Patient Group Direction
for *Pharmacists and Nurses to*
administer Hepatitis A vaccine for Travel
in adults and children aged One year and over

Number	**331**
Issued	**March 2025**
Issue Number	**2.1**
Date of review*	December 2027

*** If this PGD is past its review date then the content will remain valid until such time as the PGD review is complete and the new issue published**

It is the responsibility of the person using this PGD to ensure that they are using the most recent issue. This can be found on the NHS Fife Stafflink

Developed by	Designation	Signature	Date
Athan Tachtatzis	PGD Pharmacist, NHS Fife		05/05/2025
Dr Esther Curnock	Deputy Director of Public Health Consultant in Public Health Medicine, NHS Fife		05/05/2025
Ailean Boags	Lead Pharmacist Public Health& Community Pharmacy services 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 NHS Fife		07/05/2025
Dr Helen Hellewell	Deputy Medical Director Fife Health and Social Care Partnership		28/05/2025
Hazel Close	Deputy Director of Pharmacy & Medicines NHS Fife		12/05/2025

1. Clinical condition to which the patient group direction applies

Indication	Active immunisation of individuals who are deemed to be at risk from exposure to hepatitis A virus.
Inclusion criteria	• Valid consent to treatment according to NHS Fife policy Adults and children over 1 year old who: • intend to travel to or reside in countries where hepatitis A vaccination is currently recommended by recognised Scottish or UK national travel health websites to ensure adherence to the latest recommendations. • the risk of exposure should be determined after careful risk 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 Individuals who: • are under one year of age • have had a confirmed anaphylactic reaction to a previous dose of any hepatitis A containing vaccine or to any components of the vaccine, these may include neomycin and/or formaldehyde (refer to relevant SPC) • have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free • are solely at occupational risk of hepatitis A exposure, should be referred to their employer's occupational health provider for vaccination • previous confirmed hepatitis A infection • suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions / Circumstances when further advice should be sought from a doctor	• 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. • The Green Book advises there are very few individuals who cannot receive hepatitis A containing vaccines. <u>People with a Bleeding Disorder:</u> An individual risk assessment should be undertaken prior to vaccination. As with any intramuscular (IM) vaccination, the injection should be given with caution to patients with thrombocytopenia or any coagulation disorder as bleeding may occur following an intramuscular administration to these subjects. Therefore, patients with known bleeding disorders or on anticoagulant therapy should receive the vaccine by deep subcutaneous injection route to reduce the risk of bleeding. Individuals should be informed of the risk of developing haematoma and what to do if this occurs. (see also route of administration section) • When there is doubt, appropriate advice should be sought from the lead

	clinician rather than withholding the vaccine. • Individuals with immunosuppression and HIV infection can be given hepatitis A containing vaccines although seroconversion rates and antibody titre may be lower. Specialist advice may be required. • Avaxim® vaccines contain 10 microgram phenylalanine in each 0.5 ml dose, which is equivalent to 0.17 microgram/kg for a 60 kg person. Phenylalanine may be harmful for individuals with phenylketonuria (PKU). The amount in the vaccine is unlikely to adversely affect individuals with PKU, but they should be advised Avaxim® vaccines contain 10 micrograms of phenylalanine. These individuals will be well versed as to the amounts they can tolerate in their diet. If available offer an alternative vaccine. Havrix® Monodose® also has trace amino acids, so VAQTA® would be the preferred option. Alternatively, seek advice from the specialist endocrinologist/metabolic physician looking after the individual with PKU to confirm they are content for them to have Avaxim®. • 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. • 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. • There is no evidence of risk from vaccinating pregnant women, or those who are breast-feeding, with inactivated virus 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 • The patient must be referred to an authorised prescriber • The reason for referral should be documented 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. Refer to the lead clinician. Document the reason for exclusion and any action taken in accordance with local procedures. Advise the individual/parent/carer of preventative measures to reduce exposure to hepatitis A including careful attention to food and water hygiene and scrupulous hand washing. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Individuals who have had a confirmed anaphylactic reaction to a previous dose of

	a hepatitis A containing 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 • The reason for refusal should be documented • 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. • Advise the individual/parent/carer of preventative measures to reduce exposure to hepatitis A including careful attention to food and water hygiene and scrupulous hand washing. • Document advice given and decision reached. Inform or refer to the lead clinician in charge.

2. Medication details

Name strength & formulation of drug	Hepatitis A (inactivated) vaccine (adsorbed), either: Adults **Havrix® Monodose** vaccine, hepatitis A virus1440 ELISA units in a pre-filled syringe or vial **AVAXIM®**, hepatitis A virus, (GBM strain) 160 U, suspension for injection in a pre-filled syringe **VAQTA® Adult**, hepatitis A virus (strain CR 326F) 50 U suspension for injection in a pre-filled syringe or vial Children **Havrix® Junior Monodose** vaccine, hepatitis A virus 720 ELISA units in a pre-filled syringe or vial **AVAXIM® Junior**, hepatitis A virus, (GBM strain) 80 U, suspension for injection in a pre-filled syringe **VAQTA® Paediatric**, hepatitis A virus (strain CR 326F) 25 U suspension for injection in a pre-filled syringe or vial
Route of administration	Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm. In small infants the anterolateral thigh may be used. 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. (see also cautions section). The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration.

	The suspension for injection may sediment during storage. Shake the vaccine well before administration to obtain a slightly opaque, white suspension. 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.
Dosage	Current UK licensed hepatitis A vaccines contain different concentrations of antigen per millilitre (see table below). The choice of vaccine and dose used should be guided by the individual's age, immunocompetence and dose recommendations in the vaccine manufacturer's SmPC.

Vaccine product	Ages	Dose	Volume
ADULTS			
Vaqta® Adult	18 years or over	50 units	1.0ml
Avaxim®	16 years or over	160 units	0.5ml
Havrix® Monodose	16 years or over	1440 ELISA units	1.0ml
CHILDREN			
Vaqta® Paediatric	One to 17 years	25 units	0.5ml
Havrix® Junior Monodose	One to 15 years	720 ELISA units	0.5ml
Avaxim® Junior	One to 15 years	80 units	0.5ml

Vaccines can be used interchangeably.

Please note in clinical settings where there is more than one option for vaccination available, the following order of preference should be used.

Adults
1. VAQTA® Adult
2. Avaxim®
3. Havrix® Monodose

Children
1. VAQTA® Paediatric
2. Havrix® Junior Monodose

	3. Avaxim® Junior
Frequency of administration	**Primary immunisation:** single dose (see table above). Vaccination should ideally occur at least 2 weeks prior to possible exposure to infection with hepatitis A. For travellers, vaccine should preferably be given at least two weeks before departure, but can be given up to the day of departure. **Reinforcing Immunisation:** For those who require prolonged or subsequent protection against infection caused by hepatitis A virus, a reinforcing booster dose of a hepatitis A containing vaccine should ideally be given 6-12 months after the first dose. If the booster dose is delayed beyond 12 months, the course does NOT need to be restarted as studies have shown boosting can occur even when the second dose is delayed for several years. Monovalent Hepatitis A containing vaccines may be used interchangeably, as appropriate, to complete a course. Until further evidence is available on persistence of protective immunity, a further booster at 25 years is indicated for those at ongoing risk of hepatitis A.
Duration of treatment including maximum/ minimum period if applicable	See frequency section
Quantity to be supplied	One dose per occasion
Patient advice verbal and written	Written information to be given to individuals: • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. Individual advice / follow up treatment: • Inform the individual/carer of possible side effects and their management • Explain that to give long-lasting immunity to hepatitis A, dosing requires two injections at least six months apart • Advise the individual/parent/carer of preventative measures to reduce exposure to hepatitis A including careful attention to food and water hygiene and scrupulous hand washing • The individual/carer should be advised that hepatitis A vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis B, C and hepatitis E viruses. • The individual should be advised to seek medical advice in the event of a severe adverse reaction • 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/

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-vaccine-errors and advice must be sought from the Pharmacy Governance team by calling 01383 565347. 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 • Vaccine should be stored at a temperature of +2° to +8°C. • Store in the original packaging to protect from light. • Do not freeze. • Contact Pharmacy for advice if stored out with +2°C to +8°C • 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 • 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. Immunological response may be diminished in those receiving immunosuppressive treatment. Hepatitis A-containing vaccines can be given at the same time as other vaccines such as hepatitis B, MMR, MenACWY, Td/IPV and other travel vaccines. 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 was given should be noted in the individual's records.
Identification and management of adverse reactions	• For full details/information on possible side effects, refer to the marketing authorisation holder's SPC. • Adverse reactions to hepatitis A vaccines are usually mild and confined to the first few days after immunisation. The most common reactions are mild, transient soreness, erythema and induration at the injection site. A small, painless nodule may form at the injection site; this usually disappears and is

	of no consequence. • Other commonly reported reactions to hepatitis A vaccination include general symptoms such as fever, malaise, fatigue, irritability, drowsiness, headache, myalgia, arthralgia and gastrointestinal symptoms including nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. • As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. • In the event of severe adverse reaction individual should be advised to seek medical advice. • 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. • 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. As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.
Follow up – appointment with or notification to GP required?	See monitoring if required
Additional facilities/ supplies required	• Immediate access to anaphylaxis medication as appropriate to current NHS Fife procedure for the Management of Anaphylaxis. • Immediate telephone access to GP • Access to a BNF • NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) should be followed • 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

Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines: • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) **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 All practitioners operating this PGD must demonstrate appropriate knowledge and skills to work under the PGD All persons operating this PGD: • must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it • must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information • must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent • must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine • must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy • have undertaken NHS Fife approved anaphylaxis management training • have undertaken NHS Fife approved training in *paediatric and adult* basic life support • must be conversant with key issues in vaccine management (e.g. safe transport, maintaining cold-chain etc) in accordance with NHS Fife Policies • It is essential that the NHS Fife approved PGD e-learning programme is accessed and completed by NHS Fife employed staff • 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 <u>Employer</u> 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 • **As a minimum, competence requirements stipulated in the PGD must be adhered to**
Continued training requirements	• Maintain own professional level of competence and knowledge in this area • Keep up-to-date with information on contraindications, cautions and interactions for Havrix Monodose®,Havrix Junior Monodose®, Avaxim®, Avaxim®Junior, Vaqta Adult®, Vaqta Paediatric from the BNF, SPC and PIL and refer to a doctor if necessary • Annual update of anaphylaxis management according to NHS Fife Policy • Annual update of training in paediatric and adult basic life support • A 2 yearly update of the PGD e-learning programme is essential

4. Referral arrangements/Audit trail

Arrangements for referral to medical advice	• The patient may be referred to a doctor at any stage, if this is necessary, in the professional opinion of the *healthcare professional*. • Patients should be referred to the doctor if treatment proves to be ineffective in relieving the symptoms
Records/Audit trail	• Enter in record - date - name of patient - Date of birth/ CHI no. - name of medicine - batch number and manufacturer - expiry date - dose/volume - quantity administered - route and site of administration - name of clinician providing treatment - signature / individual log-on details of clinician providing treatment • details of the source of the recommendation to vaccinate • Record on appropriate form. • Record medical history taken, diagnosis and the advice given to the patient/carer
References/ Resources & comments	• BNF / BNFc latest edition available at www.medicinescomplete.com • NHS Fife Consent Policy • NHS Fife Procedure for the Management of Anaphylaxis • NHS Fife Resuscitation Guidelines • NMC/RPS Administration of Medicines Guidance Jan 2019 • NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) • Summary of Product Characteristics available at www.medicines.org.uk • Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Immunisation against Infectious Disease [Green Book] chapter 17 https://www.gov.uk/government/publications/hepatitis-a-the-green-book-chapter-17 • Current edition of British National Formulary. • Marketing authorisation holder's Summary of Product Characteristics. • 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 • 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

	• HPS Guidance for Vaccine Storage and Handling (link). • HPS Vaccine Incident Guidance vaccine-incident-guidance-actions-to-take-in-response-to-vaccine-errors • PHS PGD template Hepatitis A for travel V2.1, Jan 6, 2025

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 **Hepatitis A vaccine** for Travel
in adults and children aged One year 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 **Havrix Monodose®, Havrix Junior Monodose®, Avaxim®, Avaxim®Junior**, **Vaqta Adult®, Vaqta® Paediatric** 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

If this PGD is past its review date then the content will remain valid until such time as the PGD review is complete and the new issue published