

COVID-19 vaccine (5 years and over) Vaccine Group Direction (VGD)

This VGD is for the administration of COVID-19 vaccine to eligible individuals from the age of 5 years, in accordance with the national COVID-19 vaccination programme.

This VGD is for use by registered healthcare practitioners identified in [section 3](#), subject to any limitations to authorisation detailed in [section 2](#).

Reference no: COVID-19 vaccine (5 years and over) VGD

Version no: v1.0

Valid from: 24 April 2026

Expiry date: 30 June 2026

The Strategic Planning and Performance Group (SPPG) and the Public Health Agency (PHA) have adapted the COVID-19 vaccine (5 years and over) Vaccine Group Direction (VGD) from the UK Health Security Agency (UKHSA) (**Publications approval reference: PRN02434**). SPPG and PHA have developed this VGD for authorisation by the Department of Health Northern Ireland (DoH) to facilitate the delivery of the national COVID-19 vaccination programme in Northern Ireland.

Primary Care/Trusts must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. Section 2 may be amended only by the person(s) authorising the VGD, in accordance with (HMR2012)¹ regulation 235A, on behalf of DoH. In addition, authorising organisations must not alter section 3 (Characteristics of staff). **Section 7 can be edited within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the commissioned organisation using the VGD. The fields in section 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the SPPG/PHA clinical content authorisation which is provided in accordance with the regulations. The legal validity of this VGD is contingent on those authorising section 7 complying with the above.**

Operation of this VGD is the responsibility of commissioners and service providers. The final authorised copy of this VGD should be kept by the authorising organisation completing Section 2 for 25 years after the VGD expires². Provider organisations adopting authorised versions of this VGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, to work according to the current version of this VGD by signing section 7. A manager with the relevant level of authority should also provide a countersignature unless by exception there are arrangements for self-declaration. Providers are also reminded to ensure vaccination is in line with the contractual arrangements and limitations of service provision agreed with the service commissioner as well as the criteria for inclusion.

Practitioners and organisations should be aware that operating department practitioners are not enabled to work under step 1 of a VGD. However, these staff groups may work under steps 2 through 4 of this VGD, provided they are supervised by a registered healthcare professional who has already consented the individual to be vaccinated (see [section 3 – characteristics of staff](#)).

Practitioners and organisations must check that they are using the current version of the VGD. Amendments may become necessary prior to the published expiry date. Current versions of SPPG/PHA developed COVID-19 vaccine templates can be found via:

¹ This includes any relevant amendments to legislation

² Department of Health, Good Management, Good Records, [Disposal Schedule - Section G part 2](#), G84.

- Trust Intranet or
- [Primary Care Intranet](#)

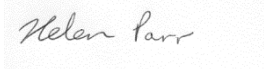


Any concerns regarding the content of this VGD should be addressed to:
pha.immunisation@hscni.net

Change history

Version number	Change details	Date
v1.0	New COVID-19 vaccine Vaccine Group Direction.	8th April 2026

1. VGD Development

This VGD has been developed by the following health professionals on behalf of SPPG/PHA:

Developed by:	Name	Signature	Date
Pharmacist	Helen Parr Pharmacist, SPPG		8 th April 2026
Doctor	Laura McCartney, Speciality Doctor in Health Protection, PHA		16 th April 2026
Registered Nurse	Shauna Armstrong Health Protection Nurse, PHA		14 th April 2026


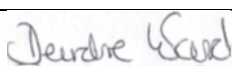
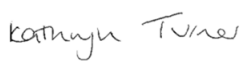
Reviewed by	Role	Date
Claire King	Pharmacist, SPPG	20/04/26

Any provider/contractor administering COVID-19 vaccines under this VGD must work strictly within the terms of this VGD and any relevant contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme.

Assembly, preparation and administration of vaccines supplied and administered under this VGD must be subject to all HSC governance arrangements and standard operating procedures that ensure the safety, quality or efficacy of the product is not compromised. The assembly, preparation and administration of the vaccines should also be in accordance with the general requirements of the Human Medicines Regulations 2012 and Medicines Act 1968, and with the [Summary of Product Characteristics](#) (SPC).

Note: The national COVID-19 vaccination programme may also be provided under a patient group direction (PGD) or on a patient specific basis (that is, by or on the directions of an appropriate independent prescriber, such as under a patient specific direction (PSD)). Supply and administration in these instances should be in accordance with contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme and are not related to this VGD.


2. Clinical and Organisational Approval

Clinical Approval			
Role	Name	Sign	Date
Consultant in Service Development, PHA	Dr Louise Herron		22 nd April 2026
Strategic Public Health Lead (Starting Well) PHA	Mrs Deirdre Ward		22 nd April 2026
Interim Head of Pharmacy and Medicines Management, Directorate of Primary Care, SPPG	Mrs Kathryn Turner		21 st April 2026

This VGD is not legally valid until it has had the relevant organisational authorisation from DoH, completed below.

DoH accepts responsibility for governance of this VGD. Any provider delivering the national COVID-19 vaccination programme under VGD must work strictly within the terms of this VGD and contractual arrangements with the Commissioner for the delivery of the national COVID-19 vaccination programme.

DoH authorises this VGD for use by their commissioned providers delivering the national COVID-19 vaccination programme.

Organisational Approval (legal requirement)			
Role	Name	Signed	Date
Interim Chief Operating Officer, SPPG	Tracey McCaig		23 rd April 2026

[Section 7](#) provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this VGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this VGD.

3. Characteristics of staff

The staff qualifications and experience required to operate this VGD are dependent upon the tasks the staff member will carry out. The process of vaccination may be broken down into four steps.

	Tasks to be undertaken	Delegation (and limitations to delegation if applicable)	Who can carry out this step?
Step 1	<ul style="list-style-type: none"> •clinical assessment, including that the individual meets the inclusion criteria of this VGD •provide information and obtain informed consent •provide advice to the individual, parent or carer •clinical supervision of steps 2, 3 and 4, where any one or all of these steps are completed by another practitioner •on-site supervision is mandatory during all vaccination sessions. 		<p>Can only be carried out by practitioners named in HMR2012 (Schedule 16, Part 4) as being able to operate under a Patient Group Direction</p> <p style="text-align: center;">and</p> <p>who are named under qualifications and professional registration</p> <p>Note: Operating department practitioners (ODPs) are not eligible to work under this step of the VGD.</p>
Step 2	Vaccine preparation	<p>Permitted</p> <p>Delegation of this step must be to the same practitioner as step 3*</p>	<p>Those able to carry out step one, or other suitably trained and competent practitioners.</p> <p>If this step is delegated to another practitioner, this individual still requires supervision by the practitioner completing step 1, even if this practitioner is able to independently work under a PGD.</p>
Step 3	Vaccine administration	<p>Permitted</p> <p>Delegation of this step must be to the same practitioner as step 2*</p>	<p>Those able to carry out step one, or other suitably trained and competent practitioners</p> <p>If this step is delegated to another practitioner, this individual still requires supervision by the practitioner completing step 1, even if this practitioner is able to independently work under a PGD.</p>
Step 4	Record keeping	Permitted	<p>Those able to carry out step one, or other suitably trained and competent practitioners.</p> <p>If this step is delegated to another practitioner, this individual still requires supervision by the practitioner completing step 1, even if this practitioner is able to independently work under a PGD.</p>

*From 1 April 2026, [only the person administering a vaccine may carry out reconstitution or dilution](#). Therefore, vaccine preparation and administration must be completed by the same practitioner, where these steps have been delegated by the practitioner working under step 1.

<p>Qualifications and professional registration</p>	<p>All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below.</p> <p>Practitioners undertaking step 1 of this VGD must also be one of the following registered professionals who can legally supply and administer under a PGD:</p> <ul style="list-style-type: none"> • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the Pharmaceutical Society of Northern Ireland (PSNI) (Note: This VGD is not relevant to privately provided community pharmacy services) • dietitians, occupational therapists, paramedics, physiotherapists, and podiatrists currently registered with the Health and Care Professions Council (HCPC) <p>Please note that operating department practitioners are not permitted to conduct step one of this VGD as they are not included under Part 4 of Schedule 16 .</p>
<p>Additional requirements</p> <p>(continued over page)</p> <p>Additional requirements</p>	<p>All practitioners (irrespective of which steps are being completed)</p> <ul style="list-style-type: none"> • must be authorised by name as an approved practitioner under the current version of this VGD before working to it • should fulfil any additional requirements defined by local policy • should have access to this VGD and any associated online resources • must understand the importance of ensuring vaccine information is recorded into the relevant data system, as outlined in the Records section <p>Clinical assessment, consent and provision of advice (Step 1)</p> <ul style="list-style-type: none"> • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the Green Book), and national recommendations and commissioning arrangements for the immunisation programme • must be competent to assess individuals for suitability of vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent³ • must have undertaken training appropriate to this VGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training. See also COVID-19 vaccination programme: Information for healthcare practitioners. • must be competent to undertake immunisation and to discuss issues related to immunisation • if relevant, must have undertaken training to meet the minimum standards in relation to vaccinating those under 18 years • must be competent in the recognition and management of anaphylaxis, have completed basic life support training and able to respond appropriately to immediate adverse reactions; must be familiar with Resuscitation Council UK (RCUK) Anaphylaxis guidance for vaccination settings

³ For those lacking mental capacity, a decision may be made in the individual's best interests in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual.

<p>(continued)</p>	<ul style="list-style-type: none"> • where any one of Steps 2, 3 or 4 are undertaken by another practitioner, the practitioner carrying out step 1 must be competent and willing to act as a clinical supervisor as outlined in the national minimum standards and core curriculum for vaccination training to support the supervised individual. • all other competencies as listed above and below <p>Vaccine preparation and administration (Steps 2 and 3)</p> <ul style="list-style-type: none"> • must be competent in the appropriate administration method for the vaccine(s) listed in this VGD • if relevant, must have undertaken training to meet the minimum standards in relation to vaccinating those under 18 years of age as required by national or local policy • must be competent in the recognition and management of anaphylaxis; have completed basic life support training and be able to respond appropriately to immediate adverse reactions; must be familiar with Resuscitation Council UK (RCUK) Anaphylaxis guidance for vaccination settings • must be competent in the handling and storage of vaccines, and management of the cold chain • must be familiar with handling the vaccine and in drawing up of the correct dose • must have undertaken training appropriate to this VGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training. • must have completed the national COVID-19 vaccination e-learning programme, including the relevant vaccine specific session and/or locally-provided COVID-19 vaccine training • must either have been signed off as competent, using the COVID-19 vaccinator competency assessment tool if new to or returning to immunisation after a prolonged period (more than 12 months) or have used the tool for self-assessment if an experienced vaccinator (vaccinated within the last 12 months). • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the Green Book), national recommendations and commissioning arrangements for the vaccination programme • all other competencies as outlined above (All practitioners) • should fulfil any additional requirements defined by local policy <p>Record keeping (Step 4)</p> <ul style="list-style-type: none"> • must meet the core knowledge standard 11:documentation, record keeping and reporting (national minimum standards and core curriculum for vaccination training) • all other competencies as outlined above (All practitioners)
<p>Continued training requirements</p>	<p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from PHA/SPPG and/or DoH and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed but a PSD may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this VGD.</p>

4. Clinical condition or situation to which this VGD applies (for practitioners conducting Step 1)

<p>Clinical condition or situation to which this VGD applies (Step 1)</p>	<p>COVID-19 vaccination is indicated for the active immunisation of eligible individuals from the age of 5 years for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. Immunisation is indicated in accordance with the national COVID-19 vaccination programme (see CMO letter), recommendations given in the COVID-19 chapter of the Green Book, JCVI and subsequent correspondence and publications from the SPPG/PHA and DoH.</p>
<p>Criteria for inclusion (Step 1)</p>	<p>Individuals who have not already received a dose during the current seasonal programme who are:</p> <ul style="list-style-type: none"> (i) aged 5 years to 74 years (by 30 June 2026) who are immunosuppressed, as defined in the immunosuppression section of either table 3 or 4 of the COVID-19 chapter of the Green Book (ii) residents in a care home for older adults (iii) aged 75 years and over, including those due to turn 75 years of age on or before 30 June 2026 (iv) people in prisons aged 65 years and over, including those due to turn 65 of years on or before 30 June 2026 (v) included in the recommended cohort(s) for vaccination, if and when JCVI, DoH, PHA or other appropriate authority announce an emergency surge vaccine response is required
<p>Criteria for exclusion⁴ (Step 1)</p>	<p>Individuals for whom valid consent or a ‘best-interests’ decision in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual has not been received (for further information on consent see Reference guide to consent for examination or treatment).</p> <p>A number of PHA resources are available to inform consent (see Written information to be given to individual, parent or carer section).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are aged under 5 years • do not meet any of the criteria for inclusion, irrespective of prior vaccination status or previous vaccine eligibility • have already received a dose of COVID-19 vaccine in the last 3 months • have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of a COVID-19 vaccine or to any component or residue from the manufacturing process⁵ in the COVID-19 vaccines • have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • are suffering from acute severe illness (the presence of a minor infection is not a contraindication for vaccination)

⁴ Exclusion under this VGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

⁵ Comirnaty® and Spikevax® vaccines contain polyethylene glycol (PEG); refer to the respective [SPC](#) for a full list of excipients.

Cautions, including any relevant action to be taken

(Step 1)

(continued over page)

Facilities for management of anaphylaxis should be available at all vaccination premises (see [Chapter 8](#) of the Green Book and advice issued by the [Resuscitation Council UK](#)).

The 15 minute observation period following vaccination with the COVID-19 vaccines has been suspended for individuals who have no history of allergy [CMO letter HSS\(MD\) 21/2022](#) (see [off-label use](#) section below and [the COVID-19 chapter of the Green Book](#)).

Individuals with a personal history of allergy should be managed in line with [the COVID-19 chapter of the Green Book](#), Table 5 (management of patients with a history of allergy).

Special precautions, such as those outlined in [the COVID-19 chapter of the Green Book](#) (flowchart for managing patients who have allergic reactions to a previous dose of COVID-19 vaccine) are advised for individuals with a personal history of allergy including a:

- prior non-anaphylaxis allergic reaction to COVID-19 vaccine
- history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate polyethylene glycol (PEG) allergy)
- history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injections, laxatives)
- history of idiopathic anaphylaxis

Individuals with undiagnosed PEG allergy often have a history of immediate-onset unexplained anaphylaxis or anaphylaxis to multiple classes of drugs. Unless at least one dose of the same vaccine has been previously tolerated, it is advisable to seek advice from an allergy specialist (for further information, see [the COVID-19 chapter of the Green Book](#)).

Rarely, people with PEG allergy may also be allergic to polysorbate 80, which is present in both Nuvaxovid® JN.1 and the adjuvanted flu vaccines. Individuals who have tolerated the adjuvanted flu vaccine are likely to tolerate a non-mRNA vaccine such as Nuvaxovid®. The vaccine should be given in a setting with full resuscitation facilities and the individual should be observed for 30 minutes post administration. Giving Nuvaxovid® in this context is out of scope of this VGD and should be administered under a PSD.

Where individuals experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in [the COVID-19 chapter of the Green Book](#) in relation to the administration of subsequent doses.

Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to a COVID-19 vaccine can receive subsequent doses of vaccine in any vaccination setting. Observation for 15 minutes is recommended for these individuals.

Syncope (fainting) can occur following, or even before any vaccination as a psychogenic response to the needle injection, particularly in adolescents. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Very rare reports have been received of Guillain-Barré Syndrome (GBS) following COVID-19 vaccination (further information is available in [the COVID-19 chapter of the Green Book](#)). Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and

<p>(continued over page)</p> <p>Cautions, including any relevant action to be taken</p> <p>(Step 1)</p> <p>(continued)</p>	<p>treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk-benefit is in favour of vaccination.</p> <p>For individuals with a history of idiopathic thrombocytopaenic purpura (ITP) receiving any COVID-19 vaccine, checking their platelet count should be considered 2 to 5 days post vaccination. Individuals who previously experienced ITP after the first dose of AstraZeneca® vaccine should be assessed by a haematologist and the risk benefit of further vaccination and with which COVID-19 vaccine should be considered on an individual basis.</p> <p>Past history of COVID-19 infection</p> <p>There are no safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected, asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, though those with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others. There is no need to defer immunisation in individuals after recovery from a recent episode of compatible symptoms, whether or not they are tested for COVID-19.</p> <p>PHA have issued Guidance for vaccination in care homes during COVID / Flu like illness outbreaks.</p> <p>Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.</p>
<p>Action to be taken if the individual is excluded</p> <p>(Step 1)</p>	<p>The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may be provided by an appropriate prescriber or on a patient-specific basis, under a PSD.</p> <p>Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If an individual is acutely unwell, vaccination should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged.</p> <p>For individuals who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of COVID-19 vaccine, or any component of the vaccine, advice should be sought from an allergy specialist. Any subsequent dose should be provided by an appropriate prescriber, under a PSD.</p> <p>Individuals who have experienced myocarditis or pericarditis following COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine-related. As the mechanism of action and risk of recurrence of myocarditis and pericarditis are being investigated, the current advice is that an individual's subsequent doses should be deferred pending further investigation. Following investigation, any subsequent dose should be provided by an appropriate prescriber or on</p>

<p>(continued over page) Action to be taken if the individual is excluded (Step 1) (continued)</p>	<p>a patient-specific basis, under a PSD (see the COVID-19 chapter of the Green Book for further details).</p> <p>Individuals who have never received a dose of COVID-19 vaccine and do not meet criteria for inclusion, or who were previously eligible for a dose during previous COVID-19 programmes, but not the present one, should be reassured (or their parent or carer) that the evidence does not currently support a need to vaccinate them. If new evidence means that they are considered to be at high risk of COVID-19 during a future vaccination programme, they will then be invited for vaccination.</p> <p>When the seasonal vaccination programme has ended, individuals with severe immunosuppression (as defined in Boxes 1 and 2 of the COVID-19 chapter of the Green Book) can be considered for vaccination outside of seasonal programme periods, in accordance with the Green Book. A decision to proceed would be subject to individual clinical decision and therefore a PSD should be used to administer the vaccine.</p> <p>If COVID-19 vaccine has been given in the preceding 3 months, advise the individual to return when they are next invited forward for vaccination, which may coincide with the next seasonal COVID-19 programme.</p> <p>Document the reason for exclusion and any action taken.</p>
<p>Action to be taken if the individual or carer declines treatment (Step 1)</p>	<p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Reference guide to consent for examination or treatment.</p> <p>Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p>
<p>Arrangements for referral for medical advice (Step 1)</p>	<p>As per local policy.</p>

5. Description of treatment

Name, strength and formulation of drug (Step 1)	Comirnaty® LP.8.1 (10 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified). Each vial contains a single dose of 0.3ml. One dose (0.3ml) contains 10 micrograms of mRNA encoding LP.8.1.
	Comirnaty® LP.8.1 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified). Each pre-filled syringe contains a single dose of 0.3ml. One dose (0.3ml) contains 30 micrograms of mRNA encoding LP.8.1.
	Nuvaxovid® JN.1 dispersion for injection Each pre-filled syringe contains a single dose of 0.5ml. One dose (0.5ml) contains 5 micrograms of Omicron JN.1.
	Spikevax® LP.8.1 (0.1mg/ml) dispersion for injection Each multidose vial contains 5 doses of 0.5ml. One dose (0.5ml) contains 50 micrograms of mRNA-1273.251 encoding the viral spike protein of SARS-CoV2 (LP.8.1).
Legal category (Step 1)	Prescription only medicine (POM)
Black triangle▼ (Step 1)	Yes –all of the above COVID-19 vaccines in use for Spring 2026 are black triangle products. As new vaccine products, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for these products.

<p>Off-label use (Step 1)</p>	<p>Allergy</p> <p>The SPCs for all strengths of Comirnaty® COVID-19 mRNA vaccines and Nuvaxovid® recommend close observation for at least 15 minutes following vaccination. Following careful review of the safety data by the MHRA and advice from the Commission on Human Medicines, the 15-minute observation requirement has since been suspended for individuals who have no history of allergy, following vaccination with all COVID-19 vaccines. Refer to CMO letter HSS(MD) 21/2022 for full information. Individuals (or their parent or carer) should be counselled in line with the relevant points from the advice and follow-up treatment section.</p> <p>The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the Yellow Card reporting scheme is strongly encouraged.</p> <p>Storage</p> <p>Vaccines should be stored according to the conditions detailed in the storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to Guidance on vaccine handling & storage in GP practices for advice. Where vaccine is assessed following advice by the Medicine Information Service as appropriate for continued use, this would constitute off-label administration under this VGD.</p> <p>Where a vaccine is recommended off-label, as part of the consent process consider informing the individual, parent or carer the vaccine is being offered in accordance with national guidance but outside of product licence.</p>
<p>Drug interactions (Step 1)</p>	<p>The immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Vaccination is recommended even if the antibody response may be limited.</p> <p>Although no data for co-administration of COVID-19 vaccine with other vaccines exist, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult.</p> <p>Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination.</p> <p>For further information about co-administration with other vaccines, see additional information section.</p> <p>A detailed list of drug interactions associated with each vaccine is available from the product's SPC.</p>
<p>Identification and management of adverse reactions (Step 1)</p> <p>(continued over page)</p>	<p>The most frequent adverse reactions are injection-site pain, fatigue, headache, injection-site redness and swelling, fever, myalgia and chills.</p> <p>Diarrhoea is commonly reported with Spikevax® LP.8.1 and very commonly reported with Comirnaty® LP.8.1.</p> <p>Nausea and vomiting are very commonly reported after Nuvaxovid®, particularly after second doses.</p> <p>Lymphadenopathy is very commonly reported with Spikevax® LP.8.1 and commonly reported after Comirnaty® LP.8.1 (both strengths).</p> <p>Very rare cases of myocarditis and pericarditis have been observed following COVID-19 vaccination (including with Nuvaxovid®). The reported rate is highest in</p>

<p>Identification and management of adverse reactions</p> <p>(Step 1)</p> <p>(continued)</p>	<p>individuals under 25 years and in males, usually within a few days following vaccination, after a second dose. Most cases are mild and self-limiting. The MHRA has advised the benefits from vaccination outweigh any risk in most individuals.</p> <p>Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Individuals, parents and carers should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as acute and persisting chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.</p> <p>Heavy menstrual bleeding has been reported after vaccination with mRNA vaccines. In most cases, this is self-limiting.</p> <p>Individuals, parents and carers should be provided with the advice within the leaflet 'What to expect after your child's COVID-19 vaccination (5-11s)' or 'vaccination' as applicable, which covers the reporting of adverse reactions and their management, such as with analgesics.</p> <p>A detailed list of adverse reactions across all age groups is available in the product's SPC.</p>
<p>Reporting procedure of adverse reactions</p> <p>(Step 1)</p>	<p>The MHRA has a specific interest in the reporting of all adverse drug reactions for new COVID-19 vaccines. Healthcare professionals and individuals, parents and carers should report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed.</p> <p>Chapter 8 and the COVID-19 chapter of the Green Book provide further details regarding the clinical features of reactions to be reported as anaphylaxis. Allergic reactions that do not include the clinical features of anaphylaxis should be reported as an allergic reaction.</p>
<p>Advice and follow up treatment</p> <p>(Step 1)</p> <p>(continued over page)</p>	<p>Inform the individual, parent or carer of possible side effects and their management.</p> <p>The 15-minute observation following vaccination with COVID-19 vaccines has been suspended for individuals without a history of allergy (see off-label use section).</p> <p>Following COVID-19 vaccine administration, individuals without a history of allergy should be:</p> <ul style="list-style-type: none"> • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the premises • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms • Offered leaflets see What to expect after your child's COVID-19 vaccination (5-11s) and What to expect after your COVID-19 vaccination. Most PHA patient information leaflets are available in multiple languages. • Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic medicines compendium. • Where applicable, advised not to drive for 15 minutes after vaccination, as fainting can occur following vaccination <p>In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination.</p> <p>Individuals with a personal history of allergy should be managed in line with the</p>

<p>Advice and follow up treatment</p> <p>(Step 1) (continued)</p>	<p>COVID-19 chapter of the Green Book, Table 5. No specific management is required for individuals with a family history of allergies.</p> <p>The individual, parent or carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. Seek immediate medical attention, should the vaccinated individual experience new onset of chest pain, shortness of breath, palpitations or arrhythmias.</p> <p>Advise the individual, parent or carer they can report side effects directly via the national reporting system run by the MHRA known as the Yellow Card reporting scheme, or by searching for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, they can help provide more information on the safety of medicines.</p> <p>As with all vaccines, immunisation may not result in protection in all individuals. The individual, parent or carer should be advised that immunosuppressed individuals may not make a full immune response to the vaccine.</p> <p>When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent dose is due.</p>
<p>Special considerations and additional information</p> <p>(Step 1)</p>	<p>Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination.</p> <p>Nuvaxovid® JN.1 is suitable for use in eligible individuals from 12 years of age, in accordance with the product SPC and the COVID-19 chapter of the Green Book. It is recommended for use in this VGD for eligible individuals from 18 years of age, in line with the JCVI advice to only offer Comirnaty® vaccines to children (unless deemed clinically inappropriate following specialist review, see cautions).</p> <p>Co-administration with other vaccines</p> <p>Studies have shown that RSV and COVID-19 vaccines may be co-administered safely, with non-inferior immunogenicity and acceptable reactogenicity in both vaccines. Co-administration of inactivated shingles with COVID-19 showed an acceptable safety profile and a similar immunological response with no difference in severity, frequency of duration of adverse events when compared to sequential administration. Studies of co-administration of COVID-19 vaccines with inactivated influenza vaccines show acceptable immunogenicity and reactogenicity.</p> <p>Where individuals in an eligible cohort present having recently received one or more inactivated or live vaccines, COVID-19 vaccination should still be given. The same applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual presents requiring 2 or more vaccines. It is generally better for vaccination to proceed to prevent any further delay in protection and avoid the risk of the individual not returning for a later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings. Examples include LAIV, HPV, influenza, MenACWY and Td-IPV vaccines in the school age programmes, influenza, RSV and pertussis vaccines in pregnancy and pneumococcal, shingles and RSV vaccines in those aged over 65 years.</p> <p>When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably into different limbs. If given into the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.</p> <p>Where co-administration does occur, the individual, parent or carer should be informed about the likely timing of potential adverse events relating to each vaccine.</p>

<p>(continued over page)</p> <p>Special considerations and additional information</p> <p>(Step 1)</p> <p>(continued)</p>	<p>Immunosuppressed</p> <p>The immunological response may be lower in immunocompromised individuals, but they should still be vaccinated.</p> <p>Individuals who had received brief immunosuppression ($\geq 40\text{mg}$ prednisolone per day or equivalent for children) for an acute episode of asthma and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination.</p> <p>Individuals with severe immunosuppression</p> <p>Regardless of the time of year or previous vaccination history, additional doses of COVID-19 vaccine may be considered for individuals with severe immunosuppression (as defined by either Box 1 or Box 2: Criteria for additional doses of COVID-19 vaccine, the COVID-19 chapter of the Green Book, as applicable to the individual's age).</p> <p>The need for additional doses and the optimal dose intervals should be at the discretion of the individual's specialist. In such circumstances, the dose should be given under a PSD.</p> <p>More information on timing of additional doses may be found in the COVID-19 chapter of the Green Book.</p> <p>Due consideration must be given to the risk of delaying COVID-19 vaccination against that of delaying treatment.</p> <p>Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see Chapter 7 of the Green Book). Revaccination with COVID-19 vaccine is not covered by this VGD and should be provided on a patient-specific basis, such as via a PSD.</p> <p>Whilst JCVI do not express a preference for a specific COVID-19 vaccine in the adult population, Comirnaty[®] vaccines are advised for children and young people with severe immunosuppression.</p> <p>Pregnancy</p> <p>There is no known risk associated with being given a non-live vaccine during pregnancy when indicated (see criteria for inclusion and the COVID-19 chapter of the Green Book).</p> <p>Breastfeeding</p> <p>There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that eligible breastfeeding women may be offered any suitable COVID-19 vaccine. Emerging safety data is reassuring; mRNA was not detected in the breast milk of recently vaccinated women and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding are clear and should be discussed with the woman, along with her clinical need for immunisation against COVID-19.</p>
<p>Route and method of administration</p> <p>(Step 2, Step 3)</p>	<p>General principles</p> <p>Vaccines should be prepared in accordance with the manufacturer's recommendations (see the product's SPC) and standard operating procedures for the service.</p> <p>Vaccines should be inspected for foreign particulate matter and other variation of expected appearance not in line with the product SPC before preparation and administration. Should either occur, discard the vaccine in accordance with local procedures.</p>

(continued over page)
Route and method of administration
(Step 2, Step 3)
 (continued)

Vaccines should not be mixed in the same syringe with any other vaccines or medicinal products

Ensure vials (where applicable) are completely thawed prior to use.

Unopened vials should be used or discarded by the post-thaw expiry date indicated on the outer packaging.

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. A fine needle (23 gauge or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection.

Handling of vials

Comirnaty® LP.8.1 (10 micrograms/ dose) and Spikevax® LP.8.1 (50 micrograms/ dose) vials

Verify that the vial has the correct coloured plastic cap and the label matches the intended vaccine to be administered.

Table 1: Summary of vaccine appearance and preparation for Comirnaty® LP.8.1 and Spikevax® LP.8.1 (50 micrograms/dose) vials

Vaccine	Vial cap colour	Vaccine appearance	Vial preparation
Comirnaty® LP.8.1 (10 micrograms/dose)	Blue	White to off-white opaque amorphous particles, changing to a clear to opalescent, particle-free dispersion after mixing	Gently invert the vial 10 times prior to administration
Spikevax® LP.8.1 (50 micrograms/dose)	Blue	White to off-white dispersion which may contain white or translucent product-related particulates	Gently swirl the vial after thawing and before withdrawing each dose

Do not shake or dilute the vial contents. Thawed vials may be handled in room light conditions.

The vial should be marked with the appropriate expiry date and time, once punctured. From a microbiological point of view, the product should be used as soon as practicably possible once opened.

Immediately prior to administration, recheck the product name, batch number, dose volume and post-thaw expiry date, including the expiry date and time of the thawed, punctured vial.

Administer 0.3ml or 0.5ml of COVID-19 vaccine (as outlined in [Table 2](#)) by intramuscular injection only, preferably into the deltoid muscle of the upper arm.

<p>(continued over page) Route and method of administration (Step 2, Step 3) (continued)</p>	<p>To extract the anticipated number of doses from a multidose vial, low dead-volume syringes and/or needles should be used, with a combined dead volume of no more than 35 microlitres.</p> <p>An additional overfill is included in each Spikevax[®] vial to ensure that 5 doses of 0.5ml can be given. It is advised that the stopper of the Spikevax[®] vial is pierced at a different site each time a dose is withdrawn.</p> <p>Care should be taken to ensure a full 0.3ml or 0.5ml dose is given. Each dose must contain the correct volume of vaccine. If a full dose cannot be extracted from the remaining amount in the vial, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.</p> <p>Handling pre-filled syringes</p> <p>Comirnaty[®] LP.8.1 30 micrograms/ dose dispersion for injection in a pre-filled syringe</p> <p>The dispersion is white to off-white in appearance.</p> <p>Do not dilute prior to use. Do not mix the vaccine in the same syringe with any other vaccines or other medicinal products.</p> <p>Do not shake the prefilled syringe.</p> <p>Nuvaxovid[®] JN.1 dispersion for injection in a pre-filled syringe</p> <p>The vaccine comes ready to use and is for single use only.</p> <p>The dispersion is colourless to slightly yellow and clear to mildly opalescent in appearance, free from visible particles. Do not shake the prefilled syringe.</p>														
<p>Dose and frequency of administration (Step 3)</p>	<p>Vaccination should be offered to individuals eligible for the current programme, in accordance with the recommendations from the JCVI and in the COVID-19 chapter of the Green Book, at a minimum interval of 3 months from the previous dose of COVID-19 vaccine.</p> <p>In line with the COVID-19 chapter of the Green Book, there is no requirement to administer the same vaccine brand as previously administered.</p> <p>JCVI do not have a preference for a specific COVID-19 vaccine in the adult programme. Children and young people with severe immunosuppression should be offered a Comirnaty[®] vaccine at a dose appropriate to their age.</p> <p>Table 2: Age-specific recommendations on vaccine type and dose regimes</p> <table border="1" data-bbox="357 1469 1469 1861"> <thead> <tr> <th>Age</th> <th>Recommended COVID-19 vaccine(s)⁶</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>5 to 11 years old</td> <td>Comirnaty[®] LP.8.1 (10 micrograms/dose)</td> <td>0.3ml</td> </tr> <tr> <td>12 to 17 years old</td> <td>Comirnaty[®] LP.8.1 (30 micrograms/dose)</td> <td>0.3ml</td> </tr> <tr> <td rowspan="2">18 years and over</td> <td>Spikevax[®] LP.8.1 (50 micrograms/dose)</td> <td>0.5ml</td> </tr> <tr> <td>Nuvaxovid[®] JN.1 (5 micrograms/dose)</td> <td>0.5ml</td> </tr> </tbody> </table> <p>Note: use of alternative variant vaccines such as KP.2 are not covered by this VGD.</p>	Age	Recommended COVID-19 vaccine(s) ⁶	Dose	5 to 11 years old	Comirnaty [®] LP.8.1 (10 micrograms/dose)	0.3ml	12 to 17 years old	Comirnaty [®] LP.8.1 (30 micrograms/dose)	0.3ml	18 years and over	Spikevax [®] LP.8.1 (50 micrograms/dose)	0.5ml	Nuvaxovid [®] JN.1 (5 micrograms/dose)	0.5ml
Age	Recommended COVID-19 vaccine(s) ⁶	Dose													
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	Nuvaxovid [®] JN.1 (5 micrograms/dose)	0.5ml													

⁶ As outlined in the Green Book, vaccines that target the latest variant are preferable. However, an available, authorised and age-appropriate vaccine should be offered without delay, in preference to a substantial delay to vaccination with a slightly better matched vaccine.

	Nuvaxovid® JN.1 may be offered to any eligible individual over the age of 18 years. If being offered to an individual who is allergic to mRNA vaccines, this should be done under specialist supervision, as advised in the cautions section. This VGD cannot be used for this purpose.				
Duration of treatment (Step 3)	See dose and frequency of administration above.				
Quantity to be supplied and administered (Step 3)	A single dose, as outlined for the individual's age in Table 2 .				
Supplies (Step 2, Step 3)	A central supply of COVID-19 vaccines has been procured. Standard operating procedures should be followed for appropriate supply, storage, handling, preparation, administration and waste minimisation of COVID-19 vaccines, which ensure use is in accordance with the product's SPC and official national recommendations. Further information is also available in the Green Book Chapter 3 .				
Storage (Step 2, Step 3)	Table 3: Summary of vaccine handling and storage (thawed vial product)				
	Vaccine product	Transportation time	Product shelf life		
			Thawed vial (unopened)	Punctured vial	Temperature deviations
	Comirnaty® LP.8.1 (10 micrograms/dose)	Up to 10 weeks at 2°C to 8°C (within the 18-month shelf life) Punctured vial: up to 6 hours at 2°C to 30°C	10 weeks at 2°C to 8°C and 12 hours at 8°C to 30°C	Up to 12 hours at 2°C to 30°C	Up to 24 hours at 8°C to 30°C (includes up to 12 hours following first puncture)
Spikevax LP.8.1 (50 micrograms/dose)	Up to 36 hours at 2°C to 8°C (up to 30 hours by road and up to 6 hours by air) within the 14 or 30 day thawed shelf life	14 days or 30 days* at 2°C to 8°C as indicated on outer packaging	Up to 6 hours at 2°C to 25°C	Up to 24 hours at 8°C to 25°C	
*Unopened Spikevax® vials stored for 12 months at -50°C to -15°C must be used within a maximum of 14 days. When stored for 9 months at the same temperature, the thawed vial may be stored refrigerated at 2°C to 8°C for a maximum of 30 days. The total storage time will not exceed 12 months.					
Comirnaty® LP.8.1 (10 micrograms/dose) COVID-19 mRNA vial					
Thawed vial					
Up to 10 weeks storage and transportation at 2°C to 8°C within the overall product shelf life. Thawed vaccines must not be re-frozen. Store in original packaging to					

<p>(continued over page)</p> <p>Storage</p> <p>(Step 2, Step 3) (continued)</p>	<p>protect from light if not in use. During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.</p> <p>Except where a shelf-life extension applies, the 10-week post thaw shelf life should not exceed the printed manufacturer's expiry date (EXP) on the outer carton.</p> <p>Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8°C and 30°C.</p> <p>Thawed vials can be handled in room light conditions.</p> <p>Punctured vial</p> <p>Chemical and physical in-use stability has been demonstrated for 12 hours at 2°C to 30°C, which includes up to 6 hours transportation time. From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used as soon as practicably possible. Otherwise, in-use storage times and conditions are the responsibility of the user.</p> <hr/> <p>Spikevax® LP.8.1 (50 micrograms/ dose) COVID-19 mRNA vial</p> <p>Thawed vial</p> <p>When stored for 12 months at -50°C to -15°C, once thawed and stored at 2°C to 8°C and protected from light, the unopened vial has a maximum of 14 days shelf life. This increases to a maximum of 30 days when the vials are removed from the freezer within 9 months. The expiry date on the outer carton should be updated by Movianto to reflect the refrigerated expiry. Thawed vials should not be refrozen. The unopened vaccine may be stored at 8°C to 25°C up to 24 hours after removal from refrigerated conditions.</p> <p>Available data support transportation of one or more thawed vials in liquid state for up to 36 hours (maximum of 30 hours by road and up to 6 hours by air) at 2°C to 8°C (within the 30 days or 14 days shelf life, respectively, at 2°C to 8°C). Once thawed and transported in liquid state at 2°C to 8°C, vials should not be refrozen and should be stored at 2°C to 8°C until use.</p> <p>Punctured vial</p> <p>Chemical and physical in-use stability has been demonstrated for 6 hours at 2°C to 25°C after initial puncture (within the allowed use period of 30 days at 2°C to 8°C and 24 hours at 8°C to 25°C).</p> <p>From a microbiological point of view, the product should be used immediately. If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user.</p> <hr/> <p>General advice (including Comirnaty® LP.8.1 (30 micrograms/ dose) and Nuvaxovid® JN.1 prefilled syringes)</p> <p>Store between +2°C to +8°C. Store in original packaging to protect from light. Do not freeze. Comirnaty® LP.8.1 prefilled syringes may be stored for up to 12 hours at temperatures between 8°C and 30°C. Immediately prior to use, remove Nuvaxovid® prefilled syringes from the carton in the refrigerator.</p> <p>Manufacturer storage details relate to storage requirements and available stability data at the time of product authorisation. Refer to standard operating procedures for the service and the most up to date manufacturer's recommendations in the product's SPC. The product's SPC also contains further information on stability to guide healthcare professionals only in case of temporary temperature excursion.</p> <p>However, in the event of an inadvertent or unavoidable deviation of these conditions vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued</p>
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	<p>off-label use or appropriate disposal. Further advice re use should be sought from the NI Medicines Information Service, see Guidance on vaccine handling and storage in GP practices for contact details.</p> <p>Vaccine losses outside of secondary care should be reported to the PHA Duty Room (telephone 0300 555 0119) for further risk assessment, including whether individuals need revaccination following a cold chain breach. Refer to Guidance on vaccine handling & storage in GP practices for advice. Where vaccine is assessed following advice by Duty Room as appropriate for continued use, this would constitute off-label administration under this VGD.</p>
<p>Disposal (Step 2, Step 3)</p>	<p>Follow local clinical waste policy and standard operating procedures to ensure safe and secure waste disposal.</p> <p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local waste disposal and securely according to local authority arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste.</p>
<p>Written information to be given to individual (parent) or carer (Step 3)</p>	<p>Ensure the individual, parent or carer has been provided with appropriate written information such as the:</p> <ul style="list-style-type: none"> • patient information leaflet (PIL) for the administered COVID-19 vaccine as appropriate: Comirnaty® LP.8.1 (10 micrograms/dose) Comirnaty® LP.8.1 (30 micrograms/dose) Spikevax® LP.8.1 (50 micrograms/dose) Nuvaxovid® JN.1 (5 micrograms/dose) • a guide for parents of children 6 months to 11 years of age at high risk • COVID-19 vaccination - easy read guide • COVID-19 vaccination – guide for people with a weakened immune system • What to expect after your child's COVID-19 vaccination (5-11s) • What to expect after your COVID-19 vaccination <p>Most PHA patient information leaflets are available in multiple languages.</p> <p>Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility by providing the medicine name and product code number, as listed on the eMC.</p>
<p>Records (Step 4)</p>	<p>The practitioner must ensure the following is recorded:</p> <ul style="list-style-type: none"> • where different practitioners carried out steps 1, 2, 3 and/or 4, their names and the step(s) of the vaccination process they carried out. These practitioners must be named in section 7 of this VGD. • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date

<p>(continued over page)</p> <p>Records</p> <p>(Step 4)</p> <p>(continued)</p>	<ul style="list-style-type: none"> • anatomical site of vaccination • advice given, including advice given if the individual is excluded or the individual, (or parent or carer) declines immunisation • details of any adverse drug reactions and actions taken • administered via VGD <p>Records should be signed and dated (or password-controlled on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination.</p> <p>For pregnant women, also record immunisation in the hand-held and electronic maternity record if available.</p> <p>The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway when vaccine is administered to individuals under 19 years of age.</p> <p>A record of all individuals receiving treatment under this VGD should also be kept for audit purposes.</p>
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6. Key references

<p>Key references</p>	<p>COVID-19 vaccines</p> <ul style="list-style-type: none"> • UKHSA COVID-19 vaccine VGD (5 years and over) v1.0 (with thanks) • Department of Health Letter re end of Covid-19 2025/2026 Campaign and details of spring 2026 vaccination campaign <p>HSS MD 07 2026 - END OF COVID-19 2025 26 CAMPAIGN AND DETAILS OF SPRING 2026 VACCINATION CAMPAIGN.pdf</p> <ul style="list-style-type: none"> • Immunisation Against Infectious Disease: The Green Book, COVID-19 chapter • Summary of Product Characteristics for Comirnaty® LP.8.1 (10 micrograms/dose) COVID-19 mRNA vaccine, updated 18 August 2025 https://www.medicines.org.uk/emc/product/101151/smhc • Summary of Product Characteristics for Comirnaty® LP.8.1 (30 micrograms/dose) COVID-19 mRNA vaccine, updated 30 September 2025 https://www.medicines.org.uk/emc/product/101150/smhc • Summary of Product Characteristics for Nuvaxovid®JN.1 (5 micrograms/dose) COVID-19 vaccine, updated 14 April https://www.medicines.org.uk/emc/product/101554/smhc • Summary of Product Characteristics for Spikevax® LP.8.1 (0.1mg/ml) dispersion for injection, updated 18 February 2026 https://www.medicines.org.uk/emc/product/101925/smhc • JCVI statement on COVID-19 vaccination in 2025 and spring 2026, updated 14 November 2024 • National minimum standards and core curriculum for vaccination training https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • National COVID-19 vaccination e-learning programme https://www.e-lfh.org.uk/programmes/covid-19-vaccination/ • Vaccinator competency assessment tool https://assets.publishing.service.gov.uk/media/688a481f1affbf4bedb7b0f1/UKHSA_Appendix A Vaccinator competency assessment tool workbook.pdf • COVID-19 vaccination programme: information for healthcare practitioners https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners <p>General</p> <ul style="list-style-type: none"> • Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste. NHS England, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration, updated 7 July 2022 https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • Guidance on vaccine handling & storage in GP practices. PHA, HSC, DH(NI). Updated August • Reference guide to consent for examination or treatment, Department of Health. Published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition
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7. Practitioner authorisation sheet

COVID-19 vaccine VGD (5 years and over) v1.0

Valid from: 24 April 2026

Expiry: 30 June 2026

Before signing this VGD, check that the document has had the necessary authorisation in [section 2](#). Without this, this VGD is not lawfully valid.

Practitioner undertaking step 1 (and steps 2, 3 and 4 if not delegating these tasks)

By signing this VGD you are indicating that you agree to its contents and that you will work within it. Where you delegate administration or record keeping tasks, you are professionally accountable for ensuring the individual performing that task is competent to do so, **including supervising administration of the vaccine, at the time and location that vaccination is being undertaken.**

VGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this VGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Practitioners undertaking steps 2, 3 and/or 4 only: vaccine preparation, administration and/or record keeping duties

Practitioners assisting with the vaccination process are reminded that they remain individually and professionally accountable for the tasks they undertake.

I confirm that I have read and understood the content of this VGD, I have received training appropriate to the step(s) I am conducting, I require supervision when conducting these duties and that I am willing and competent to work to it within my professional code of conduct where applicable.				
Name	Designation	Signature	Step(s) of the VGD covered (write as step 2,3,4 as applicable)	Date

Clinical supervisor declaration (where applicable)

I confirm that the above-named **practitioners undertaking steps 2, 3 and/or 4** have been assessed as competent to undertake the step(s) of vaccine administration for which they have declared their competency and have received appropriate supervision and training to undertake the step(s) of the VGD process as declared above.

Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this VGD. I give authorisation on behalf of **insert name of organisation** for the above-named healthcare professionals who have signed this VGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this VGD.