Cheshire and Wirral Partnership NHS
NHS Foundation Trust

Document level: Trustwide (TW)
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Patient Group Directions (PGDs)

Lead executive	Medical Director
Authors details	Senior Clinical Pharmacist - Pharmacy Department

Type of document	Policy
Target audience	All clinical staff
Document purpose	To highlight the proposal, development, review and authorising process relating to the use of PGDs in an area of clinical practice; and provide PGD development template documentation.

Approving meeting	Medicines Management Group	Date 14-Sep-14
Implementation date	Sep-14 followed by an annual compliance review	

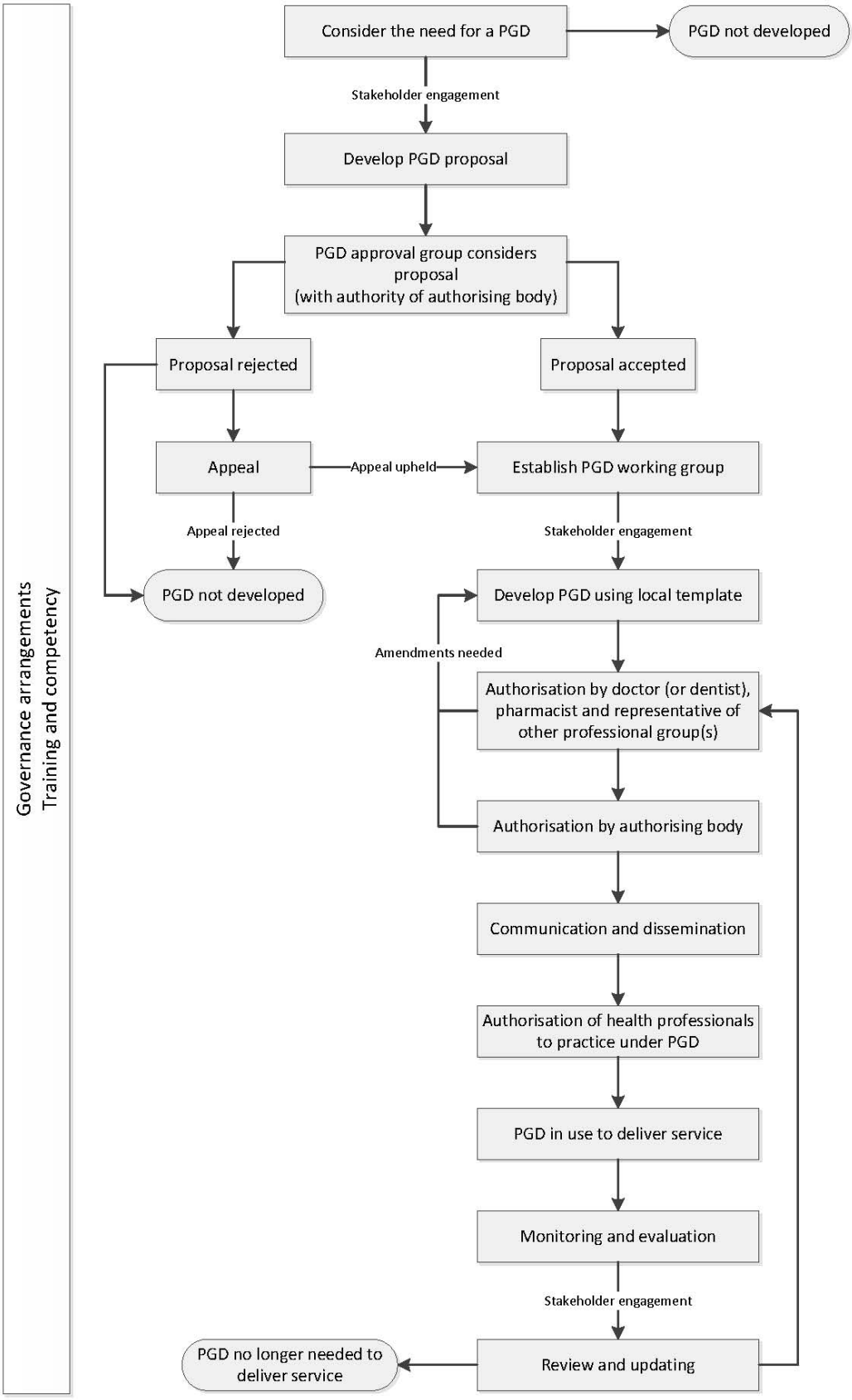
CWP documents to be read in conjunction with	
HR6	Mandatory Employee Learning (MEL) policy
IC3	Standard universal infection control precaution policy
CP3	Health records policy
MP1	Medicines policy

Document change history	
What is different?	1. Major changes to reflect NICE medicine practice guidance Aug-13 2. Major changes to reflect organisational change Apr-12 3. Update with new PGD template
Appendices / electronic forms	New Appendix 1 Patient Specific Direction (PSD) New Appendix 2 To PGD or not to PGD flowchart New Appendix 3 New Patient Group Direction (PGD) proposal form New Appendix 4 PGD template - incorporated into the document New Appendix 5 Patient Group Direction (PGD) approval checklist New Appendix 6 Managerial contents of PGD sheet New Appendix 7 External Patient Group Direction (PGD) authorisation
What is the impact of change?	To have a more robust governance structure around PGDs including a PGD sub group feeding into MMG.

To view the documents Equality Impact Assessment (EIA) and see who the document was consulted with during the review please click here

Content

Quick reference flowchart for the development of patient group directions
For quick reference the guide below is a summary of actions required.



1. Introduction

This policy has been updated to reflect NICE: Medicine practice guidance – Patient Group Directions 2013 and highlights the processes for identifying, proposing, developing, reviewing and authorising patient group directions within the Trust.

Patient Group Directions (PGD's) provide a legal framework that allows the supply and/or administration of a specified medicine(s), by named authorised health professionals, to a pre-defined group of patients needing treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber. Using a PGD is **not** a form of prescribing.

The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration of medicines under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising safety), and where it is consistent with appropriate professional relationships and accountability. Furthermore consideration should be given to ensure the PGD will deliver effective patient care that is appropriate in a pre-defined clinical situation

It will be the responsibility of the Trusts' PGD sub-group, on behalf of the Trust Medicines Management Group to oversee all aspects covered within this policy.

The Trust Medicines Management Group (MMG) will be responsible for approving new and reviewed PGDs and the Medical Director; Quality, Compliance and Assurance will have designated responsibility for signing PGDs on behalf of Cheshire and Wirral Partnership NHS Foundation Trust, the authorising body.

2. Definitions

A PGD is defined in Health Service Circular (HSC 2000/026) as:

- '*A written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment*.

3. Exclusions

This policy does not cover Patient Specific Directions (PSDs). These are covered within the medicines management policy and where a PSD exists, there is no need for a PGD.

(A PSD is a traditional written instruction, from any qualified prescriber (doctor, dentist, nurse or pharmacist independent prescriber) for medicines to be supplied or administered to a named patient. A PSD may take the form of an instruction in the patient's notes, written on an in-patient medicine chart, or written on an authorisation to administer form in the community setting. The majority of medicines are supplied or administered using this process).

Occasionally where a medicine is administered against a PGD, the branded preparation listed within the PGD becomes unavailable and it is then appropriate to use a PSD to deliver an alternative. A template PSD is listed in appendix 1 for those departments that do not routinely use Trust medicine charts or authorisation to administer forms e.g. Occupational Health.

4. Procedure

The following will be covered within this policy:

- Patient group direction sub-group;
- Patient group direction tracker;
- Considering the need for a new patient group direction;
- Obtaining agreement to develop a patient group direction;
- Developing patient group directions;
- Authorising patient group directions;
- Using patient group directions;
- Reviewing and updating patient group directions;
- Archiving expired patient group directions;

- Appeals process;
- Adopting patient group directions from external authorising bodies;
- Training and competency.

4.1 Patient group directions sub-group

This multidisciplinary group will have delegated lines of responsibility from the Trust MMG to ensure that agreement to develop a new PGD, or review of an existing PGD, will follow a robust and transparent process, engage with relevant stakeholders, clinical groups, patients and commissioners

Members of the sub group will be trained and competent in all aspects of PGDs.

4.2 PGD tracker spreadsheet

On behalf of the PGD sub group the Pharmacy department will hold a PGD tracker spreadsheet listing all current and expired PGDs that are or have been used within the Trust. It will detail the clinical service and service lead, the PGD main author, link pharmacist and working group members involved in writing the PGD and its review date. The tracker will include an electronic copy of the PGD plus the authorisation signature sheet. The tracker will be used by the PGD subgroup to highlight to the relevant clinical service lead any PGDs approaching expiry and request commencement of the review process.

Proposals for new PGDs will be logged on the tracker.

4.3 Considering the need for a new PGD

4.3.1 Assessment of suitability

Where a new PGD is identified for a clinical service unit, the clinical lead should refer to the flowchart "to PGD or not to PGD" (see appendix 2*)* to determine if a PGD is appropriate and legally permitted; and refer to the tracker via the Pharmacy department to avoid unnecessary duplication of PGDs. They must then submit a new PGD proposal to the PGD sub group. The proposal must include:

- The title of the PGD;
- Details of the proposer and other individual people who would be involved in developing and authorising the PGD;
- Details of the organisation delivering the service (if this organisation is not the authorising body);
- The setting where the PGD would be used;
- The condition to be treated, considering patient inclusion and/or exclusion criteria;
- Benefits to patient care;
- Potential risks to patient safety;
- Details of medicine(s) to be supplied and/or administered, including dosage;
- Quantity, formulation and strength, route and frequency of administration, duration of treatment and whether it is included in the local formulary;
- Health professional groups who would work under the PGD, including training and competency needs;
- Current and / or future service provisions for supplying and/or administering the medicine(s), including its position within the care pathway;
- Evidence to support the proposal;
- Resources needed to deliver the service;
- A timescale for developing the PGD.

The proposal must then be submitted to the PGD sub-group for consideration to develop.
A template PGD proposal form is listed in appendix 3.

4.4 Obtaining agreement to develop a new PGD

The PGD sub-group must be satisfied the new PGD listed in the proposal complies with the following criteria before approving its development:

- The medicine(s) listed can be supplied or administered within the remit of a PGD, and other options for supplying and/or administering the medicine(s) have been explored;
- The service proposing the PGD has appropriate registered health professionals, adequate resources available for service delivery, a robust local process and clear governance arrangements in place to work within the remit of the proposed PGD;
- The PGD will deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety;
- The views of stakeholders, such as clinical groups, patients and the public, and the provider or commissioning organisation have been considered and decisions are aligned with local clinical commissioning frameworks;
- Any training and competency needs are addressed for those staff expecting to work within the PGD;
- The need for appropriately labelled packs and safe storage can be met. Requirements for the procurement and supply of over-labelled medicines need to be considered and the proposer aware of a potential lag time between PGD approval and implementation due to specialist procurement;
- Adequate resources are available to ensure that processes are followed within any locally agreed timeframe.

The PGD sub group will invite the proposer to present their proposal at the next scheduled PGD sub group meeting and a written communication will be sent within two weeks to inform of the outcome of the proposal submission. The two week period can be used for clarifying questions raised within the proposal if necessary. If the proposal is rejected the rationale for the decision will be detailed. Appropriate stakeholders will also be informed of any decisions.

If the proposal is rejected, the proposer can re-submit at the next scheduled subgroup meeting. The proposal must include additional information to address concerns raised within the original rejection.

Where a new PGD proposal is subject to time constraints and consideration is required out of the routine scheduled PGD subgroup meetings, the Chair of the PGD subgroup will have authority to approve development.

4.5 Developing a new PGD

4.5.1 PGD working group

Following approval to develop a new PGD, the PGD subgroup, along with the proposer, will identify members of a PGD multidisciplinary working group responsible for the development, consultation and review of the PGD. The PGD working group will have a named lead author and must include a doctor (or dentist), a pharmacist and a healthcare professional who will practice under the PGD, plus any other relevant healthcare professionals.

Where it is not possible to name a doctor for the working group, another lead clinician e.g. non-medical prescriber can be dominated to be a member of the PGD working group.

Any training and competency needs of the working group need to be identified by the PGD sub-group.

Each new PGD must have a named PGD working group; the group may be responsible for more than one PGD.

4.5.2 Antimicrobials

Where a PGD includes an antimicrobial, input from a local microbiologist must be sought. This is important so that compliance with local and national strategies to combat antimicrobial resistance are not compromised.

Antimicrobials must only be included in a PGD when:

- Clinically essential and reflects clinical best practice or national guidance;

- It is supported by a local specialist in microbiology and is clearly documented;
- There is assurance the PGD will be monitored and reviewed regularly.

4.5.3 Consultation

The PGD working group must demonstrate that full consultation has taken place with relevant clinicians, stakeholders and commissioning groups where appropriate.

4.5.4 PGD template

CWP will adopt the NICE Medicine Practice Guidance, 2013 PGD template for the development and review of PGDs in the Trust. By using this template, the PGD working group can ensure that all legally required information is captured and complies with legislation and good practice, and there is consistency of presentation across the Trust.

Considerations for completing the PGD:

The PGD template can be found in appendix 4 – All sections of the template must be completed in full to ensure the PGD complies with the law.

- Key references such as NICE guidance, Summary of Product Characteristics and other national guidance should be listed within appendix A of the PGD. Reference any documents referred to within the PGD, giving the author[s], title, publication source and date. If accessed electronically include date accessed;
- Additional sections can be added if the PGD includes more than one medicine;
- Additional appendices should be kept to a minimum and signposted within additional information;
- Signatures can be electronic;
- The lead author is nominated from the PGD working group;
- The **red text** is for guidance and should be deleted as the document is completed;
- The **black** text is standard to all PGDs and should be left in if applicable to the medicine / situation;
- Checklists or consent forms may be added if appropriate to assist with the patient consultation;
- Abbreviations or Latin terms must not be used;
- It is a legal requirement to keep records of administration / supply under PGD for audit purposes – specify in the PGD specific records to be maintained.

Once the new PGD has been completed and signed by the working group it must be submitted to the Chair of the PGD subgroup for final checking, prior to submission to Medicines Management Group for approval and authorisation.

A PGD approval checklist must be submitted with the PGD to Medicines Management Group. See appendix 5

5. The review process for existing PGDs

Utilising the PGD tracker, the PGD sub group will identify PGDs at least six months prior to the review date of the current version, and notify the service lead working within the PGD that a review is required. The PGD sub group and service lead will identify the PGD working group responsible for the review.

The review should determine whether the PGD remains the most appropriate option to deliver the service. This should be informed by local monitoring and evaluations, frequency of use of the PGD, views of relevant stakeholders and health professionals working under the PGD.

Where CWP are commissioned to provide a service, and utilise a PGD for part or full delivery of the service, CWP should show the Commissioners the relevant PGD as part of the review process.

An unscheduled review of a PGD may be required when responding to:

- Changes in legislation or local organisations;
- Important new evidence or guidance that changes the PGD, such as new NICE guidance;
- New information on drug safety;
- Changes in the summary of product characteristics;
- Changes to the local formulary.

Once a PGD has been reviewed and signed by the working group it must be submitted to the Chair of the PGD subgroup for final checking, prior to submission to Medicines Management Group (MMG) for approval and authorisation.

A PGD approval checklist must be submitted with the PGD to MMG. See appendix 5

6. Approval and authorisation process

MMG will utilise the PGD approval checklist (appendix 5) to ensure all legal aspects of a PGD are fulfilled prior to approval.

Following MMG approval and authorisation, a copy of the original signed document must be sent to the service lead along with a letter from the Chief Pharmacist notifying approval. These can be in electronic and scanned format. The service lead, via line managers where appropriate, must then arrange to obtain individual signatures from authorised staff working within the PGD. Each staff member must sign a copy of the completed PGD, along with their line manager, and also both must sign the managerial contents list (appendix 6).

The list of authorised staff must be accessible for viewing at all times and held by the line manager or service lead. The PGD sub group will hold a list of line managers and service leads responsible for collating the signatures of their authorised staff.

Authorised staff should keep a copy of their fully signed PGD, and line managers/service leads must keep a copy of the approved PGD with the list of authorised staff working within the PGD.

The original signed copy of the PGD will be retained by the Pharmacy department.

Electronic versions must be placed on the CWP intranet (http://nww.cwp.nhs.uk/medicinesandpharmacyservices/Pages/PatientGroupDirections.aspx) and the PGD tracker updated accordingly by the pharmacy team.

The review date for a PGD will be considered on a case–by-case basis. There is no legislation governing PGD expiry dates currently, but the recommendation from Health Service Circular (HSC 2000/026) states that ‘generally, a direction should be reviewed every two years’.

CWP will implement up to a maximum two year review date from the date of MMG authorisation and implementation for new and reviewed PGDs (with the exception of the Influenza PGD which is reviewed annually to reflect Department of Health requirements). Any changes that are necessary to the direction before its review date must be submitted to the Trust’s MMG for re-approval.

7. Archiving expired PGDs

The PGD sub group will be responsible for ensuring that signed originals of expired and superseded PGD’s are archived in line with patient records. PGDs that apply to adults must be kept for a minimum of 8 years and those that apply to children must be kept for 25 years.

The pharmacy department will retain any expired and superseded PGDs.

8. Appeals process

The PGD subgroup will work with MMG and the PGD working group to resolve issues that arise from a PGD being refused approval. They will define an acceptable timescale and action plan.

9. Adopting PGD from other authorising bodies

Where another authorising body develops and approves a PGD that will be recommended and suitable for use within CWP, for example to support the annual national influenza vaccination programme and the childhood immunisation programme, MMG can authorise the adoption of the external PGD. The authorisation signatures within the 'PGD adoption by the provider' section on the PGD template will be completed by the Chair of MMG and Medical Director.

CWP will adopt the review date cycle of the authorising body providing the PGD.

An external authorisation sheet can be used for external PGDs not presented in NICE template format (appendix 7)

10. Training and competency

There are national resources available to support staff in their training and competency needs around PGDs.

The national PGD website: http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/

NPC 2009 Patient Group Directions – a practical guide and framework of competencies for all professional using patient group directions:
http://www.npc.nhs.uk/search/searchresults.php?cx=015644094789835009003%3A1u0dt86ay1m&cof=FORID%3A10&ie=UTF-8&q=patient+group+directions

Putting NICE guidance into practice - competency frameworks:
http://www.nice.org.uk/mpc/medicinespracticeguidelines/MPG2.jsp

CWP will provide specific patient group direction training when this is identified, and the use of patient group directions will be included within the immunisation and vaccination annual updates.

Appendix 1 – Patient Specific Direction (PSD)

Patient's name		DOB	
Allergies and sensitivities			

For occupational health use only – where applicable			
Job title		Department	
Employer			

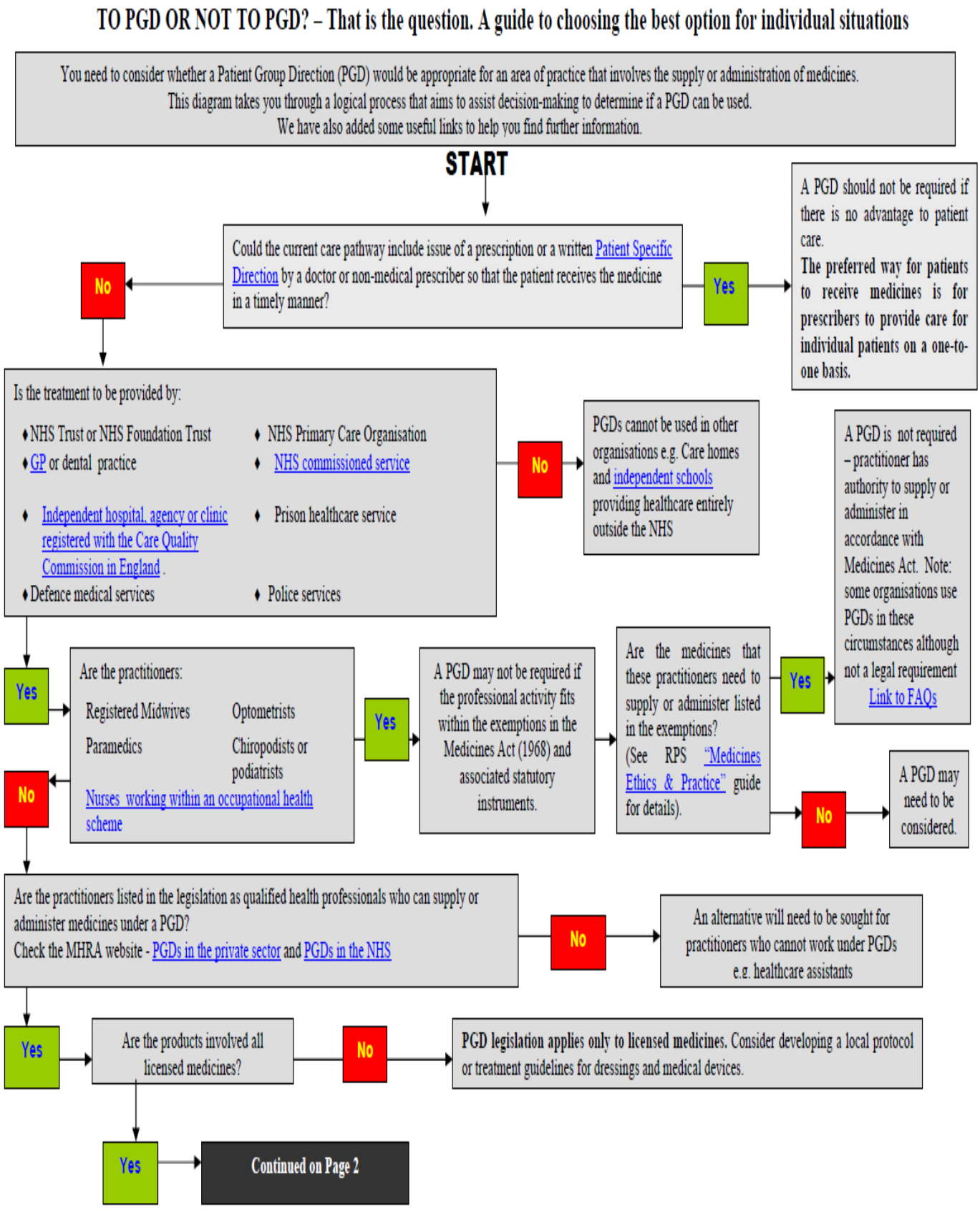
Medicine	
Form	
Strength	
Route of administration	
Dose	
Frequency	
Start date	
Finish date	

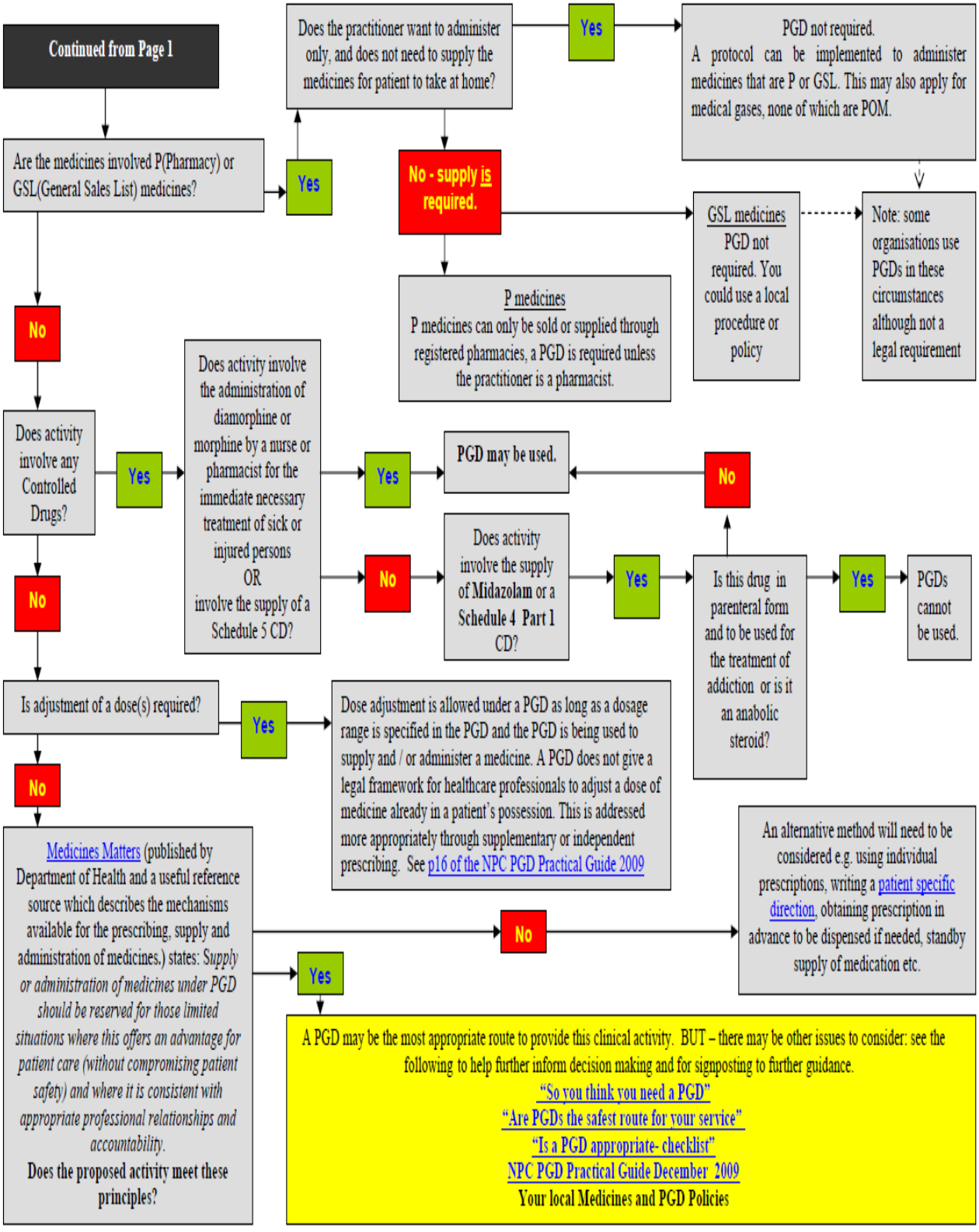
For vaccine administration confirm:
- Patient does not have a febrile fever
- Patient not allergic to vaccine or component of vaccine
- Patient not immunosuppressed for any reason
- Patient not pregnant

Subject to the above please administer medicine / vaccine as prescribed

Registered prescriber's name			
Prescriber's signature		Date	

Appendix 2 - To PGD or not to PGD flowchart




Continued from Page 1
Are the medicines involved P(Pharmacy) or GSL(General Sales List) medicines?
Yes
Does the practitioner want to administer only, and does not need to supply the medicines for patient to take at home?
Yes
PGD not required.
A protocol can be implemented to administer medicines that are P or GSL. This may also apply for medical gases, none of which are POM.
No - supply is required.
GSL medicines
PGD not required. You could use a local procedure or policy
Note: some organisations use PGDs in these circumstances although not a legal requirement
P medicines
P medicines can only be sold or supplied through registered pharmacies, a PGD is required unless the practitioner is a pharmacist.
No
Does activity involve any Controlled Drugs?
Yes
Does activity involve the administration of diamorphine or morphine by a nurse or pharmacist for the immediate necessary treatment of sick or injured persons
OR
involve the supply of a Schedule 5 CD?
Yes
PGD may be used.
No
No
Does activity involve the supply of Midazolam or a Schedule 4 Part 1 CD?
Yes
Is this drug in parenteral form and to be used for the treatment of addiction or is it an anabolic steroid?
Yes
PGDs cannot be used.
No
Is adjustment of a dose(s) required?
Yes
Dose adjustment is allowed under a PGD as long as a dosage range is specified in the PGD and the PGD is being used to supply and / or administer a medicine. A PGD does not give a legal framework for healthcare professionals to adjust a dose of medicine already in a patient's possession. This is addressed more appropriately through supplementary or independent prescribing. See p16 of the NPC PGD Practical Guide 2009
No
Medicines Matters (published by Department of Health and a useful reference source which describes the mechanisms available for the prescribing, supply and administration of medicines.) states: Supply or administration of medicines under PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.
Does the proposed activity meet these principles?
No
An alternative method will need to be considered e.g. using individual prescriptions, writing a patient specific direction, obtaining prescription in advance to be dispensed if needed, standby supply of medication etc.
Yes
A PGD may be the most appropriate route to provide this clinical activity. BUT – there may be other issues to consider: see the following to help further inform decision making and for signposting to further guidance.
"So you think you need a PGD"
"Are PGDs the safest route for your service"
"Is a PGD appropriate- checklist"
NPC PGD Practical Guide December 2009
Your local Medicines and PGD Policies

Appendix 3 – New Patient Group Direction (PGD) proposal form

The patient group direction sub-group (on behalf of the Trust's Medicines Management Group) must approve the development of all NEW PGDs.

Please complete the following proposal and submit (electronic version preferred) to the secretary of the patient group direction sub-group for consideration.

Title of PGD	
Proposer	
Service delivering the PGD	
Clinical setting	
Clinical indication	
Patient inclusion criteria	
Patient exclusion criteria	
Benefits to patient care	
Medication details – including dose, formulation, strength, quantity and duration of treatment	
Formulary status	
Health professional group working under PGD	
Training and competency needs identified	
Current / future service provisions for supplying the medication	
Existing or new resources needed to deliver the service	
Timescale for developing the PGD	
Other additional evidence to support the proposal	

PGD sub group only				
Proposal considered				
Proposal outcome				
Proposer informed	Date		By	

Appendix 4 - Patient Group Direction (PGD) template

This Patient Group Direction (PGD) must only be used by registered health 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.

Patient Group Direction

for the supply and / or administration of

Name of medicine

by registered health professional group(s) for

Condition / situation / patient group

in location / service / organisation

Version number:

Change history

Version number	Change details	Date

PGD development

Name	Job title and organisation	Signature	Date
Lead author			
Lead doctor (or dentist)			
Lead pharmacist			
Representative of other professional group using PGD			
Other members of the PGD working group			

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor (or dentist)	Consultant Psychiatrist and Chair of Medicines Management Group, CWP		
Senior pharmacist	Chief Pharmacist and Secretary of Medicines Management Group, CWP		
Senior representative of professional group using the PGD			
Person signing on behalf of authorising body	Medical Director, Quality, Compliance and Assurance, CWP		

PGD adoption by the provider[1]

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

[1] Delete section if not relevant

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	
Initial training	
Competency assessment	
Ongoing training and competency	

Clinical condition	
Clinical condition or situation to which this PGD applies	*Define the actual clinical condition or situation* *Alternative options to PGDs should be used when:* *managing complex long-term conditions, such as hypertension or diabetes* *in a particular setting, significant uncertainty remains about the differential diagnosis* *an antimicrobial is needed (this may be appropriate in some circumstances, such as chlamydia treatment in a sexual health clinic)* *the medicine needs frequent dosage adjustments, for example warfarin* *the medicine needs frequent or complex monitoring, for example immunosuppressants* *the medicine is a high-risk medicine, for example insulin.* *Do not use a PGD to make dose adjustments when a medicine is in a patient's possession.*
Inclusion criteria	*Use bullet points to list inclusions* *Who is eligible e.g. age, sex, national/ local guidelines* *Clinical criteria* *The patient/client understands and agrees to treatment within the PGD*
Exclusion criteria	*Use bullet points to list exclusions and explain reason where necessary* *Who is not eligible to receive medicine e.g.* *National/local guidelines* *Age restrictions* *Concurrent medical conditions* *Contra-indications to medicine or exclusions specified in SPC* *Cautions/concerns requiring medical assessment and advice* *Concurrent medication or treatments* *Previous adverse reactions or hypersensitivity reactions to medicine or ingredients* *Consider pregnancy and breast feeding*
Cautions (including any relevant action to be taken)	
Arrangements for referral for medical advice	
Action to be taken if patient excluded	
Action to be taken if patient declines treatment	

Details of the medicine	
Name, form and strength of medicine *Include ▼for black triangle medicines*	*Use BNF style format to express generic name, form and strength e.g. Aspirin soluble tablets 300mg, Amoxicillin Suspension 125mg/5ml* *Carefully consider the risks and benefits of including more than 1 medicine in a PGD. Ensure all legal requirements are met for each medicine.* *Ensure use of a black triangle medicine is exceptional and is justified by best clinical practice*
Legal category	*Controlled drugs, with the **exception** of the following controlled drugs may be considered:* *morphine and diamorphine, listed in schedule 2 of the Misuse of Drugs Regulations (2001) by registered nurses and pharmacists for the immediate necessary treatment of a sick or injured person (except for treating addiction)* *midazolam, listed in schedule 3 of the Misuse of Drugs Regulations (2001)* *all drugs, such as benzodiazepines and ketamine, that are listed in schedule 4 of the Misuse of Drugs Regulations (2001), except anabolic steroids and any injectable preparation used for treating addiction* *all drugs, such as codeine that are listed in schedule 5 of the Misuse of Drugs Regulations (2001).* *General Sales List (GSL) medicines do not require a PGD* *Pharmacy (P) medicines can be supplied through registered pharmacies without the need for a PGD.*
Indicate any off-label use (if relevant)	.. *PGDs must not include **unlicensed** medicines.* *Ensure **off label** use of a medicine is exceptional and justified by best clinical practice. Clearly state on the PGD that the medicine is being used outside the terms of the marketing authorisation. Consider informing the patient or their carer that the use is off-label.*
Route / method of administration	*In full e.g. oral, inject subcutaneously (Do not use Latin or abbreviations) State practical information such as "after food", "dissolve in water"* *Specify preferred site of injection*
Dose and frequency	*Enter dose or dose range in full - if dose is outside SPC (Summary of Product Characteristics) enter details of specific dose and reference the guidance followed. Do not use Latin or abbreviations* *Specify maximum dosages*
Quantity to be administered and / or supplied	*As per SPC or local / national guidelines and clinical lead* *When supplying a medicine provide an appropriately labelled pack. A manufacturer's patient information leaflet must be provided to patients who have a medicine supplied under a PGD. Do not split the pack. Standard prescription charge rules and exemptions also apply to patients receiving a supply of medicine(s) under a PGD*

Maximum or minimum treatment period	
Adverse effects	*Black triangle drugs (see BNF) are newly licensed medicines that are closely monitored by the MHRA. All suspected reactions should be reported using yellow cards* *Enter specific side effects* Refer to current BNF and SPC for complete list (and Green Book for immunisations) Use the Yellow Card System to report adverse drug reactions directly to the MHRA. Guidance on the use of the Yellow Card System and Yellow Cards is available in the current BNF and can also be completed via: http://yellowcard.mhra.gov.uk/
Records to be kept	

Patient information	
Written information to be given to patient or carer	*Enter specific counselling points* *Enter appropriate storage and handling information* *Note: a manufacturers PIL MUST be provided to patients who have a medicines supplied under a PGD. This is not required when a medicines is administered under a PGD.* Issue patient information leaflet (PIL).
Follow-up advice to be given to patient or carer	Explain possible adverse reactions and what to do if they occur

Appendices

Appendix A Key references

E.g. NICE guidance and the Summary of Product Characteristics

Appendix B Health professionals' agreement to practise

I have read and understood the Patient Group Direction and agree to administer this medicine only in accordance with this PGD.

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence. Note to Authorising Managers: Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the authorisation sheet showing their authorisation.

Name of health professional	Signature	Senior representative authorising health professional	Date

Other appendices may be added as agreed locally.

Appendix 5 - Patient Group Direction (PGD) approval checklist

Title of PGD			
Name of Ratification Group		Date	

Present in paper?	Please tick			Comments
	Yes	No	N/A	
Signatures				
Signatures of all individuals who developed the PGD;				
Signatures of individuals approving the PGD: 1. A senior doctor – Chair of MMG				
2. Chief Pharmacist				
3. Clinical lead of service using PGD				
Content				
Name of the service(s) to which the direction applies.				
Staff characteristics section				
Link to appropriate Green Book chapter for immunisation?				
Clinical details section				
Alternative options considered?				
Inclusion / exclusion criteria fully documented?				
Description of treatment section				
More than one medicine?				
Defined legal classification?				
Black triangle medicine used?				
Off label use?				
Records and follow up section completed?				
References and Bibliography section completed?				
Date the direction comes in to force and the date it expires				
Administration only				
PGD added to CWP tracker?				
Signature page added to CWP tracker?				
Letter and signed PGD sent to service lead?				
Electronic version supplied for intranet?				

Appendix 6 - Managerial contents of PGD sheet

Managerial content of patient group direction for

Individual Authorisation

I have read and understood the Patient Group Direction and agree to supply and administer this medicine only in accordance with this PGD.

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence. Note to Authorising Managers: Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the authorisation sheet showing their authorisation.

Name of Health Professional	Signature	Authorising Manager	Date

Appendix 7 - External Patient Group Direction (PGD) authorisation

Cheshire and Wirral Partnership NHS Foundation Trust (CWP) will adopt the following Patient Group Direction (PGD) for use within CWP:

Title and version of Patient Group Direction (PGD)	
Written by	
Valid from	
Review date	
Expiry date	
Supersedes	

Authorised for use within CWP by			
CWP Medicines Management Group			
Name			
Signature		Date	
Trust Clinical Governance Lead			
Name			
Signature		Date	