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

Rotavirus (ROTARIX) vaccine

Rotavirus vaccine (ROTARIX) (PGD)	**LEGAL STATEMENT**		
Protocol Issuer	Director of Public Health Gibraltar Health Authority St. Bernard's Hospital Gibraltar - Contact Telephone: +(350) 20079160		
Date effective	11th April 2025		
Date of expiry	11th April 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		
Legal Authorisation		SIGNATURE	DATE
With the consent of Minister	The Honourable Minister for Health Gemma Arias-Vasquez MP[2]		

[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) • Paramedics or other Professionals 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) and arrangements for the Gibraltar small pox vaccination programme • must have undertaken training appropriate to this PGD as required by local policy and national NHS 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 Capacity 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	Rotavirus vaccine is indicated for the active immunisation of infants aged 6 weeks to 23 weeks and 6 days for the prevention of gastro-enteritis due to rotavirus infection, in line with the recommendations given in Chapter 27b of the Immunisation Against Infectious Disease: 'The Green Book'

Criteria for inclusion	Infants presenting for the administration of their first or second rotavirus vaccine in the correct time window, that is: • infants aged 6 weeks to 14 weeks and 6 days of age presenting for first dose primary immunisation against rotavirus **Note:** • the minimum age for the first dose of rotavirus vaccine is 6 weeks 0 days • the maximum age for the first dose is 14 weeks and 6 days • infants aged up to 23 weeks and 6 days who have received their first dose of rotavirus vaccine a minimum of 4 weeks previously **Note:** • the maximum age for the second dose of rotavirus vaccine is 23 weeks and 6 days **Note:** Vaccination of preterm infants using rotavirus vaccine is indicated (without correction for prematurity) if the infant is clinically stable. As the benefit of vaccination is high in premature and very premature infants, vaccination should not be withheld or delayed. Vaccination is advised in infants with HIV who are asymptomatic or mildly symptomatic. Additionally, infants with unknown HIV status but born to HIV positive mothers should be offered vaccination (see Chapter 27b and SPC). Refer to Special considerations.

	In an outbreak situation, under written instruction from the Director of Public Health, specific additional groups of the population may be offered an inactivated seasonal influenza vaccine as specified in the written instruction.

Criteria for exclusion[3]	Infants for whom no valid consent has been received. Rotavirus vaccine should NOT be given to infants who: •are under six weeks of age •are 15 weeks of age or older who have not received their first rotavirus vaccine dose •are aged 24 weeks or older •have had a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine or any component of the vaccine •have a previous history of intussusception •have an uncorrected (congenital) malformation of the gastrointestinal tract that could predispose them to intussusception •have Severe Combined Immunodeficiency Disorder (SCID) •have mothers who received immunomodulating biologics (such as monoclonal antibodies or receptor antagonists which interfere with the immune system, for instance anti-TNF agents) in pregnancy •have rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency •are immunosuppressed or those on systemic (oral or parenteral) immunosuppressive treatment •are suffering from acute severe febrile illness (see below). The presence of a minor infection is not a contra-indication for immunisation •are suffering from acute diarrhoea or vomiting (see below)

[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 UK. Healthcare professionals should be aware of a small but increased risk of intussusception, mostly within 7 days (but up to 21 days) after the first rotavirus vaccination dose. Parents/guardians should be advised to promptly seek medical help if their infant becomes unwell during this period. There is a potential for transmission of the live attenuated vaccine strain in rotavirus vaccine from the immunised infant to severely immunocompromised contacts through faecal material for at least 14 days. However, vaccination of the infant will offer protection to household contacts from wild-type rotavirus disease and outweigh any risk from transmission of vaccine virus to any immunocompromised close contacts. Those in close contact with recently vaccinated infants should observe good personal hygiene, for instance wash their hands after changing infant's nappies.

Action to be taken if the patient is excluded	**Important - see above exclusion criteria regarding age of infant, no further action will be required for individuals exceeding the age for vaccination.** Infants excluded for reasons other than immunosuppression (see below) or acute illness (see below) are excluded because rotavirus vaccine is contraindicated or the risk versus benefit is unlikely to support vaccination; parents/carers should be advised accordingly. **Infants who are immunosuppressed** or those on systemic (oral or parenteral) immunosuppressive treatment should be referred to their GP or appropriate specialist clinician to assess the risk versus benefit of rotavirus vaccination. If vaccination is to proceed this may be administered by a prescriber or under a PSD. **In case of acute illness** (febrile illness, diarrhoea or vomiting), postpone vaccination until the infant is recovered and, if the infant will still be within the age range recommended above, advise the parent/carer when the infant may be vaccinated. Ensure another appointment is arranged. If as a result of postponement the infant will exceed the recommended age for vaccination, advise the parent/carer of the reason why vaccination will no longer be indicated. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the infant's clinician as required. The risk to the infant of not being immunised must be taken into account. Document the reason for exclusion and any action taken in infant's clinical records. In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from a person legally able to act on the infant's behalf, must be obtained for each administration. Advise the parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and decision reached. In a GP practice setting, inform or refer to the GP as appropriate
Arrangements for referral for medical advice	As per GHA policy

3. Description of treatment

Name, strength & formulation of drug	Rotavirus vaccine (live, attenuated) oral suspension: for instance •Rotarix® oral suspension (1.5 ml) in pre-filled oral applicator •Rotarix® oral suspension (1.5 ml) in a squeezable tube 1 dose (1.5 ml) contains: Human rotavirus RIX4414 strain (live, attenuated, produced in Vero cells) not less than 106.0CCID50 Rotarix® is not known to be interchangeable with other rotavirus vaccines. However, Rotarix® tube and oral applicator (oral syringe) presentations may be used interchangeably.
Legal category	Prescription Only Medicine (POM).
Black triangle	No
Off-label use	Administration of Rotarix® vaccination to infants born before 27 weeks gestation is off-label. However, all clinically stable preterm infants, including those born before 27 weeks gestation, should be vaccinated in accordance with the recommendations in Chapter 27b of 'The Green Book' unless exclusion criteria apply (see Criteria for exclusion). 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 parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Route / method of administration	Rotavirus vaccine is given orally. The vaccine is ready to use (no reconstitution or dilution is required). The vaccine is to be administered orally without mixing with any other vaccines or solutions. The vaccine is presented as a clear, colourless liquid, free of visible particles. The vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine. **Instructions for administration of the vaccine** To administer the vaccine, use either 1.5 ml of oral suspension in a prefilled oral applicator with a protective tip cap or 1.5ml oral suspension in a squeezable tube fitted with a membrane and tube cap. If using the oral applicator, first carefully remove the protective tip-cap. If using the tube: • check the tube has not been damaged nor is already open • pull off the cap, keep the cap to pierce the membrane • hold upright and clear any liquid from the thinnest section of the tube by flicking just below the membrane. • keeping upright and holding the sides of the tube, pierce the membrane using the spike end of the cap (press on; there is no need to twist). After piercing, there should be a hole at the top. If the membrane has not been pierced, repeat the above step (see SPC). You may need to squeeze the tube presentation a few times to get all the vaccine out; it is okay if a drop remains in the tip of the tube. The SPC for Rotarix® provides further guidance on administration and can be found inside the product packaging or from the electronic Medicines Compendium website: www.medicines.org.uk

Dose and frequency of administration	Rotavirus vaccine should be administered as a course consisting of two doses (1.5ml per administration) separated by at least 4 weeks. Administer the first dose of 1.5 ml of rotavirus vaccine ideally at eight weeks of age in accordance with the UK routine immunisation schedule. However, the first dose may be given from 6 weeks to 14 weeks and 6 days of age. Administer the second dose of 1.5 ml at least 4 weeks after the first dose, ideally at the 12 weeks of age immunisation visit. The second dose must be given by the age of 23 weeks and 6 days. It is preferable that the full course of 2 doses of rotavirus vaccine be completed before 16 weeks of age, allowing at least 4 weeks between the first and second dose. This is to provide early protection and avoid temporal association between vaccination and intussusception. If the course is interrupted, it should be resumed but not repeated, provided that the second dose can be given before 24 weeks of age.
Duration of treatment	Two dose schedule (see Dose and frequency of administration).
Quantity to be supplied / administered	Single (1.5ml) dose In the unlikely event that an infant spits out or regurgitates most of the vaccine dose, a single replacement dose may be given at the same immunisation visit.
Supplies	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).
STORAGE	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. 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 discharged vaccines in a syringe or oral applicator, should be disposed of, as medicinally-contaminated clinical waste for incineration, in a yellow UN-approved waste receptacle (this is usually a sharps box), according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).

Drug interactions	Rotavirus vaccine can be given at the same time as, or any time before or after, any of the other vaccines administered as part of the routine infant immunisation programme, including BCG vaccine. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium
Identification & management of adverse reactions	The most common adverse reactions observed after administration of rotavirus vaccine are diarrhoea and irritability. Other reactions commonly reported include vomiting, abdominal pain, flatulence, skin inflammation, regurgitation of food, fever and loss of appetite. A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium **Intussusception** Intussusception is a naturally-occurring condition where the part of the intestine prolapses, or telescopes, into another part causing an obstruction. In England, intussusception has a background annual incidence of around 120 cases per 100,000 children aged under one year. The background risk of intussusception in the UK increases with age to a peak at around five months of age. Some countries have reported a small increase in the risk of intussusception within seven days of rotavirus immunisation and rotavirus vaccine prescribing information includes this as a possible side effect. The benefits of immunisation in preventing the consequences of rotavirus infection outweigh this small potential risk in young children. However, because of this potential risk, and to reduce the likelihood of a temporal association with rotavirus immunisation, the first dose of vaccine must not be given after 15 weeks of age and the second dose must not be given after 24 weeks of age.
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 yellowcard.mhra.gov.uk Any adverse reaction to the vaccine should be documented in the infant's record and the infant'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 the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: •A guide to immunisations for babies up to 13 months of age •A quick guide to childhood immunisation for the parents of premature babies Available from:www.gov.uk/government/collections/immunisation
Patient advice / follow up treatment	Inform parent/carer of possible side effects and their management. The parent/carer should be advised to seek medical advice in the event of a severe adverse reaction. Parents/carers should be advised to promptly report any of the following symptoms indicative of intussusception: •severe abdominal pain •persistent vomiting •bloody stools •abdominal bloating •high fever When applicable, advise parent/carer when the subsequent dose is due. When administration is postponed, advise when the infant should return for immunisation, with due consideration of the infant's age to ensure they will meet the inclusion criteria for rotavirus immunisation. Those in close contact with recently vaccinated infants should observe good personal hygiene, for instance wash their hands after changing the infant's nappies and before food preparation or direct contact with the immunocompromised person(see Cautions). There are no restrictions on the infant's consumption of food or liquid, either before or after vaccination.

Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. Consider giving the oral rotavirus vaccine before administration of any vaccine injections which may unsettle the infant. There are no restrictions on an infant's consumption of food or drink before or after immunisation. Breast-feeding may be continued during the vaccination schedule. Postpone vaccination for infants with acute diarrhoea or vomiting until they have recovered, to ensure the vaccine is not regurgitated or passed through the intestines too quickly, which could reduce the effectiveness. Vaccination is advised in HIV infected infants. Additionally, infants with unknown HIV status but born to HIV positive mothers should be offered vaccination (see Chapter 27b). Rotarix® does not protect against gastro-enteritis due to other pathogens than rotavirus **IMMEDIATE ACCESS TO OXYGEN IS NOT A NECESSITY UNDER THIS PGD.** **BASIC LIFE SUPPORT & CALLING EMERGENCY SERVICES IS SUFFICIENT**
Records	**Record:** • that valid informed consent was given • name of infant, address, date of birth 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 • 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 immunisers 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	**Rotavirus** • Summary of Product Characteristics for Rotarix®. GlaxoSmithKline UK Updated 01 January 2021 http://www.medicines.org.uk/emc/medicine/17840 • Immunisation Against Infectious Disease: The Green Book, Chapter 27b . Updated August 2015 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Public health commissioning in the NHS: 2020 to 2021 https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2020-to-2021 **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • 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 • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

5. Practitioner authorisation sheet

Rotavirus vaccine (live, attenuated) oral suspension: for instance

- **Rotarix® oral suspension (1.5 ml) in pre-filled oral applicator**
- **Rotarix® oral suspension (1.5 ml) in a squeezable tube. 1 dose (1.5 ml) contains: Human rotavirus RIX4414 strain (live, attenuated, produced in Vero cells) not less than 106.0CCID50**

DATE OF ISSUE 11th April 2025 DATE OF EXPIRY: 11th April 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.

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