# PATIENT GROUP DIRECTIONS POLICY

<table>
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<tr>
<th>Document Author</th>
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<tr>
<td><strong>Written By:</strong> CSG Quality Advisor and CSG Pharmacist Representative</td>
<td><strong>Authorised By:</strong> Chief Executive</td>
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<td><strong>Date:</strong> June 2017</td>
<td><strong>Date:</strong> 13th February 2018</td>
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<td><strong>Lead Director:</strong> Clinical Director Pharmacy</td>
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## DOCUMENT HISTORY

(Procedural document version numbering convention will follow the following format. Whole numbers for approved versions, e.g. 1.0, 2.0, 3.0 etc. With decimals being used to represent the current working draft version, e.g. 1.1, 1.2, 1.3, 1.4 etc. For example, when writing a procedural document for the first time – the initial draft will be version 0.1)

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<th>Date of Issue</th>
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<th>Director Responsible for Change</th>
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<td>0.1</td>
<td></td>
<td>Clinical Director Pharmacy</td>
<td>First draft of new policy</td>
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<td>Clinical Director Pharmacy</td>
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NB This policy relates to the Isle of Wight NHS Trust hereafter referred to as the Trust.
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1. **Executive Summary**

This policy covers the governance and procedures around Patient Group Directions (PGDs) and describes the legal framework and roles and responsibilities of staff in the planning, development and implementation of PGDs within the Trust.

2. **Introduction**

The majority of clinical care should be provided on an individual patient specific basis. The preferred way for patients to receive the medicines they need is by a prescriber (including a non medical prescriber), to provide care for an individual patient on a one-to-one basis.

The supply and administration of medicines under PGDs should be reserved for situations where this method offers advantages for patients without compromising safety.

Patient Group Directions (PGDs) are documents that allow professional groups to administer or supply medication to patients in the absence of an individual prescription written by a doctor or non-medical prescriber.

PGD definition: “A PGD is a written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment”.

Each condition to be treated, with an individual drug, needs a specific PGD to be written. There are restrictions on the type of drug that can be prescribed under a PGD. PGDs are not appropriate for all clinical situations. They should only be used in specific circumstances when other means of prescribing, supply or administration are not possible.

Before considering development of a PGD it is important to consider whether other forms of supply or administration are more suitable.

3. **Definitions**

PGD - Patient Group Direction is a written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

4. **Scope**

This policy relates to all staff employed by the Trust who use or have involvement in developing PGDs.

5. **Purpose**

The purpose of the PGD Policy is to:
- Ensure effective patient care that is appropriate in a pre-defined clinical situation is delivered, without compromising patient safety.
- Offer a significant advantage to patient care by improving access to appropriate medicines.
- Provide equity in the availability and quality of services when other options for supplying and / or administering medicines are not available.
- Provide a safe legal framework to protect patients and relevant staff.
- Reduce delays in treatment.
- Maximise the use of the skills of a range of health professionals.
- Set out the mechanism for developing and using PGDs within the Trust.

The purpose of this document is to ensure adherence to legislation governing the provision of medicines by Patient Group Directions:
- Health Service Circular HSC 2000/026.
- The Human Medicines Regulations 2012.

It will provide guidance on the process for the identification, development, dissemination, implementation, monitoring, audit and review of (PGDs) within the Trust and assist compliance with best practice as recommended by NICE.

This policy will provide the framework for service leads to assist in the identification and outline the process for the development of PGDs.

6. **Roles and Responsibilities**

6.1 **Role of Trust Directors**

Directors are accountable for the implementation of the PGD policy across all clinical services where staff operate under the PGDs.

6.2 **Role of staff developing a PGD**

Staff developing a PGD should first identify whether one is appropriate or required by discussing with service manager and consulting the NHS PGD website, the 'To PGD or not to PGD' (Appendix B) decision sheet and NICE MPG2.

Staff should complete the Trust PGD proposal form for presentation to the Clinical Standards Group (CSG), and consider competencies required.

It is the responsibility of staff developing a PGD to identify and liaise with an appropriate multidisciplinary group – this should include a doctor, pharmacist, the line manager of the service and a representative of the professional group who will administer / supply medicines under the PGD.

Staff should also ensure the PGD is put into the current Trust template, ensure all legal requirements are met for each medicine, consider the required staff qualifications and competencies and liaise with appropriate stakeholders.

It will be the responsibility of the staff developing a PGD to disseminate ratified PGDs to appropriate line managers and / or service leads.
6.3 Role of Individual Line Managers, Professional and Clinical Leads

Individual line managers, professional and clinical leads should explore all the available options for supplying and/or administering medicines in a specific clinical situation. They should consider whether one option or a range of options is appropriate. They should also consider investing in the training of additional non-medical prescribers to enable redesign of services if necessary, as part of a wider development or review of local medicines policy.

Individual line managers, professional and clinical leads are responsible for informing staff of this policy and any associated policies, standard operating procedures (SOPs), guidelines and protocols and the identification of staff who may operate under PGDs.

They must also ensure that PGDs are only used by named and authorised registered health professionals who can legally supply and/or administer medicines using a PGD.

Individual line managers, professional and clinical leads are responsible for ensuring each new or revised PGD is available to all appropriate staff, staff are aware of criteria for use and any changes and PGDs are signed to ensure competencies are reviewed and up to date.

Individual line managers, professional and clinical leads must ensure staff have the appropriate training and competencies to operate under PGDs and have access to relevant protocols and have the appropriate training and competencies as outlined in NICE MPG2 framework to operate under each individual PGD.

6.4 Role of all Staff using PGDs

- Staff must ensure they have an up to date working knowledge of the clinical condition they are treating, its diagnosis and treatment, and the medication they are supplying and / or administering under a Trust ratified PGD.
- Staff are accountable for their own professional practice and must work within this policy and their respective professional codes.
- Staff operating under a PGD must work within any relevant protocols identified within the PGD.
- Staff operating under this policy will identify any training needs and attend required study sessions relating to this policy.
- Professionals using a PGD must hold a current registration as identified within the PGD and act within their appropriate professional codes of conduct.
- Individuals must be named and authorised to practice under a PGD.
- Each new or revised PGD should be signed by all appropriate staff to demonstrate competencies are reviewed and up to date.
- When supplying and/or administering a medicine under a PGD, health professionals should follow Trust policies and act within their code(s) of professional conduct and local governance.
- When supplying and/or administering a medicine under a PGD staff should document the clinical assessment and specify that the medicine has been supplied and/or administered under a PGD.
PGDs must be used only by named and authorised registered health professionals who can legally supply and/or administer medicines using a PGD.

Classes of registered individuals by whom administration or supply of a medicine may be made under PGD:

- chiropodists and podiatrists
- dental hygienists
- dental therapists
- dieticians
- midwives
- nurses
- occupational therapists
- optometrists
- orthoptists
- orthotists and prosthetists
- paramedics
- pharmacists
- physiotherapists
- radiographers
- speech and language therapists

6.5 Role of Quality Advisors
- Maintaining an up to date database of current and expired PGDs.
- Developing the work plan to inform the agenda of the Clinical Standards Group (CSG).
- Setting the agenda of the CSG.
- Attending the CSG and minuting the discussions and actions.
- Ensuring the PGD template is up to date and version control and history are accurate.
- Uploading ratified versions of the PGDs onto the Trust’s website and alerting the Trust e-bulletin

6.6 Role of the Clinical Standards Group (CSG)

The CSG is designated the Trust PGD Approval group and is responsible for ensuring that this policy is applied ensuring appropriate representation at meetings of the CSG.

The Chair of CSG has designated responsibility for signing PGDs on behalf of the authorising body.

CSG members are responsible for reading all PGD documentation submitted for the agenda to inform decision making.
7 Policy Detail / Course Of Action

7.1 Identifying the Need and obtaining agreement to develop a Patient Group Direction

Before writing a PGD staff must assess and establish the clinical need and use the national PGD website tools to consider whether a PGD is necessary. PGDs should not be used for medicines when exemptions in legislation allow their supply and/or administration without the need for a PGD.

Service leads identifying the need for a PGD must complete a PGD Proposal Form and PGD Proposal Form Checklist in full (Appendix A) and send to CSG.

The PGD application will be considered at the next meeting of the CSG where the service lead is required to attend and present the request for a PGD.

If a PGD is required and approval received from the CSG to develop a PGD, then it is the proposer’s responsibility to liaise with the relevant multidisciplinary group (see 6.2) and other stakeholders when writing the PGD.

Decisions to accept or reject the proposal, including the rationale for the decision, will be recorded in the meeting’s minutes. The decision will be communicated in writing to the person who submitted the proposal, within two working days. It will be the author’s responsibility to ensure that the decision is communicated to other appropriate stakeholders.

7.1.1 Appeals process

If the proposal is rejected it may then be re-submitted at a later meeting. Only one appeal shall be considered for each PGD.

7.2 Medicines that can be included in a PGD

- PGDs must only include medicines with a UK marketing authorisation, in line with legislation.
- Ensure that off-label use of a licensed medicine is included in a PGD only when clearly justified by best clinical practice. Clearly state that the medicine is being used outside the terms of the marketing authorisation on the PGD.
- Inform the patient or their carer that the use is off-label
- Ensure that a black triangle medicine is included in a PGD only when clearly justified by best clinical practice. Clearly indicate the black triangle status on the PGD.
- Ensure that a controlled drug is included in a PGD only when legally permitted and clearly justified by best clinical practice.
- Do not include a medicine needing frequent dosage adjustments or frequent or complex monitoring in a PGD (for example, anticoagulants or insulin). Adjustments should not be made to doses of a medicine supplied under a PGD when the medicine is already in the patient's possession.
- Carefully consider the risks and benefits of including more than one medicine in a PGD on a case-by-case basis. Ensure all legal requirements are met for each medicine.
• Do not use PGDs for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.

Local and national strategies to combat antimicrobial resistance and healthcare-associated infections should not be jeopardised. Ensure that an antimicrobial is included in a PGD only when:
• clinically essential and clearly justified by best clinical practice, such as Public Health England guidance
• a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented
• use of the PGD is monitored and reviewed regularly.

When a PGD has been developed and authorised by a commissioning organisation for use across multiple provider organisations, it should be adopted for use within the provider organisation.

7.3 Information that must be legally contained in a PGD

According to the legal requirements, a PGD must include:

• the name of the business who owns the direction
• the start and end date of the PGD
• a description of the medicine(s)
• the class of the health professional who can supply or administer the medicine
• a signature of a doctor or dentist (as appropriate) and a pharmacist
• a signature by an appropriate organisation (eg clinical commissioning groups, local authorities, NHS trusts or NHS foundation trusts, special health authorities, the NHS Commissioning Board)
• the clinical condition or situation to which the direction applies (eg the specified condition/conditions that can be treated)
• a description of patients excluded from treatment under the direction
• a description of when you should get more advice from a doctor (or dentist, as appropriate) and arrangements for referral
• details of appropriate dosage, maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period to administer the medicine
• relevant warnings, including potential adverse reactions
• details of any necessary follow-up actions
• a statement of the records to be kept for audit purposes

Clinical guidelines, consensus statements from professional groups, e.g. British Association for Sexual Health and HIV, British Thoracic Society, Resuscitation Council, Faculty for Sexual & Reproductive Health, British Society of Gastroenterology do not need to form part of the PGD but should be used as a basis for producing it and should be referenced.
7.4 Development, Authorising and Implementing PGDs

PGDs must be developed, revised and updated by a multidisciplinary group involving a doctor, pharmacist, the line manager of the service and a representative of the professional group who will administer / supply medicines under the PGD.

Not all medicines are able to be included in a PGD and there are legal restrictions on others.

If a PGD is to be used to provide or administer an antibiotic the Consultant Microbiologist must be involved in the PGD’s production.

The PGD should be informed by legislation, Trust protocols, pathways and policies. Authors must ensure PGDs are consistent with the relevant summary of product characteristics, unless the medicine is being used off-label or relevant national guidance is being followed.

PGDs should be developed within criteria of NICE Medicines Practice guidelines and the IW formulary. Include key references in an appendix to the PGD.

The PGD authors will liaise with members of the Drugs Advisory committee and/or Trust Drugs and Therapeutics committee.

The PGD author(s) will put the draft PGD is put into the current PGD template (available from the Quality Advisors or intranet) and ensure that the version control is accurate (if applicable).

The PGD author(s) will send out the draft PGD to relevant stakeholders for comments and will collate responses, including any necessary changes in the draft PGD.

After consultation, a signed copy should be sent to the Quality Advisors to be tabled for discussion at the CSG. The PGD should be signed by the doctor, pharmacist, service lead and specialist practitioner involved in developing the PGD. The PGD author(s) should identify a senior, responsible person from within the service to authorise named, registered health professionals to practise under the PGD.

When acting as a doctor, dentist or pharmacist signatory, staff should establish that the clinical and pharmaceutical content is accurate and supported by the best available evidence.

The Clinician / Service Lead will be expected to attend the CSG meeting(s) when the PGD is being developed and/or reviewed.

If approved, the PGD will be signed by the Chair of the group to confirm ratification.

Expiry dates for individual PGDs will be determined on a case-by-case basis, with patient safety paramount. If no shorter date is required a standard expiry date of two years will be issued.
The signed copy will be returned to the department where is should be read, understood then signed by all staff who will be authorised to work under the PGD. A copy of the signature sheet should be returned to the Quality Advisor.

Service managers are responsible for ensuring that only fully competent, qualified and trained health professionals use PGDs. Service managers should identify gaps in competency and establish a comprehensive and appropriate training programme for all people involved in considering the need for, developing, authorising, using and updating PGDs.

The ratified PGD is to be logged, converted to PDF format by the Quality Advisor prior to uploading onto the Trust website. The Quality Advisor will also send out a message on the Trust’s e-bulletin.

PGDs will be disseminated to the relevant professional / clinical leads, senior managers by the PGD author(s) or service manager.

Professional leads and clinical leads / senior managers will disseminate the ratified PGD to relevant staff. They will ensure that those who are going to operate under the PGD have access to the document, have signed to operate under it and that any training needs have been identified and addressed.

Professionals using a PGD must hold a current registration as identified within the PGD and act within their appropriate professional codes of conduct.

Managers will retain a copy of the signed authorisation sheet and keep a record of staff who have signed up to the PGD. These records may be inspected by relevant bodies, e.g. Trust directors, CQC, Medicines Management representatives.

In the area where the PGD is used the following must be in place:

- A copy of the protocol should be available in the clinical setting in which the care is provided.
- Lines of professional accountability must be clearly specified and agreed by all relevant groups.
- Care under PGDs should only be provided where there are clear arrangements stated in respect of dealing with adverse reactions and where staff are adequately trained to manage such reactions.
- Staff should be provided with a signed copy of the PGD as written evidence that they are authorised to provide care under specified PGDs.

### 7.5 Working under a PGD

Before practising under a PGD, health professionals

- have a responsibility under their code of professional conduct to maintain their competence and identify any training needs required to safely operate under each PGD.

They should ensure that they:

- agree to operate under the PGD by signing each individual PGD authorisation sheet.
- have undertaken the necessary initial training and continuing professional development.
• have been assessed as competent and authorised to practise by the provider organisation
• have signed the appropriate documentation
• are using a copy of the most recent and in date final signed version of the PGD
• have read and understand the context and content of the PGD.

When practising under a PGD, health professionals should:
• not delegate their responsibility
• ensure that they can determine that the patient meets the inclusion criteria as set out in the PGD
• ensure that they can determine that no exclusion criteria apply
• discuss alternative options for treating the patient’s condition, when appropriate
• assess each individual patient's circumstances and preferences
• recognise when signposting or referral to another health professional or service is needed, as specified in the PGD
• understand relevant information about the medicine(s) included in the PGD, such as:
  - how to administer the medicine
  - how the medicine acts within the body
  - dosage calculations
  - potential adverse effects and how to manage them
  - drug interactions, precautions and contraindications
  - storage requirements, including maintenance of the 'cold chain'
  - follow-up arrangements
• be able to advise the patient or their carer about the medicine(s), as appropriate.

When supplying a medicine(s), pharmacy should provide an appropriately labelled pack. Health professionals (other than pharmacists or dispensing doctors) should not split packs. During the review/audit process service managers should check this and pharmacist to review labels for OTC & P packs.

On distributing a medicine under a PGD staff should ensure that the patient receives a manufacturer's patient information leaflet with each medicine.

Staff should identify whether patients supplied with a medicine(s) under a PGD are exempt from NHS prescription charges. The appropriate prescription charge(s) must be collected from patients who are not exempt, in line with legislation.

The following information should be documented about the clinical assessment and supply and/or administration of the medicine(s):
• date and time of supply and/or administration
• patient details, such as name, date of birth, allergies, previous adverse events and how the patient met the criteria of the PGD
• details of medicine, such as name, strength, dose, frequency, quantity, route and site (if by injection) of administration (record the batch number and expiry date for vaccines, blood-derived products and other medicines if recommended by relevant national guidance)
- a statement that supply or administration is by using a PGD
- name and signature (which may be an electronic signature) of the health professional supplying or administering the medicine
- relevant information that was provided to the patient or their carer whether patient consent to treatment was obtained, in line with the Department of Health's advice on consent (2009).

### 7.6 Review of PGDs

A PGD is not a legal document if it has passed its expiry date. It is not acceptable or legal for an individual practitioner to decide to use a PGD that has expired.

PGDs will be due for review 6 months before the expiry date. It is the author(s) responsibility to monitor the expiry date of the PGD and ensure that the review paperwork is completed (including the record and signatures of health professionals authorised to practise under the PGD) (appendix C), any updates are made, the consultation process is followed and the completed PGD is sent to the Quality Advisor for scheduling on a CSG agenda.

The Quality Advisors will also monitor the PGDs and any that have passed the expiry date will be removed from the intranet. When an expired PGD is removed from the intranet the Quality Advisor will inform the professional leads and clinical leads / senior managers.

Professional Leads and clinical leads / senior managers will be responsible for informing their staff of PGDs that are expired/withdrawn from use.

If the lead author has left the Trust it will be the responsibility of the other members of the original MDT team to review the PGD. If they have left the Trust/are unable to review the PGD it will be the Service Managers responsibility to put together a new working team for the PGD. If a new MDT is unable to be put together the Service Manager should inform the Quality Advisor who will remove the PGD from the intranet.

When reviewing the PGD, the author(s) should conduct an appropriate literature search to identify new evidence. They should also ensure that this evidence is evaluated to assess its relevance and validity.

When reviewing the PGD, author(s) 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 health professionals working under the PGD and views of relevant stakeholders, such as patients or their carers.

Updated PGDs must be sent for ratification at the CSG. Use of a PGD that has not followed the correct governance process is illegal.

As with the initial ratification it will be the responsibility of the author to disseminate the PGD to the relevant professional / clinical leads and senior managers. It will be the Quality Advisor’s responsibility to send an alert to the Trust e-bulletin.
In the case of an unscheduled review, the process will remain the same as for the scheduled review. This should include responding to:

- changes in legislation
- 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.

Each new or revised PGD should be read, understood and re-signed by all appropriate staff to ensure and demonstrate that competencies are reviewed and up to date.

Revised / expired PGDs will be archived and stored in accordance with the guidelines for Trust’s Information Governance.

The original signed version of the PGD will be retained by the Patient Safety, Experience and Clinical Effectiveness team.

8. Consultation

The policy will be sent to managers within the Quality Governance team, pharmacy, Professional Leads, Clinical Leads, Senior Managers and the CSG for consultation.

9. Training

This PGD Policy does not have a mandatory training requirement however staff should work to comply with NICE MPG2 Patient Group Directions Competency frameworks for:

- Staff developing PGDs
- Staff managing PGDs
- Staff working under PGDs

Support can be sourced by via NICE, the NHS PGD website and professional organisations or by contacting service leads in the first instance.

Specific training needs for individual PGDs must be identified by the Service Leads. Records of training are to be retained by the Service Lead.

Service managers should consider collaborating with other organisations and sharing existing educational materials to ensure a comprehensive approach.

Service managers should ensure that training and re-training of health professionals using PGDs incorporates a post-training assessment of competency.

10. Monitoring Compliance and Effectiveness

Audit of PGDs

It is the responsibility of the service lead to monitor and audit the use of PGDs within their service setting.
An audit should be conducted at the time of review (6 months before expiration date) using the PGD Audit Forms (appendix C) and these sheets and a short summary should be attached to the PGD when it is sent for review. Authors should also include:

- How many patients have been treated under the PGD
- Patient safety incidents, such as medication errors, near misses and suspected adverse events

The service lead is to retain a list of named, registered health professionals authorised to practise under each PGD used within their service.

Monitoring and evaluation of PGDs used within the Trust may be undertaken in conjunction with IW NHS TRUST Directors, CQC or the Medicines Management team.

11 Links to Other Policies/Documents

- Medicines Policy
- Consent Policy
- PGD template
- PGD Monitoring sheets

12 References

Health Service Circular HSC 2000/02 August 2000 Patient Group Directions[England]  

National Institute for Health and Care Excellence. Medicines Practice Guideline MPG2  
Patient Group Directions August 2013  
http://www.nice.org.uk/guidance/mpg2/chapter/1-introduction

NICE MPG2 Tools and Resources, competency frameworks  
http://www.nice.org.uk/guidance/mpg2/resources

NHS Patient Group Directions (PGDs)  
http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/

NHS Patient Group Directions Legislation and guidance Toolkit  

NHS Patient Group Directions To-PGD-or-not-to-PGD-that-is-the-question

MHRA at Gov.uk  

Patient Group Directions in the NHS MHRA
13. Appendices

A  PGD Proposal Form
B  ‘To PGD or not to PGD’ decision sheet
C  PGD Audit Forms
D  PGD Process Flowchart
E  Financial and Resourcing Impact Assessment on Policy Implementation
F  Equality Impact Assessment (EIA) Screening Tool
# PGD proposal form

**Title:**

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<td>Department of use:</td>
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<tr>
<td>Condition to be treated:</td>
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<tr>
<td>Patient inclusion criteria:</td>
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<tr>
<td>Benefits to patient care:</td>
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<td>Potential risks to patient safety:</td>
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<td>Details of medicines to be supplied/administered</td>
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<tr>
<td>Dosage</td>
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<td>Quantity</td>
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<td>Formulation and strength</td>
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<td>Route and frequency of admission:</td>
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<td>Duration of treatment:</td>
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<tr>
<td>Is this included in the local formulary?</td>
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<tr>
<td>Health professional groups who would work under the PGD, including training and competency needs</td>
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<tr>
<td>Current and/or future service provisions for supplying the medicine(s), including its position within the care pathway</td>
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<td>Evidence to support the proposal:</td>
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<td>Resources needed to deliver the service:</td>
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<td>A timescale for developing the PGD:</td>
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Appendix B

'To PGD or not to PGD' Decision sheet (current version)

http://www.medicinesresources.nhs.uk/en/Download/?file=MDs1MTQ0MDQ7L3VwbG9hZC9kb2N1bWVudHMvQ29tbXVuaXRpZXMvUEdEcy9Ub29scy9UbyBQR0RfdjkgMl9EZWNlbWJlcjwMTUucGRm.pdf

via
**PGD audit forms**

Patient Group Direction Audit Form 1 – For Managers

Form for the audit of compliance with PGD or PGDs

All PGDs should be audited 6 months after they have been issued as new or revised versions to your service.

| Name and post of Designated Lead person within each practice/clinic base:.............................. |
| Location/Clinic Base: ......................... Date of audit:.............................................. |

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<tr>
<th>Tick as appropriate. If ‘no’, state action required</th>
<th>Y</th>
<th>N</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>For all PGDs:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Do the managers listed on the PGD or PGDs hold a current list of authorised staff?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Are all staff authorised to work under the PGD or PGDs members of one of the health professions listed in the PGD?</td>
<td></td>
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</tr>
<tr>
<td>Are you confident that all medicines supplied or administered under the PGD or PGDs are stored according to the PGD where this is specified?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Do the staff working under the PGD or PGDs have a copy of the PGD which has governance sign off and is in date and, available for reference at the time of consultation?</td>
<td></td>
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<tr>
<td>Where the medicine requires refrigeration. (Delete if not required).</td>
<td></td>
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</tr>
<tr>
<td>Is there a designated person responsible for ensuring that the cold chain is maintained?</td>
<td></td>
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</tr>
<tr>
<td>Is there a record that the fridge temperature has been monitored to required levels?</td>
<td></td>
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</tbody>
</table>

The questions below refer to the two audit forms which follow:

Was all the information completed on audit form 2 for staff records?

Was all the information completed on audit form 3 for patient records?
Patient Group Direction Audit form 2 - For Service Leads - auditing whether the individuals working under a PGD are authorised, trained and competent.

Form for Audit of Completion of Staff Records for the following PGD or PGDs:

1. ......................................................
2. ......................................................
3. ......................................................
4. ......................................................
5. ......................................................
6. ......................................................
7. ......................................................
8. ......................................................
9. ......................................................
10. .....................................................

<table>
<thead>
<tr>
<th>Staff Initials</th>
<th>Training specific to each PGD for which the staff member has signed up for, is up to date. (Yes or No)</th>
<th>Member of staff is a member of one of the health professions listed in the PGD or PGDs (Yes or No)</th>
<th>Name of staff member is on the master list of staff authorised to work under the PGD or PGDs, and entry is dated (Yes or No)</th>
<th>Staff member eligible to authorise staff has signed the PGD or PGDs (Yes or No).</th>
<th>Comments.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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</table>
Patient Group Direction Audit Form 3 - For staff - to audit patient record keeping and compliance with clinical practice as stated in the PGD

Form for audit of completion of Patient Records for supply or administration under a PGD

<table>
<thead>
<tr>
<th>Patient Initials</th>
<th>PGD number/medication given</th>
<th>Was medicine given according to the inclusion criteria Y/N</th>
<th>Was a drug history taken? Y/N</th>
<th>Is allergy status documented? Y/N</th>
<th>Were exclusion criteria checked? Y/N</th>
<th>Was injection site, route, batch number, expiry date recorded? Y/N</th>
<th>Was health professional's signature recorded? Y/N</th>
<th>Was patient consent obtained? Y/N</th>
<th>Was patient info leaflet supplied to patient Y/N</th>
<th>Does it state &quot;given under pgd?&quot; in the notes Y/N</th>
<th>Is there a separate log by drug name to show what was supplied/given including batch number or expiry date etc: Y/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td>7.</td>
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<td>8.</td>
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<td>9.</td>
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<td>10.</td>
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</tbody>
</table>
Appendix E

Financial and Resourcing Impact Assessment on Policy Implementation

NB this form must be completed where the introduction of this policy will have either a positive or negative impact on resources. Therefore this form should not be completed where the resources are already deployed and the introduction of this policy will have no further resourcing impact.

<table>
<thead>
<tr>
<th>Document title</th>
<th>PGD Policy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Totals</th>
<th>WTE</th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manpower Costs</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Training Staff</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Equipment &amp; Provision of resources</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Summary of Impact:
This policy confirms current practice within the trust. There are no cost implications

Risk Management Issues:

Benefits / Savings to the organisation:

Equality Impact Assessment

- Has this been appropriately carried out? YES/
- Are there any reported equality issues? /NO

If “YES” please specify:

Use additional sheets if necessary.

Please include all associated costs where an impact on implementing this policy has been considered. A checklist is included for guidance but is not comprehensive so please ensure you have thought through the impact on staffing, training and equipment carefully and that ALL aspects are covered.

<table>
<thead>
<tr>
<th>Manpower</th>
<th>WTE</th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operational running costs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Totals:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Staff Training Impact</th>
<th>Recurring £</th>
<th>Non-Recurring £</th>
</tr>
</thead>
<tbody>
<tr>
<td>Totals:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment and Provision of Resources</td>
<td>Recurring £ *</td>
<td>Non-Recurring £ *</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>---------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Accommodation / facilities needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Building alterations (extensions/new)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IT Hardware / software / licences</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stationery / publicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Travel costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Utilities e.g. telephones</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rolling replacement of equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment maintenance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marketing – booklets/posters/handouts, etc</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Capital implications £5,000 with life expectancy of more than one year.

Funding /costs checked & agreed by finance:

Signature & date of financial accountant:

Funding / costs have been agreed and are in place:

Signature of appropriate Executive or Associate Director:
### Equality Impact Assessment (EIA) Screening Tool

<table>
<thead>
<tr>
<th>Document Title:</th>
<th>Patient Group Direction Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose of document</td>
<td>This policy covers the governance and procedures around Patient Group Directions (PGDs) and describes the legal framework and roles and responsibilities of staff in the planning, development and implementation of PGDs within the Trust.</td>
</tr>
<tr>
<td>Target Audience</td>
<td></td>
</tr>
<tr>
<td>Person or Committee undertaken the Equality Impact Assessment</td>
<td></td>
</tr>
</tbody>
</table>

1. To be completed and attached to all procedural/policy documents created within individual services.

2. Does the document have, or have the potential to deliver differential outcomes or affect in an adverse way any of the groups listed below?

   If no confirm underneath in relevant section the data and/or research which provides evidence e.g. JSNA, Workforce Profile, Quality Improvement Framework, Commissioning Intentions, etc.

   If yes please detail underneath in relevant section and provide priority rating and determine if full EIA is required.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Positive Impact</th>
<th>Negative Impact</th>
<th>Reasons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Asian or Asian British People</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or Black British People</td>
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<td></td>
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<tr>
<td>Chinese people</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>People of Mixed Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White people (including Irish people)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual Orientation</td>
<td>People with Physical Disabilities, Learning Disabilities or Mental Health Issues</td>
<td></td>
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<tr>
<td>--------------------</td>
<td>---------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td></td>
<td>Transgender</td>
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</tr>
<tr>
<td></td>
<td>Lesbian, Gay men and bisexual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>Children</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Older People (60+)</td>
<td></td>
<td></td>
</tr>
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<td></td>
<td>Younger People (17 to 25 yrs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Faith Group</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Pregnancy &amp; Maternity</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Equal Opportunities and/or improved relations</td>
<td></td>
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</tbody>
</table>

Notes:

Faith groups cover a wide range of groupings, the most common of which are Buddhist, Christian, Hindus, Jews, Muslims and Sikhs. Consider faith categories individually and collectively when considering positive and negative impacts.

The categories used in the race section refer to those used in the 2001 Census. Consideration should be given to the specific communities within the broad categories such as Bangladeshi people and the needs of other communities that do not appear as separate categories in the Census, for example, Polish.

3. **Level of Impact**

If you have indicated that there is a negative impact, is that impact:

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal (it is not discriminatory under anti-discriminatory law)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intended</td>
<td></td>
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</tbody>
</table>

If the negative impact is possibly discriminatory and not intended and/or of high impact then please complete a thorough assessment after completing the rest of this form.

3.1 Could you minimise or remove any negative impact that is of low significance? Explain how below:

3.2 Could you improve the strategy, function or policy positive impact? Explain how below:

3.3 If there is no evidence that this strategy, function or policy promotes equality of opportunity or
improves relations – could it be adapted so it does? How? If not why not?

<table>
<thead>
<tr>
<th>Scheduled for Full Impact Assessment</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of persons/group completing the full assessment.</td>
<td></td>
</tr>
<tr>
<td>Date Initial Screening completed</td>
<td></td>
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</tbody>
</table>