapy should ideally receive booster dose two weeks before treatment. The recommended minimum interval may be used. **Pregnancy:** Primary vaccination during pregnancy: • For those aged 30 years and older, 2 doses 4 weeks apart is recommended. A minimum interval of three weeks may be used if there is urgency to achieve protection. Booster vaccination during pregnancy: **First booster** For pregnant adults aged 30years and older a **first COVID-19 booster vaccine** (for those who have not already received a first booster COVID-19 vaccine) is recommended at least **4 months** since the last COVID-19 vaccine dose or confirmed SARS-CoV-2 infection. • This first booster vaccine can be given at any stage in pregnancy **Further boosters (for those who received their first booster vaccine before pregnancy)** For pregnant adults aged 30years and older a COVID-19 booster vaccine once in pregnancy is recommended if it is more than **six months** since their previous COVID-19 vaccine or infection. ● COVID-19 vaccine can be given at any stage in pregnancy ● the booster is ideally given between 20-34 weeks gestation ● if it is more than 12 months since their previous COVID-19 vaccine or infection administration earlier in pregnancy should be considered. (Of note: If an individual is immunocompromised and eligible for a further booster in pregnancy, then a 6 month interval since their previous COVID-19 vaccine dose or infection is recommended (irrespective of the number of weeks gestation and they may get two booster vaccine doses in pregnancy). **Breastfeeding:** ● There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping. **Individuals who are immunocompromised due to disease or treatment (see the NIAC chapter 5a)** ● Those aged 30 and older with immunocompromise condition due to disease or treatment who have completed their primary course and additional dose may then receive a first booster dose at least 4 months after their additional dose or confirmed COVID-19 infection (laboratory-confirmed/antigen-positive with symptoms) (3 months in exceptional circumstances).

Exclusion criteria for vaccine recipient using the medicine protocol	Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL COVID-19 mRNA Vaccine should not be given under this medicine protocol to those aged under 30 years of age or if the vaccine recipient has: ● Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG) and trometamol). ● Anaphylaxis following another mRNA vaccine. ● Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine.
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. ● 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 Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL 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. Advise 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 if available • Health Products Regulatory Authority (HPRA) Adverse Reaction Reporting forms • 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 Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL which includes the following: • Medicine Protocol for the Administration of Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL COVID-19 mRNA Vaccine to vaccine recipients • Please refer to Section B for registered nurses / midwives and *Self-Assessment of Competency Form* • Health Service Executive (2021) *Induction, Supervision, and Competency Assessment and Practice Protocol for Students as Vaccinators*.

	• Anaphylaxis: Immediate Management in the community. NIAC, *Immunisation Guidelines for Ireland*. https://rcpi.access.preservica.com/uncategorized/IO_4283f8d0-dcaf-4fae-974e-71421ddcc51f/ • HSE NIO *Clinical Guidance for COVID-19 Vaccination* https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf • COVID-19 chapter from NIAC *Immunisation Guidelines for Ireland* (2023) https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
3.0 Name of Medicine	Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL COVID-19 mRNA Vaccine
Dose & Route of administration	• The dose is 0.5ml Note: Currently recommended for the 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
Booster dose of Spikevax®(COVID-19 Vaccine Moderna) See the NIAC Chapter 5a	**First Booster dose** People aged 30 years and older who have completed their primary course with any COVID-19 vaccine type are recommended a single dose of Spikevax bivalent Original/Omicron BA. 4-5 COVID-19 mRNA vaccine as a first booster dose. The booster dose can be given at the same time or at any interval before or after seasonal influenza vaccine. This applies whether the primary course was an mRNA or viral vector vaccine or a protein subunit vaccine. **Recommended intervals:** **First booster** • A **four month** interval from last vaccine dose or confirmed COVID-19 infection (laboratory-confirmed/antigen-positive with symptoms) is recommended for all aged 30 years and older receiving a **first booster** dose of vaccine, in exceptional circumstances a minimum interval of three months may be used. **Recommended intervals for further booster vaccination in Spring 2023** • A **six month** interval from previous COVID-19 booster vaccine or infection is recommended **for those aged 50 years and older** receiving a further booster as part of the Spring vaccination programme 2023. • A **nine month** interval from previous COVID-19 booster vaccine or infection is recommended for those aged **30** - **49 years** receiving a further booster as part of the Spring vaccination programme 2023 (except in the case of those immunocompromise associated with a suboptimal response to vaccination, where an interval of six months following any previous COVID-19 vaccine dose or infection is recommended) • A **minimum interval of three months** is permissible from last booster or COVID-19 infection in exceptional circumstances e.g. heightened epidemiologic risk or for operational reasons • **Of note:** Those aged 30 - 49 years not in other groups who did not choose to receive a second COVID-19 booster vaccine when it was previously offered to them may still receive a second booster vaccine if there is at least a nine **month** interval after their first COVID-19 booster vaccine or SARS-CoV-2 infection.

<table>
<tr><td></td><td>The booster dose can be given at the same time or at any interval before or after seasonal influenza vaccine. This applies whether the primary course was an mRNA or viral vector vaccine or a protein subunit vaccine.</td></tr>
<tr><td>Booster vaccination in Spring 2023 (irrespective of the number of prior booster doses)</td><td>
<table>
<tr><th>Age group</th><th>Booster vaccination in Spring (2023) is recommended irrespective of the number of prior booster doses</th></tr>
<tr><td colspan="2">A six month interval from previous booster vaccine or infection is recommended for those aged 50 years and older.
A nine month interval from previous booster vaccine or infection is recommended for those aged between 30-49 years except those immunocompromise associated with a suboptimal response to vaccination with an interval of six months.</td></tr>
<tr><td>70yrs and older</td><td>A booster vaccine is recommended in spring</td></tr>
<tr><td>50-69yrs</td><td>A booster vaccine is recommended in spring for
-those living in long term care facilities for older adults
-those with immunocompromise associated with a suboptimal response to vaccination.</td></tr>
<tr><td>30-49yrs</td><td>A booster vaccine is recommended in spring for
-those with immunocompromise associated with a suboptimal response to vaccination with an interval of six months.
-those living in long term care facilities for older adults</td></tr>
</table>
</td></tr>
<tr><td>Link to Medicine

Details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA)</td><td>Link to SmPC and Patient Information Leaflet available at:
https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf</td></tr>
</table>

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 The vaccine recipient should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the COVID-19 Vaccine Spikevax 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 should be informed of any clinically significant reported adverse reaction. 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), available at https://rcpi.access.preservica.com/uncategorized/IO_4283f8d0-dcaf-4fae-974e-71421ddcc51f/
Procedure for the reporting and documentation of errors and near misses involving the medicine	In the case of medicine errors that directly involve the 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. The vaccine recipient 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 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	● A multidose vial of Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL COVID-19 mRNA Vaccine ● 1 ml/2ml/2.5ml syringe, 23/25 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_4283f8d0-dcaf-4fae-974e-71421ddcc51f/ ● 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 Spikevax bivalent Original/Omicron BA. 4-5 (50 micrograms/50 micrograms)/mL 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/medicines/human/EPAR/spikevax Discuss potential side effects as below. Side effects may occur with following frequencies: **Local:** Very common: injection site pain, swelling and erythema Common: injection site rash and urticaria Uncommon: injection site pruritus. **General:** Very common: arthralgia, chills, fatigue, headache, lymphadenopathy, myalgia, nausea, pyrexia, vomiting Common: diarrhoea, rash Uncommon: abdominal pain, Rare: acute peripheral facial paralysis, facial swelling, hypoaesthesia, paraesthesia Very rare: myocarditis, pericarditis (see NIAC guidelines, Section 5a.4.2) Unknown frequency: erythema multiforme, extensive swelling of the limb, heavy menstrual bleeding, hypersensitivity

	There is an increased risk for myocarditis and pericarditis following vaccination with Spikevax particularly in males aged under 30 years, and following the second dose of Spikevax (original). These conditions can develop in the days after vaccination. Healthcare professionals should advise vaccinated individuals to seek immediate medical attention should they experience chest pain, shortness of breath, or palpitations. Details of adverse reactions may be found in the SmPC available at https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf
Advice to be given to the recipient after treatment	**After Treatment** Discuss potential side effects 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. 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

Health Service Executive (2010) *Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste.* Dublin: Health Service Executive.

National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community. Available at https://rcpi.access.preservica.com/uncategorized/IO_4283f8d0-dcaf-4fae-974e-71421ddcc51f/

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland (2023)* Dublin: Royal College of Physicians Ireland. Online update available at https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/

HSE National Immunisation Office (2020) *Clinical Guidance for COVID-19 Vaccinations* available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf

S.I. No. 81/2021 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No.4) Regulations 2021. Available at http://www.irishstatutebook.ie/eli/2021/si/81/made/en/pdf

S.I. No. 698/2020 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. Available at http://www.irishstatutebook.ie/eli/2020/si/698/made/en/pdf

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

S.I. No. 11 of 2023 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2022. Available at http://www.irishstatutebook.ie/eli/2022/si/467/made/en/pdf