## Document Control

### Title

**Patient Group Direction Policy**

<table>
<thead>
<tr>
<th>Version</th>
<th>Date Issued</th>
<th>Status</th>
<th>Comment / Changes / Approval</th>
</tr>
</thead>
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<tr>
<td>0.1</td>
<td>12/2012</td>
<td>Draft</td>
<td>Initial version for consultation</td>
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<tr>
<td>1.2</td>
<td>01/2013</td>
<td>Revision</td>
<td>NHS Devon policy updated to include Northern Devon Healthcare NHS Trust.</td>
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<tr>
<td>1.3</td>
<td>04/2013</td>
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<td>1.4</td>
<td>05/2013</td>
<td>Final Draft</td>
<td>To Drugs and Therapeutics Committee for Northern Devon Healthcare NHS Trust approval.</td>
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<tr>
<td>1.5</td>
<td>08/2013</td>
<td>Draft</td>
<td>Changes required after discussion at Drugs and Therapeutics Committee to have a separate meeting entitled “PGD Development meeting” which took place on 9 July 2013.</td>
</tr>
<tr>
<td>2.0</td>
<td>09/2013</td>
<td>Final</td>
<td>Harmonised policy as a result of the merging of Northern Devon Healthcare NHS Trust and NHS Devon Community Services. Approved and ratified by Drugs and Therapeutics Committee on 19 September 2013 for Trust wide implementation.</td>
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<td>2.1</td>
<td>10/2015</td>
<td>Final</td>
<td>PGD Flowchart revised according to this Policy section 11.2.1 due to the ceasing of Pan Devon PGD Group in November 2015. Update also to include: PGD Training to be updated every 3 years. The requirement for temporary staff to operate under the governance requirements of this Policy. Staff operating under the PGD to communicate clinical details of supply to on-going responsible healthcare provider.</td>
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<td>3.0</td>
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<tr>
<td>4.0</td>
<td>07/2016</td>
<td>Final</td>
<td>Addition and inclusion of NDHCT competency assessment document in sections 5 and 9. Agreed at Drugs and Therapeutics on 21st July 2016</td>
</tr>
</tbody>
</table>

### Main Contact

Medicines Management PGD Administrator
Northern Devon Healthcare Trust
Unit 1 Exeter International Office Park
Clyst Honiton
Exeter EX5 2HL

### Lead Director

Medicines Management – Eastern
PGD Policy V4.0 21.07.16
### Medical Director/Chief Pharmacist

<table>
<thead>
<tr>
<th>Superseded Documents</th>
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<tr>
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<td>August 2016</td>
<td>June 2019</td>
<td>Three years</td>
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Consulted with the following stakeholders: (list all)
- Infection Control
- Medicines Management
- Chief Pharmacist
- Head of Patient Safety
- Corporate Governance Manager
- Non-Medical Prescribing Lead
- Principal Clinical Pharmacist
- Governance Pharmacist
- Director & Assistant Director of Nursing
- Physiotherapy Professional Leads
- Assistant Medical Director
- Chair of Drugs and Therapeutics Committee

### Approval and Review Process

- Drugs and Therapeutics Committee

### Local Archive Reference

**Local Path**
Medicines Management Shared Drive

**Filename**
G:\MEDICINES MANAGEMENT\PGDs\11. PGD Policy\PGD Policy update 2016\PGD Policy - with Competecies v4 00 July 2016 FINAL.docx

### Policy categories for Trust’s internal website (Bob)

Location(s) on BoB Policies
Pharmacy/Medicines Management

### Tags for Trust’s internal website (Bob)
PGD, Patient Group Direction
# 1. Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Control</td>
<td>1</td>
</tr>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Purpose</td>
<td>4</td>
</tr>
<tr>
<td>Definitions</td>
<td>5</td>
</tr>
<tr>
<td>Responsibilities</td>
<td>6</td>
</tr>
<tr>
<td>Policy Document Development</td>
<td>9</td>
</tr>
<tr>
<td>Professional groups and individuals who can operate under PGDs</td>
<td>9</td>
</tr>
<tr>
<td>PGD Development</td>
<td>10</td>
</tr>
<tr>
<td>Training Requirements</td>
<td>13</td>
</tr>
<tr>
<td>Equality Impact Assessment</td>
<td>14</td>
</tr>
<tr>
<td>Consultation, Approval and Ratification Process</td>
<td>15</td>
</tr>
<tr>
<td>Review and Revision Arrangements including Document Control</td>
<td>15</td>
</tr>
<tr>
<td>Dissemination and Implementation</td>
<td>16</td>
</tr>
<tr>
<td>Document Control including Archiving Arrangements</td>
<td>16</td>
</tr>
<tr>
<td>Monitoring Compliance with and the Effectiveness of the Policy</td>
<td>17</td>
</tr>
<tr>
<td>References</td>
<td>18</td>
</tr>
<tr>
<td>Associated Documentation</td>
<td>18</td>
</tr>
<tr>
<td>Appendix 1 – Health Service Circular 2000/026</td>
<td>19</td>
</tr>
<tr>
<td>Appendix 2 – To PGD or Not to PG</td>
<td>23</td>
</tr>
<tr>
<td>Appendix 3 – PGD Flowchart</td>
<td>26</td>
</tr>
<tr>
<td>Appendix 4 – PGD Request Form</td>
<td>27</td>
</tr>
<tr>
<td>Appendix 5 – Equality Impact Assessment Screening Form</td>
<td>29</td>
</tr>
<tr>
<td>Appendix 6 – Assessment of Clinical Competency</td>
<td>31</td>
</tr>
</tbody>
</table>
2. **Introduction**

This document sets out Northern Devon Healthcare NHS Trust’s process for Patient Group Directions. It provides a robust framework to ensure a consistent approach across the whole organisation, and supports our statutory duties as set out in the NHS Constitution.

This policy reflects the incorporation of community services in Exeter, East and Mid Devon with Northern Devon Healthcare NHS Trust in April 2011.

In August 2000, the legal status of group protocols was clarified. Patient Group Directions (PGDs) became an additional way in which medicines could be supplied and administered to patients by a specified range of registered health care professionals without first being assessed by a licensed prescriber.

The legislation enabling registered practitioners to operate under a PGD was outlined in the Health Service circulator (HSC 2000/026 – Appendix 1) this sets out the legal requirements to develop and operate under a PGD. The relevant provisions are contained in the Human Medicines Regulations 2012 (SI 2012 No 1916. This can be accessed at www.legislation.gov.uk

Additional guidance was subsequently produced by a number of bodies, e.g. Nursing and Midwifery Council (NMC), National Prescribing Centre (NPC).

The majority of clinical care should be provided on an individual patient specific basis. The supply and administration of medicines under PGDs should be reserved for situations where this method offers advantages for patients without compromising safety.

3. **Purpose**

The purpose of this document is to ensure adherence to legislation governing the provision of medicines by Patient Group Directions (PGDs) including:

- Review of the Prescribing, Supply and Administration of Medicines 1998
- The Prescription Only Medicines (Human Use) Amendment Order 2000
- The Medicines (Pharmacy and General Sale Exemption) Amendment Order 2000
- The Medicines (sale Or supply)(Miscellaneous Provisions) Amendment (no 2) Regulations 2000
- 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 Patient Group Directions (PGDs) within Northern Devon Healthcare Trust and ensure compliance with Patient Group Directions: Good Practice Guide : NICE August 2013
http://www.nice.org.uk/about/nice-communities/medicines-and-prescribing

The objective of this policy is to set out the mechanism for developing and using PGDs within the organisation, which will then enable registered staff to provide patients with a service which is effective and timely by providing safe access to medicines.

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

The policy should be read in conjunction with supporting policies, guidelines, protocols and standard operating procedures (SOPs) listed in section 14 and 15.

This policy relates to all staff employed by Northern Devon Healthcare Trust.

4. Definitions

4.1. Patient Group Direction

“A PGD is a specific written instruction for the supply or administration of a licensed named medicine including vaccines to specific groups of patients who may not be individually identified before presenting for treatment” (HSC 2000/026 – Appendix 1).

4.2. Glossary

- POM (prescription only medicine) – patients can only obtain the medicine on prescription through a pharmacy.
- P (pharmacy medicine) – medicines can be sold in pharmacies by or under the supervision of a pharmacist.
- GSL (general sales list) – medicines can be sold in general shops as well as in pharmacies. GSL medicines can be sold directly to the public from any lockable business premises (for example, a petrol station, a supermarket) without any professional supervision. GSL medicines must be sold in certain quantities in an unopened manufacturers pack.
- Policy – A Northern Devon Healthcare Trust wide document informed and guided by national principles, which determines the expected conduct of all Northern Devon Healthcare NHS Trust employees and is legally and contractually binding upon them. A policy sets out clearly the responsibilities of both the individual and the organisation as general principles and establishes the actions to be taken in specific circumstances.
- Procedure – A procedure sets out the organisations approved method of doing a specific task by following a series of steps or stages to completion (from the Latin to move forward). A procedure is prescriptive and does not allow a practitioner any flexibility in interpretation. It is useful as an educational tool or for use by practitioners inexperienced in the particular field of practice.
- Standard Operating Procedure (SOP) – A Standard Operating Procedure describes the methods and steps to undertake a specific task which is identified within the document title of the SOP. It will outline who is responsible within the organisation and/or profession for undertaking aspects of the task. It will provide an accurate step-by-step description of how the task is to be carried out.
- Protocol – An evidence based document which assists a Healthcare Practitioner in the decision making process by guiding their assessment of a defined situation. A protocol provides scope for the practitioner to use their experience and judgement within a safe framework that clearly specifies when and what additional advice should be sought.
- Clinical Guidelines – Systemically developed directions or principles from current best available evidence that inform Healthcare Practitioners’ clinical decision making about diagnostic therapeutic or other clinical procedures in specific clinical circumstances. Clinical Guidelines are not prescriptive and are used by experienced and competent practitioners working autonomously to enhance their decision making.
- Standard – Evidence based target to measure whether the desired outcome of an intervention has been achieved.
- Care Pathway – A care pathway is an evidenced based multi-disciplinary document which describes the treatment of patients with similar problems and enables the collection of information about variations between planned and actual care.

5. Responsibilities

5.1. Role of Trust Directors

Northern Devon Healthcare NHS Trust directors are accountable for the implementation of this policy across all clinical services where staff currently or may in the future operate under PGDs.

5.2. Role of Corporate Governance Manager

Northern Devon Healthcare NHS Trust Governance Manager will assist in the distribution of this policy and the ratified Patient Group Directions will be posted on the organisations intranet.

5.3. Role of Lead Pharmacist

The Lead Pharmacist is responsible for ensuring that this Policy is applied by identifying a Chair of a Patient Group Direction Development Group and Administrator to support the management of the process.
PGDs are developed, revised or updated by the PGD Development Group which is a multidisciplinary development group, involving a doctor, a pharmacist and representatives of professional groups who will administer/supply medicines under the PGDs developed in line with the recommendation within the Health Service circular (HSC 2000/026 – Appendix 1).

Following the development of the PGD it will be signed by the medical practitioner, pharmacist and practitioner involved in the development of the PGD in accordance with the organisations ratification process as set out in the Health Service circular (HSC 2000/026 – Appendix 1).

5.4. **Role of Non-Medical Prescribing Lead**

The Non-Medical Prescribing Lead is responsible for providing training on the legal and professional aspects of operating under PGDs,

Support the development of PGD audit

Manage the development and dissemination process

5.5. **Role of the PGD administrator**

The PGD Administrator is responsible for

- Maintaining an up to date database of current and expired PGDs,
- Developing the work plan to inform the agenda of the PGD Development Group.
- Setting the agenda of the PGD Development Group
- Attending the PGD Development Group and minute the actions
- Ensuring the template is up to date and version control and history are accurate
- Responding to requests for new PGDs by distributing the application form
- Formatting new PGDs and sending for ratification
- Ensuring that PGDs and added and removed from the Trust Intranet site
- Compiling quarterly report for the D&TC/ICS of all PGDs developed and ratified during the quarter

5.6. **Role of Line Managers, Professional and Clinical Leads**

Individual line managers, professional and clinical leads are responsible for the identification of staff, which may operate under PGDs.

Individual line managers, professional and clinical leads are responsible for informing staff of this policy.
Individual line managers, professional and clinical leads must ensure staffs have attended PGD training organised by the Workforce Development department, prior to operating under a PGD and have completed the competency assessment document.  

#Appendix 6 – Assessment of Clinical Competency

This must be signed in accordance with the Assessment of Clinical Competency Policy and kept in the staff member’s personal file.


Individual line managers, professional and clinical leads must ensure staff have the appropriate training and competencies outlined in the National Prescribing Centre (NPC) PGD Framework and Patient Group Directions: Good Practice Guide : NICE August 2013 to operate under each individual PGD.

http://www.nice.org.uk/about/nice-communities/medicines-and-prescribing
http://www.nice.org.uk/guidance/mpg2

5.7. Role of All Staff using PGDs

Staff must ensure they have an up to date working knowledge of the medication they are supplying and/or administering under a Northern Devon Healthcare NHS Trust ratified PGD.

Staffs are accountable for their own professional practice and must work within this policy and their respective professional codes. PGDs must not be used as a method for self-administration.

Staff operating under a PGD must work within the relevant protocols identified within the PGD and ensure that information about the supply of a medication under a PGD is passed on to healthcare practitioners responsible for the on-going care of the patient.

Staff operating under this policy will identify any training needs and attend completed required training via Workforce Development.

PGDs must be developed, revised or updated by a multidisciplinary group involving a doctor, a pharmacist and a representative of the professional group who will administer/supply medicines under this PGD in line with the recommendation within the Health Service circular (HSC 2000/026 – Appendix 1)
6. **Policy Document Development**

6.1. **Prioritisation of Work**

This will be determined by the Drugs and Therapeutics Committee.

6.2. **Responsibility for Document Development**

As the author, the Lead Pharmacist is responsible for developing the policy and for ensuring stakeholders were consulted.

Draft copies were circulated for comment before approval was sought from the Drugs and Therapeutics Committee.

6.3. **Equality Impact Assessment**

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. An Equality Impact Assessment Tool has been undertaken and there are no adverse or positive impacts.

7. **Professional groups and individuals who can operate under PGDs**

7.1. **Classes of individuals who may supply and/or administer under a PGD are:**

- Pharmacists
- Registered chiropodists and podiatrists
- Registered dental hygienist
- Registered dental therapist
- Registered dieticians
- Registered midwives
- Registered nurses
- Registered occupational therapists
- Registered optometrists
- Registered orthoptists
- Registered orthotists and prosthetists
Registered paramedics
Registered physiotherapists
Registered radiographers
Registered speech and language therapist

7.2. These professionals can only operate under PGDs as named individuals (HSC 2000/026 – Appendix 1).

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

7.4. In order to operate under a PGD a registrant including temporary staff must:
   - Be able to **demonstrate** that they have received Northern Devon Healthcare NHS Trust or equivalent training on the principles of operating under a PGD.
   - Demonstrate that they are able to maintain their competence and identify any training needs required to safely operate under each PGD.
   - Agree to operate under the PGD by signing each individual PGD authorisation sheet.

7.5. Managers of services using PGDs must ensure that all staff who are operating under a PGD have signed the PGD authorisation sheet by countersigning the staff signature on the authorisation sheet.

8. **PGD Development**

8.1. **Identifying the need for a PGD**


Services identifying the need for a PGD must complete a PGD Development Request Form (Appendix 4) and send to the PGD Administrator.

The development of an associated Clinical protocol to be used in conjunction with the PGD will also be required if there is no current ratified protocol in place. The clinical lead of the service concerned will be responsible for producing this protocol document, which must be ratified by the Drugs and Therapeutics Committee.
Requests for a PGD received by the PGD Administrator will be considered by Drugs and Therapeutics Committee and the Patient Group Direction Development Group. If a PGD is not required the decision and rationale will be returned to the person requesting a PGD.

If a PGD is required then it will be added to the PGD Development Group work plan for allocation to a pharmacist to develop the PGD in conjunction with a clinical expert, i.e. service lead/service specialist and include medical expert in the speciality.

Those involved in the development of a PGD will attend the PGD Development Group meeting once the PGD has been prepared, to discuss and agree the content.

The Patient Group Development Group providing this service is the PGD Development Group and meetings are held on a monthly basis. The Terms of Reference will define roles and work plan for the Group.

### 8.2. Producing and Authorising PGDs

Legislation requires PGDs to be developed, revised or updated by a multidisciplinary group involving a doctor, pharmacist and a representative of the professional group who will administer/supply medicines under the PGD.

The PGD will be informed by Northern Devon Healthcare NHS Trust protocols, pathways and policies.

PGDs are developed within national and local frameworks for medicines use, such as NICE (National Institute for Clinical Excellence) guidelines and local formularies, as appropriate.

The PGD Development Group will liaise with local Drug and Therapeutic/Medicines Management/Optimisation and Formulary committees, and similar bodies with medicines expertise.

Antibiotic PGDs will be developed with guidance from a microbiologist and Formulary consideration.

Staff developing the PGD will ensure the draft PGD is put into the approved current PGD template which includes guidance for completion.

The Northern Devon Healthcare NHS Trust template complies with the legal requirements set out in HSC 2000/26 (Appendix 1) and will be reviewed at regular intervals by the PGD Development Group.

The draft PGD will be distributed to the PGD Development Group members for comments.

The final draft PGD will be tabled at the next PGD Development Group.
The PGD administrator will ensure version control and version history.

The PGD will be approved and signed by the doctor, pharmacist and service lead involved in developing the PGD.

The PGD will be logged, converted to PDF.

A final authorising signature will be required by the authorising authority for the organisation in which the PGD is used. This will be the Chair of the NDHCT Drugs and Therapeutics Committee for NDHCT

Following D&T Chair’s signature the final authorised document will be held securely by the PGD Administrator. A final copy will be distributed to line managers of the practitioners required to operate under the PGD

A watermarked ‘copy’ will be sent to the Corporate Governance Manager and uploaded onto Northern Devon Healthcare NHS Trust’s intranet for reference purposes only by the PGD Administrator. This ‘copy’ will not be signed but will be watermarked to prevent actual downloading and use outside this Policy. New PGDs will be uploaded within 1 month of authorisation

Professional/clinical leads and 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.

Annual audit of PGD use/signed documents will be undertaken by the Non-Medical Prescribing Lead PGD and the manager.

PGDs will be reviewed every two years or before if necessary.

Revised/expired PGDs will be removed from the organisation’s intranet by the PGD Administrator. Professional/clinical leads and senior managers will be advised of any PGDs which are withdrawn from use by a withdrawal letter produced by the PGD Administrator.

Revised/expired PGDs will be archived and stored in accordance with the Information Governance Policy.

8.3. **Information that must be legally contained in a PGD**

- The name of the business to which the direction applies
- The date the direction comes into force and the date it expires
- A description of the medicine(s) to which the direction applies
- Class of health professional who may supply and/or administer the medicine
- Signature of a doctor or dentist (as appropriate), a pharmacist and member of the profession to which the PGD applies
- Signature by an appropriate health organisation
• The clinical condition or situation to which the direction applies
• A description of those patients excluded from treatment under the direction
• A description of the circumstances in which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral
• Details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration and minimum or maximum period over which the medicines should be administered
• Relevant warnings, including potential adverse reaction
• Details of any necessary follow up action
• A statement of the records to be kept for audit purposes

All PGDs must be underpinned by the current best possible evidence-based e.g. clinical guidelines, consensus statements from professional groups.

These guidelines do not need to form part of the PGD but should be used as a basis for producing it and be referenced.

8.4. Medicines that can be included in a PGD

Medicines to be included in a PGD will be evaluated on receipt of the request form and discussion with the service leads. Guidance is available at:

http://www.nice.org.uk/about/nice-communities/medicines-and-prescribing

8.5. Medicines, which are excluded from a PGD

See Appendix 1 (Health Service Circular 2000.026 – pages 3 and 4).

9. Training Requirements

9.1. All staff that is required to undertake Patient Group Direction training will be identified by their line managers and service leads.

9.2. Booking for Patient Group Direction training will be through STAR. Signed records must be kept of all training undertaken in the Trust. These records will be added to ESR records. Individuals are encouraged to keep a copy in their portfolio.

9.3. All staff must complete the competency assessment document.

#Appendix 6 – Assessment of Clinical Competency

This must be signed in accordance with the Assessment of Clinical Competency Policy and kept in the staff member’s personal file.
9.4. PGD training must be updated every 3 years.

10. **Equality Impact Assessment**

10.1. The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. An Equality Impact Assessment Tool has been undertaken and there are no adverse or positive impacts. Table 1:

<table>
<thead>
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<td>Age</td>
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<td></td>
<td>PGDs will specify appropriate age bands for doses of medicines and required dose amendments in relation to age for medicines supplied/administered under that PGD</td>
</tr>
<tr>
<td>Disability</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>Gender</td>
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<td></td>
<td>X</td>
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<tr>
<td>Gender Reassignment</td>
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<tr>
<td>Human Rights (rights to privacy, dignity, liberty and non-degrading treatment)</td>
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<td></td>
<td>X</td>
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<td>Marriage and civil partnership</td>
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11. Consultation, Approval and Ratification Process

11.1. Consultation Process

The author consulted with stakeholders, including:

- Chief Pharmacist
- Head of Patient Safety
- Principal Clinical Pharmacist
- Governance Pharmacist
- Non-Medical Prescribing Lead
- Professional Groups enabled to operate under PGDs: Nursing Professional Leads, Physiotherapy Professional Leads
- Assistant Medical Director
- Chair of Drugs and Therapeutics Committee

Consultation took the form of a request for comments and feedback via email.

11.2. Policy Approval Process

Approval of the policy will be sought from the Drugs and Therapeutics Committee.

12. Review and Revision Arrangements including Document Control

12.1. Process for Reviewing the Policy

The policy will be reviewed every three years. The author will be sent a reminder by the Corporate Governance Manager four months before the due review date. The author will be responsible for ensuring the policy is reviewed in a timely manner.

The reviewed policy will be approved by the Drugs and Therapeutics Committee.

If this policy has been identified as required by the NHS Litigation Service (NHSLA), the author will ensure the Compliance Manager is sent an electronic copy.

The author must update the Document Control Report each time the policy is reviewed. Details of what has changed between versions should be recorded in the Document Control Report.

12.2. Process for Revising the Policy
In order to ensure the policy is up-to-date, the author may be required to make a number of revisions, e.g. committee changes or amendments to individuals’ responsibilities. Where the revisions are minor and do not change the overall policy, the author will make the amendments, record these in the document control report and send to the Corporate Governance Manager for publishing.

Significant revisions will require approval by the Drugs and Therapeutics Committee.

For NHS Litigation Authority (NHSLA) policies, the author will notify the Compliance Manager when a revision is being made or when the document is reviewed. The Compliance Manager will ensure that the revised document meets the NHSLA/CNST standards.

12.3. Document Control

The author will comply with the Trust’s agreed version control process, as described in the organisation-wide Guidance for Document Control.

13. Dissemination and Implementation

13.1. Dissemination of the Policy

After approval by the Drugs and Therapeutics, the author will provide a final copy of the policy to the Corporate Governance Manager to have it placed on the Trust’s intranet. The policy will be referenced on the home page as a latest news release and staff will be informed that this policy replaces any previous versions.

Information will also be included in the weekly Chief Executive’s Bulletin which is circulated electronically to all staff.

13.2. Implementation of the Policy

Line managers are responsible for ensuring this policy is implemented across their area of work.

Support for the implementation of this policy will be provided by Medicines Team and Pharmacy

14. Document Control including Archiving Arrangements

14.1. Library of Procedural Documents

The author is responsible for recording, storing and controlling this policy.
Once the final version has been approved, the author will provide a copy of the current policy to the Corporate Governance Manager so that it can be placed on the Trust’s Intranet site (Bob). Any future revised copies will be provided to ensure the most up-to-date version is available on the Trust’s Intranet site (Bob).

14.2. Archiving Arrangements

All versions of this policy will be archived in electronic format within the Medicines Management Team policy archive. Archiving will take place by the Medicines Management Team administrator once the final version of the policy has been issued.

Revisions to the final document will be recorded on the Document Control Report. Revised versions will be added to the policy archive held by Medicines Management Team on the Medicines Management Shared Drive.

14.3. Process for Retrieving Archived Policy

To obtain a copy of the archived policy, contact should be made with the Medicines Management Team administrator.

15. Monitoring Compliance with and the Effectiveness of the Policy

15.1. Standards/ Key Performance Indicators

Key performance indicators comprise:

- This policy specifically relates to CQC Essential Standards – Outcome 9.
- Patients have timely access to medicines - medication incidents will be monitored.
- All services using PGDs have current signed copies of PGDs available.
- All managers of services using PGDs will return operator signed PGD copies to the PGD Administrator for audit purposes.

15.2. Process for Monitoring Compliance and Effectiveness

- The Director of Pharmacy in conjunction with the Head of Patient Safety will put in place a programme to monitor compliance and effectiveness of this policy.
- This programme will include reviewing incidents reported through the incident reporting process and annual PGD audit.
- Where non-compliance is identified, support and advice will be provided to improve practice.
16. References

National Prescribing Centre – Patient Group Directions – December 2009
http://www.nice.org.uk/about/nice-communities/medicines-and-prescribing

Department of Health – Patient Group Directions (England) / Health Service Circular 2000/026


Nursing and Midwifery Council NMC – Standards for Medicines Management (2010)
http://www.nmc-uk.org.uk/

The Medicines & Healthcare products Regulatory Agency (MHRA)

National electronic Library of Medicines NeLM PGDs

Patient Group Directions: Good Practice Guide: NICE August 2013
http://www.nice.org.uk/about/nice-communities/medicines-and-prescribing

17. Associated Documentation

- Medicines Policy and associated SOPs
- Injectable Medicines Policy and associated SOPs
- Consent Policy
- Anaphylaxis Policy
- Latex Policy
- Clinical Record Keeping Policy
Appendix 1 – Health Service Circular 2000/026

Health Service Circular

Series Number: HSC 2000/026
Issue Date: 09 August 2000
Review Date: 09 August 2003
Category: General Health Service
Status: Action

sets out a specific action on the part of the recipient with a deadline where appropriate

PATIENT GROUP DIRECTIONS [ENGLAND ONLY]

For action by: Health Authorities (England) - Chief Executive
NHS Trusts (England) - Chief Executives

Cc: Regional Office Prescribing Leads
Health Authorities (England) – Medical and Pharmaceutical Advisers
Health Authorities (England) – Directors of Public Health
NHS Trusts (England) – Medical Directors
NHS Trusts (England) – Chief Pharmacists
NHS Trusts (England) – Nursing Directors
Primary Care Groups/Trusts – Chief Executives

Further details from: Colin Pearson
8E59 Quarry House
Quarry Hill
0113 2545975
colin.pearson@doh.gsi.gov.uk

Additional copies of this document can be obtained from:
Department of Health
PO Box 777
London
SE1 6XH
Fax 01623 724524
It is also available on the Department of Health website at
http://www.doh.gov.uk/coinh.htm
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9 August 2000
PATIENT GROUP DIRECTIONS [ENGLAND ONLY]

Action
1. Chief executives should ensure that any current or new patient group directions comply with new legal requirements and the guidance set out in this circular. Failure to comply with the law could result in a criminal prosecution under the Medicines Act.

Background
2. HSC 1998/061 enclosed copies of a Report on the Supply and Administration of Medicines under Group Protocols (the legal term for which is now Patient Group Directions). These are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. The Report recommended that the legal position should be clarified.

3. The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration of medicines under patient group directions 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.

The law
4. The relevant modifications to the provisions in and under the Medicines Act 1998 are contained in the Prescription Only Medicines (Human Use) Amendment Order 2000, the Medicine (Pharmacy and General Sale – Exemption) Amendment Order 2000 and the Medicines (Sale and Supply) (Miscellaneous Provisions) Amendment (No2) Regulations 2000. The changes come into force on 9 August 2000. The legislation applies to the NHS, including private and voluntary sector activity funded by the NHS. Therefore it covers treatment provided by NHS Trusts, Primary Care Trusts, Health Authorities (including SHAs), GP or dental practices, Walk-in Centres and NHS funded family planning clinics. It does not otherwise apply to the private and voluntary sectors (further legislation is proposed in due course).

5. The patient group direction must be signed by a senior doctor (or, if appropriate, a dentist) and a senior pharmacist, both of whom should have been involved in developing the direction. Additionally the patient group direction must be authorised by the HA, SHA, NHS Trust, Primary Care Trust or Primary Care Group (in its capacity as a sub-committee of the HA). Clinical Governance Leads are probably best placed to do this.

6. The qualified health professionals who may supply or administer medicines under a patient group direction are nurses; midwives; health visitors; optometrists; pharmacists; chiropodists; radiographers; orthopists; physiotherapists and ambulance paramedics. They can only do so as named individuals.

7. The legislation specifies that each patient group direction must contain the following information:
   - the name of the business to which the direction applies;
   - the date the direction comes into force and the date it expires;
   - a description of the medicine(s) to which the direction applies;
   - class of health professional who may supply or administer the medicine;
   - signature of a doctor or dentist, as appropriate, and a pharmacist;
   - signature by an appropriate health organisation;
   - the clinical condition or situation to which the direction applies;
   - a description of those patients excluded from treatment under the direction;

9 August 2000
Additional guidance

8. NHS bodies should already be following the recommendations in the Review Team’s Report. In particular

- Patient group directions should be drawn up by a multi-disciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to supply medicines under the PGD. It is good practice to involve local Drug and Therapeutics Committees, Area Prescribing Committees and similar advisory bodies.

- A senior person in each profession should be designated with the responsibility to ensure that only fully competent, qualified and trained professionals operate within directions.

- All professions must act within their appropriate Code of Professional Conduct.

- Appropriate document(s) should be signed by each member of the multi-disciplinary group, the Clinical Governance lead on behalf of the authorising NHS organisation and the individual health professionals working under the direction. Generally, a direction should be reviewed every two years.

9. There must be comprehensive arrangements for the security, storage and labelling of all medicines. Wherever possible, medicines should be supplied in pre-packs made up by a pharmacist. In particular there must be a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient by patient basis. Names of the health professionals providing treatment, patient identifiers and medicine provided should all be recorded. The NHS Executive document Controls Assurance Standard – Medicines Management (Safe and Secure Handling) provides guidance on related legislative requirements and best practice.

10. The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicines, including those supplied under patient group directions.

11. It is important that the use of any medicine is consistent with the Summary of Product Characteristics for the relevant product (save in special circumstances – see paragraph 13) and any relevant guidance from NICE.

Antimicrobials

12. Particular caution should be exercised in any decision to draw up PGDs relating to antibiotics. Microbial resistance is a public health matter of major importance and great care should be taken to ensure that their inclusion in a direction is absolutely necessary and will not jeopardise strategies to combat increasing resistance. A local microbiologist should be involved in drawing up the PGD. The local Drug and Therapeutics Committee or Area Prescribing Committee should ensure that any such directions are consistent with local policies and subject to regular external audit.

Black Triangle Drugs and medicines used outside the terms of the Summary of Product Characteristics

13. Black triangle drugs (ie, those recently licensed and subject to special reporting arrangements for adverse reactions) and medicines used outside the terms of the Summary of Product

9 August 2000
Health Service Circular

Characteristics (e.g., as used in some areas of specialist paediatric care) may be included in PGDs provided such use is exceptional, justified by current best clinical practice (e.g., NICE guidance) and that a direction clearly describes the status of the product. Black triangle vaccines used in immunisation programmes may be included in PGDs, provided they are used in accordance with the schedules recommended by the Joint Committee on Vaccination and Immunisation. Where the medicine is for children, particular attention will be needed to specify any restrictions on the age, size and maturity of the child. Each PGD should clearly state when the product is being used outside the terms of the SPC and the documentation should include the reasons why, exceptionally, such use is necessary.

Controlled Drugs

14. The use of controlled drugs continues to be regulated under the Misuse of Drugs Act 1971. However, the Medicines Control Agency is initiating discussion with the Home Office about a possible amendment to the Misuse of Drugs Regulations to allow the use of substances on schedules 4 & 5 under PGDs.

Other exemptions and restrictions

15. Ambulance paramedics, midwives and chiropodists are already exempt from certain requirements of the Medicines Act. These exemptions, which allow them to administer or supply certain specified medicines without the directions of a doctor, will continue and are not affected by the new provisions for PGDs. The administration of radiopharmaceuticals continues to be regulated by the Medicines (Administration of Radioactive Substances) Regulations 1978 and should not be included in patient group directions.

Regional Office monitoring

16. Regional Offices have been asked to develop arrangements to monitor and share good practice. A website will be developed to provide examples of model directions. The Joint Colleges Ambulance Liaison Committee is devising a set of model directions for use by ambulance paramedics.

This Circular has been issued by:

Dr Sheila Adam
Deputy Chief Medical Officer/Health Services Director
Appendix 2 – To PGD or Not to PGD

TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations

**BEBEFORE YOU START**

We recommend that you have a multidisciplinary discussion to carefully consider if there is, or could be, an opportunity in the care pathway to use a prescription or a written **Patient Specific Direction** by a doctor or non-medical prescriber. **Patient Group Directions (NICE Guideline MPOD1) (2013)** states that you should consider investing in the training of additional non-medical prescribers to enable redesign of some services if necessary.

---

**IF YOU HAVE CONSIDERED AND ACTED ON THE ABOVE STATEMENT**

**START HERE**

Do you still want to consider if a PGD is an appropriate option?

No or not sure

---

The preferred way for patients to receive medicines is for a prescriber to provide care for an individual patient on a one-to-one basis.

Options include:
- Individual written prescription to be dispensed by a registered pharmacy
- **Patient Specific Direction**
- Health professionals should refer to their own regulatory or professional bodies standards/guidance where available e.g. NMC Standards and GMC Prescribing Guidance. General good practice principles are relevant to all prescribers.
- Do not use PGDs unless there are clear benefits for patient care without compromising patient safety and there are clear governance arrangements and accountability.

---

Are the health professionals?
- [ ] Registered Medical
- [ ] Registered Optometrist
- [ ] Registered Paramedic
- [ ] Registered Physiotherapist or podiatrist
- [ ] Registered Nurse working within an occupational health scheme

---

A PGD may not be required if the professional activity fits within the exemptions in Schedule 17 Human Medicines Regulations (HMFR) 2012 and associated advisory instruments.

---

Are the medicines that these registered health professionals need to supply or administer listed in the exemptions?

---

A PGD may need to be considered.

---

A PGD is not required. The registered health professional has authority to supply or administer in accordance with Human Medicines Regulations (HMFR) 2012

---

Some organisations use PGD’s in these circumstances although it is not a legal requirement.

---

Are the medicines involved all licensed medicines?

---

A **Patient Specific Direction** or a prescription must be written by a doctor, dentist or non-medical prescriber to instruct other suitably trained and competent health professionals to supply and administer a medicine. There should be clear governance arrangements and accountability.

---

Only licensed medicines (i.e. those with a UK marketing authorisation (UKMA)) can be supplied and administered via a PGD.

---

**OFF label** use of a licensed medicine can be included in a PGD only when clearly justified by best clinical practice. See **Patient Group Directions (NICE Guideline MPOD1) (2013)** Recommendation 3.1.7 and note that some organisations have additional policies with reference to off label use. Medicines which do not have a UKMA must be prescribed. Consider developing a local protocol or treatment guidelines for dressings and medical devices.

---

The MHRA states that the mixing of two separate medicinal products will result in a new, unlicensed product if one product cannot be described as a vehicle for the administration of the other e.g. as a reassessment or diluting agent. A PGD cannot be used for unlicensed products. These must be prescribed.

---

If you are referring to a hard copy of this document – please check the NHS PGD Website (England) www.pgd.nhs.uk to make sure that you are using the most recent version.
TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations

This diagram is designed to take you through a process to aid decision making and help you consider whether a Patient Group Direction (PGD) is appropriate for an area of practice that involves the supply or administration of medicines. The diagram also has links which may impact legislation, national guidelines, Patient Group Directions [NICE Guideline MP02] (2013), and other PGD Website resources.

- Is the PGD to be used for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis?
- Will the medicines involved require frequent or complex monitoring — e.g. background or insulin?
- Are the medicines involved antibiotics?
- Are the medicines involved black triangle medicines?

A PGD should not be used. Patient Group Directions [NICE Guideline MP02] (2013) Recommendation 2.1.14

A PGD may be used but see Patient Group Directions [NICE Guideline MP02] (2013) Recommendation 2.1.10 before proceeding.

A PGD may be used but see Patient Group Directions [NICE Guideline MP02] (2013) Recommendation 2.1.18 before proceeding.

This chart may not cover all situations proposed for using PGDs. The proposed activity should meet the principles stated in Patient Group Directions [NICE Guideline MP02] (2013) 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.

FAQ – V4.0
FAQ: labelling of POMs supplied under PGD
FAQ: dispensation
FAQ: training supervision
All other PGD Website tools and other PGD Website FAQs
Patient Group Directions [NICE Guideline MP02] (2013) Pathway and tools and resources
CPSI PGD learning package
Your local medicines and PGD policies

To PGD or not to PGD Version 9. Published by NHS PGD Website (England) June 2015. THIS VERSION IS FOR ENGLAND ONLY. Review due June 2018 (or earlier subject to legislation or other guidelines changed). If you are referring to a hard copy of this document, please check the NHS PGD Website (England) www.pgd.nhs.uk to make sure that you are using the most recent version.
Appendix 3 – PGD Flowchart

FLOWCHART FOR THE IDENTIFICATION, DEVELOPMENT, DISSEMINATION, IMPLEMENTATION, MONITORING, AUDIT AND REVIEW OF PATIENT GROUP DIRECTIONS (PGDs) WITHIN NORTHERN DEVON HEALTHCARE TRUST

Identification by clinician / service to develop a PGD

Complete PGD Development Request form and send to PGD Administrator

Request received by Drugs and Therapeutics Committee and PGD Group to be considered

If YES, proceed as follows

If NO, refer back to clinician

A Pharmacist will be identified to develop the PGD working in conjunction with the professional and medical lead in the service where the PGD will be used. Expert opinion will be sought and documented.

PGD to be put into current template

Draft PGD to be distributed to PGD Development Group for comment

Final draft PGD to be tabled at PGD Development Group meeting by pharmacist and medical and professional lead developing the PGD

PGD to be approved and signed by Pharmacist, Medical Practitioner and professional lead at PGD Development Group

Chair of Drugs and Therapeutics Committee to be notified by email of PGDs to be ratified by Drugs and Therapeutics Committee

Ratification of PGD – signed off by Chair of Drugs and Therapeutics Committee and reported to Drugs and Therapeutics Committee

To ICS under SLA for CCG authorisation

PGD Document Control sheet to be updated and date as ratified at Drugs and Therapeutics Committee

Final Document Control Sheet and PGD to be scanned as one document and disseminated, along with standard covering letter to identified professional leads for cascade

Document Control sheet and PGD to be watermarked “For Electronic Reference Only – this must not be printed out” and uploaded onto Intranet

PGD Administrator to provide regular PGD status reports to Drugs and Therapeutics Committee and update Work plan for NDHCT
### Appendix 4 – PGD Request Form

**REQUEST FOR THE DEVELOPMENT OF A PATIENT GROUP DIRECTION (PGD) WITHIN NORTHERN DEVON HEALTHCARE NHS TRUST**

<table>
<thead>
<tr>
<th>Your Name: (please print)</th>
<th>Job Title: (please print)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

Where are you based: (organization name and full postal address and telephone number)

<p>| |</p>
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On whose behalf are you requesting this PGD (name of organisation / service):

<p>| |</p>
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Their address if different from your base address:

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</table>

Your contact details:

<table>
<thead>
<tr>
<th>Telephone:</th>
<th>Mobile:</th>
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<tbody>
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<td></td>
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<table>
<thead>
<tr>
<th>Email:</th>
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Please identify the lead clinician who has agreed to work on the development of the PGD:

<p>| |</p>
<table>
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</thead>
</table>
Details of the PGD required:

Name of the medication/service for which you need a PGD *(please print)*

________________________________________________________________________

________________________________________________________________________

Is this request supported by a protocol? If so, please provide details:

________________________________________________________________________

________________________________________________________________________

Please detail the benefit to the patient:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Please provide details of the clinical evidence to support this request: *(this may be attached as a separate document)*

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Please return this form to:

PGD Administrator
Northern Devon Healthcare Trust
Unit 1
Exeter International Business Park
Clyst Honiton, Exeter
EX5 2HL

Application for PGD
Accepted / Not Accepted
✓ / X
Date: ................

Reason/s why the application for PGD has not been accepted and suggestions for the supply/administration of the medication identified.

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Appendix 5 – Equality Impact Assessment Screening Form

<table>
<thead>
<tr>
<th>Equality Impact Assessment Screening Form</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>Author</strong></td>
</tr>
<tr>
<td><strong>Directorate</strong></td>
</tr>
<tr>
<td><strong>Team/ Dept.</strong></td>
</tr>
<tr>
<td><strong>Document Class</strong></td>
</tr>
<tr>
<td><strong>Document Status</strong></td>
</tr>
<tr>
<td><strong>Issue Date</strong></td>
</tr>
<tr>
<td><strong>Review Date</strong></td>
</tr>
</tbody>
</table>

1. What are the aims of the document?
   This document sets out Northern Devon Healthcare NHS Trust’s system for Patient Group Directions. It provides a robust framework to ensure a consistent approach across the whole organisation, and supports our statutory duties as set out in the NHS Constitution.

2. What are the objectives of the document?
   The purpose of this document is to ensure adherence to legislation governing the provision of medicines by Patient Group Directions (PGDs) It will provide guidance on the process for the identification, development, dissemination, implementation, monitoring, audit and review of Patient Group Directions (PGDs) within Northern Devon Healthcare Trust.

3. How will the document be implemented?
   The Policy will be published on the Trust Intranet and included in the Chief Executives Bulletin within two weeks of ratification. All service managers will receive an emailed copy for implementation for use in their services. Training will be provided via Workforce Development for staff operating under this Policy. Line managers are responsible for ensuring this policy is implemented across their area of work. Support for the implementation of this policy will be provided by Medicines Management Team and Pharmacy.

4. How will the effectiveness of the document be monitored?
   - The Director of Pharmacy in conjunction with the Head of Patient Safety will put in place a programme to monitor compliance and effectiveness of this policy.
   - This programme will include reviewing incidents reported through the incident reporting process and annual PGD audit.
   - Where non-compliance is identified, support and advice will be provided to improve practice.

5. Who is the target audience of the document?
   All staff operating under PGDs and their appropriate line managers and service leads

6. Is consultation required with stakeholders, e.g. Trust committees and equality groups?
   Yes
### 7 Which stakeholders have been consulted with?
- Director of Pharmacy
- Head of Patient Safety
- Corporate Governance Manager
- Non-Medical Prescribing Lead
- Principal Clinical Pharmacist
- Governance Pharmacist
- Director & Assistant Director of Nursing
- Physiotherapy Professional Leads

### 8 Equality Impact Assessment
Please complete the following table using a cross, i.e. X. Please refer to the document “A Practical Guide to Equality Impact Assessment”, Appendix 3, on the Trust’s Intranet site (Bob) for areas of possible impact.

- Where you think that the policy could have a **positive** impact on any of the equality group(s) like promoting equality and equal opportunities or improving relations within equality groups, cross the ‘Positive impact’ box.

- Where you think that the policy could have a **negative** impact on any of the equality group(s) i.e. it could disadvantage them, cross the ‘Negative impact’ box.

- Where you think that the policy has **no impact** on any of the equality group(s) listed below i.e. it has no effect currently on equality groups, cross the ‘No impact’ box.
Appendix 6 – Assessment of Clinical Competency

Assessment of Clinical Competency

Competency: Using Patient Group Directions

Competency statement:
The practitioner has been assessed as competent in the task of using Patient Group Directions on the date recorded below.

Underpinning Knowledge (including relevant policies and procedures):

<table>
<thead>
<tr>
<th>Competency area:</th>
<th>Patient consultation</th>
<th>Date of assessment and assessor initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>For every PGD used understands the clinical condition(s) being treated/given prophylaxis for, their natural progress and how to assess their severity</td>
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<tr>
<td>Understands and follows any local or national protocols or policies that underpin the PGDs used (e.g. Green Book)</td>
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<tr>
<td>Demonstrates an up-to-date knowledge about the medicine(s) included in each PGD used, including its basic mode of action, indication, contraindications, cautions and important drug interactions</td>
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<tr>
<td>Is able to undertake an appropriate clinical assessment, including taking medical history and medication history</td>
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<tr>
<td>Is able to make, or understand, the diagnosis by considering and systematically decidng between the various possibilities</td>
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<td></td>
</tr>
<tr>
<td>Knows when to consider alternative options for treating the service user’s condition, including no treatment, non-drug and drug interventions</td>
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<td></td>
</tr>
<tr>
<td>Is able to select the most appropriate PGD for an individual service user</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is able to explain the service user’s condition and the rationale behind the treatment options, including the risk of harm and potential benefit, and the consequences of refusing the treatment</td>
<td></td>
<td></td>
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<tr>
<td>Knows how to assess the service user’s understanding of, and commitment to, their treatment/prophylaxis, monitoring and follow-up</td>
<td></td>
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</tbody>
</table>

Competency area: Safe and effective

Knows how to identify and report safety incidents relating to the PGD, such as medication errors, near misses and suspected adverse events. Is aware of Trust incident reporting policy and medication errors standard operating procedure.
<table>
<thead>
<tr>
<th>Competency</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is able to assess the risk of, and deal with, adverse events after administration of a medicine, including supportive measures for potentially life-threatening adverse events</td>
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<tr>
<td>Is able to check doses and calculations to ensure accuracy and safety</td>
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<tr>
<td>Understands and works within relevant code(s) of professional conduct and organisational governance arrangements</td>
<td></td>
</tr>
<tr>
<td>Understands and follows the Trust PGD policy and medicines policy</td>
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</tr>
<tr>
<td>Has completed PGD governance training (either face-to-face or online) within the last three years</td>
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<tr>
<td>Knows the limits of their own knowledge, skills and experience and works within them</td>
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</tr>
<tr>
<td>Thinks and acts as part of a multidisciplinary team to ensure that continuity of care is developed and not compromised.</td>
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</tr>
<tr>
<td>Knows when to refer to, or seek guidance from, another member of the team or a specialist.</td>
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</tr>
</tbody>
</table>

**Signatures on completion:**

<table>
<thead>
<tr>
<th>Role</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature of Practitioner:</td>
<td>Print Name:</td>
</tr>
<tr>
<td>Position:</td>
<td>Ward/Dept.:</td>
</tr>
<tr>
<td>Date:</td>
<td></td>
</tr>
<tr>
<td>Signature of Assessor:</td>
<td>Print Name:</td>
</tr>
<tr>
<td>Position:</td>
<td></td>
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<tr>
<td>Date:</td>
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</table>

This competence document is based on the NICE PGD competence framework (2014).