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

Human Papillomavirus (HPV) Vaccine

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	21st July 2025		
Date of expiry	21st July 2027		
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		

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[2] see footnote 1

Legal Authorisation		SIGNATURE	DATE
With the consent of Minister	The Honourable Minister for Health Gemma Arias-Vasquez MP[2]		
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. 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), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain and drawing up the correct dose • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • 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

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	• should fulfil any other additional requirements defined by local GHA 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 the GHA, UKHSA and/or NHS England and NHS Improvement 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	Indicated for the active immunisation of individuals from 12 years of age or from school year 8 for the prevention of human papillomavirus infection in accordance with the national immunisation programme and recommendations given in Chapter 18a of Immunisation Against Infectious Disease: The 'Green Book'. Updated 18th August 2023 for implementation from 1st September 2023 a reduction to single dose of HPV vaccine reducing from a 2 dose schedule.

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Criteria for inclusion	Individuals who: • are aged 12 to 13 years in the birth cohort for school year 8[1]. This is defined as the routine adolescent program • have been previously eligible for HPV immunisation: that is, boys who attained the birth cohort for school year 8 on or after 1 September 2019[1] and girls who attained eligibility on or after 1 September 2008 before their 25th birthday[2,3] • Gay, bi-sexual or other men who have sex with men (GBMSM) from the age of 25 years old before their 45th birthday • individuals who are immunosuppressed and those known to be HIV-positive at the time of vaccination before their 25th birthday or 45th birthday (if GBMSM). • Women with a cervix, who are aged over 25 years old, who are identified by a GHA consultant as being able to clinically benefit from receiving a HPV vaccine, on a case by case basis, as approved through the Drugs and Therapeutics Committee

Criteria for exclusion[4]	Individuals for whom no valid consent has been received. For further information on consent see Chapter 2 of the 'Green Book'. Individuals who: • are less than 12 years of age and in school year 7 or lower • are less than 9 years of age • are aged 25 years and over, except those who have received a partial course of HPV immunisation or determined to be able to clinically benefit on a case by case basis, approved through the GHA Drugs and Therapeutics Committee • have had a confirmed anaphylactic reaction to a previous dose of HPV vaccine or to any components of the vaccine • have completed a course of HPV vaccine • are known to be pregnant (Note: routine questioning about last menstrual period and/or pregnancy testing is not required before offering HPV vaccine) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • Individuals for whom valid consent, or 'best-interests' decision in accordance with the Mental Capacity Act 2016 and the Lasting Powers of Attorney and Capacity Act 2018, has not been obtained.

[1] Individuals in school year 8 who are aged outside the designated birth cohort for the school year may be immunised with their peers

[2] Transgender girls and transgender boys, in birth cohorts eligible for the girl's programme from 1 September 2008, may be vaccinated in accordance with this PGD as appropriate.

[3] Individuals who enter an eligible cohort for HPV vaccination will retain their eligibility until their 25th birthday.

[4] 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

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Cautions including any relevant action to be taken	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. Further details are provided on page 32 of the Green Book chapter 14a for the management of individuals who have had a previous allergic or suspected allergic reaction to the vaccine.
Action to be taken if the patient is excluded	If aged less than 12 years and in a school year below year 8, advise when national routine immunisation is indicated. If aged less than 9 years HPV vaccination is off-label. Immunisation is not indicated unless in school year 8 or above and a PSD would be required. If aged 25 years and over advise that vaccination against HPV is not provided under the routine GHA HPV immunisation programme. An assessment needs to be undertaken by a GHA consultant on a case by case basis. If a confirmed anaphylactic reaction has been experienced after a previous dose of HPV vaccine, or any of its components, specialist advice should be sought. Individuals known to be pregnant should complete immunisation after their pregnancy. If high-risk sexual activity continues during pregnancy, and the opportunity for vaccination after pregnancy is uncertain, the benefit of vaccination during pregnancy is likely to outweigh any potential risk. Vaccination during pregnancy is not covered by this PGD so in such instances the individual may need to be referred and/or a PSD may be required. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity. 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. If required seek appropriate advice from the Director of Public Health or the individual's clinician as required.

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Action to be taken if the patient or carer declines treatment	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. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached.
Arrangements for referral for medical advice	As per local GHA policy

3. Description of treatment

Name, strength & formulation of drug	Human papillomavirus 9-valent vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed): Gardasil® 9, suspension for injection in a pre-filled syringe or vial
Legal category	Gardasil 9 HPV Vaccine Prescription only medicine (POM) These products are categorised as a prescription only medicine (POM). In Gibraltar, the POM status is conferred through GHA policies/legislation.
Black triangle	No
Off-label use	The use of a one-dose schedule of Gardasil® 9 is off-label however, it is in accordance with national recommendations by JCVI and Chapter 18a of the 'Green Book'. The SPC does not recommend the use of Gardasil® 9 during pregnancy and advises to postpone the vaccination until completion of pregnancy. However, vaccination in pregnancy can be given in accordance with the Green Book, Chapter 18A (see Special considerations). Completion of a HPV vaccine course using Gardasil® 9 when it was not commenced with the same HPV vaccine product is off-label but is in accordance with official recommendations and Chapter 18a of the Green Book.

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	The HPV vaccine SPC states that 'vaccinees should be observed for approximately 15 minutes after vaccine administration'. In line with advice in Chapter 4 of the 'Green Book', recipients of any vaccine should be observed for immediate adverse drug reactions. There is no evidence to support the practice of keeping individuals under longer observation. Vaccine 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 vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

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Route / method of administration	Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm. 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 in different limbs. If given in 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. 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 vaccine's normal appearance is a white cloudy liquid which may settle to a clear liquid and white precipitate. Shake well before use. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.

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Dose and frequency of administration	**This PGD was updated on 21st July 2025 to include women, over the age of 25 years old, who have been identified by a GHA consultant as being able to clinically benefit from a single HPV vaccine.** **The previous PGD was updated on 18th August 2023 for introduction from 1st September 2023:** in June 2022 the Joint Committee for Vaccinations and Immunisations in the UK confirmed its advice. The main change is a reduction in dosage from a 2 dose schedule to a single dose schedule for the adolescent programme. This PGD covers the following cohorts: i. a one-dose schedule for the routine adolescent programme ii. a one-dose schedule for those eligible for the GBMSM programme who come forward before their 25th birthday iii. a one-dose schedule have been previously eligible for HPV immunisation: that is, boys who attained the birth cohort for school year 8 on or after 1 September 2019[1] and girls who attained eligibility on or after 1 September 2008 before their 25th birthday iv. a two-dose schedule from the age of 25 in the GBMSM programme before their 45th birthday v. a three-dose schedule for individuals who are immunosuppressed and those known to be HIV-positive at the time of vaccination before their 25th birthday or 45th birthday (if GBMSM). vi. a two dose schedule for women over the age of 25 years old who are identified by a GHA consultant as being able to clinically benefit from a HPV vaccine **A one-dose schedule**: for cohorts i) and ii) and iii) and vi) • Single 0.5ml dose per administration **A two-dose schedule**: cohort iv Administer a course of two doses with at least a 6-month interval between doses, for instance: • first dose of 0.5ml of HPV vaccine, then • second dose at least 6 months after and ideally within 24 months of the first dose If the course is interrupted it should be resumed but not repeated, even if more than 24 months have elapsed since the first dose. Where two doses have been administered less than 6 months apart a third dose should be given at least 3 months after the second dose. **A three dose schedule:** cohort v

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	Administer a course of three doses on a 0, 1 and 4-6 month schedule, for instance: • first dose of 0.5ml of HPV vaccine, then • second dose of 0.5ml at least one month after the first dose, then • a third dose of 0.5ml at least three months after the second dose All three doses should ideally be given within a 12-month period. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses. Whenever possible, immunisations for all individuals on the 3-dose schedule should follow the recommended 0, 1, 4-6 month schedule. There is no clinical data on whether the interval between doses two and three can be reduced below three months. Where the second dose is given late and there is a high likelihood that the individual will not return for a third dose after three months or if, for practical reasons, it is not possible to schedule a third dose within this time-frame, then a third dose can be given at least one month after the second dose. **Vaccination of individuals with unknown or incomplete vaccination status** Unimmunised individuals who enter an eligible cohort for HPV vaccination (see Criteria for inclusion) will retain their eligibility until their 25th birthday or 45th birthday if GBMSM and should be vaccinated in accordance with the schedules above.
Duration of treatment	A one, two or three dose course (see Dose and Frequency section above)
Quantity to be supplied / administered	Single 0.5ml dose per administration.
Supplies	Gardasil 9 Vaccines for the GHA programme are kept in secure cold storage at St Bernard's Hospital and can only be obtained by request from the Chief Pharmacist at the Hospital or their deputy GHA/NHS standard operating procedures should be followed for appropriate storage, handling, preparation, administration and waste minimisation of HPV Vaccine (Gardasil 9) which ensure use is in accordance with SPCs for Gardasil 9

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Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Gardasil® should be administered as soon as possible after being removed from the cold chain. Data from stability studies demonstrate that the Gardasil® 9 vaccine components are stable for 96 hours when stored at temperatures from 8°C to 40°C or for 72 hours when stored at temperatures from 0°C to 2°C. These data are intended to guide healthcare professionals in case of temporary temperature excursion only. This PGD may be used to administer vaccine that has not exceeded these stability data parameters. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.
Disposal	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 authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. This vaccine may be given at the same time as other vaccines. Gardasil® 9 may be administered concomitantly with dTaP, dT/IPV or dTaP/IPV with no significant interference with antibody response to any of the components of either vaccine. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website.
Identification & management of adverse reactions	Local reactions following vaccination are very common, such as pain, swelling or redness at the injection site. Mild side effects such as headache, nausea, dizziness, pain in extremity, fatigue, fever, injection-site haematoma and injection-site pruritus are reported as common.

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	Other adverse events have been reported in post-marketing surveillance but the frequency of these is not known. Hypersensitivity reactions and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the SPC which is available from the electronic Medicines Compendium website.
Reporting procedure of adverse reactions	Healthcare professionals and individuals/parents/carers are encouraged to 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. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP and Director of Public Health should be informed. **INFORM THE DIRECTOR OF PUBLIC HEALTH IMMEDIATELY IF SUSPECTED SEVERE ADVERSE REACTION**
Written information to be given to patient or carer	Ensure the individual has been provided appropriate written information such as the: Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • Immunisations for young people • Your HPV vaccination guide • The HPV vaccine: beating cervical cancer – questions and answers Available via the UKHSA Immunisation Collection webpage.

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Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. Advise individual/parent/carer when the next dose is due. Advise that individuals should continue to take appropriate precautions to protect themselves from sexually transmitted diseases and unwanted pregnancy. Advise that HPV vaccination is not a replacement for the national cervical screening programme which should be accessed by individuals with a cervix at the appropriate age. When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Individuals who are not educated in a school year corresponding their birth cohort may be immunised with their eligible peers as assessed as appropriate. For individuals who commenced but did not complete the vaccination course, it is reasonable to complete their HPV vaccination course with Gardasil® 9. There is no data on fewer than 3 doses of HPV vaccine among HIV-positive or immunocompromised populations. Therefore, a 3-dose schedule should be offered to individuals who are known to be HIV positive, including those on antiretroviral therapy, or who are known to be immunocompromised at the time of immunisation. HPV vaccination is for prophylaxis against future HPV infection. It will not treat pre-existing HPV infection. Gardasil® 9 vaccine will protect against HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58. Appropriate precautions against sexually transmitted diseases should continue to be used. For children under the age of 16 years being offered HPV vaccine, those assessed as Gillick competent can self-consent. For further information on consent see Chapter 2 of the 'Green Book'.

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Records	Record: • that valid informed consent was given • name of individual, address, date of birth, sex and GP with whom the individual is registered • 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 • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password-controlled immuniser'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 via uploading the information onto the GHA Primary Care Centre IT system. Systems should be in place to ensure that the HPV vaccination record is uploaded onto patient record systems. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

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4. Key references

Key references	**Human papillomavirus (HPV) vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 18a, last updated 19th June 2023. https://assets.publishing.service.gov.uk/media/649032b6b32b9e000ca969a7/HPV-green-book-chapter-18a-June-2023.pdf • Summary of Product Characteristic for Gardasil®, MSD Ltd. Last updated 24th September 2024. https://www.medicines.org.uk/emc/product/7330/pil **General** • 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/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • 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 • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

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5. Practitioner authorisation sheet

HPV Vaccine (Gardasil 9) v2.1 Valid from: 21/07/2025 Expiry: 21st August 2027

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.

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

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