Gibraltar Health Authority

PATIENT GROUP DIRECTION

Issued Under Part 2 of the Medicines (Prescriptions Only) Regulations, 1987 by the Director of Public Health with the consent of the Minister

for

Comirnaty®
30 micrograms/dose dispersion for injection
COVID-19 mRNA Vaccine

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	06/07/2026		
Date of expiry	06/07/2028		
Staff characteristics	See below (section 1)		
Professional Authorisation		SIGNATURE	DATE
Lead Doctor	Dr Helen Carter Director of Public Health[1]		
In Consultation with		SIGNATURE	DATE
Lead Pharmacist	Ms Melanie Gordon Chief Pharmacist		
Lead Nurse	Ms Sandra Gracia Director of Nursing		
Legal Authorisation		SIGNATURE	DATE

With the consent of Minister	The Honourable Minister for Health[2] Arias-Vasquez MP		
This PGD has been taken for peer review at the Gibraltar Health Authority Immunisation Committee. It has been ratified by the GHA Executive Team.			

[1] A Patient Group Direction issued shall only have effect if it is signed by the Director of Public Health with the consent of the Minister.
[2] See footnote 1.

1. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses or midwives currently registered with the Gibraltar Nursing Registration Board (NRB) • practitioners currently registered with the Gibraltar Medical Registration Board (MRB) Anyone deemed by the Director of Public Health to be competent who meets the additional requirements below.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC) • must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book • must be familiar with, and alert to changes in the relevant GHA standard operating procedures (SoPs) • must have undertaken training appropriate to this PGD as required by local policy and national GHA standard operating procedures • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016) and to discuss issues related to vaccination • must be competent in the correct handling and storage of vaccines, and management of the cold chain • must be competent in the handling of the vaccine product, procedure for dilution of the vaccine and use of the correct technique for drawing up the correct dose • must be competent in the injection technique

	• 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 have access to the PGD • should fulfil any other additional requirements defined by local policy **THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT**
Continued training requirements	• 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). • Practitioners should be constantly alert to any subsequent recommendations from Public Health Gibraltar and/or the GHA and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus, in accordance with the national COVID-19 vaccination programme under direction of the Director of Public Health.

Criteria for inclusion	Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine should be offered to individuals aged 12 years and over in accordance with the directions from the Director of Public Health. The Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine is indicated for the active immunisation of individuals for the prevention of coronavirus infection in people: • Over 50 years old • Having a long term health condition • Living with someone who is immunocompromised: an indication of this is someone who received a letter from the GHA advising them that they are at more risk of the complications of COVID-19 and if they develop symptoms should call 111 to be assessed for eligibility

	for receiving antiviral medication • Pregnant • Living in a closed residential setting such as ERS or the prison • Working in a Health and social care environment The vaccine will be offered as part of the annual seasonal booster program that is held between 1st September until 31st March. Gibraltar no longer offers a primary course of covid containing vaccines and only offers a single dose booster. This is because antibody studies in the UK demonstrated that most older children and adults in the UK had antibodies, Chapter 14a. In an outbreak situation, under written instruction from the Director of Public Health, specific additional groups of the population may be offered an additional Comirnaty® 30 mcg/dose dispersal for injection or outside of this typical seasonal program, as specified in the written instruction.

Criteria for exclusion[3]	Individuals for whom valid consent, or 'best-interests' decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016, has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). The Patient Information Leaflet (PIL) for Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine should be available to inform consent. Individuals who: • are less than 12 years of age • have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of a COVID-19 mRNA vaccine or to any component or residue from the manufacturing process in the Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine • have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination) • have received a full dose of COVID-19 vaccine in the preceding 21 days

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

Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council. **Allergy** Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms. • In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. Individuals with a personal history of allergy should be managed in line with Chapter 6. Special precautions 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 injection, laxative) • history of idiopathic anaphylaxis Individuals with undiagnosed polyethylene glycol (PEG) allergy often have a history of immediate onset-unexplained anaphylaxis or anaphylaxis to multiple classes of drugs. Such individuals should not be vaccinated with the Comirnaty® 30 micrograms/dose COVID-19 mRNA vaccine, except on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously. • Where individuals experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in Chapter 6 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. • No specific management is required for individuals with a family history of allergies. • Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. 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.

- As fainting can occur following any vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination.

Myocarditis and pericarditis

- There is an increased risk of myocarditis and pericarditis following vaccination with Comirnaty® 30 mcg/dose. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. Available data indicate that most cases recover. Some cases required intensive care support and fatal cases have been observed.
- Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis.
- Vaccinees (including parents or caregivers) 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.

Bleeding disorders

- Individuals with a bleeding disorder may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor 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/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/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 receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. The individual/parent/carer should be informed about the risk of haematoma from the injection.
- Very rare reports have been received of Guillain-Barre Syndrome (GBS) following COVID-19 vaccination (further information is available in Chapter 14a). 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 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 completing a full COVID-19 vaccination schedule. On a precautionary basis, however, where GBS occurs within six weeks of an Astra Zeneca vaccine, for any future doses Pfizer or Moderna COVID-19 vaccines are preferred. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered. • Guidance produced by the UK Immune Thrombocytopenia (ITP) Forum Working Party advises discussing the potential for a fall in platelet count in patients with a history of ITP receiving any COVID-19 vaccine and recommends a platelet count check 2-5 days after the vaccine (British Society for Haematology-COVID-19). **Past history of COVID-19 infection** There is no convincing evidence of any 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 or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. For children in a risk group and adults, vaccination after COVID-19 infection should ideally be deferred until clinical recovery to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive specimen. This is to avoid confusing the differential diagnosis as clinical deterioration can occur up to 2 weeks after infection. For children and young people under 18 years who are not in a risk group, vaccination after COVID-19 infection should ideally be deferred until 12 weeks from onset (or sample date). These recommended intervals after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required, for example in periods of high incidence or circulation of a new variant in a vulnerable population. When rapid protection is required, any reduction in the recommended interval after COVID-19 infection will be advised by the Director of Public Health. Current advice in Paediatric multisystem inflammatory syndrome temporally associated with SARS-CoV-2 infection (PIMS-TS) cases suggests that an interval of 12 weeks should be observed, although earlier administration can be considered in those at high risk of infection and/or who are fully recovered. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection. 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.

	Pregnancy No data are available yet regarding the use of Comirnaty® during pregnancy. However, a large amount of observational data from pregnant women vaccinated with the initially approved Comirnaty® vaccine during the second and third trimester have not shown an increase in adverse pregnancy outcomes. While data on pregnancy outcomes following vaccination during the first trimester are presently limited, no increased risk for miscarriage has been seen. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3). Based on data available with other vaccine variants, Comirnaty® can be used during pregnancy. **Breast-feeding** No data are available yet regarding the use of Comirnaty® during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated since the systemic exposure of breast-feeding woman to the vaccine is negligible. Observational data from women who were breast-feeding after vaccination with the initially approved Comirnaty® vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty® can be used during breast-feeding. **Fertility** Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity Further information is contained on the emc Health Professionals (SmPC) website

Action to be taken if the patient is excluded	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 that 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. For individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of COVID-19 mRNA vaccine, or any component of the vaccine, advice should be sought from an allergy specialist.

Action to be taken if the patient is excluded (continued)	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 second or subsequent doses should be deferred pending further investigation. Following investigation any subsequent dose should be provided by an appropriate prescriber or on a patient specific basis, under a PSD. In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged. Document the reason for exclusion and any action taken
Action to be taken if the patient or carer declines treatment	In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the Director of Public Health or the individual's clinician where appropriate. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform, or refer to, the GP or a prescriber as appropriate. Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2018, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of 'The Green Book'. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given, and the decision reached. Inform, or refer to the GP or a practitioner as appropriate.
Arrangements for referral for medical advice	As per GHA policy

3. Description of treatment

Name, strength & formulation of drug	Comirnaty LP .8.1 30 micrograms/dose dispersion for injection in pre-filled syringe. Supplied in a single dose pre-filled syringe with plunger stopper (*synthetic* bromobutyl rubber) and a tip cap (synthetic bromobutyl rubber) without needle. One dose (0.3 mL) contains 30 micrograms of mRNA encoding LP.8.1, a COVID−19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles). Note: Where appropriate to the delivery model, this PGD may also be used for the administration of vaccine that has been prepared (diluted) by another person in accordance with the manufacturer's instructions and Human Medicines Regulation 3A (inserted by UK Statutory Instrument 2020 No. 1594), that is prepared by or under the supervision of a doctor, a registered nurse or a pharmacist
Legal category	Prescription only Medicine (POM)
Black triangle	Yes. As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product
Off-label use	**Allergy** According to the Comirnaty® 30microgram/dose SPC, it is recommended that all recipients are kept for observation and monitored for a minimum of 15 minutes. 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. However, vaccinated individuals should be informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. As fainting can occur following vaccination, all those vaccinated with any of theCOVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. Individuals with a personal history of allergy should be managed in line with Chapter 14a, Table 5. No specific management is required for individuals with a family history of allergies. The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the Coronavirus Yellow Card reporting scheme is strongly encouraged. **Storage**

	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 Vaccine Incident Guidance. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD. In the event that available data supports extension to the vaccine shelf life, any resulting off-label use of expiry extended vaccine under this PGD should be supported by NHS guidance or standard operating procedures. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.

Route / method of administration	Comirnaty® 30 micrograms/dose dispersion for injection should be administered intramuscularly Do not dilute prior to use The preferred site is the deltoid muscle of the upper arm The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products. Each single dose pre-filled syringe of Comirnaty contains 1 dose of 0.3 mL of vaccine. • Attach a needle appropriate for intramuscular injection and administer the entire volume.

Dose and frequency of administration	Individuals 12 years of age and older • Comirnaty® 30 micrograms/dose is administered intramuscularly as a single dose of 0.3 mL for individuals 12 years of age and older regardless of prior COVID-19 vaccination status • For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty® should be administered at least 3 months after the most recent dose of a COVID-19 vaccine. • Severely immunocompromised aged 12 years and older: additional doses may be administered to individuals who are severely immunocompromised in accordance with national recommendations
Duration of treatment	Single dose
Quantity to be supplied / administered	Administer 0.3ml (30 micrograms) per booster dose.
Supplies	GHA clinics should order/receive COVID-19 vaccines from the SBH Pharmacy dept. The Pharmacy dept will source the vaccine via the national appointed supply route for the GHA. GHA/NHS standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of Comirnaty® 30 mcg/dose COVID-19 mRNA Vaccine, which ensure use is in accordance with product's SPC and official national recommendations
Storage	*Glass pre-filled syringes* The vaccine will be received and stored at 2 °C to 8 °C (refrigerated only). 12 months when stored at 2 °C to 8 °C. Prior to use, pre-filled syringes can be stored for up to 12 hours at temperatures between 8 °C and 30 °C and can be handled in room light conditions. Refrigerated only glass pre-filled syringes Store refrigerated only glass pre-filled syringes at 2 °C to 8 °C. DO NOT FREEZE. Pre-filled syringes Store the vaccine in the original package in order to protect from light. During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. • Prior to use, pre-filled syringes can be stored for up to 12 hours at temperatures between 8 °C to 30 °C and can be handled in room light conditions. • Remove tip cap by slowly turning the cap counterclockwise. Do not shake.

	Attach a needle appropriate for intramuscular injection and administer the entire volume.
Disposal	Follow local GHA clinical waste policy and GHA/NHS standard operating procedures and ensure safe and secure waste disposal. Equipment used for vaccination, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local authority arrangements and guidance in the technical memorandum 07-01 Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Comirnaty® 30 mcg/dose may be administered concomitantly with seasonal influenza vaccine. Different injectable vaccines should be given at different injection sites. See the special considerations/additional information section for further details where a 7 day interval for shingles vaccine administration is advised. No other drug interactions have been identified as yet at the time of writing this PGD. The most up to date list should be checked prior to administration.
Identification & management of adverse reactions	The most frequent adverse reactions in participants 16 years of age and older that received 2 doses were: injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia (> 40%), chills (> 30%), arthralgia (> 20%), pyrexia and injection site swelling (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age. The safety profile in 545 participants 16 years of age and older receiving Comirnaty, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population. **Booster dose following primary vaccination with another authorised COVID-19 vaccine** In 5 independent studies on the use of a Comirnaty booster dose in individuals who had completed primary vaccination with another authorised COVID-19 vaccine (heterologous booster dose), no new safety issues were identified

	For full details of potential adverse reactions please see the emc website
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store and send a copy of the Yellow card to the Director of Public Health Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. **INFORM GIBRALTAR DIRECTOR OF PUBLIC HEALTH IMMEDIATELY IF SEVERE ADVERSE REACTION IS SUSPECTED**
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Patient Information Leaflet Signpost to the GHA website for further information including PGD, PIL, FAQs: • https://www.gha.gi/public-health/

Patient advice / follow up treatment	There continues to be a suspension of the recommended observation and monitoring for 15 minutes in individuals without a history of allergy Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms (see leaflets What to expect after your COVID-19 vaccination and Waiting after COVID-19 vaccination) Individuals with a personal history of allergy should be managed in line with Chapter 14a Table 5 Inform the individual/parent/carer of possible side effects and their management. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. The individual/parent/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Advise the individual/parent/carer that they can report side effects directly via the national reporting system run by the MHRA known as the Coronavirus Yellow Card reporting scheme or search 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. As with all vaccines, immunisation may not result in protection in all individuals. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. When applicable, advise the individual/parent/carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations / additional information	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. 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.

	Pregnancy Vaccination in pregnancy should be offered in accordance with recommendations in Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman. In December 2021, following the recognition of pregnancy as a risk factor for severe COVID-19 infection and poor pregnancy outcomes during the Delta wave, pregnancy was added to the clinical risk groups recommended COVID19 vaccination. Because of wider experience with mRNA vaccines, these are currently the preferred vaccines to offer to pregnant women. If a woman finds out she is pregnant after she has started a course of vaccine, she should complete vaccination at the recommended interval. **Breastfeeding** There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that 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. **Previous incomplete vaccination** Gibraltar is no longer offering a primary course of covid-19 containing vaccines. Evidence suggests that those who receive previous mixed schedules, including mRNA and adenovirus vectored vaccines make a good immune response, although rates of side effects with heterologous doses are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency (EMA) **Co-administration with other vaccines** 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 COVID19 vaccination has been received first or where an individual presents requiring 2 or more vaccines. It is generally better for vaccination to proceed and it may be provided under this PGD, to avoid any further delay in protection and to 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 (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in the schools programmes). The only exceptions to this are the shingles vaccines, where a seven-day interval should ideally be observed. This is based on the potential for an

	inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine. A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, individuals should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or 2 will avoid confusion over systemic side effects. **Non-responders / immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. JCVI advises that a third primary vaccine dose be offered to individuals aged 12 years and over who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule (see 'Box 1: Criteria for a third primary dose of COVID-19 vaccine in those aged 12 years and above' in Chapter 14a). Most individuals whose immunosuppression commenced at least 2 weeks after the second dose of vaccination do not require an additional primary vaccination at this stage. Individuals who had received brief immunosuppression (≤40mg prednisolone per day) for an acute episode (for example, asthma / COPD / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination. Third primary doses should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until 2 weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or when the degree of immunosuppression is at a minimum. 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). This is not covered by this PGD and should be provided on a patient specific basis

Records	Record: that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2018 1. 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) 2. name of vaccinator 3. name and brand of vaccine 4. date of administration 5. dose, form and route of administration of vaccine 6. quantity administered 7. batch number and expiry date 8. anatomical site of vaccination 9. advice given, including advice given if excluded or declines vaccination 10. details of any adverse drug reactions and actions taken 11. supplied via PGD Records should be signed and dated (or a password-controlled vaccinator's record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Key references	• Immunisation Against Infectious Disease: The Green Book, Chapter 14a. • • https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • • https://www.medicines.org.uk/emc/product/13134/smpc • COVID-19 vaccination programme. Updated 3 March 2022. • • https://www.gov.uk/government/collections/covid-19-vaccination-programme • Training recommendations for COVID-19 vaccinators. Updated 4 October 2021. https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators • National COVID-19 vaccination e-learning programme • • https://www.e-lfh.org.uk/programmes/covid-19-vaccination/ • COVID-19 vaccinator competency assessment tool. Updated 16 March 2021 • • https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19: vaccination programme guidance for healthcare practitioners. Updated 10 March 2022. • • https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners • • **General** • Laws of Gibraltar Website: https://www.gibraltarlaws.gov.gi/ • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. • • https://www.nice.org.uk/guidance/mpg2/resources

	• Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. • • https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them • UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/contents • UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1125/contents/made UK Statutory Instrument 2020 No. 1594, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 • https://www.legislation.gov.uk/uksi/2020/1594/regulation/4/made

5. Practitioner authorisation sheet

Comirnaty® 30 mcg/dose dispersion for injection PGD Valid from 06/07/2026 to 06/07/2028:

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions 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 Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the **GHA** for the above named health care professionals who have signed the PGD 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 PGD.