1. INTRODUCTION

1.1. The preferred way for patients to receive the medicines they need is for a prescriber (Doctor, dentist or non-medical prescriber) to issue a prescription for a medicine for an individual patient. That prescription would then be dispensed by a pharmacist or dispensing doctor and the medicine issued to the patient.

1.2. Following the Crown Report (Review of prescribing, supply and administration of medicines) in 1999, Legal frameworks were developed that have allowed services to be redesigned and health professionals to work more flexibly for the benefit of patients. As a result of these changes, there are now several legal options for supplying and/or administering medicines, one of which is the use of Patient Group Directions (PGDs). Legislation establishing PGDs was introduced in 2000 and the Health Service Circular (HSC 2000/026) provided additional guidance. The current legislation for PGDs is included in The Human Medicines Regulations 2012 (amended 2013)

1.3. PGDs provide a legal framework that allows specified categories of registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber. However, supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care, without compromising patient safety.

1.4. In August 2013 NICE produced guidance on the production, implementation and use of Patient Group Directions (NICE medicines practice guidelines: Patient Group Directions [MPG2], August 2013). The purpose of this protocol is to ensure that the production and use of PGDs within the Trust complies with NICE MPG2 recommendations.

2. SCOPE

2.1. This procedure describes the processes required for the development, review, authorisation, and monitoring of new and existing PGDs. It also describes the competencies required of the people involved in the development and review of PGDs, the authorisation of PGDs and the healthcare professionals working under PGDs, within the Trust. It applies to all healthcare professionals developing and reviewing PGDs, all registered healthcare professionals working under PGDs, and all managers considering the need for PGDs when looking at service redesign, or the introduction of new services.
3. DEFINITION OF A PGD

3.1. A PGD is defined as 'Written instructions for the supply or administration of medicines to groups of patients who may or may not be individually identified before presentation for treatment.' This means that patients may either be known to a service, e.g. a list of children provided to an immunisation clinic for vaccination, or may not be known before they arrive, e.g. patients turning up at a no-appointment walk-in centre.

3.2. A PGD is NOT a form of prescribing

4. ASSESSING THE NEED FOR NEW PGDS

4.1. Approval from the Medicines Management Group must be obtained before any PGD can be developed, unless the PGD is necessary in order to provide a national service e.g. National Immunisation Programme.

4.2. A PGD Working Group consisting of a lead author, supported by a doctor (or dentist), a pharmacist and a representative of any other professional group who will practise under the PGD must be convened to develop the PGD proposal at service/directorate level and make an initial assessment and recommendation to the Medicines Management Group. The proposal must demonstrate that:

- A PGD is the most appropriate method to supply and/or administer the medicine.
- Treatment cannot be delivered on an individual named basis either by prescription or Patient Specific Direction.
- The PGD is a legal method for supply and/or administration of the medicine in the proposed care setting.

4.3. The PGD Working Group will use the national PGD website tools to consider whether a PGD is necessary or appropriate. E.g. “To PGD or Not to PGD” (Annex 3) They will ensure that the health professional group being considered to practice under the PGD can legally do so, and also consider other options e.g. exemptions in legislation which may allow medicine supply and/or administration without the need for a PGD. The Group will consider the following:

- There must be a UK marketing authorisation for the medicine, in line with legislation.
- If the use is Off-label of a licensed medicine, it must be clearly justified by best clinical practice. (e.g. The Green Book recommendations for immunisation)
- Off-label use must have Trust approval. Refer to CLPG13 for further information
- Black triangle medicines should only be included in a PGD when clearly justified by best clinical practice.
A controlled drug will only be included in a PGD when legally permitted and clearly justified by best clinical practice. The Trust CD Accountable Officer must be aware and agree in principle with the PGD Proposal.

Dose adjustments to a medicine supplied under a PGD cannot be made when the medicine is already in the patient's possession.

A PGD should not normally include more than one medicine. The risks and benefits should be considered on a case-by-case basis.

A PGD should not be used for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.

The appropriate consultation with antimicrobial experts has taken place if the PGD is for an antimicrobial medicine.

A PGD should not include a medicine needing frequent dosage adjustments or frequent or complex monitoring (for example, anticoagulants or insulin).

If the medicine is to be supplied to a patient rather than administered, the availability and cost of prepacks.

How and where the medicine will be stored.

4.4. The PGD Working Group will submit the PGD Proposal using the PGD Proforma and Checklist (Annex1) to the MMG for approval once they are satisfied that the necessary criteria have been met and there is sufficient information to support the proposal.

4.5. The Medicines Management Group will consider the following in relation to the PGD Proposal:

- all legal requirements have been met
- robust local processes and clear governance arrangements are in place
- the risks and benefits of all options for supplying and/or administering the medicine(s) have been explored
- the PGD will deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety
- the views of stakeholders, such as clinical groups, patients and the public, and the commissioning organisation have been considered
- appropriate registered health professionals are available to use the PGD, and training and competency needs are addressed
- people who are developing, authorising, monitoring, reviewing and updating the PGD are identified, and their training and competency needs are addressed
- the need for appropriately labelled packs and safe storage can be met
- adequate resources, such as finance, training, medicines procurement and diagnostic equipment are available for service delivery
- adequate resources are available to ensure that processes are followed within any locally agreed timeframe
- decisions are aligned with local clinical commissioning frameworks.
5. DEVELOPING PGDS

5.1. Development of a PGD should not proceed until the Medicines Management Group has formally agreed that a PGD is needed.

5.2. The PGD will be developed by the PGD Working Group.

5.3. A named lead author as identified on the approved PGD Proposal has responsibility for developing a PGD, supported by the PGD working group, as specified in the approved PGD Proposal.

5.4. The lead author must not work in isolation. Members of the PGD working group should be regularly involved at each stage of the process.

5.5. The Working Group may communicate “virtually” rather than face-to-face.

5.6. When developing a PGD that includes an antimicrobial medicine, the Working Group must liaise with a local specialist in microbiology. Where the PGD is intended for use in more than one locality, the specialists for each locality must be consulted.

5.7. The Working Group must seek views on draft PGDs and agree final draft PGDs with relevant stakeholders, including clinicians and local medicines decision-making groups where applicable.

5.8. The Trust PGD Template (see Annex 2) must be used to write the PGD.

5.9. PGDs must be consistent with the relevant Summary of Product Characteristics (SPC), unless the medicine is being used off-label or relevant national guidance is being followed.

5.10. Where a medicine is to be used off-label, this must be clearly stated in the relevant section of the PGD. The best available up to date evidence must be used, such as NICE guidance and other sources of high-quality information when developing PGDs. References must be listed.

5.11. A senior responsible person who will authorise named registered health professionals to work under the PGD should be made known to the Working Group.

6. REVIEWING AND UPDATING PGDS

6.1. A structured work programme for reviewing, updating and re-authorising PGDs must be in place and regularly reviewed. PGDs should normally be scheduled to be reviewed and updated within 6 months of their expiry date.

6.2. All amendments, regardless of how minor, require a PGD to be re-authorised.

6.3. Where review of a PGD results in no changes to practice, it must still be re-authorised when it is due to expire within the next six months.
6.4. The named lead author of the existing PGD is responsible for reviewing and updating it, and for reconvening the PGD Working Group. Membership should be reviewed to ensure that existing membership remains appropriate and departing members are replaced. Where the lead author is no longer with the Trust/changed roles, the Chief Pharmacist will identify a new lead author.

6.5. When reviewing the PGD, the Working Group will conduct an appropriate literature search to identify, evaluate and assess new evidence for relevance and validity.

6.6. When reviewing the PGD, the Working Group must determine whether the PGD remains the most appropriate option to deliver the service. This should be informed by local monitoring and evaluations, frequency of use of the PGD, views of health professionals working under the PGD and views of relevant stakeholders, such as patients or their carer. Any changes in legislation must also be considered.

6.7. Any changes to the existing PGD should be made using “Track Changes” facility of Microsoft Word.

6.8. If it is decided that a PGD is no longer appropriate or necessary, the lead author should inform the Medicines Management Committee. The Professional Lead should make arrangements to ensure that all practitioners are aware that the PGD is to be withdrawn from practice and that any associated changes in procedure are communicated appropriately.

6.9. Expiry dates of updated/reviewed PGDs must be determined on a case-by-case basis and must not exceed 3 years.

6.10. All reviewed and updated PGDs must be re-authorised by the Trust (see section 5) and communicated to services via the EPUT Intranet as per section 5.9. Tracked versions should be presented to Medicines Management Group for approval and ratification and to authorising signatories.
This Proforma must be completed for all new PGD applications. The checklist must be used when considering a new PGD to ensure that a PGD is appropriate and legal, to help ensure the necessary people and personnel are involved at the outset and to agree a work plan locally. Supporting information may be required as evidence that treatment cannot be delivered on an individual named basis and that a PGD is a safe method for supply and/or administration of this medicine in this care setting before a PGD is developed.

All sections of this form must be completed. Please complete electronically where possible. Refer to CLPG13 appendix 9 for further guidance.

<table>
<thead>
<tr>
<th>TITLE OF PGD</th>
<th>Add detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Medicine</td>
<td></td>
</tr>
<tr>
<td>Form and Strength</td>
<td></td>
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<tr>
<td>Dose and Route</td>
<td></td>
</tr>
<tr>
<td>Frequency</td>
<td></td>
</tr>
<tr>
<td>Main inclusion criteria</td>
<td></td>
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<tr>
<td>Main exclusion criteria</td>
<td></td>
</tr>
<tr>
<td>PGD Proposer</td>
<td>Add Name and Job Title</td>
</tr>
<tr>
<td>Service/setting where the PGD is to be used</td>
<td>Add detail</td>
</tr>
<tr>
<td>Condition to be treated</td>
<td>Add detail</td>
</tr>
</tbody>
</table>

### CHECKLIST

<table>
<thead>
<tr>
<th>People and Resources</th>
<th>YES/NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>A local PGD Working group (including doctor/dentist and senior clinical pharmacist/Lead Pharmacist for the speciality) have been identified to support the development of a PGD.</td>
<td></td>
</tr>
<tr>
<td>Additional co-authors for the PGD have been identified if appropriate e.g. member of specialist service</td>
<td></td>
</tr>
<tr>
<td>All of the above agree to provide dedicated time and resource for this commitment within agreed timeframes.</td>
<td></td>
</tr>
<tr>
<td>Adequate resources are (or will be) available for the development, implementation and monitoring/audit of the PGD i.e. finance, time, equipment, training. (NB Resources must be adequate enough to ensure that due process is followed within PGD protocol and within any locally agreed timeframes)</td>
<td></td>
</tr>
<tr>
<td>If the proposed PGD is for a new service or re-designed care pathway, patients and the public have been involved.</td>
<td></td>
</tr>
</tbody>
</table>
Prescribing or PGD – decision making

<table>
<thead>
<tr>
<th>YES/NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is a new PGD.</td>
</tr>
<tr>
<td>A PGD is appropriate and legal. See To PGD or not to PGD annex 1 See PGD Protocol (CLPG13 Appendix 9) for information that should be covered to ensure that any final decision is robust.</td>
</tr>
<tr>
<td>Prescribing on an individual basis by a doctor, dentist or non-medical prescriber is not appropriate or achievable within the care pathway and there is a clear patient benefit.</td>
</tr>
<tr>
<td>The patient group and the condition to be treated are well defined and apply to a discrete episode of care.</td>
</tr>
</tbody>
</table>

Supporting information has been provided

<table>
<thead>
<tr>
<th>YES/NO</th>
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</thead>
<tbody>
<tr>
<td>The Medicine(s)</td>
</tr>
<tr>
<td>The medicine has a UK Marketing Authorisation (licensed)</td>
</tr>
<tr>
<td>The medicine is being used within its licensed indications or is being used outside of licensed indications but is already Trust approved.</td>
</tr>
<tr>
<td>An appropriately labelled pack is available where the medicine is to be supplied for the patient to take home.</td>
</tr>
<tr>
<td>If the medicine is an antibiotic – Infection Control Committee are aware and agree in principle with the PGD Proposal.</td>
</tr>
<tr>
<td>Supporting Guidance and/or Trust Patient Information leaflet are used to support practice under this PGD and are approved by the Trust.</td>
</tr>
<tr>
<td>If the medicine is a controlled drug, it is legally permitted and the Trust CD Accountable Officer is aware and agrees in principle with the PGD Proposal.</td>
</tr>
</tbody>
</table>

Practice

<table>
<thead>
<tr>
<th>YES/NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered health professionals who will practice under the PGD are registered with the appropriate professional body and are listed in PGD legislation</td>
</tr>
<tr>
<td>Consideration has been given to the design of and resources for training and competency assessment of practitioners and ongoing support</td>
</tr>
<tr>
<td>If answers to any of the above are No or if you have any questions, please contact CHS Lead Pharmacists/Mental health Pharmacy Dept as appropriate</td>
</tr>
<tr>
<td>If answers to ALL of the above are Yes, proceed to Declaration</td>
</tr>
</tbody>
</table>

Declaration of PGD Working Group

The people named below support this proposal and agree to be involved, undertaking responsibilities and duties as laid out in the Trust PGD Protocol.
<table>
<thead>
<tr>
<th>Name and Job Title</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lead Author</strong></td>
<td>This may be either the professional lead for the service where the PGD is to be used or the lead pharmacist as appropriate</td>
</tr>
<tr>
<td><strong>Co-authors</strong></td>
<td>This may be any other professionals involved in writing the PGD</td>
</tr>
<tr>
<td><strong>Doctor/dentist</strong></td>
<td>A doctor (or dentist as applicable) is required to be involved in the development of a PGD</td>
</tr>
<tr>
<td><strong>Professional lead in service where PGD is proposed</strong></td>
<td>If not the lead author</td>
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</tbody>
</table>

**Supporting Information**

<table>
<thead>
<tr>
<th>People and Resources</th>
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<tbody>
<tr>
<td>State which service budget will fund the cost of the medicine</td>
<td></td>
</tr>
<tr>
<td>Name of manager who has identified and authorised funding</td>
<td></td>
</tr>
<tr>
<td>State who will be responsible for training staff to work under the PGD</td>
<td></td>
</tr>
<tr>
<td>If the proposed PGD is for a new service or re-designed care pathway, state how patients and the public have been involved</td>
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<table>
<thead>
<tr>
<th>Prescribing or PGD – decision making</th>
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</thead>
<tbody>
<tr>
<td>State why prescribing on an individual basis by a doctor, dentist or non-medical prescriber is not appropriate or achievable within the care pathway</td>
<td></td>
</tr>
<tr>
<td>State how a PGD for the service will benefit the patient</td>
<td></td>
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<tr>
<td>State the patient group to which the PGD will apply</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>The Medicine(s)</th>
<th></th>
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<tbody>
<tr>
<td>State how the medicine is to be obtained</td>
<td></td>
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<tr>
<td>State how the medicine will be stored at the clinic/unit</td>
<td></td>
</tr>
<tr>
<td>State how the medicine will be supplied to the patient (e.g. original pack, pre-pack etc)</td>
<td></td>
</tr>
<tr>
<td>State Name of antimicrobial professional involved in proposed PGD if medicine is an antimicrobial</td>
<td></td>
</tr>
<tr>
<td>Provide copies of patient information leaflets other than manufacturer’s PIL if using</td>
<td></td>
</tr>
<tr>
<td>Date of approval in principle by Trust Accountable Officer for Controlled Drugs if PGD is a Controlled Drug</td>
<td></td>
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</tbody>
</table>

**Practice**

| State which group/s of registered healthcare professionals will be working under the PGD |
| State how competency of registered professional to work under the PGD will be assessed |
| State what training will be put in place |

**Medicines Management Group Approval:**

This PGD proposal has been considered by the Medicines Management Group and is/is not approved as the most appropriate route to provide this clinical activity.

**Date approved/rejected:**

**If proposal is rejected, state reasons:**

**Signature of MMG Chair:**
PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY AND/OR ADMINISTRATION (DELETE AS APPROPRIATE) OF (INSERT Drug Name) For the treatment/prevention of /immunisation against (delete as appropriate) XXXXXXXXX

CLASS: e.g. POM

Controls Assurance Statement
The aim of this Patient Group Direction is to ensure that the supply and administration of medicines under a Patient Group Direction complies with the legal requirements and guidance set out in HSC2000/026: Patient Group Directions (England Only). Failure to comply with the law could result in criminal prosecution under the Medicines Act.

Patient Group Direction Development

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Base</th>
</tr>
</thead>
<tbody>
<tr>
<td>Louise Crowley</td>
<td>Lead Pharmacist</td>
<td>St Margaret’s Hospital, Epping</td>
</tr>
</tbody>
</table>

This patient group direction must be agreed to and signed by all health care professionals involved in its use. The NHS Trust should hold the original signed copy. The PGD must be easily accessible in the clinical setting.

Authorisation

<table>
<thead>
<tr>
<th>Lead Doctor</th>
<th>Name:</th>
<th>Position:</th>
<th>Signature:</th>
<th>Date:</th>
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<tr>
<th>Lead Nurse/healthcare professional</th>
<th>Name:</th>
<th>Position:</th>
<th>Signature:</th>
<th>Date:</th>
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<table>
<thead>
<tr>
<th>Lead Pharmacist</th>
<th>Name:</th>
<th>Position:</th>
<th>Signature:</th>
<th>Date:</th>
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<thead>
<tr>
<th>Clinical Governance Lead</th>
<th>Name:</th>
<th>Position:</th>
<th>Signature:</th>
<th>Date:</th>
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</table>
Responsibility for ensuring this PGD is reviewed

Position: Community Health Services Lead Pharmacists

Clinical Condition

Indication

Need to be specific on the clinical condition to be treated. Is it a licensed indication - check SPC, BNF.

Inclusion criteria

Follow any clinical guidelines or policies that are available either locally or nationally e.g. SIGN, NICE, Prodigy.
Check SPC.
Consult clinicians working in that area.

Exclusion criteria

Check SPC/published guidelines such as SIGN, NICE, Prodigy.
Decide if there are limitations for service i.e. to age or patient groups (e.g. immunocompromised patients).

Explain reason for exclusion if necessary e.g.
- Patients on methotrexate – reduced excretion, increasing risk of toxicity.
  Provide cut off points for exclusion e.g. not just “children” but for example “children under two years old”
- Include interactions here that may give rise to toxicity or need for an increased dose e.g. salbutamol PGD would exclude patients taking beta blockers.

Explain action to take if patient is to be excluded e.g.
- Should a doctor wish to exclude a particular patient from these directions this must be recorded in the patient’s notes and on the prescription and administration record.

Cautions/Need for further advice

- Check SPC / published guidelines such as SIGN, NICE, Prodigy.
- Pregnancy and breast feeding – explain reason for inclusion, exclusion or caution whenever possible.
- Interactions – list ones that are clinically significant and relevant to this PGD and provide advice if possible e.g.:
  - Anticoagulants – effects may be enhanced (prolonging the prothrombin time). Advise patient that INR may change whilst taking drug X and to monitor more closely if appropriate.

Action if patient declines or is excluded

Enter details of action to be taken according to local policy e.g.
- Excluded patients will have their treatment managed by the appropriate medical team.

Referral arrangements for medical advice

Enter details of local arrangements e.g. contact appropriate doctor (GP, ward doctor, team doctor, or duty doctor through EPUT switchboard).

Evaluation of treatment and follow up action

To be decided locally.

Drug Details

Responsibility for ensuring this PGD is reviewed

Position: Community Health Services Lead Pharmacists

Clinical Condition

Indication

Need to be specific on the clinical condition to be treated. Is it a licensed indication - check SPC, BNF.

Inclusion criteria

Follow any clinical guidelines or policies that are available either locally or nationally e.g. SIGN, NICE, Prodigy.
Check SPC.
Consult clinicians working in that area.

Exclusion criteria

Check SPC/published guidelines such as SIGN, NICE, Prodigy.
Decide if there are limitations for service i.e. to age or patient groups (e.g. immunocompromised patients).

Explain reason for exclusion if necessary e.g.
- Patients on methotrexate – reduced excretion, increasing risk of toxicity.
  Provide cut off points for exclusion e.g. not just “children” but for example “children under two years old”
- Include interactions here that may give rise to toxicity or need for an increased dose e.g. salbutamol PGD would exclude patients taking beta blockers.

Explain action to take if patient is to be excluded e.g.
- Should a doctor wish to exclude a particular patient from these directions this must be recorded in the patient’s notes and on the prescription and administration record.

Cautions/Need for further advice

- Check SPC / published guidelines such as SIGN, NICE, Prodigy.
- Pregnancy and breast feeding – explain reason for inclusion, exclusion or caution whenever possible.
- Interactions – list ones that are clinically significant and relevant to this PGD and provide advice if possible e.g.:
  - Anticoagulants – effects may be enhanced (prolonging the prothrombin time). Advise patient that INR may change whilst taking drug X and to monitor more closely if appropriate.

Action if patient declines or is excluded

Enter details of action to be taken according to local policy e.g.
- Excluded patients will have their treatment managed by the appropriate medical team.

Referral arrangements for medical advice

Enter details of local arrangements e.g. contact appropriate doctor (GP, ward doctor, team doctor, or duty doctor through EPUT switchboard).

Evaluation of treatment and follow up action

To be decided locally.
| **Name, form & strength of medicine** | References include: BNF/SPC/ Medicines for Children  
Use clear format to express strength and form e.g. BNF style: Amoxicillin Capsules 250 mg; Amoxicillin Suspension 250mg in 5mL |
| **Storage requirements** | e.g. temperature restrictions e.g 2-8°C; protect from light etc |
| **Route/Method** | References: BNF/SPC /Medicines for Children  
To avoid errors, state in full and do not use abbreviations e.g. oral not p.o. |
| **Dosage** | References: BNF/SPC/Medicines for Children  
Are dosages licensed – need to add reference / note to support use in unlicensed / off-label circumstances.  
Decide on format to express dosage, especially in children – will it be on weight-adjusted basis or would doses be rounded up to the nearest spoonful etc. Liaise with Community Health Services Pharmacy Lead on practical issues relating to dosage and quantity to supply.  
State in full and do not use abbreviations e.g. Take one capsule three times a day not 1 tds. |
| **Frequency** | References: BNF/SPC/ local and guidelines/ Medicines for Children |
| **Maximum or minimum treatment period** | State duration of treatment if applicable |
| **Quantity to supply/administer** | Depends on above i.e. dosage, frequency and duration. |
| **Side effects** | Useful references: SPC/BNF/Minor/Medicines for Children.  
List common side effects and may need to refer to other sources for full details. Advisable to warn about potential adverse effects e.g. any CSM advice. |
| **Advice to patient/carer** | • Manufacturer’s Patient Information Leaflet  
• Any further instructions to aid compliance  
• Storage or expiry details  
• Practical advice on self-care if appropriate  
• Advice on recognising side effects and what to do  
• Advice on where to seek help if treatment fails or condition worsens |
| **Audit Trail** | **Records/audit trail**  
• Patient’s name, hospital unit number, date of birth  
• Diagnosis  
• Dose and form administered  
• Batch and expiry details  
• Advice given to patient (including side effects)  
• Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment  
• Details of any adverse drug reaction and actions taken including
documentation in the patient’s medical record

• Referral arrangements (including self-care)

Think about what you would want to find out from an audit so you can make sure you have covered the important points to record for the audit but do not exclude any of the above.

Record of Medication Supplied

Think about what records need to be completed when medication is supplied. eg

• A record of all supplies must be made in the patient’s medical records. A record sheet detailing all packs of medication supplied under this direction must be completed and retained. This must include the patient’s name, the quantities and details of medication supplied, and the date on which the supply was made.

• The signature / identification of the person making the supply must be recorded.

References/Resources and comments

COMPETENCY – GENERAL REQUIREMENTS

Staff Characteristics

Qualifications

Registered professional [appropriate qualification to be listed] with a current [professional] registration e.g.

• Registered nurse who holds a valid current NMC registration.

• The Nurse will be in the employ of EPUT

Specialist competencies or qualifications

Refer to guidelines relating to this drug and nurses must be trained in anaphylaxis if administering vaccines e.g.

• Nurse to have undertaken an education programme in the management of relevant conditions recognised by EPUT.

• Training to demonstrate competence in understanding diagnosis and management of relevant conditions, performing competent and safe assessment interviews with patients and managing ongoing monitoring

Continuing training & education

The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

Include training in the recognition and treatment of anaphylaxis, including practical training in Basic Life Support, if relevant for the medicine listed.
## COMPETENCY CHECKLIST

<table>
<thead>
<tr>
<th>Name of practitioner:</th>
</tr>
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</table>
| Clinical and Pharmaceutical knowledge | □ Understands and has an up-to-date knowledge of:  
  - the condition and its assessment  
  - non-drug treatment alternatives  
  - the medicine, including its mode of action and dosing details  
  - potential side-effects, and adverse-drug-reaction reporting  
  - any misuse potential of the medicine |
| Establishing options | □ Can establish why the medicine is needed, and can choose a suitable treatment, referring for medical advice where necessary and following up appropriately |
| Communicating with the patient | □ Does not encourage the expectation that a medicine will be given  
  □ Helps the patient make an informed choice  
  □ Negotiates an outcome that both patient and staff are satisfied with  
  □ Gives clear instructions to the patient about their medication  
  □ Checks the patient's understanding of the treatment |
| Safe PGD use | □ Knows the limits of own knowledge and skills, and works within them  
  □ Knows when to refer to another member of the multidisciplinary team  
  □ Will advise line manager if unable to maintain confidence and competence in using PGDs  
  □ Understands the need for, and makes complete and timely records  
  □ Recognises and deals with pressures that result in inappropriate use of PGDs |
| Professional standards | □ Accepts personal responsibility for working within PGDs and understands the legal implications  
  □ Understands and works within the scope of the PGD  
  □ Makes clinical decisions based on patient’s needs, not personal considerations  
  □ Reflects on own practice and performance |
| Practice development | □ Actively participates in the review and development of practice to improve patient care |
| Information in context | □ Knows how to access relevant information.  
  □ Can critically appraise and apply information in practice |
| The NHS in context | □ Understands, and works with, local and national policies and services |
that impact on PGD use.

The team and individual context

- Works in partnership with colleagues for the benefit of patients. Is self-aware and confident in own ability to use PGDs

COMPETENCY APPROVAL AND INDIVIDUAL AUTHORISATION OF PRACTITIONER TO USE PGD

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

Registered Healthcare Practitioner

I confirm that I:
- have read and understand this PGD
- am of the opinion I am competent to use this PGD effectively
- agree to supply and administer the medicine only in accordance with this PGD

Name: 
Signature: 
Position: 
Date: 

Senior Clinician/manager authorising this PGD

The above-named practitioner is competent in all areas listed in the Competency Checklist, has achieved all the specialist competencies and qualifications required, and is authorised to use this PGD.

Name: 
Signature: 
Position: 
Date: 

SAMPLE - DO NOT USE
Annex 3

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

You need to consider whether a Practitioner Group Decision (PGD) would be appropriate for an area or practice that involves the供应 or administration of medicines.

This diagram shows a logical process that helps to make decisions about whether a PGD can be used.

We have also added some useful links to help you find further information. To read – see NICE MPO PGD Guidance 2013.

A PGD should not be required if there is an alternative process. The preferred way for practitioners to receive medicines for use in prescribing is to use the appropriate process for their area and practice. Providing medicines in this way will be faster and more secure.

A PGD is not required – practitioners have the ability to supply or administer medicines in accordance with Medicines Act 1968. Some organisations use PGDs in these circumstances although not a legal requirement. Link to PGDs.

A practitioner must consider the professional activity within the exceptions in the Human Medicines Regulations 2012 and associated secondary instruments. See NICE MPO PGD Guidance 2013.

A PGD may be required if the medicines are not licensed. A PGD may be required if the medicine is not licensed. An alternative will need to be sought for practitioners who have very few patients or who are working in a hospital environment only.

PGD legislation applies only to licensed medicines. Consider developing a local protocol for dispensing medicines for special and medical uses.