# Patient Group Direction

for *Pharmacists and Nurses to*
administer Cholera vaccine for Travel
in individuals aged 2 years and over

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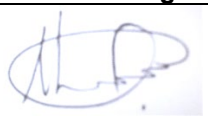
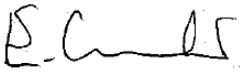
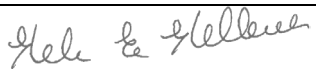
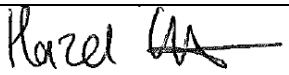
| Developed by | Designation | Signature | Date |
|---|---|---|---|
| Athan Tachtatzis | PGD Pharmacist,<br>NHS Fife |  | 05/05/2025 |
| Dr Esther Curnock | Deputy Director of Public Health<br>Consultant in Public Health Medicine, NHS Fife |  | 05/05/2025 |
| Aileen Boags | Lead Pharmacist<br>Public Health& Community Pharmacy services<br>NHS Fife |  | 05/05/2025 |

This Patient group Direction has been approved on behalf of NHS Fife by:

| Name | Designation | Signature | Date |
|---|---|---|---|
| Nicola Robertson | Director of Nursing<br>NHS Fife |  | 07/05/2025 |
| Dr Helen Hellewell | Deputy Medical Director<br>Fife Health and Social Care Partnership |  | 28/05/2025 |
| Hazel Close | Deputy Director of Pharmacy & Medicines<br>NHS Fife |  | 12/05/2025 |

## 1. Clinical condition to which the patient group direction applies

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| Indication | Active immunisation of adults and children over 2 years who are deemed to be at risk of disease caused by *Vibrio cholera* serogroup 01. |
| Inclusion criteria | • Valid consent to treatment according to NHS Fife policy<br>Adults and children over 2 years old who:<br>• intend to travel to or reside in countries where cholera vaccination is currently recommended by recognised Scottish or UK national travel health websites to ensure adherence to the latest recommendations.<br>the risk of exposure should be determined after careful risk of assessment of an individual's itinerary, duration of stay, planned activities and medical history. |
| Exclusion criteria | • No valid consent to treatment according to NHS Fife policy<br>Individuals who:<br>• are under 2 years of age<br>• have had a confirmed anaphylactic reaction to a previous dose of cholera vaccine or to any of the components of the vaccine these may include formaldehyde (refer to relevant SPC)<br>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)<br>• are suffering from acute gastro-intestinal illness, immunisation should be postponed until fully recovered. Pre-existing gastro-intestinal disorders are not a contraindication to giving the vaccine. |
| Cautions / Circumstances when further advice should be sought from a senior clinician | • It is the responsibility of the designated, authorised staff using this PGD to ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt, advice should be sought and recorded before the drug is administered / supplied.<br>• The Green Book advises there are very few individuals who cannot receive cholera vaccine. When there is doubt, appropriate advice should be sought from the lead clinician rather than withholding the vaccine.<br>• Individuals with immunosuppression and HIV infection can be given Dukoral® . However, these individuals may not develop a full antibody response and vaccine efficacy has not been studied. Specialist advice may be required.<br>• Dukoral® contains approximately 1.1g sodium per dose which should be taken in to consideration by patients on a controlled sodium diet.<br>• The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.<br><u>Co-administration with other vaccines</u><br>Dukoral® can be given at the same time as injected vaccines. |

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| | Pregnancy and breastfeeding<br>No data are available on the safety of oral cholera vaccine in pregnant or breast-feeding women. There is no evidence of risk from vaccinating these individuals with other inactivated viral or bacterial vaccines or toxoids. Vaccination should be considered when the risk of infection is high and benefits are considered to outweigh the risks. |
| Action if excluded | • Do not use the PGD<br>• The patient must be referred to an authorised prescriber<br>• The reason for referral should be documented<br>• Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.<br>• Document the reason for exclusion and any action taken in accordance with local procedures.<br>• Advise the individual/parent/carer of preventative measures to reduce exposure to cholera including careful attention to food and water hygiene and scrupulous hand washing.<br>• Inform or refer to the lead clinician in charge.<br>• In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.<br>• Individuals who have had a confirmed anaphylactic reaction to a previous dose of cholera vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management. |
| Action if patient declines treatment | • The patient must be referred to an authorised prescriber<br>• The reason for refusal should be documented<br>• Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.<br>• Advise the individual/parent/carer of preventative measures to reduce exposure to cholera including careful attention to food and water hygiene and scrupulous hand washing.<br>• Document advice given and decision reached. Inform or refer to the lead clinician in charge. |

## 2. Medication details

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| Name strength & formulation of drug | **Dukoral®** Inactivated oral cholera vaccine plus buffer sodium hydrogen carbonate as effervescent granules.<br>Each dose of vaccine suspension (3ml) contains four strains of killed Vibrio cholerae 01 bacteria and 1mg of recombinant cholera toxin B subunit (rCTB) (as detailed in product SPC). |

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| Route of administration | The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration.<br><br>*Adults and children over 6 years of age:*<br>The sodium hydrogen carbonate effervescent granules, should be dissolved in approximately 150ml of cool water. The entire contents of the vaccine vial should then be mixed with the sodium hydrogen carbonate solution and the dose drunk within 2 hours.<br><br>*Children 2 to 6 years of age:*<br>The sodium hydrogen carbonate effervescent granules, should be dissolved in approximately 150ml of cool water. Half of this buffer solution should be discarded and the remaining part (approx. 75 ml) mixed with the entire contents of the vaccine vial and the dose drunk within 2 hours.<br><br>**Food, drink and administration of other oral medicinal products should be avoided 1 hour before and after administration of Dukoral®.** |
| Dosage | One dose on each occasion as above |
| Frequency of administration | **Primary immunisation schedule:**<br><br>Immunisation should be completed at least one week prior to potential exposure to *V. cholerae* 01.<br><br>*Children 2 to 6 years of age:*<br><br>**Three** doses administered with at least one week interval between doses, but less than 6 weeks* between doses.<br><br>*Adults and children over 6 years of age*:<br><br>**Two** doses with an interval of at least 1 week but less than 6 weeks* between doses.<br><br>**If more than six weeks have elapsed between doses, the primary immunisation course should be restarted.*<br><br>**Reinforcing (booster) dose:**<br><br>*Children 2 to 6 years of age:*<br><br>For continuous protection against cholera a single booster dose is required six months after completion of the primary immunisation schedule.<br><br>*Adults and children over 6 years of age:*<br><br>For continuous protection against cholera a single booster dose is required at two years following completion of the primary immunisation schedule. |

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| | There is no evidence to support further booster doses. But if more than two years have elapsed since the last vaccination (or more than *6 months* for children aged 2 to 6 years), then the primary course should be repeated.<br><br>Repeating the primary schedule is unique to this vaccination. |
| Duration of treatment including maximum/ minimum period if applicable | See frequency section |
| Quantity to be supplied | Single dose on each occasion |
| Patient advice verbal and written | Written information to be given to individuals:<br>• Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.<br><br>Individual advice / follow up treatment:<br>• Inform the individual/carer of possible side effects and their management.<br>• Advise the individual/parent/carer of preventative measures to reduce exposure to cholera including careful attention to food and water hygiene and scrupulous hand washing.<br>• The individual should be advised to seek medical advice in the event of a severe adverse reaction.<br>• For continuous protection against cholera a booster dose is recommended as detailed above.<br>• Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk/<br>• When administration is postponed advise the individual how future vaccination may be accessed.<br>• Where a supply for subsequent self-administration is made, the individual should be counselled on appropriate intervals, storage, and advice on how to access further information, as necessary. |
| Black Triangle Drug ▲ | No |
| Legal category | Prescription Only Medicine (POM) |
| Use outwith SPC | • Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions the PHS Guidance for Vaccine Storage and Handling must be followed (link). If a vaccine or cold chain incident occurs the Health Protection Scotland Vaccine Incident Guidance should be followed vaccine-incident-guidance-actions-to-take-in-response-to- |

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| | vaccine-errors and advice must be sought from the Pharmacy Governance team by calling 01383 565347.<br>• Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed. |
| Storage requirements | • Ensure within expiry date<br>• Vaccine should be stored at a temperature of +2° to +8°C.<br>• Store in the original packaging to protect from light.<br>• Do not freeze.<br>• Dukoral®: Product in the unopened vial and sachet, stored in the outer carton, is stable at temperatures up to +25ºC for a period of 14 days. At the end of this period the product should be used or discarded.<br>• Contact Pharmacy for advice if stored out with +2°C to +8°C<br>• There may be circumstances when vaccines stored out with the recommended storage temperatures of +2 to +8°C can be administered providing the product has been confirmed as suitable for use by the manufacturers and Pharmacy<br>• the PHS Guidance for Vaccine Storage and Handling must be followed (link) see above. 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. |
| Additional information | • Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.<br>• Immunological response may be diminished in those receiving immunosuppressive treatment.<br>• Where a supply is made which is intended for self-administration following an initial administration by a registrant, please note in accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. |
| Identification and management of adverse reactions | • For full details/information on possible side effects, refer to the marketing authorisation holder's SPC.<br>• As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.<br>• In the event of severe adverse reaction individual should be advised to seek medical advice.<br>• Most commonly reported adverse reactions to cholera vaccine are usually mild and confined to the first few days after immunisation. The most common reactions are mild gastrointestinal symptoms including nausea, diarrhoea, abdominal pain, cramping. |

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| | • Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.<br>• All suspected serious reactions should be reported directly to the MHRA/Commission on Human Medicines through the Yellow Card scheme and recorded in the patient's medical notes. Reports should be made online at https://yellowcard.mhra.gov.uk |
| Monitoring if required | Following immunisation, patients remain under observation in line with NHS Fife policy. |
| Follow up – appointment with or notification to GP required? | See frequency section |
| Additional facilities/ supplies required | • Immediate access to anaphylaxis medication as appropriate to current NHS Fife procedure for the Management of Anaphylaxis.<br>• Immediate telephone access to a senior clinician/authorised prescriber<br>• Access to a BNF<br>• NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) should be followed<br>• Adhere to hand decontamination policy |
| Disposal | Sharps, vials and other vaccine equipment, and any reconstituted vaccine that has not been used should be disposed of following NHS Fife policies for disposal of sharps and other harmful substances |

## 3. Staff characteristics

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| Professional qualifications | The following classes of registered healthcare practitioners are permitted to administer vaccines:<br>• pharmacists currently registered with the General Pharmaceutical Council (GPhC)<br>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)<br>**Under PGD legislation there can be no delegation. Supply of the medication must be completed by the same practitioner who has assessed the patient under this PGD.** |
| Specialist competencies or qualifications | Persons must only work under this PGD where they are competent to do so<br>All practitioners operating this PGD must demonstrate appropriate knowledge and skills to work under the PGD<br>All persons operating this PGD:<br>• must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it<br>• must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information<br>• must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent<br>• must be competent in the correct storage of vaccines and management of the cold |

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| | chain if receiving, responsible for, or handling the vaccine<br>• must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions<br>• must have access to the PGD and associated online resources<br>• should fulfil any additional requirements defined by local policy<br>• have undertaken NHS Fife approved anaphylaxis management training<br>• have undertaken NHS Fife approved training in *paediatric and adult* basic life support<br>• must be conversant with key issues in vaccine management (e.g. safe transport, maintaining cold-chain etc) in accordance with NHS Fife Policies<br>• It is essential that the NHS Fife approved PGD e-learning programme is accessed and completed by NHS Fife employed staff<br>• It is the responsibility of the designated authorised staff using this PGD to ensure that treatment with the vaccine detailed in the direction is appropriate. If in any doubt, advice should be sought and recorded before the vaccine is administered<br><br><u>Employer</u><br>The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD<br><br>**As a minimum, competence requirements stipulated in the PGD must be adhered** |
| Continued training requirements | • Maintain own professional level of competence and knowledge in this area<br><br>• Keep up-to-date with information on contraindications, cautions and interactions for **Dukoral®** from the BNF, SPC and PIL and refer to a senior clinician if necessary<br><br>• Annual update of anaphylaxis management according to NHS Fife Policy<br><br>• Annual update of training in paediatric and adult basic life support<br><br>• A 2 yearly update of the PGD e-learning programme is essential for NHS Fife employed staff. |

## 4. Referral arrangements/Audit trail

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| Arrangements for referral to medical advice | • The patient may be referred to a senior clinician at any stage, if this is necessary, in the professional opinion of the *healthcare professional*. |
| Records/Audit trail | • Enter in record<br>- date<br>- name of patient<br>- Date of birth/ CHI no.<br>- name of medicine<br>- batch number and manufacturer<br>- expiry date<br>- dose/volume<br>- quantity administered<br>- route and site of administration<br>- name of clinician providing treatment<br>- signature / individual log-on details of clinician providing treatment<br>• details of the source of the recommendation to vaccinate<br>• Record on appropriate form.<br>• Record medical history taken, diagnosis and the advice given to the |

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| | patient/carer |
| References/ Resources & comments | • BNF / BNFc latest edition available at www.medicinescomplete.com<br>• NHS Fife Consent Policy<br>• NHS Fife Procedure for the Management of Anaphylaxis<br>• NHS Fife Resuscitation Guidelines<br>• NMC/RPS Administration of Medicines Guidance Jan 2019<br>• NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP)<br>• Summary of Product Characteristics available at www.medicines.org.uk<br>• Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book<br>• Immunisation against Infectious Disease [Green Book] chapter 14 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/263838/Green-Book-Chapter-14v2_0.pdf<br>• Current edition of British National Formulary.<br>• Marketing authorisation holder's Summary of Product Characteristics.<br>• Professional Guidance on the Administration of Medicines in Healthcare Settings 2019 https://www.rpharms.com/Portals/0/RPS document library/Open access/Professional standards/SSHM Admin/Admin Meds prof guidance.pdf/ver=2019-01-23-145026-567<br>• Professional Guidance on the Safe and Secure Handling of Medicines https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines<br>• HPS Guidance for Vaccine Storage and Handling (link).<br>• HPS Vaccine Incident Guidance vaccine-incident-guidance-actions-to-take-in-response-to-vaccine-errors<br>• https://publichealthscotland.scot/publications/patient-group-direction-template-administration-of-cholera-vaccine/patient-group-direction-template-administration-of-cholera-vaccine-version-2.1/ |

**This Patient Group Direction has been assessed for Equality and Diversity Impact**

## 5. Management and monitoring of patient group direction

**Patient Group Direction**
for *Pharmacists and Nurses to*
administer **Cholera vaccine for Travel**
in individuals aged 12 months and over

This patient group direction is to be read, agreed to, and signed by all *healthcare professionals* it applies to. One signed copy is to be given to each clinician with the original being kept on file by the line manager. One signed copy should be forwarded to the appropriate lead nurse / lead clinician where applicable.

**Pharmacist/Nurse Agreement**

I _____, confirm that I have read and understood the above Patient Group Direction. I confirm that I have the necessary professional registration, competence, and knowledge to apply the Patient Group Direction. I will ensure my competence is updated as necessary. I will have ready access to a copy of the Patient Group Direction in the clinical setting in which supply or administration of the medicine will take place.

I understand that it is the responsibility of the healthcare professional to act in accordance with the GPhC/ NMC Guidelines for Professional Practice and Guidelines for the Administration (or Supply) of Medicines and to keep an up to date record of training and competency.

Name of clinician----------

Professional Category----------

Registration No.----------

Is authorised to give **Dukoral®** under this patient group direction

Place of Work----------

Signature of clinician----------

Date----------

Authorised by: **(not required for pharmacists)**

Name of authorising clinician/manager----------

Signature----------

Date----------

**Pharmacists send signed copy of this page to fife.pgd@nhs.scot**

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