Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

Hepatitis A virus (inactivated) vaccine (adsorbed)

by registered healthcare professionals

to

individuals considered at high risk of exposure to hepatitis A or post exposure to hepatitis A virus in accordance with national recommendations

in Powys Teaching Health Board

Version number: PGD 0088-D

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Reference Number: PGD 0088-D
Valid from: 01/11/2023
Review Date: 31/03/2026
Expiry Date: 31/10/2026

Change History

Version number	Change details	Date
PGD0088	Initial Issue	2/05/2018
PGD0088-A	Review issue PHE adapted PHE Hepatitis A vaccine PGD amended to: insert missing amended paragraph into 'Additional information' section, relating to the hyperlink from the inclusion criteria for MSM.	13/5/21
PGD0088-B	Review issue PHE adapted and amended to include: • phenylalanine content in Avaxim® vaccine and action to be taken • booster dosing delays still provide protection • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates	25/10/2021
PGD0088-C	Review issue to remove the exclusion for use in PTHB occupational health department for their own staff	15/05/2023
PGD0088-D	Review issue to adopt UKHSA template v5.00 to include: • new vaccine licensed for children 1 to 15 years old (Avaxim® Junior) • phenylalanine content in Avaxim® Junior, Havrix® and Havrix® Junior Monodose® • removal of the subcutaneous route being off-label for Havrix® Monodose and Havrix® Monodose Junior • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates • replacement of 'Public Health England' and 'PHE' with UKHSA, including updated contact details	01/11/2023

This Powys Teaching Health Board PGD is based on a template developed by the following health professionals on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy (also ratified by the UKHSA Medicines Governance Group).

Developed by the following health professionals on behalf of the UKHSA:

Developed By:	Name
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist – Immunisation and Vaccine Preventable Diseases Division, UKHSA
Doctor	Dr Sema Mandal Deputy Director and Consultant Epidemiologist, Blood Safety, Hepatitis, STIs and HIV, UKHSA
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Rosie Furner	Specialist Pharmacist, Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead, Southbourne Surgery
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Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
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Tushar Shah	Lead Pharmacy Advisor, NHSE London
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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Richard Stratton**	Assistant Medical Director: Primary Care and Community; Service Development	DocuSigned by: A4AB87B5EE40479...	10/27/2023
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	10/27/2023
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche FC9C4C63FC374A7...	11/1/2023
Clinical Governance Lead **Claire Madsen**	Clinical Governance Lead for PTHB – Director Of Therapies & Health Science	DocuSigned by: Claire Madsen 51D92655B6B7468...	10/27/2023

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

PGD adoption by the provider

[1] This includes any relevant amendments to legislation

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

1. Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
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 and administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must have completed Patient Group Directions training available via ESR or eLearning for Healthcare (e-LfH) • 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 and online training.

	Please contact PTHB immunisation co-ordinator for further information. • 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'. Completion of cold chain training (also available via ESR) • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the recognition, management, and reporting of adverse drug reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Life Support skills (Basic Life Support Skills are PTHB standard; Intermediate Life Support Skills for MIU). • must have access to the PGD and associated online resources • should fulfil any 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). Evidence of ongoing PGD training to be submitted to Line Manager annually. Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. Practitioners must make a self-declaration of competency on PADR. Compliance with all mandatory NHS training. Practitioners should be constantly alert to any subsequent recommendations from the UKHSA, NHS England, Welsh Government and/or Public Health

	Wales and/or NHS Wales 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. **It is the responsibility of the healthcare professional to maintain their own competency to practice within 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 against hepatitis A infection in accordance with national recommendations including: • Chapter 7 and Chapter 17 of Immunisation Against Infectious Disease: The Green Book • NaTHNaC - Hepatitis A (travelhealthpro.org.uk) recommendations for hepatitis A vaccination for travel • Public health control and management of hepatitis A guidance. **If used in PTHB Occupational Health Service, the PGD must be used in line with PTHB Occupational Health Immunisation policy.** **It is the responsibility of the administering healthcare professional to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.**
Criteria for inclusion	Adults and children over 1 year old who: • intend to travel, where hepatitis A vaccination is currently recommended for travel by NaTHNaC (see the Travel Health Pro website for country-specific advice on hepatitis A vaccine recommendations) • are at risk of hepatitis A infection because of their sexual behaviour, including men who have sex with men (MSM), see Additional information section • are people who inject drugs (PWID)

	• have haemophilia • have chronic liver disease (including alcoholic cirrhosis, chronic hepatitis B, chronic hepatitis C, autoimmune hepatitis, primary biliary cirrhosis) • Are at increased risk of hepatitis A infection because of their occupation (NB ONLY when administered by PTHB occupational health department) Adults and children from 2 months old who: • are recommended hepatitis A vaccine in accordance with Public health control and management of hepatitis A guidance Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained prior to administration. Medical and drug history taken, no reason for exclusion NB Refer to PTHB Consent to Treatment and Examination Policy.
Criteria for exclusion (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)	Individuals for whom valid consent or best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent, see Chapter 2 of The Green Book). Several resources are available to inform consent (see written information to be given to individual or carer section). Individuals who: • are under one year of age, with the exception of those over 2 months of age requiring vaccination in accordance with Public health control and management of hepatitis A guidance • have had a confirmed anaphylactic reaction to a previous dose of hepatitis A vaccine or to any component of the vaccine (including trace components from the manufacturing process which may include formaldehyde, neomycin, ethanol, phenylalanine (see Cautions), polymixin B, egg products or chicken protein see SPCs) • are at increased risk of hepatitis A infection because of their occupation (except when administered by PTHB occupational health department to their own staff) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

	Refer to sections "Action to be taken if the individual is excluded" and "Action to be taken if the individual or carer declines treatment".
Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). VAQTA®, and VAQTA® Paediatric, syringe plunger stopper and tip cap contain dry natural latex rubber that may cause allergic reactions. As a precaution, if an individual has a history of severe (anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain latex should not be administered, unless the benefit of vaccination outweighs the risk of an allergic reaction to the vaccine. If possible, an alternative latex-free vaccine should be administered (such as AVAXIM® or Havrix®). Individuals who are immunosuppressed or have HIV infection may not make a full antibody response and revaccination on cessation of treatment/recovery may be required. This should be discussed with the appropriate specialist. **Phenylalanine and individuals with phenylketonuria (PKU)** Avaxim® and Avaxim® Junior vaccines contains 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® (or Avaxim® Junior) vaccines contains 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; as Havrix® Monodose® also has trace amino acids, VAQTA® would be the preferred option. Alternatively, seek advice from the specialist endocrinologist or metabolic physician looking after the individual with PKU to confirm they are content for them to have Avaxim® or Avaxim® Junior as applicable.

	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. Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding Leads
Action to be taken if the individual is excluded	Individuals under one year of age are not recommended pre-exposure hepatitis A vaccination. Individuals from 2 months of age may be considered for immunisation in accordance with Public health control and management of hepatitis A. Where vaccine is not recommended (and even when it is), the importance of stringent hygiene measures should be reinforced. Individuals who have had a confirmed anaphylactic reaction to a previous dose of hepatitis A vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management. Individuals who are solely at occupational risk of hepatitis A exposure should be referred to their employer's occupational health provider for vaccination (NB. PTHB occupational health department may work to this PGD for their own staff).

	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. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. 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. For PTHB Occupational Health Service- refer to Occupational Health Consultant as necessary and document advice given.
Action to be taken if the individual 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. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of The Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. Inform or refer to the GP as appropriate. Inform child health if appropriate – if any vaccination is declined for a child under 18 years, child health must be informed and the appropriate form completed. Where appropriate, complete the letter on the WPAS system and send to the GP.

	For PTHB Occupational Health Service- refer to Occupational Health Consultant as necessary and document advice given.
Arrangements for referral for medical advice	Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary. Document any advice given.

3. Description of treatment

Name, strength and formulation of drug	Hepatitis A (inactivated) vaccine (adsorbed), either: • **Havrix® Monodose®** vaccine, hepatitis A virus 1440 ELISA units in a pre-filled syringe or vial • **Havrix® Junior Monodose®** vaccine, hepatitis A virus 720 ELISA units in a pre-filled syringe or vial • **AVAXIM®**, hepatitis A virus, (GBM strain) 160 ELISA units, suspension for injection in a pre-filled syringe • **AVAXIM® Junior**, hepatitis A virus (GBM strain) 80 ELISA units suspension for injection in a prefilled syringe • **VAQTA® Adult**, hepatitis A virus (strain CR 326F) 50 units suspension for injection in a pre-filled syringe or vial • **VAQTA® Paediatric**, hepatitis A virus (strain CR 326F) 25 units suspension for injection in a pre-filled syringe or vial In the absence of an international standardised reference, the antigen content is expressed using an in-house method of the manufacturer. An appropriate vaccine product should be selected for the individual, see Dose and Frequency of Administration section.
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	Hepatitis A vaccine may be administered off-label to infant hepatitis A contacts from 2 months of age in accordance with Public health control and management of hepatitis A guidance.

	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 the All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance or any subsequent UKHSA update and any relevant local policies/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 or carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route and method of administration	Administer by intramuscular injection into the deltoid muscle of the upper arm (see 'The Green Book' Chapter 4). In small infants the anterolateral thigh may be used. The buttock should not be used because vaccine efficacy may be reduced. 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. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the Green Book Chapter 4. The suspension for injection may sediment during storage. Shake the vaccine well before administration to obtain a homogenous (Avaxim® and Avaxim® Junior) or slightly opaque, white suspension (Havrix® Monodose, Havrix® Junior Monodose, VAQTA® Adult and VAQTA® Paediatric).

<table>
<tr><td></td><td>The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, discard the vial in accordance with local procedures.

The vaccine SPCs provides further guidance on preparation and administration and are available from the electronic Medicines Compendium website: www.medicines.org.uk</td></tr>
<tr><td>Dose and frequency of administration</td><td>Current UK licensed hepatitis A vaccines contain different concentrations of antigen per millilitre (see table 1 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 SPC.

Table 1: Primary dosing information for Hepatitis A vaccines in the UK
<table>
<tr><th>Vaccine</th><th>Age (licenced use)</th><th>Dose*</th><th>Volume</th></tr>
<tr><td>Havrix Monodose®</td><td>16 years or over</td><td>1440 ELISA units</td><td>1.0ml</td></tr>
<tr><td>Havrix® Junior Monodose®</td><td>One to 15 years</td><td>720 ELISA units</td><td>0.5ml</td></tr>
<tr><td>AVAXIM®</td><td>16 years or over</td><td>160 ELISA units</td><td>0.5ml</td></tr>
<tr><td>AVAXIM® Junior</td><td>One to 15 years</td><td>80 ELISA units</td><td>0.5ml</td></tr>
<tr><td>VAQTA® Adult</td><td>18 years of age and older</td><td>50 units</td><td>1ml</td></tr>
<tr><td>VAQTA® Paediatric</td><td>One to 17 years</td><td>25 units</td><td>0.5ml</td></tr>
<tr><td colspan="4">*in the absence of an international standardised reference, the antigen content is expressed using an in-house method of the manufacturer</td></tr>
</table>
1. Primary course
A single dose (see table 1 above).</td></tr>
</table>

	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 2 (preferably 4) weeks before departure, but can be given up to the day of departure. **2. Reinforcing immunisation** For those who require long-term or subsequent protection against infection caused by hepatitis A virus, a single reinforcing dose appropriate to the individual's age (as per table 1 above) should be given, leaving a minimum interval of 6 to 12 months after the first dose. Studies have shown successful boosting can occur even when the second dose is delayed for several years, so a course does not need to be restarted. Hepatitis A containing vaccines may be used interchangeably, as appropriate, to complete a course. Specific details regarding recommended intervals when using the same and mixed brands of vaccine may be found in the product's SPC. Until further evidence is available on persistence of protective immunity, a further booster at 25 years is indicated for those at ongoing risk. For post-exposure prophylaxis, individuals requiring a second dose of vaccine should be vaccinated 6 to 12 months after the first dose, in line with advice from local health protection teams and Public health control and management of hepatitis A.
Duration of treatment	Dependent on vaccine schedule. See Dose and frequency of administration.
Quantity to be supplied and administered	Dose of 0.5ml or 1.0ml per administration depending on the age of the individual and vaccine product used, see Dose and frequency of administration and Table 1.
Supplies	Hepatitis A vaccine is not usually centrally supplied and should be obtained directly from manufacturers or their wholesalers unless otherwise advised by the UKHSA/Public Health Wales/Welsh Government.

	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.
Storage	Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Stability data indicate that Havrix® Monodose® and Havrix® Junior Monodose® vaccine is stable at temperatures up to 25°C for 3 days. 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 or any subsequent UKHSA update, or protocols for the storage and handling of vaccines (see All Wales Advisory document on Ordering Storage and Handling of Vaccines and Green Book Chapter 3). Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk), and via the Once for Wales Reporting System.
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 NHSE guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2023) and

	guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. Hepatitis A vaccine may be given at the same time as other vaccines and human normal immunoglobulin (HNIG). A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification and management of adverse reactions	Adverse reactions to hepatitis A vaccines are usually mild and confined to the first few days after immunisation. Very common reactions include mild and 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. Commonly reported adverse reactions include fever, malaise, headache, nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. 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: www.medicines.org.uk. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone must be available for immediate use. In case of anaphylaxis:- • Refer to adrenaline (epinephrine) PGD and anaphylaxis policy

	• Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO Hepatitis A virus (inactivated) vaccine (adsorbed).** • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers Report via Once for Wales Reporting System.
Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents and 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 should be informed. All significant adverse drug reactions and any administration errors must be recorded via PTHB Once for Wales Reporting System.
Written information to be given to individual or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Further information for printing and website links suitable for patients can be found on NHS 111 Wales and Public Health Wales Health Information Resources For resources in accessible formats and alternative languages, please visit Home- Health Publications. Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the SPC.
Advice and follow-up treatment	Give appropriate advice if medication is used off-label. Inform the individual, parent or carer of possible side effects and their management.

	The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme. When applicable, advise the individual, parent or carer when the subsequent dose is due. When administration is postponed advise the individual, parent or carer when to return for vaccination. Advise the individual, parent or carer of preventative measures to reduce exposure to hepatitis A including careful attention to food and water hygiene and scrupulous hand washing.
Special considerations and additional information	Ensure there is immediate access to resuscitation equipment including adrenaline (epinephrine) 1 in 1000 injection and access to a working telephone at the time of vaccination. Immunisation is recommended for MSM and they should also be informed about the risks of hepatitis A, and about the need to maintain high standards of personal hygiene during sex. There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since hepatitis A vaccine is an inactivated vaccine, the risks to the foetus are negligible and it should be given where there is a definite risk of infection. Hepatitis A vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis B, hepatitis C and hepatitis E viruses. NB. Consult the PTHB Occupational Health Immunisation policy for staff requiring immunisation.
Records	Record consultation details as required by local procedures. The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005

	• name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • 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 • administered via PGD, record PGD version number Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous. When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Services team (CHIS) (Child Health Records Department) using the appropriate documentation or pathway as required by any local or contractual arrangement (based in Brecon Hospital for under 5 years and Llandrindod Hospital for school age). 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.

4. Key references

Key references	Hepatitis A vaccine:

- Immunisation Against Infectious Disease: The Green Book Chapter 4, updated June 2012, Chapter 7, updated 10 January 2020, and Chapter 17, updated 07 February 2022. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Summary of Product Characteristic for AVAXIM®, Sanofi Pasteur. Last updated 30 September 2021 https://www.medicines.org.uk/emc/medicine/6206
- Summary of Product Characteristics for AVAXIM® Junior, Sanofi Pasteur. Last updated 20 June 2023. https://www.medicines.org.uk/emc/product/14684
- Summary of Product Characteristic for Havrix® Junior Monodose®, GlaxoSmithKline UK. Last updated 20 July 2023. https://www.medicines.org.uk/emc/medicine/2040
- Summary of Product Characteristic for Havrix® Monodose®, GlaxoSmithKline UK. Last updated 20 July 2023 https://www.medicines.org.uk/emc/medicine/2041
- Summary of Product Characteristic for VAQTA® Paediatric, MSD Ltd. Last updated 6 December 2022 https://www.medicines.org.uk/emc/product/1397/smpc
- Summary of Product Characteristic for VAQTA® Adult, MSD Ltd. Last updated 6 December 2022 https://www.medicines.org.uk/emc/medicine/6210
- NaTHNaC recommendations for hepatitis A vaccination for travel. Accessed 10 August 2023 https://travelhealthpro.org.uk/disease/70/hepatitis-a
- Public health control and management of hepatitis A guidance. Updated 16 November 2018

https://www.gov.uk/government/publications/hepatitis-a-infection-prevention-and-control-guidance

- NHS – travel vaccinations. Last updated 16 March 2023 https://www.nhs.uk/conditions/travel-vaccinations/

	General • NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023 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 • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance: responding to errors in vaccination storage, handling and administration. Updated 7 July 2022. https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition September 2017 • Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste

Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager may wish to use the competency checklist.*

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs 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.

Printed name of health professional	**Signature of health professional**	**Printed name of senior representative authorising health professional (Authorising Manager)**	**Signature of senior representative authorising health professional (Authorising Manager)**	**Date**

The authorising manager should retain a copy of the list and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU for audit purposes.
The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " " comments	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager, to the staff member, and to medicines management department (info.medicinesmanagement.powys@wales.nhs.uk), in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.