



PHE publications gateway number: GW-1012

Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) Patient Group Direction (PGD)

This PGD is for the administration of pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) (PCV13) to individuals from 12 weeks to under 2 years of age in accordance with the national immunisation programme for active immunisation against pneumococcal disease and to individuals from 6 weeks of age recommended PCV13 in response to an outbreak of pneumococcal disease.

This PGD is for the administration of PCV13 by registered healthcare practitioners identified in [Section 3](#), subject to any limitations to authorisation detailed in [Section 2](#).

Reference no: PCV PGD
Version no: v03.00
Valid from: 26 February 2020
Review date: 1 September 2021
Expiry date: 28 February 2022

Public Health England has developed this PGD to facilitate the delivery of publicly-funded immunisation 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)¹. **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 within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

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-patient-group-direction-pgd>


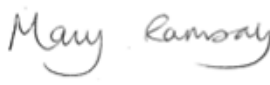

Any concerns regarding the content of this PGD should be addressed to:
immunisation@phe.gov.uk

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	19 January 2016
V02.00	PHE PCV PGD amended to: <ul style="list-style-type: none"> • include early administration from 6 weeks of age • include administration for the management of outbreaks • include additional healthcare practitioners in Section 3 • add paragraph on patient consent to the off-label section • reference the protocol for ordering storage and handling of vaccines • include additional stability data from products SPC • refer to PHE vaccine incident guidance within the off-label and storage sections • include rewording, layout and formatting changes for clarity and consistency with other PHE PGDs 	28 November 2018
V03.00	PHE PCV PGD amended to: <ul style="list-style-type: none"> • reflect the 1+1 schedule for individuals born on or after 1 Jan 2020 and immunisation from 12 weeks of age • refer to the PCV Risk Groups PGD for the immunisation of individuals with asplenia, splenic dysfunction, complement disorder and severe immunocompromise • include rewording, layout and formatting changes for clarity and consistency with other PHE PGDs 	20 December 2019

1. PGD development

This PGD 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 and Countermeasures, PHE		20/12/2019
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		14/01/2020
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		20/12/2019

This PGD 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
Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
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 (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Co-ordinator, Public Health England / NHS England and NHS Improvement Leicestershire, Lincolnshire and Northamptonshire
Tushar Shah	Pharmacy Advisor, NHS England and NHS Improvement London Region
Sharon Webb	Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England


2. Organisational authorisations

This 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 and NHS Improvement - Midlands authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Primary Care services and all organisations commissioned to, or contracted by, NHS England and NHS Improvement – Midlands to provide immunisation services. Each provider organisation using this PGD should formally adopt it via a signature from the provider's authorised governance lead/s or lead practitioner
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director NHS England and NHS Improvement - Midlands	Ken Deacon		10/2/20

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to: The Screening and Immunisation Teams, NHS England and NHS Improvement - Midlands
Derbyshire/Nottinghamshire <mailto:ENGLAND.SCRIMMS@nhs.net>
Shropshire/Staffordshire <mailto:PHE.sssit@nhs.net>

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

<p>Qualifications and professional registration</p>	<p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> • 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 Health and Care Professions Council (HCPC) <p>The practitioners above must also fulfil the Additional requirements detailed below.</p> <p>Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<p>Additional requirements</p>	<p>Additionally practitioners:</p> <ul style="list-style-type: none"> • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), 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 • 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 PGD and associated online resources • should fulfil any additional requirements defined by local policy <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
<p>Continued training requirements</p>	<p>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).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information.</p> <p>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.</p>

4. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<p>Indicated for the active immunisation of individuals from 12 weeks to under 2 years of age for the prevention of pneumococcal disease in accordance with the national immunisation programme and recommendations given in Chapter 25 of Immunisation Against Infectious Disease: the 'Green Book' and to individuals from 6 weeks of age recommended PCV13 in accordance with PHE Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals.</p>
<p>Criteria for inclusion</p>	<p>Individuals from 12 weeks to under 2 years of age who:</p> <ul style="list-style-type: none"> • require a primary dose of PCV13 • require a reinforcing booster dose of PCV13 against pneumococcal disease <p>Individuals from 6 weeks of age recommended PCV13 in accordance with PHE Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals.</p> <p>Note: Individuals with an underlying medical condition which puts them at increased risk from pneumococcal disease may require additional vaccination outside the inclusion criteria for this PGD - see PCV Risk Groups PGD and Chapter 25 of the 'Green Book'.</p>
<p>Criteria for exclusion²</p>	<p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are less than 12 weeks of age, unless PCV13 is recommended in response to an outbreak of pneumococcal disease • are aged 2 years and over, unless PCV13 is recommended in response to an outbreak of pneumococcal disease • have had a confirmed anaphylactic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine, including diphtheria toxoid • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
<p>Cautions including any relevant action to be taken</p>	<p>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects and additional doses may be recommended, see the 'Green Book' Chapter 7 and Chapter 25 and the PCV Risk Groups PGD.</p> <p>Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. Very premature infants (born ≤ 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hrs.</p>

² 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
 PCV PGD v03.00 Valid from: 26/02/2020 Expiry: 28/02/2022

<p>Action to be taken if the patient is excluded</p>	<p>If aged less than 12 weeks and born on or after 1/1/2020 advise to return for routine immunisation at 12 weeks of age and provide an appointment as appropriate. The PCV PGD V02.00 may continue to be used until 27/3/2020 to administer the first priming dose to individuals born on or before 31 December 2019 and less than 12 weeks of age. Immunisation can be administered to infants from 6 weeks of age if at increased risk of exposure due to an outbreak (see Dose and frequency of administration).</p> <p>If aged 2 years and over routine immunisation with pneumococcal vaccine is not indicated. If the individual is at increased risk of pneumococcal disease, in accordance with the 'Green Book' Chapter 7 and Chapter 25, refer to the PCV Risk Groups PGD.</p> <p>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.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p>
<p>Action to be taken if the patient or carer declines treatment</p>	<p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration.</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the GP as appropriate.</p>
<p>Arrangements for referral for medical advice</p>	<p>As per local policy</p>

<p>Route / method of administration continued</p>	<p>The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
<p>Dose and frequency of administration</p> <p>Continued over page</p>	<p>Single 0.5ml dose per administration</p> <p>Routine Childhood Immunisation Schedule</p> <p><u>Infants born on or after 1 January 2020</u>, and who do not have asplenia, splenic dysfunction, complement disorder or severe immunocompromise³, should be offered a 1+1 PCV schedule, that is:</p> <ul style="list-style-type: none"> • a single priming dose of PCV13 to be administered from 12 weeks of age, followed by • a PCV13 booster dose to be administered at one year old, on or soon after their first birthday and before 2 years of age. <p>Since the immunogenicity of PCV13 will be lower if given at a younger age, any dose given before 12 weeks of age should not be counted as the single priming dose for the 1+1 schedule and the routine PCV dose should be given once the infant reaches 12 weeks of age, leaving a minimum 4-week interval between the priming dose and any preceding dose.</p> <p><u>Infants born on or before 31 December 2019</u>, should continue to be offered a 2+1 PCV schedule, that is:</p> <ul style="list-style-type: none"> • a 2-dose priming schedule of PCV13 vaccine with an 8-week interval (routinely scheduled at 8 and 16 weeks of age) and • a booster dose to be administered at one year old, preferably on or soon after their first birthday and before 2 years of age. <p>Note: Individuals with asplenia, splenic dysfunction, complement disorder and severe immunocompromise³ also continue to require a 2-dose priming schedule of PCV13, a booster at one year old and an additional booster of PCV after the booster dose administered at one year old. Individuals with asplenia, splenic dysfunction, complement disorder and severe immunocompromise³ should be vaccinated in accordance with the PCV Risk Groups PGD and Chapter 7 and Chapter 25 of the 'Green Book' and the first dose given as soon as possible ideally with the first primary immunisations if diagnosis is known.</p> <p>Unimmunised or partially immunised children</p> <p>Unimmunised or partially immunised infants <u>born on or after 1 January 2020</u> and who do not have asplenia, splenic dysfunction, complement disorder or severe immunocompromise³ who present late for vaccination, and before one year of age, should receive a primary dose of PCV13 before the age of one year, and a booster dose at one year of age, leaving an 8-week interval between the primary PCV13 dose and the booster*.</p> <p>Unimmunised or partially immunised infants <u>born on or before 31 December 2019</u> who present late for vaccination should receive two doses of PCV13 8 weeks apart* before the age of one year (if possible), and a further dose at one year of age (8 weeks after the last PCV13 dose)*.</p> <p>*The immunisation interval may be reduced to 4-weeks if necessary to ensure the immunisation schedule is completed.</p>

³ Examples of severe immunocompromise include bone marrow transplant patients, patients with acute and chronic leukaemia, multiple myeloma or genetic disorders affecting the immune system (such as IRAK-4, NEMO)

<p>Dose and frequency of administration continued</p>	<p>An unimmunised or partially immunised child aged between one year and under two years of age should have a single dose of PCV13.</p> <p>See flow chart for vaccination of individual with uncertain or incomplete immunisation status.</p> <p>Management of a pneumococcal disease clusters and outbreaks in closed settings with high-risk individuals.</p> <p>A single dose may be administered to adults and children from 6 weeks of age who have not received PCV13 vaccine in the preceding 4 weeks and who are identified as requiring PCV13 immunisation in accordance with PHE Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. Note: PPV23 would ordinarily be used in an outbreak with the exception of serotype 6A/6C disease, individuals under 2 years of age, and where PPV23 is unavailable or otherwise inappropriate.</p>
<p>Duration of treatment</p>	<p>See Dose and frequency of administration section above</p>
<p>Quantity to be supplied / administered</p>	<p>Single 0.5ml dose per administration.</p>
<p>Supplies</p>	<p>Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).</p>
<p>Storage</p>	<p>Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.</p> <p>Prevenar® 13 is stable at temperatures up to 25°C for four days. At the end of this period Prevenar® 13 should be used or discarded. These data are intended to guide health care professionals in case of temporary temperature excursions.</p> <p>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 PHE Vaccine Incident Guidance.</p>
<p>Disposal</p>	<p>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 regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).</p>
<p>Drug interactions</p>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p>May be given at the same time as other vaccines.</p>
<p>Continued over page</p>	

Drug interactions continued	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	<p>Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the injection site.</p> <p>The most commonly reported adverse reactions include vaccination-site reactions, fever, irritability, decreased appetite, increased and/or decreased sleep, rash, vomiting and diarrhoea.</p> <p>Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Reporting procedure of adverse reactions	<p>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 on: http://yellowcard.mhra.gov.uk</p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p>
Written information to be given to patient or carer	<p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> • A guide to immunisations for babies up to 13 months of age • A quick guide to childhood immunisation for the parents of premature babies <p>Available from: www.gov.uk/government/collections/immunisation</p>
Patient advice / follow up treatment	<p>Inform the individual/parent/carer of possible side effects and their management.</p> <p>The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>Advise the individual/parent/carer when any subsequent immunisations are due.</p> <p>When administration is postponed advise the individual/parent/carer when to return for vaccination.</p>
Special considerations / additional information	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.</p> <p>Individuals with asplenia, splenic dysfunction, complement disorder and severe immunosuppression³ are at increased risk of pneumococcal disease and require additional doses of PCV13 in accordance with the 'Green Book' Chapter 7 and Chapter 25. The administration of PCV13 for these individuals is covered by the PCV Risk Groups PGD.</p>
Records Continued over page	Record: <ul style="list-style-type: none"> • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser

<p>Records continued</p>	<ul style="list-style-type: none"> • 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) <p>Records should be signed and dated (or a password controlled immuniser's record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>The local Child Health Information Services team must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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6. Key references

Key references	<p>Pneumococcal conjugate vaccine</p> <ul style="list-style-type: none">• Immunisation Against Infectious Disease: The Green Book Chapter 25. January 2020. https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25• Summary of Product Characteristics for Prevenar® 13 suspension for injection, Pfizer Ltd. 16 December 2019. http://www.medicines.org.uk/emc/medicine/22689• Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. 16 December 2019. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status• Changes to the infant pneumococcal conjugate vaccine schedule: Information for healthcare practitioners. Public Health England. 13 December 2019. https://www.gov.uk/government/publications/pneumococcal-vaccination-guidance-for-health-professionals• Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals. Public Health England. https://www.gov.uk/government/publications/managing-clusters-of-pneumococcal-disease-in-closed-settings <p>General</p> <ul style="list-style-type: none">• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources• PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation• PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors
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7. Practitioner authorisation sheet

PCV PGD v03.00 Valid from: 26/02/2020 Expiry: 28/02/2022

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 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 PGD 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.