Policy for the Development and Authorisation of Patient Group Directions

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<tr>
<th>Ratified</th>
<th>Medicines Management Committee</th>
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<td>Approved</td>
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<td>June 2016</td>
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<tr>
<td>Author</td>
<td>Marie Thompkins</td>
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Policy Validity Statement
This policy is due for review on the date shown above. After this date, policy and process documents may become invalid.

Policy users should ensure that they are consulting the currently valid version of the documentation.
Version Control

<table>
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<th>Release Date</th>
<th>Author</th>
<th>Update comments</th>
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<td>V1</td>
<td>June 2016</td>
<td>Marie Thompkins</td>
<td>Non-Applicable New</td>
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Approval

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<tr>
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<th>Name</th>
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<tr>
<td>Approver</td>
<td>Executive Committee</td>
<td>18th May 2016</td>
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Review

This document will be reviewed two years from its issue date.
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1. Introduction

The supply and administration of medicines is controlled by The Medicines Act 1968 and controlled drugs (CDs) are regulated by The Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001. Following a parliamentary review these were amended to allow for the supply and administration of medicines, without the need for an individual prescription, by a defined group of health professionals under Patient Group Directions (PGDs).

The Health Service Circular 2000/026 (9th August, 2000) Patient Group Directions (PGDs)1, subsequent amendments and more recently PGD guidance issued by the Medicines & Healthcare Regulatory Agency (MHRA)2, Regulations 229-232 of the Human Medicines Regulations 20123 and NICE Good Practice Guidance 20134 detail the legislation and guidance governing the development, implementation, use and review of PGDs within the NHS and other organisations providing NHS health care services. This policy ensures South Tyneside CCG complies with these regulations.

Many health care providers such as NHS Acute Trusts, Foundation Trusts and organisations outside of the NHS, e.g. Independent hospitals, agencies and clinics, police, armed forces healthcare services, prison healthcare services, are able to both develop and authorise PGDs under their own internal governance arrangements for use in their organisation. However, for the provision of NHS commissioned services then only the following organisations are allowed to authorise patient group directions. These are: Clinical Commissioning Groups, Local Authorities, NHS Trusts, NHS Foundation Trusts, Special Health Authorities and NHS England. The development of the PGD is to be determined locally by the commissioner and provider.

For organisations such as General Practice, Dental Practice, Community Pharmacy and for other NHS services commissioned from non NHS organisations, there is a requirement for any PGD for use in these organisations to be authorised by the appropriate authorising body; for services commissioned by and delivered within South Tyneside and provided by any of these organisations the authorising body is as listed above.

The development of a PGD should not proceed until the South Tyneside Medicines Management Committee, with the delegated authority of South Tyneside CCG has formally agreed that a PGD is needed.

Either the commissioner of the NHS services or provider organisation may have responsibility for developing PGDs.

The transitional arrangements that commenced on 1st April 2013 meant that responsibility for PGDs previously authorised by a PCT was transferred to the new body responsible for the service in question. Therefore, for example, the PGDs that supported the national immunisation programs were transferred to NHS England Area Teams. The receiving bodies will be responsible for having clear arrangements in place for the ongoing review and development of all relevant inherited PGDs.

The process for development, approval and management of PGDs must be followed on all occasions.
PGD Development, Approval and Management Process

**PGD Working Group**
Develops PGDs to support specific services
- 1 Pharmacist
- 1 Doctor

**Medicines Management Committee**
Approves new and reviewed PGDs
Approves the use of new PGDs for individual services before development

**Governance Approval**
- Director of Nursing Quality and Safety and
- Clinical Director, Prescribing Lead

**Quality and Patient Safety Committee**
Considers all exceptions before

**Circulation**
- To clinicians who will work under authorisation of PGD
- Available on website
- Managed by NECS Medicines Optimisation team
2. Purpose and Scope

The policy document outlines the role of South Tyneside CCG in the authorisation of PGDs that support NHS health care services commissioned by South Tyneside CCG and provided by:

- Doctors
- Dentists
- Persons lawfully conducting a registered retail pharmacy

Any other healthcare provider providing NHS services funded by South Tyneside CCG who is unable by law, to authorise PGDs within their own organisation.

In addition, the policy document outlines the role of South Tyneside CCG in the development and distribution of PGDs they have authorised.

The policy describes the role of South Tyneside CCG in ensuring compliance with current legislation, guidance and best practice.

3. Definitions

A PGD is defined as “a written direction relating to the supply or administration of a named medicine in an identified situation. It applies to groups of patients (rather than named patients) who may not necessarily be individually identified prior to presentation for treatment.”

A PGD must be developed in accordance with legislation and national guidance as listed below. A PGD is NOT an authorisation to prescribe i.e. instruct others to supply or administer a medicine.

- Human Medicines Regulations 2012 (SI 2012 No 1916)
- Good Practice Guidance (No. 02) - Patient Group Directions (NICE 02/08/13)
- Standards for the Medicines Management (NMC 2009)
- The Code. Standards of conduct, performance and ethics (NMC 2008)
- British National Formulary (current online edition)
- Immunisation against Infectious Disease (The Green Book) (current online edition)
- Patient Group Directions website http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/
## 4. Duties and Responsibilities

| **Director of Nursing, Quality and Safety** | • Overall responsibility for ensuring that there are processes in place to ensure that PGDs are authorised in accordance with legislation and national guidance within South Tyneside CCG.  
• Overall responsibility for ensuring that the PGDs that support South Tyneside CCG commissioned NHS services are developed and distributed in line with current legislation, local organisation policies, governance arrangements and best practice. |
| **Authorised signatories** | • The joint authorised signatories will be the Director of Nursing, Quality and Safety and the Clinical Director with responsibility for prescribing.  
• They will be responsible for ensuring effective implementation of this policy.  
• Responsibility for ensuring the provision for the necessary pharmaceutical, medical and other appropriate clinical expertise for the development of commissioned NHS services requiring PGDs.  
• Responsibility for providing assurance of competence of the pharmaceutical, medical and other clinician expertise provided for the development of South Tyneside CCG PGDs. (see NICE GPG2 competency frameworks)  
• Responsibility for ensuring the service provider has access to copies of approved PGDs |
| **PGD Approval Group** | The Medicines Management Committee (MMC) will act as the PGD approval group. The MMC has delegated responsibilities that include:  
• Considering requests for new PGDs following the criteria in section 5.  
• A robust and transparent appeals process  
• Prioritising proposals to develop a PGD  
• Seeking the views of stakeholders on proposals, for example, from clinical groups, patients and the public, and the commissioning or provider organisation(s)  
• Gathering intelligence about local service delivery and exploring all the options for  
• Prescribing, supplying and/or administering medicines in a specific situation  
• Considering the arrangements for the security, storage, packaging and labelling of medicines  
• Considering the resources needed to deliver the service, such as medicines procurement from a licensed manufacturing unit and any diagnostic equipment  
• Engaging with finance and commissioning to align decisions within the framework of clinical commissioning  
• Considering the resources, training and competencies needed for developing, authorising, using, monitoring, reviewing and updating the PGD  
• Ensuring decision-making is robust and transparent with final decisions on proposals formally recorded and communicated to appropriate stakeholders. |
Ensuring all approved PGDs are reviewed in a timely manner.

**PGD Working groups**
The working group(s) are multidisciplinary and include a lead author, a doctor, a pharmacist, a representative of other professional groups who will practice under the PGD. Other experts may be seconded to the group as needed. Any of these professionals may be the lead author as agreed by the group. The working groups are responsible for the development and review of one or a number of PGDs as agreed with the Approval Group. In addition the working group is responsible for ensuring all PGDs are updated and maintained appropriately. Working groups will be formed as needed for each individual PGD or groups of PGDs. The working group is accountable to the MMC.

### 5. Identifying the need for a Patient Group Direction

Wherever possible medicines are to be administered or supplied on an individual patient basis following the direction of a prescriber for that specifically named patient.

Patient Group Directions should not be used to provide long term treatment. Patient Group Directions should normally be reserved to meet immediate or short term conditions or health needs. Using a PGD is not a form of prescribing and PGDs do not allow professionals to use prescription forms or other means to order medicines to be supplied by others.

The use of a PGD does not remove the inherent professional obligation and accountability of a registered healthcare professional as defined by their registration body. It is the responsibility of each professional to ensure that they understand the use, dose, adverse effects, cautions and contraindications of each medicines they supply or administer. Professionals must continue to use their professional judgement in each individual situation.

A Patient Group Direction will only be developed:
- In response to an identified service need or development.
- For situations where the use of PGDs will benefit patient care, without compromising safety, compared to other mechanisms for the supply or administration of medicines.
- Where other options for the supply or administration of a medicine have been considered and appraised.
- Where exemptions in legislation are not in place to allow supply / administration without the need for a PGD.
6. Medicines that may be included in a Patient Group Direction

All medicines may be considered for inclusion in a PGD with the exception of:

- Unlicensed medicines (i.e. medicines that do not have a current UK/EU marketing authorisation). This includes 2 or more separate licensed medicines mixed together.
- Medicines used outside their licensed indications, unless the indication is justified by current best practice i.e. as described in Public Health England: Immunisation Against Infectious Disease – The Green Book;
- Radiopharmaceuticals
- New drugs under intensive monitoring and subject to special adverse drug reaction reporting requirements (‘Black Triangle drugs’), unless the use is justified by current best practice
- Controlled Drugs:
  - Schedule 2 controlled drugs (with the exception of morphine and diamorphine by registered pharmacists and nurses in any setting for the immediate and necessary treatment of a sick or injured person (except for treatment of addiction)).
  - Schedule 3 controlled drugs with the exception of midazolam
  - Schedule 4 Part 1 controlled drug used in parenteral form for the management of drug addiction.

The inclusion of antimicrobial agents in a Patient Group Direction must be absolutely necessary and not jeopardise strategies to combat increasing resistance. The local Trust Consultant Microbiologist should be part of the multidisciplinary group developing the PGD. Legally a PGD is not required to administer a Pharmacy Only (P) Medicine or administer or supply a General Sales List (GSL) medicine, but can be used.

A decision to allow a medicine to be included in a PGD is to be taken in relation to issues of governance rather than legal eligibility.

7. Request to develop a Patient Group Direction

Persons identifying a need for a PGD must obtain approval for its development and subsequent use by submitting a PGD development proposal request to the MMC using the approved PGD Request Form (see Appendix A).

Requests are to include the following information:

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

The PGD approval group will consider requests for PGD development and approve if appropriate. Prior to approval of a request other individuals or groups may be consulted, as appropriate Approval is to be granted in writing (see Appendix B), following consideration of the information provided (see section 7.2), benefits and risks and the principles outlined in section 5, and is to include:

• Approval of the doctor, pharmacist and other members of the working group proposed or, if not identified in the request, identification and approval of the persons to develop the PGD. Where appropriate to do so, staff employed by external organisations such as Commissioning Support Unit may be involved in the development of a PGD.

• Stipulation of any specific requirements or limitations to the PGD including:
  - Minimum qualification/training requirements for those using the PGD
  - Maximum doses or length of treatment
  - Criteria for patients to be excluded from the PGD
  - Criteria for exclusions or restrictions on the use of the PGD regarding service provision.

• All exceptions must be referred to Quality and Patient safety Committee for final approval

8. Development of a Patient Group Direction (PGDs)

PGDs will only be developed in response to an identified service need. The PGD must take into account the priorities of the NHS organisation and Providers and be supported by appropriate training.

PGDs must be developed in accordance with legislation, national guidance and include any specific requirements stipulated in the approval of the development of the PGD (see section 7). South Tyneside CCG will take the lead on developing PGDs for services commissioned by South Tyneside CCG that specifically require and specify the use of PGDs, unless otherwise stated in the service specification.
South Tyneside CCG will develop PGDs in collaboration with the service provider(s). PGDs must be written using the standard format and presentation template (see Appendix B). The development of new PGDs, which are not part of any nationally endorsed programme, should not be commenced until the person(s) that have identified the need for the PGD, have followed the pathway in Appendix C and obtained the appropriate approval for its development and use, by completion of the “PGD Development Request Form (see Appendix A).

The update and renewal of existing Patient Group Directions will follow the same process as for the development of new PGDs, but without the need for the completion of a PGD Development Request form as described in Appendix A.

The PGD Working Group may consult with other relevant stakeholders or persons during the development of the PGD. In submitting the PGD for authorisation to the Approval group, the working group must detail any consultation that has been undertaken.

The PGD must enable the highest standard of practice for each clinical situation to be achieved. Patient Group Directions must be signed by the senior doctor, pharmacist and at least one representative of the professional group(s) involved in the development of the PGD prior to submitting it for approval. Signatures of the doctor(s) and pharmacist(s) are an acceptance of responsibility for the clinical and pharmaceutical accuracy and appropriateness of a PGD in the circumstances in which it will be used. Those signing PGDs need to ensure adequate indemnity arrangements are in place.

The supply and administration of medicines under Patient Group Direction should be reserved for those limited situations where this offers an advantage to patient care without compromising patient safety and be consistent with appropriate professional relationships and accountability. The majority of clinical care should still be provided on an individual, patient specific basis, as recommended by legislation. The algorithm “To PGD or not to PGD – That is the Question” shown in Appendix C, should be used prior to submitting any PGD development request, as it supports & clarifies the needs assessment for a PGD for any particular service.

An example PGD document layout is shown in Appendix B.

**9. Who should be involved in the development of a Patient Group Direction?**

The PGD Working Group is a multidisciplinary group including as a minimum, a senior doctor, a senior pharmacist and a representative of each of any professional groups expected to supply/administer medicines under that PGD. All of the group should be involved in the development of the PGD and are responsible for ensuring that supply and administration of medicines by PGD is within the law. One of the involved professionals will be nominated as Lead Author.

The Medicines Management Committees must be consulted prior to development and it is good practice to involve similar advisory bodies.

The senior doctor should be a doctor who has expert knowledge in the therapeutic field the PGD is addressing. (refer to GPG2 competency framework).
The senior pharmacist should be a pharmacist who has expert knowledge in the therapeutic field the PGD is addressing together with expert knowledge on the development and use of PGDs.

The representative of the other professional group(s) should also be a specialist in the particular clinical field being addressed within the PGD.

The senior doctor, pharmacist and member(s) of the healthcare profession expecting to use the PGD, must sign the PGD Front Sheet to indicate satisfactory completion of the PGD, (See also Appendix B). The signature may be added electronically with permission from the signatory. All group members should have appropriate training and competence to carry out their expected role as defined in NICE GPG2 competency framework.

10. What should be included in a Patient Group Direction

The legislation specifies that each PGD 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 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 medicine should be administered
- Relevant warnings, including potential adverse reactions
- Details of any necessary follow-up action and the circumstances
- A statement of the records to be kept for audit purposes

It should be noted that any adverse clinical incidents that occur in relation to the supply and/or administration of medications within a PGD should be recorded using local reporting mechanisms. Any serious adverse side effects of medications should be reported in the usual way, using the yellow card system.
11. **Who is permitted to use Patient Group Directions**

The following health professionals covered by the legislation to date to supply or administer medicines under a Patient Group Direction (PGD) and currently registered include:

<table>
<thead>
<tr>
<th>Pharmacists</th>
<th>Nurses</th>
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<tr>
<td>Radiographers</td>
<td>Physiotherapists</td>
</tr>
<tr>
<td>Chiropodists/Podiatrists</td>
<td>Midwives</td>
</tr>
<tr>
<td>Orthoptists</td>
<td></td>
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<tr>
<td>Optometrists</td>
<td>Dieticians</td>
</tr>
<tr>
<td>Occupational Therapists</td>
<td>Prosthetists and Orthotists</td>
</tr>
<tr>
<td>Dental Hygienists</td>
<td>Dental Therapists</td>
</tr>
<tr>
<td>Speech and Language Therapists</td>
<td>Paramedics</td>
</tr>
</tbody>
</table>

These professionals may only supply or administer medicines under a PGD as named individuals.

12. **Authorisation of Patient Group Directions**

Prior to authorisation the senior doctor, pharmacist and other appropriate members of the PGD working group must have signed the appropriate section of the PGD front sheet to indicate satisfactory completion of that PGD.

Before new or reviewed PGDs can be issued for use, the PGD must be authorised by the Director of Nursing, Quality and Safety and the Clinical Director with responsibility for prescribing (See section 4). They must both sign and date the PGD Front Signature Sheet (see Appendix B – page 1).

Any proposed changes or updates to an existing PGD must follow the same authorisation procedure. Once authorised, the amended PGD will immediately supersede the previous PGD for that area of practice.
13. Dissemination of patient group directions

When a new or revised PGD is developed and authorised, an electronic copy, will be sent to all appropriate suppliers. A pdf copy of the original document will be available on the South Tyneside Information Portal and Medicines website.

The original signed master copy of all PGDs will be retained for 8 years after the PGD expiry date and a log of all PGDs in use will also be maintained.

14. Review of Patient Group Directions

A Patient Group Direction is to be reviewed, if necessary revised, and re-authorised every 2 years or sooner if new information becomes available.

The MMC is responsible for ensuring that PGDs are reviewed in a timely manner and for identifying appropriate persons to form the working group.

The MMC is responsible for highlighting new information or circumstances which may require a PGD being reviewed.

Unless there are major changes to the personnel reviewing or using the PGD or the use of the PGD, the process in section 7 does not need to be followed.

Revised PGDs are to be developed, authorised and distributed as detailed in section 8, 9, 10, 11 and 12.

When a PGD is reviewed all the changes made must be highlighted when submitting to the MMC for authorisation. Major changes to an existing PGD will be highlighted (see section 13) when distributed.

15. Competence to develop and authorise Patient Group Directions

NICE has published good practice guidance on the use of PGDs

The guidance includes the core competencies needed for the safe use of PGDs in practice. This guidance should be read by all those involved with development, authorisation and users of PGDs. South Tyneside CCG will meet the requirement of national guidance “to ensure that only fully competent, qualified & trained professionals operate within directions,”

- By ensuring that PGDs developed, include minimum requirements and standards of training, experience and skills.
- By identifying any additional training requirements, standards of training and the necessary experience/skills needed in specific circumstances, when approving PGDs.
- Where required, through service specifications and monitoring of services in which a PGD is used.
16. Training

Any persons developing and authorising PGDs must be appropriately trained and competent for this role (see section 15).

17. References


18. **Equality Analysis**

An Equality Impact Assessment (EIA) is a process of analysing a new or existing service, policy or process. The aim is to identify what is the (likely) effect of implementation for different groups within the community (including patients, public and staff).

We need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Equality Act 2010
- Advance equality of opportunity between people who share a protected characteristic and those who do not
- Foster good relations between people who share a protected characteristic and those who do not

This is the law. In simple terms it means thinking about how some people might be excluded from what we are offering.

The way in which we organise things, or the assumptions we make, may mean that they cannot join in or if they do, it will not really work for them.

It’s good practice to think of all reasons why people may be excluded, not just the ones covered by the law. Think about people who may be suffering from socio-economic deprivation or the challenges facing carers for example.

This will not only ensure legal compliance, but also help to ensure that services best support the healthcare needs of the local population.

Think of it as simply providing great customer service to everyone.
As a manager or someone who is involved in a service, policy, or process development, you are required to complete an Equality Impact Assessment using this toolkit.

| **Policy** | A written statement of intent describing the broad approach or course of action the Trust is taking with a particular service or issue. |
| **Service** | A system or organisation that provides for a public need. |
| **Process** | Any of a group of related actions contributing to a larger action. |

**STEP 1 - EVIDENCE GATHERING**

| Name of person completing EIA: | Marie Thompkins |
| Title of service/policy/process: | Policy for the Development and Authorisation of Patient Group Directions |
| Existing: | ☐ New/proposed: ✓ Changed: ☐ |

What are the intended outcomes of this policy/service/process? Include outline of objectives and aims

To ensure that all Patient Group Directions approved for use in South Tyneside are of an appropriate quality and enhance patient safety. All patient group directions should be appropriate for the service.

Who will be affected by this policy/service/process? (please tick)

- ✓ Staff members
- ✓ Other

If other please state:

Anyone wishing to develop a Patient Group Direction for use in services commissioned by South Tyneside CCG

What is your source of feedback/existing evidence? (please tick)

- ✓ National Reports
- ☐ Staff Profiles
- ☐ Staff Surveys
- ☐ Complaints/Incidents
- ☐ Focus Groups
- ☐ Previous EIAs
- ☐ Other

If other please state:
<table>
<thead>
<tr>
<th>Evidence</th>
<th>What does it tell me? (about the existing policy/process? Is there anything suggest there may be challenges when designing something new?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Reports</td>
<td>NICE: Good Practice Guidance 02 sets out the requirements of legislation related to Patient Group Directions and also defines best practice</td>
</tr>
<tr>
<td>Staff Profiles</td>
<td></td>
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<tr>
<td>Staff Surveys</td>
<td></td>
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<tr>
<td>Complaints and Incidents</td>
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<tr>
<td>Staff focus groups</td>
<td></td>
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<tr>
<td>Previous EIA's</td>
<td></td>
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<tr>
<td>Other evidence (please describe)</td>
<td></td>
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STEP 2 - IMPACT ASSESSMENT

What impact will the new policy/system/process have on the following staff characteristics: (Please refer to the ‘EIA Impact Questions to Ask’ document for reference)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Definition</th>
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<tbody>
<tr>
<td><strong>Age</strong></td>
<td>A person belonging to a particular age</td>
</tr>
<tr>
<td><strong>Disability</strong></td>
<td>A person who has a physical or mental impairment, which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities</td>
</tr>
<tr>
<td><strong>Gender reassignment (including transgender)</strong></td>
<td>Medical term for what transgender people often call gender-confirmation surgery; surgery to bring the primary and secondary sex characteristics of a transgender person's body into alignment with his or her internal self perception.</td>
</tr>
<tr>
<td><strong>Marriage and civil partnership</strong></td>
<td>Marriage is defined as a union of a man and a woman (or, in some jurisdictions, two people of the same sex) as partners in a relationship. Same-sex couples can also have their relationships legally recognised as 'civil partnerships'. Civil partners must be treated the same as married couples on a wide range of legal matters</td>
</tr>
<tr>
<td><strong>Pregnancy and maternity</strong></td>
<td>Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the period after the birth, and is linked to maternity leave in the employment context.</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td>It refers to a group of people defined by their race, colour, and nationality, ethnic or national origins, including travelling communities.</td>
</tr>
<tr>
<td><strong>Religion or belief</strong></td>
<td>Religion is defined as a particular system of faith and worship but belief includes religious and philosophical beliefs including lack of belief (e.g. Atheism). Generally, a belief should affect your life choices or the way you live for it to be included in the definition.</td>
</tr>
<tr>
<td><strong>Sex/Gender</strong></td>
<td>A man or a woman.</td>
</tr>
<tr>
<td><strong>Sexual orientation</strong></td>
<td>Whether a person's sexual attraction is towards their own sex, the opposite sex or to both sexes</td>
</tr>
<tr>
<td><strong>Carers</strong></td>
<td>A family member or paid helper who regularly looks after a child or a sick, elderly, or disabled person</td>
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</tbody>
</table>

STEP 3 - ENGAGEMENT AND INVOLVEMENT

How have you engaged with staff in testing the policy or process proposals including the impact on protected characteristics?

- Discussed at Medicines Management Committee and with Director of Nursing and Quality

Please state how staff engagement will take place:

- None required
### STEP 4 - METHODS OF COMMUNICATION

<table>
<thead>
<tr>
<th>What methods of communication do you plan to use to inform staff of the policy?</th>
</tr>
</thead>
<tbody>
<tr>
<td>x Verbal – through focus groups and/or meetings</td>
</tr>
<tr>
<td>□ Written – Letter</td>
</tr>
<tr>
<td>□ Email x Internet</td>
</tr>
</tbody>
</table>

If other please state:

### STEP 5 - SUMMARY OF POTENTIAL CHALLENGES

Having considered the potential impact on the people accessing the service, policy or process please summarise the areas have been identified as needing action to avoid discrimination.

<table>
<thead>
<tr>
<th>Potential Challenge</th>
<th>What problems/issues may this cause?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
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<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

### STEP 6 - ACTION PLAN

<table>
<thead>
<tr>
<th>Ref no.</th>
<th>Potential Challenge/ Negative Impact</th>
<th>Protected Group Impacted (Age, Race etc)</th>
<th>Action(s) required</th>
<th>Expected Outcome</th>
<th>Owner</th>
<th>Timescale/ Completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>Ref no.</td>
<td>Who have you consulted with for a solution? (users, other services, etc)</td>
<td>Person/People to inform</td>
<td>How will you monitor and review whether the action is effective?</td>
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</table>

**SIGN OFF**

Completed by: Marie Thompkins  
Date: 9th May 2016  
Signed:  
Presented to: (appropriate committee) Executive Committee  
Publication date: June 2016
## Appendix A

### Request for the Development of a Patient Group Direction

The following document should be completed prior to the development of a full PGD.

**Request to Develop a Patient Group Direction**

<table>
<thead>
<tr>
<th>Title of PGD</th>
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</table>

<table>
<thead>
<tr>
<th>Name of service in which the PGD is to be used</th>
</tr>
</thead>
<tbody>
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</table>

<table>
<thead>
<tr>
<th>Circumstances in which the PGD is to be used</th>
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</table>

<table>
<thead>
<tr>
<th>Condition or health need to be met &amp; benefit to patient care</th>
</tr>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Medicine(s) to be included in PGD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
Please tick below to indicate how the medicine will be provided:

<table>
<thead>
<tr>
<th>Supply</th>
<th>Administration</th>
<th>Both</th>
</tr>
</thead>
</table>

**Professional group(s) to be included in PGD**

**Specific qualifications or training requirements.**

**Benefits and advantages of using a PGD over other methods of supply or administration e.g. prescribing, patient specific direction.**
<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the PGD required to support a new service development?</td>
</tr>
<tr>
<td>If yes please provide details including indication as to whether service development has been approved and funded.</td>
</tr>
</tbody>
</table>

| Details of how medicine will be funded, purchased and stored. |

<table>
<thead>
<tr>
<th>If known please name the healthcare professionals who will be writing the PGD.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
</tr>
<tr>
<td>Pharmacist</td>
</tr>
<tr>
<td>Other(s)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposer</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please send completed form to: marie.thompkins@nhs.net
The request will be considered by the Medicines Management Committee at the next meeting and you will be informed of the outcome within 7 days.

The request to develop a Patient Group Direction for use within South Tyneside has / has not been (delete as appropriate) approved for development.

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
<td>………………………………</td>
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</tbody>
</table>

Medicines Management Committee Chair

Approval has been granted on the condition that the following requirements or restrictions are included in the Patient Group Direction.

**Qualifications, training and competency**

**Other requirements / restrictions**

Other comments:
### Patient Group Direction (PGD) for the Administration of

Name of medication

by Registered Professionals to Individuals Accessing Name of Service NHS Service in

Name of Commissioning Organisation

---

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

Direction Number: - XXXX

Valid from: XX XX XXXX
Review date: XX XX XXXX

Expiry date: XX XX XXXX

---

<table>
<thead>
<tr>
<th>This patient group direction has been developed &amp; produced by: -</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>Senior Pharmacist</td>
</tr>
<tr>
<td>Senior Doctor</td>
</tr>
<tr>
<td>Senior Professional</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>This PGD has been approved for use in South Tyneside by: -</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>Director of Nursing, Quality and Safety</td>
</tr>
<tr>
<td>Clinical Director</td>
</tr>
</tbody>
</table>
1. Clinical Condition or Situation to Which the Direction Applies

**Indication** (defines situation or condition)

**Objectives of care**

**Inclusion criteria** (as per Public Health England (PHE) Green Book Guidance (Sept. 2013))

Only use those criteria that are specific to your authorised role & competence.

**Exclusion criteria** (Refer to current SPC and Green Book Guidance (Online version) for additional details)

**Precautions**

**Action if excluded**

**Circumstances in which further advice should be sought from doctor and/or specialist**
### Action if patient declines treatment

<table>
<thead>
<tr>
<th>Name, strength &amp; formulation of drug</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Legal Status:</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Dosage/Dose range:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Route/Method:</th>
</tr>
</thead>
</table>

**Frequency of Administration:** (Refer to PHE Green Book Guidance (Sept. 2013) for additional details)

<table>
<thead>
<tr>
<th>Maximum dose / Maximum number of vaccinations:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Follow up treatment:</th>
</tr>
</thead>
</table>
### 3. Further Aspects of Treatment:

#### Relevant Warnings & Potential Adverse Effects

**Relevant Warnings:**

**Potential Adverse Effects/ Reactions:** -

See Manufacturers SPC for full details of all potential adverse reactions.

#### Identification and Management of Adverse Reactions

#### Reporting Procedure of Adverse Effects

See manufacturers Summary of Product Characteristics for details of all potential adverse reactions.

#### Advice to Patient / Carer (verbal or written)

#### Arrangements for Referral to Medical Advice

#### Records

#### Additional Facilities
4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

<table>
<thead>
<tr>
<th>Pharmacists</th>
<th>Nurses</th>
<th>Chiropodists/Podiatrists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Visitors</td>
<td>Physiotherapists</td>
<td>Midwives</td>
</tr>
<tr>
<td>Dieticians</td>
<td>Optometrists</td>
<td>Registered Orthoptists</td>
</tr>
<tr>
<td>Prosthetists and Orthotists</td>
<td>Radiographers</td>
<td>Occupational Therapists</td>
</tr>
<tr>
<td>Speech and Language Therapists</td>
<td>Dental Hygienists</td>
<td>Dental Therapists</td>
</tr>
</tbody>
</table>

State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.

**Qualifications required (professional registration applies to specific professions)**

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council
<table>
<thead>
<tr>
<th><strong>Additional requirements</strong> (applies to all staff)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th><strong>Continued training requirements</strong> (applies to all staff)</th>
</tr>
</thead>
</table>
Management & Monitoring of Patient Group Direction  

**PGD Number**

<table>
<thead>
<tr>
<th>Name of Medication</th>
</tr>
</thead>
</table>

**Individual Healthcare Professional Authorisation**

*This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.*

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional: - ________________________________________________

is authorised to administer ______________________ under this Patient Group Direction (*PGD Number*)

Signature of Healthcare Professional: - ________________________________________________

Date signed: - ______________________

State profession: - ________________________________________________

**Authorisation to use this PGD by:** -

This above named healthcare professional has been authorised to work under this PGD by:

Name of Manager/Clinical Lead: - ________________________________________________

Signature of Manager/Clinical Lead: - ________________________________________________

Date signed: - ______________________

<table>
<thead>
<tr>
<th>PGD Valid from:</th>
<th>Review Date:</th>
<th>Expiry Date:</th>
</tr>
</thead>
</table>
Management & Monitoring of Patient Group Direction  **PGD Number**

**Name of Medication**

**Healthcare Professional Authorisation (service/practice list)**

*This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.*

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

**Name of Medication** under the Patient Group Direction (*PGD number*)

**PGD Valid from date:**  **PGD Expiry Date:**

<table>
<thead>
<tr>
<th>Healthcare Professional</th>
<th>Authorised by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Signature</td>
</tr>
<tr>
<td></td>
<td>Name</td>
</tr>
</tbody>
</table>

**PGD Valid from:**  **Review Date:**  **Expiry Date:**
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 augment to legislation, national guidelines Patient Group Directions (NHS Guideline MDDO01632) and other NHS FOD websites resources.

Continued from page 1, do not start from this point.

Is the medicine involved a Pharmacy P or General Sales List (GSL) medicine?

Yes

Is the practice under the PGD administration only?

Yes

PGD is not required. A protocol should be implemented to administer medicines that are P or GSL. This also applies to medical gases, none of which are POM.

No

Is the practice under the PGD only for supply to the patient to take the medicine home?

Yes

Note – some organisations choose to use PGDs in these circumstances although not a legal requirement.

No

Supply of a P Medicine is required

A PGD is required unless the medicine is being sold or supplied by a registered pharmacist from a registered pharmacy. Note: some community pharmacy contractors may be commissioned to use PGDs to supply P medicines for NHS or public funded services but this is not a legal requirement.

Is adjustment of a dose required?

Yes

Dose adjustment is only allowed under a PGD where the PGD is being used to supply and administer the medicine. A PGD does not give a legal framework for registered health professionals to adjust the dose of a medicine already in a patient’s possession. A PGD cannot be used.

No

A PGD can specify a dose range to allow selection of an appropriate dose for a patient.

Is the medicine involved Controlled Drugs?

Yes

Are the medicines involved Controlled Drugs?

Yes

Dose the activity involve the administration of diamorphine or morphine by a registered nurse or pharmacist for the immediate necessary treatment of nil or acute pain? Involve the supply of a Schedule 2 CD?

Yes

Is this drug to be used for the treatment of addiction or is it an anabolic steroid?

Yes

A PGD cannot be used. See CD PGD

No

No

No

A PGD may be used. See CD PGD

Go to page 8

No

No

To PGD or not to PGD Version 9. Published by NHS PGD Website (England) June 2015. THIS VERSION IS FOR ENGLAND ONLY. Review date 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.
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 links with which support to suppose, sections guidelines Patient Group Directions HCP Guidance MPh24(2016) and other MPh PGD clinical resources.

Continued from page 2, do not start from this point.

Is the PGD to be used for managing long-term conditions, such as hypertension or diabetes, or where uncertainty remains about the differential diagnosis?

Yes

No

A PGD should not be used.
Patient Group Directions HCP Guidance MPh24(2016) Recommendations 2.1.14

A PGD may be used if you see Patient Group Directions HCP Guidance MPh24(2016) Recommendations 2.1.10 before proceeding.

Are the medicines involved antibiotics?

Yes

No

A PGD may be used if you see Patient Group Directions HCP Guidance MPh24(2016) Recommendations 2.1.10 before proceeding.

Are the medicines involved black triangle medicines?

Yes

No

A PGD may be used if you see Patient Group Directions HCP Guidance MPh24(2016) Recommendations 2.1.10 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 HCP Guidance MPh24(2016). 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.

If having considered all of the above, you decide that a PGD may be an appropriate route to provide this clinical activity, also ensure that you consider other medicines legislation and clinical governance issues at all stages of the process. We recommend that you also refer to the following:

- PGD -什麼是? PGD - 什麼是?
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Appendix D

Additional guidance

- 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.

- The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicines, including those supplied under PGDs. A patient information leaflet should be made available to patients treated under PGDs.

- 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) and any relevant authoritative good practice guidance.