Master Medicine Protocol for the Administration of Comirnaty© 30 micrograms/dose (Pfizer/BioNTech) COVID-19 Vaccine to Vaccine Recipients

This medicine protocol is a specific written instruction for the administration of Comirnaty© 30 micrograms/dose (Pfizer/BioNTech) COVID-19 Vaccine to vaccine recipients by healthcare professionals included in Statutory Instruments S.I. No. 698 of 2020, S.I. No. 81 of 2021 S.I. No. 245 of 2021 who are registered with their respective regulatory body and students in healthcare professions included in S.I. No. 245 of 2021 and S.I. No. 411 of 2021 S.I. No. 492 , S.I .No. 558 of 2021, S.I. No. 578 of 2021, S.I. No. 605 of 2021 and S.I. No. 692 of 2021 and S.I. No. 84 of 2022 on additional and booster doses. This medicine protocol is valid for the 2020/2021/2022/2023 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 Comirnaty© 30 micrograms/dose (Pfizer/BioNTech) 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 for Comirnaty© 30 micrograms/dose (Pfizer/BioNTech) COVID-19 Vaccine as detailed by the European Medicines Agency (EMA). The vaccine is referred to as Comirnaty® (Pfizer/BioNTech) throughout the protocol.

- 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 (2023) *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/medicines/human/EPAR/comirnaty#product-information-section

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, related 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 Comirnaty© 30 micrograms/dose (Pfizer/BioNTech) COVID-19 Vaccine to vaccine recipients

Document reference number	NIO 001.1
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 centers. This Medicine Protocol applies to: Registered healthcare professionals included in S.I. 698 of 2020, S.I. 81 of 2021 and S. I. 245 of 2021 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	December 2020
Date for review of medicine protocol	December 2023 (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 12 years of age and older. **Precautions** ● Acute severe febrile illness: defer until recovery ● Consider non mRNA vaccination for those aged 18 years and older, including pregnant women, with: • 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 monkeypox/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis ● Primary vaccination should be deferred until clinical recovery from COVID-19 at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic ● 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 under 50 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). ● For those who are immunocompromised and receiving an additional dose of vaccine: if they have had laboratory-confirmed/antigen positive infection with symptoms, breakthrough COVID-19 disease since completion of primary vaccination, the additional dose should be

deferred until at least 4 months following diagnosis.

- 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 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.
- Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used

Pregnancy:

Primary vaccination during pregnancy:

- For those aged 12-29 years, 2 doses 8 weeks apart is recommended. A minimum interval of three weeks may be used if there is urgency to achieve protection.
- 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 adolescents and adults 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 adolescents and adults 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.
Exclusion criteria for vaccine recipient using the medicine protocol	Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine should not be given under this medicine protocol 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)). ● 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 18 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 Comirnaty© (Pfizer/BioNTech) COVID-19 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© (Pfizer/BioNTech) COVID-19 Vaccine which includes the following: ● *Medicine Protocol for the Administration of Comirnaty© (Pfizer/BioNTech) COVID-19 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 *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) available at https://rcpi.access.preservica.com/uncategorized/IO_15ead882-dd37-4d61-a213-b692c930564c/
3.0 Name of Medicine	Comirnaty© (Pfizer/BioNTech) COVID-19 Vaccine
Dose & Route of administration	● The dose is 0.3ml, 2 doses 4 weeks apart ● For those aged **12-29** years, an interval of **eight weeks** between the first and second doses of an mRNA vaccine is now recommended, with a minimum interval of three weeks if there is urgency to achieve protection. ● 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. ● Route of administration: Intramuscular (IM) ● Site: The preferred site is the deltoid muscle ● If the second dose is given before 17 days, this is not considered a valid vaccine. ● A third dose should be given at least four weeks after the second (invalid) dose for those aged 30 years and older, or at least eight weeks after the second (invalid) dose for those aged 12-29 years. ● Exceptionally the minimum interval may be used for the third dose after an invalid dose Of note: For those immunocompromise due to disease or treatment a third dose should be given at least four weeks after the second (invalid) dose irrespective of their age. ● If the second dose is given between 17 and 20 days after the first dose, it is a valid dose. ● If the interval between doses is longer than 28 days, the second dose should still be given as soon as possible. The course does not need to be restarted. ● Individuals who have received one dose of Comirnaty© (Pfizer/BioNTech) COVID-19 Vaccine should receive a second dose of Comirnaty© (Pfizer/BioNTech) COVID-19 Vaccine to complete the

	vaccination series • Do not inject the vaccine intravascularly, subcutaneously or intradermally • For those who have received Vaxzevria® or Spikevax® as a first dose and are receiving Comirnaty® as a second dose, there should be at least a 28 day interval between doses. • Children who received a first dose of Comirnaty® 10 micrograms/dose when they were 11, and have now turned 12, should receive Comirnaty© 30 micrograms/dose (Pfizer/BioNTech) as a second dose, at least 8 weeks after the first dose.
Individuals who are immunocompromised due to disease or treatment: (see the NIAC chapter 5a	**Primary course** For those aged 12yrs and above 2 doses to be given with an interval of 4 weeks. Minimum interval of three weeks can be applied if there is urgency to achieve protection. • An additional mRNA vaccine dose should be given to those aged 12 and older with immunocompromise due to disease or treatment who have completed their primary course, regardless of whether the primary course was of an mRNA or an adenoviral vector vaccine. This is an extended primary vaccination course. • The additional vaccine should be given after an interval of 8 weeks following the last dose of an authorised COVID-19 vaccine or infection. (a minimum interval of 28 days may be used in exceptional circumstances) • Those 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).
Booster dose of COVID-19 Vaccine See the NIAC chapter 5a	**<u>First booster dose</u>** People aged 12 years and older who have completed their primary course with any COVID-19 vaccine type are recommended a single dose (0.3ml) of an Comirnaty© (Pfizer/BioNTech) 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 12 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 **12 - 49 years** receiving a further booster as part of the Spring vaccination programme 2023

<table>
<tr><td></td><td>(except in the case of those with 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

• <u>Of note:</u> Those aged 18 - 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.</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 under 50 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>12-49yrs</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
-Aged 18+ years living in long term care facilities for older adults</td></tr>
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<tr><td>Link to medicine

Details of product information and other data including instructions for supply and administration is available from the European Medicines</td><td>Link to Summary of Product Characteristics and Patient Information Leaflet available at:
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty</td></tr>
</table>

Agency (EMA)	
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© (Pfizer/BioNTech) COVID-19 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 2022), available online 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 and/or carer should be informed of the incident. 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 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 Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.
Resources and equipment required	• Vaccine • Sodium Chloride 0.9% Solution for injection • 2ml/ 2.5ml / 3ml syringe and 21 gauge green needle for reconstitution • 23 gauge / 25g 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 Comirnaty© (Pfizer/BioNTech) COVID-19 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/comirnaty Discuss potential side effects as below Side effects may occur with following frequencies: **Local:** Very common: injection site pain and swelling Common: injection site erythema Uncommon: injection site pruritus. **General:** Very common: arthralgia, diarrhoea fatigue, fever, headache, myalgia Common: nausea, vomiting Uncommon: insomnia, hypersensitivity reactions (e.g. rash, pruritus, angioedema),lymphadenopathy, malaise, extremity pain, Hyperhidrosis (night sweats), decreased appetite, asthenia and lethargy Rare: acute peripheral facial paralysis, facial swelling (in those with a history of facial fillers) Very rare: myocarditis and pericarditis Frequency unknown: Erythema Multiforme While there are no immediate serious safety concerns, accumulating data indicates that the rates of side effects may be higher in those receiving an mRNA vaccine as a second dose, following a first dose of Vaxzevria®. As per the EMA advice, cases of myocarditis and pericarditis have been reported very rarely following vaccination with the COVID-19 mRNA Vaccines including Comirnaty®. Healthcare professionals should advise vaccinated individuals to seek immediate medical attention should they experience chest pain, shortness of breath, or palpitations. The cases primarily occurred within 14 days after vaccination, more often after the second dose and in younger men. A full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC), available at https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty Individuals may not be protected until at least 7 days after their second dose of the vaccine.

Advice to be given to the recipient after treatment	**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

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/

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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