



Master medicine protocol for the administration of Comirnaty KP.2 30 micrograms/dose dispersion for injection 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 dispersion for injection 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 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 dispersion for injection 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 dispersion for injection 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, *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 202)


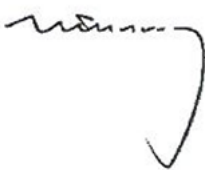
The Nursing and Midwifery Board of Ireland (NMBI) defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to 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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30 micrograms/dose dispersion for injection COVID-19 mRNA vaccine to vaccine
recipients aged 12 years and older (*Ready to use - Do not dilute*)**

Document reference number	Version 2-NIO - Comirnaty KP.2 30 micrograms/dose-March 2025
1.0 Critical elements	
Name of organisation and settings where medicine protocol applies	<p>Health Service Providers across the voluntary and statutory services of the HSE, non-HSE healthcare facilities, HSE mobile vaccination clinics and central vaccination centres.</p> <p>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.</p>
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 & Department of Health 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 <i>“On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation”</i>	<p>Name: Dr. Éamonn O’ Moore, Director of National Health Protection, HSE</p> <p> Signature:</p> <p>Name: Dr Colm Henry, Chief Clinical Officer, HSE</p> <p> Signature:</p>



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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 aged 12 years and older 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 Department of Health.
Exclusion criteria for vaccine recipient using the medicine protocol	<p>Comirnaty KP.2 30 micrograms/dose dispersion for injection COVID-19 mRNA vaccine should not be given under this medicine protocol if the vaccine recipient has:</p> <ul style="list-style-type: none"> • 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	<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • 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. <p>Note: This vaccine is recommended for primary and booster vaccine doses</p> <p>Note: Booster vaccination is recommended for those aged 12 years and older with certain health care conditions only. Refer to the booster dose section of this protocol.</p> <p>Precautions</p> <ul style="list-style-type: none"> • Acute severe illness: <ul style="list-style-type: none"> ◦ Defer until recovery • Recent mpox vaccine: <ul style="list-style-type: none"> ◦ 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): <ul style="list-style-type: none"> ◦ 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: <ul style="list-style-type: none"> ◦ Consult with Cardiologist • Children with a previous history of Multisystem Inflammatory Syndrome (MIS-C): <ul style="list-style-type: none"> ◦ Vaccination should be postponed in until clinical recovery or until at least 3 months since diagnosis, whichever is the longer • Mastocytosis: <ul style="list-style-type: none"> ◦ Vaccinate as scheduled and observe for 30 minutes • Idiopathic Anaphylaxis or Anaphylaxis after food, venom or medication: <ul style="list-style-type: none"> ◦ Vaccinate as scheduled and observe for 15 minutes



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	<ul style="list-style-type: none"> 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 thrombocytopenia (platelet count $<50 \times 10^9/L$) 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 supervising Consultant. Vaccination is not contraindicated for those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration <p>Co-administration</p> <ul style="list-style-type: none"> COVID-19 vaccines and other vaccines (except mpox) 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
Actions to be taken for those who are excluded from the medicine protocol	<ul style="list-style-type: none"> Refer to/discuss with the relevant Medical Practitioner/clinical lead/lead vaccinator for an individual clinical 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 <p>Where Comirnaty KP.2 30 micrograms/dose dispersion for injection COVID-19 mRNA vaccine is prescribed following medical assessment, the vaccinator may administer the vaccine within his/her scope of practice.</p> <p>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</p>
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.
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	<ul style="list-style-type: none"> 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 http://www.hpra.ie National Incident Management System Form NIRF-01-v12 available at: https://www.hse.ie/eng/about/who/ngpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf



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	<p>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 dispersion for injection COVID-19 mRNA Vaccine which includes the following:</p> <ul style="list-style-type: none"> • <i>Medicine Protocol for the Administration of Comirnaty KP.2 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine to vaccine recipients (Ready to use - Do not dilute)</i> • Please refer to the relevant Section B for your healthcare profession and <i>Self-Assessment of Competency Form</i> • <i>Anaphylaxis: Immediate Management in the community</i>. NIAC, <i>Immunisation Guidelines for Ireland (2023)</i>. https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ • HSE National Immunisation Office, <i>Clinical Guidance for Covid-19 Vaccination</i> https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf • COVID-19 chapter from NIAC <i>Immunisation Guidelines for Ireland</i> https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
3.0 Name of Medicine	<p>Comirnaty KP.2 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine (Grey cap) Ready to use - Do not dilute</p>
Dose & Route of administration	<ul style="list-style-type: none"> • 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
Primary course	<p>For primary course the dose is 0.3ml, 1 dose.</p> <p>For those aged 12 years and older, a primary schedule of a COVID-19 vaccine is recommended for:</p> <ul style="list-style-type: none"> • Those aged 60 years and older • Those aged 18-59 years living in long term care facilities for older adults • Those aged 12-59 years with: <ul style="list-style-type: none"> ○ Immunocompromise associated with a suboptimal response to vaccination (see further details about the dose and schedule below) ○ Medical conditions associated with a suboptimal response to vaccination • Healthcare workers • Pregnant adolescents and adults (see further information below) <p>For those aged 12-59 years who are healthy, a primary schedule of a COVID-19 vaccine is not routinely recommended. However, access to a primary schedule of a COVID-19 vaccine should be available for those in this age group who, following discussion of their reasons with a healthcare provider (e.g., GP, pharmacist or HSE vaccinator), request vaccination.</p>
Immunocompromised due to disease or treatment: (see the NIAC chapter 5a)	<p><u>Primary schedule:</u> 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.</p> <p>For people who are 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</p>



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	<p>weeks (i.e., 28 days) between dose two and dose three, if there is urgency to achieve protection.</p> <ul style="list-style-type: none">• 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 in Spring 2025	<p>For the COVID-19 Spring booster vaccination programme, antigenically updated COVID-19 mRNA vaccines are the preferred vaccine for use. The antigenically available vaccine for those aged 12 years and older is Comirnaty KP.2 30 micrograms</p>										
	<table><tr><td>Age</td><td>Irrespective of the number of previous doses or types of COVID-19 vaccine received, a COVID-19 vaccine is:</td></tr><tr><td>80 years and older</td><td>Recommended.</td></tr><tr><td>70-79 years</td><td>Recommended if have not received a COVID-19 vaccine in the preceding 12 months.</td></tr><tr><td>18-79 years</td><td>Recommended for those living in long term care facilities for older adults.</td></tr><tr><td>12-79 years</td><td>Recommended for those with immunocompromise associated with a suboptimal response to vaccination.</td></tr></table>	Age	Irrespective of the number of previous doses or types of COVID-19 vaccine received, a COVID-19 vaccine is:	80 years and older	Recommended.	70-79 years	Recommended if have not received a COVID-19 vaccine in the preceding 12 months .	18-79 years	Recommended for those living in long term care facilities for older adults.	12-79 years	Recommended for those with immunocompromise associated with a suboptimal response to vaccination.
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	12-79 years	Recommended for those with immunocompromise associated with a suboptimal response to vaccination.									
<p>Of note: A COVID-19 vaccine may be given in Spring 2025 irrespective of the number of previous doses or types of COVID-19 vaccines received. The recommended minimum interval following infection or vaccination is six months, however shorter intervals down to three months are permissible in exceptional circumstances e.g., planned immunosuppressive therapy or operational reasons.</p>											
<p>For those aged 70-79 years, a spring COVID-19 booster dose is recommended for who did not receive a COVID-19 vaccine in the preceding 12 months.</p>											
<p>If a patient with planned immunosuppressant therapy has not received a booster COVID-19 vaccine in the six months prior to starting therapy, they should be offered the vaccine regardless of the time of year. Patients with planned immunosuppressing therapy should ideally complete primary vaccination two weeks before beginning treatment</p>											



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Pregnancy	<p><u>Primary schedule:</u> Single dose is recommended at any stage in pregnancy (see advice above if immunocompromised)</p> <p><u>Booster vaccination during pregnancy</u> is recommended all year and not seasonal. For pregnant adolescents and adults, a COVID-19 booster vaccine in spring 2025 once in pregnancy is recommended, if it is more than six months since their previous COVID-19 vaccine or infection.</p> <ul style="list-style-type: none">• 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. <p>(Of note: <i>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</i>).</p> <p>Breastfeeding: COVID-19 vaccines can be used during breastfeeding. There is no evidence that breastfeeding after COVID-19 vaccination causes harm to the breastfed infants or interferes with ability to breastfeed. There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping.</p>
Link to medicine details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA)	<p>Link to SmPC and Patient Information Leaflet available at: https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf</p>
Potential adverse reactions and procedures for treatment of same	<p>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</p> <ul style="list-style-type: none">• 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 <p>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.</p> <p>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 dispersion for injection COVID-19 mRNA Vaccine after the above period of observation.</p>



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Procedure for reporting adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)	<p>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.</p> <p>The vaccine recipient's General Practitioner (GP) should be informed of any clinically significant reported adverse reactions.</p> <p>In the event of anaphylaxis, the incident and all actions taken must be promptly recorded in accordance with the <i>Management of a Patient with Anaphylaxis: Immediate Management in the Community</i> (NIAC 2023), available online at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/</p>
Procedure for the reporting and documentation of errors and near misses involving the medicine	<p>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.</p> <p>Vital signs should be recorded and the vaccine recipient should be reviewed by the relevant medical practitioner/ clinical lead/lead vaccinator.</p> <p>The incident must be reported to the relevant line manager/person in charge as soon as possible.</p> <p>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</p> <p>Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.</p>
Resources and equipment required	<ul style="list-style-type: none">• Vaccine: Comirnaty KP.2 30 micrograms dispersion for injection COVID-19 mRNA 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 <i>Anaphylaxis: Immediate Management in the Community</i> (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



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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 and after vaccination	<p>Vaccine Information material must be supplied to the vaccine recipient prior to administration of the vaccine.</p> <p>Before vaccination</p> <ul style="list-style-type: none"> • Check and confirm that informed consent has been obtained. • Discuss the Comirnaty KP.2 30 micrograms/dose dispersion for injection 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 <p>Discuss common adverse events as listed below.:</p> <p>Local: Very common: injection site pain and swelling Common: injection site redness</p> <p>General: Very common: arthralgia, diarrhoea, fatigue, fever, chills, headache, myalgia, pyrexia Common: nausea, vomiting</p> <p>Myocarditis and pericarditis 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 that the course of myocarditis or pericarditis following vaccination is not different from myocarditis or pericarditis in general. The EMA concluded that the overall risk benefit profile for all authorised COVID-19 vaccines remains favourable</p> <p>A full list of and further details about 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</p> <p>After vaccination</p> <ul style="list-style-type: none"> • 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.



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	<p>Events of anaphylaxis have been reported therefore NIAC recommends the following monitoring for the post-vaccination period:</p> <ul style="list-style-type: none">• 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. <p>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.</p> <p>The vaccine recipient should be advised to report any side effects to the relevant medical practitioner.</p> <p>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.</p> <p>If more serious adverse or persistent effects occur, vaccine recipient should be advised to contact their GP/out of hours service.</p>
Details of any necessary follow-up, action and referral arrangements	<p>In the event of an adverse reaction the vaccination team must ensure that all procedures are adhered to as outlined in Section 3.</p>

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>