Public Health England

PHE publications gateway number: 2017497

PATIENT GROUP DIRECTION (PGD)

Administration of hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) to individuals requiring protection against hepatitis A and hepatitis B virus in accordance with national recommendations.

This PGD is for the administration of hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed) by registered nurses and pharmacists[1].

Reference no:	HepA/B vaccine PGD
Version no:	V01.00
Valid from:	01 November 2017
Review date:	01 May 2019
Expiry date:	31 October 2019

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 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)[2]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended.

Operation of this PGD is the responsibility of commissioners and service providers.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

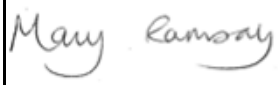
[1] This may include pharmacists working for NHS commissioned primary care providers, substance misuse or sexual health clinics. This PGD is not relevant to privately provided community pharmacy services.
[2] This includes any relevant amendments to legislation (eg 2013 No235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE HepA/B vaccine PGD	12 October 2017

1. PGD template development

This PGD template has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		12/10/2017
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		12/10/2017
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		12/10/2017

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Sema Mandal	Consultant Epidemiologist, Public Health England
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Matthew Olley	Immunisation Manager, Public Health England / NHS England London Region
Lisa Rees	Medicines Management Pharmacist, Bristol Clinical Commissioning Group
Tushar Shah	Pharmacy Advisor, NHS England London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East
Sharon Webb	Programme Manager/Registered Midwife, NBHS Infectious Diseases in Pregnancy Screening Programme, Public Health England

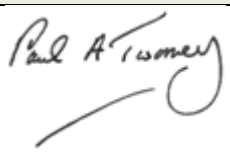
2. Organisational authorisations

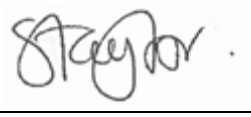
The PGD is not legally valid until it has had the relevant organisational authorisation.

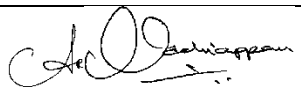
It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England (North) – Yorkshire and the Humber authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
The PGD has been authorised following NHS England's governance processes so that it meets the legal requirements for PGDs. The PGD has been authorised as a Yorkshire and the Humber Local Office wide PGD for the 'Administration of hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) to individuals requiring protection against hepatitis A and hepatitis B virus in accordance with national recommendations'. Authorisation is limited to those registered practitioners listed in Section 3 where they are **directly employed by organisations/providers commissioned by NHS England North (Yorkshire and the Humber).** In accordance with NICE Medicines Practice Guideline for PGDs, it is recommended as good practice that the PGD be formally adopted by the Governance Lead within each provider organisation signing the additional signatory's box (page 5). Individual practitioners working under the PGD must be authorised to do so by their employing organisation. This PGD has been reviewed by designated members of the NHSE Y&H PGD steering group.
Limitations to authorisation
Each practitioner is professionally accountable for ensuring they have undergone appropriate training, are competent to vaccinate and understand the contents of this PGD and the requirements of the individual vaccination programme, including route of administration, eligibility criteria, exclusions and contra-indications etc

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
NHS England North Yorkshire and the Humber Medical Director and Governance Lead	**Paul Twomey**		**17.08.18**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Locality Lead Pharmacist NHS Doncaster Clinical Commissioning Group	**Ning Wong**		**08.8.18**
Screening and Immunisation Coordinator – PHE Yorkshire and the Humber, NHS England North, Yorkshire	**Samantha Taylor**		**15.8.18**

and the Humber			
CCDC - PHE Yorkshire and the Humber	**Nachi Arunachalam**		**08.8.18**
Provider Organisation Governance Lead			

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team or the Health Protection Team Acute Response Centre (ARC): Contact Number: **0113 3860 300**

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses currently registered with the Nursing and Midwifery Council (NMC) • pharmacists[3] registered with the General Pharmaceutical Council (GPhC).
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction 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 patient group directions) • 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 for Immunisation Training (2005) • 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" • must be competent in the recognition and management of anaphylaxis • must have access to the Patient Group Direction 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). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England 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.

[3] This may include pharmacists working for NHS commissioned primary care providers, substance misuse or sexual health clinics. This PGD is not relevant to privately provided community pharmacy services.

4. 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 both hepatitis A and B infection in accordance with the recommendations given in Chapter 7, Chapter 17 and Chapter 18 of Immunisation Against Infectious Disease: "The Green Book".
Criteria for inclusion	Individuals over 1 year of age requiring Hepatitis A and Hepatitis B pre-exposure prophylaxis including individuals who: • intend to travel, where hepatitis A and hepatitis B vaccination is currently recommended for travel by NaTHNaC (see the Travel Health Pro website for country-specific advice on hepatitis A and hepatitis B vaccine recommendations) • have chronic liver disease • are haemophiliac or receive regular blood products • are at risk of hepatitis A and B infection because of their sexual behaviour, such as commercial sex workers or men who have sex with men (MSM) • are people who inject drugs (PWID) or those who are likely to progress to injecting (see Chapter 18)
Criteria for exclusion[4]	Individuals for whom no valid consent has been received. Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of hepatitis A or hepatitis B vaccine or to any component of the vaccine (including trace components from the manufacturing process such as neomycin) • are at increased risk of hepatitis A and hepatitis B infection solely because of their occupation • require solely hepatitis B vaccination for overseas travel purposes • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken	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/relevant specialist. 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.
Action to be taken if the patient is excluded Continued over page	Individuals who have had a confirmed anaphylactic reaction to a previous dose of hepatitis A or hepatitis B containing 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 and/or B exposure should be referred to their employer's occupational health

[4] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Action to be taken if the patient is excluded (continued)	provider for vaccination. Individuals requiring solely hepatitis B vaccination for overseas travel purposes should be administered hepatitis B in accordance with local policy. However, hepatitis B vaccination for travel is not remunerated by the NHS as part of additional services and is therefore not covered by this PGD unless hepatitis A vaccination is also indicated and a combined HepA/B vaccine is used. 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. In a GP practice setting, inform or refer to the GP or a prescriber as appropriate. Refer the individual to an alternative service or setting for vaccination if appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. In a GP practice setting, inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength & formulation of drug	Hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed) eg: • Twinrix® Adult, suspension for injection in a pre-filled syringe or vial, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20 micrograms • Twinrix® Paediatric, suspension for injection in a pre-filled syringe or vial, hepatitis A virus (inactivated) 360 ELISA units and hepatitis B surface antigen 10 micrograms • Ambirix®, suspension for injection in a pre-filled syringe, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20 micrograms An appropriate vaccine product should be selected for the patient see Dose and frequency of administration section.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	No
Route / method of administration	Administer by intramuscular injection. The deltoid region of the upper arm may be used in individuals over one year of age. 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 by deep subcutaneous injection to reduce the risk of bleeding (see "The Green Book" Chapter 4). However, this route of administration may result in suboptimal immune response to the vaccine. The suspension for injection may sediment during storage to leave a fine white deposit with a clear colourless layer. Shake the vaccine well before administration to obtain a uniform turbid 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. The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk

<table>
<tr><td>Dose and frequency of administration</td><td>Current UK licensed HepA/B vaccines contain different concentrations of antigen (see table below).
<table>
<tr><th>Vaccine</th><th>Age (licenced use)</th><th>Dose HepA</th><th>Dose HepB</th><th>Volume</th></tr>
<tr><td>Twinrix® Adult</td><td>16 years or over</td><td>720 ELISA units</td><td>20 micrograms</td><td>1.0ml</td></tr>
<tr><td>Twinrix® Paediatric</td><td>One to 15 years</td><td>360 ELISA units</td><td>10 micrograms</td><td>0.5ml</td></tr>
<tr><td>Ambirix®</td><td>One to 15 years</td><td>720 ELISA units</td><td>20 micrograms</td><td>1.0ml</td></tr>
</table>
Licensed dose to provide Hepatitis A and B protection
Twinrix® Adult: 1ml administered at 0, 1 and 6 months*.
Where insufficient time is available to allow the standard 0, 1, 6 month* schedule to be completed, a schedule of three intramuscular injections given at 0, 7 and 21 days* may be used. When this schedule is applied, a fourth dose is recommended 12 months after the first dose.
Twinrix® Paediatric: 0.5ml administered at 0, 1 and 6 months*
Ambirix®: 1ml administered at 0 and 6-12 months*
*where 0 is the elected start date of the course
For travellers, vaccine should preferably be given at least two weeks before departure, but can be given up to the day of departure. Although antibodies may not be detectable for 12–15 days following administration of hepatitis A vaccine, the vaccine may provide some protection before antibodies can be detected using current assays.</td></tr>
<tr><td>Duration of treatment</td><td>Dependent of vaccine schedule, see Dose and frequency of administration.</td></tr>
<tr><td>Quantity to be supplied / administered</td><td>Dose of 0.5ml to 1.0ml per an administration depending on the age of the individual and vaccine product used, see Dose and frequency of administration.</td></tr>
<tr><td>Supplies</td><td>HepA/B vaccine is not usually centrally supplied and should be obtained directly from manufacturers/wholesalers.
Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).</td></tr>
<tr><td>Storage</td><td>Store at between +2°C to +8°C.
Store in original packaging in order to protect from light.
Do not freeze.</td></tr>
<tr><td>Disposal</td><td>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant ‘sharps’ box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).</td></tr>
</table>

Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. May be given at the same time as other vaccines. 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 & management of adverse reactions	Adverse reactions to hepatitis vaccines are usually mild and confined to the first few days after immunisation. The most common reactions are mild, transient pain, redness and swelling at the injection site. Other commonly reported reactions to hepatitis A vaccination include other injection site reactions (haematoma, pruritus, bruising), general symptoms such as fever, malaise, fatigue, irritability, drowsiness, headache, and gastrointestinal symptoms including nausea, diarrhoea 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
Reporting procedure of adverse reactions	Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme at: http://yellowcard.mhra.gov.uk Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Patient advice / follow up treatment	Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek medical advice in the event of an adverse reaction. When applicable, advise individual/carer when the subsequent dose is due. When administration is postponed advise the individual/carer when to return for vaccination. Advise individuals administered the vaccine subcutaneously that this route of administration may result in suboptimal immune response to the vaccine. Advise individuals of preventative measures to reduce exposure to hepatitis A (ie careful attention to food and water hygiene and scrupulous hand washing, further details can be found on www.nhs.uk) and preventative measures to reduce exposure to hepatitis B (ie avoiding exposure to blood and bodily fluids, further details can be found on www.nhs.uk).

Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since HepA/B 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. Monovalent vaccine is preferred where vaccination is recommended post-exposure or for outbreak/incident management. During times of monovalent hepatitis vaccine shortages HepA/B vaccine may be recommended by PHE as an alternative to monovalent hepatitis vaccine. This use is not covered by this PGD; see the PHE HepA/B (Temp) PGD. HepA/B vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis C and hepatitis E viruses.
Records	Record: • that valid informed consent was given • name of individual, 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 • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled immunisers record 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 Systems team (Child Health Records Department) using the appropriate documentation/pathway as required by any local or contractual arrangement. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	Product • Immunisation Against Infectious Disease: The Green Book Chapter 4, last updated June 2012, Chapter 7, last updated October 2016, Chapter 17, last updated December 2013 and Chapter 18, last updated June 2017. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Twinrix® Adult, GlaxoSmithKline UK. Last updated 24 November 2016. https://www.medicines.org.uk/emc/medicine/2061 • Summary of Product Characteristic for Twinrix® Paediatric, GlaxoSmithKline UK. Last updated 24 November 2016. https://www.medicines.org.uk/emc/medicine/2062 • Summary of Product Characteristic for Ambirix®, GlaxoSmithKline UK. Last updated 23 November 2016. https://www.medicines.org.uk/emc/medicine/20491 • NaTHNaC resources. Accessed 10 August 2017. https://travelhealthpro.org.uk/countries • Hepatitis A infection: prevention and control guidance including PHE hepatitis A vaccination temporary recommendations and Public health control and management of hepatitis A guidance. Public Health England. Last updated 4 July 2017. https://www.gov.uk/government/publications/hepatitis-a-infection-prevention-and-control-guidance • Hepatitis B: vaccine recommendations during supply constraints including PHE hepatitis B vaccination in adults and children: temporary recommendations, last updated 21 August 2017, and What to do if you have to wait for a dose of hepatitis B vaccine: advice for patients, last updated 7 August 2017. https://www.gov.uk/government/publications/hepatitis-b-vaccine-recommendations-during-supply-constraints **General** • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • British National Formulary (BNF) and British National Formulary for Children (BNF-C) www.BNF.org https://www.medicinescomplete.com/mc/bnf/current/PHP88121-hepatitis-a-and-b-vaccine.htm • National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. https://www.nice.org.uk/guidance/mpg2/resources • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-

Continued over page

Key references (continued)	005336 • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines • 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

7. Practitioner authorisation sheet

HepA/B vaccine PGD v01.00 Valid from: 01/11/2017 Expiry: 31/10/2019

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 **INSERT NAME OF ORGANISATION** 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.