University Hospitals of Derby and Burton NHS Foundation Trust

**TRUST POLICY FOR THE DEVELOPMENT & USE OF PATIENT GROUP DIRECTIONS (PGDS) – ALL UHDB SITES**

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| **Version / Amendment History** | **Version** | **Date** | **Author** | **Reason** |
|---|---|---|---|---|
| | 1 | November 2020 | Medication Safety Officer | New Policy |
| | 2 | November 2023 | Medication Safety Officer | New content: 5.16 Protocols; 5.3-5.4 IHPs and jointly commissioned services; 5.6.4 amendments to PGDs; 5.7.1 Bank/agency staff; Appendix 4 & 5 midwife exemptions.<br><br>Updated section 5.1.4 to include other legal exemptions within Human Meds Regulations. Updated section 6 audit standards. |

**Intended Recipients:** All UHDB staff who are considering, developing, authorising, using and updating patient group directions within the trust. The policy should also be consulted by staff employed by other organisations who may have involvement in PGDs to deliver UHDB services.

**Training and Dissemination:**

Dissemination will be via professional leads for the groups of staff who can work under PGDs: Chief Dietician, Chief Pharmacist, Chief Nurse, Head of Midwifery, Divisional AHP Director for CDCS (OT, Physiotherapists, SALT, orthotists, prosthetists, radiographers), Divisional Nurse Director for Surgery (optometrists, orthoptists, chiropodists, podiatrists, dental therapists/hygienists). All DNDs to consider any of the roles above embedded

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| within their division (e.g. paramedics who may work for the acute trust or therapists who are embedded in Surgery or Medicine rather than CDCS).<br><br>Core training module (My Learning Passport) to be used to provide baseline knowledge for staff on PGD legislation.<br><br>Training then takes the form of reading and understanding this policy. This policy incorporates procedural elements and adopts best practice from NICE guidance and hence will provide staff with enhanced knowledge of legislation and options for provision of medicines in the absence of a prescriber. | |
| **To be read in conjunction with:**<br><br>UHDB Medicines policy<br><br>UHDB Non-medical prescribing policy. | |
| **In consultation with and Date:** Version 2 review: consultation with Medicines Safety Group (September 2023) & PGD Governance Group (September 2023). Original version 1: Medicines Safety Group (December 2019) and Chief Nurses Group (August 2020). | |
| **EIRA stage One** Completed Yes | stage Two Completed No |
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| **Review Date and Frequency** | November 2026 – Review every 3 years |
| **Contact for Review** | Medication Safety Officer |
| **Executive Lead Signature** |  <br><br>Garry Marsh, Executive Chief Nurse |

**TRUST POLICY FOR Development of Patient Group Directions (PGDs) – All UHDB sites**

## Contents

## 1. Introduction

Patient group directions allow defined healthcare professionals to supply and/or administer specified medicines to pre-defined groups of patients, without a prescription.

Legislative requirements and national guidance on appropriate use of PGDs combine to necessitate a robust process for assessing the 'case of need' and then the governance around the development or review of the proposal and PGD template. A PGD provides a very well defined and intentionally restrictive framework from which healthcare professionals can consider the supply and/or administration of certain medicines. This requires a large amount of resource for the development and maintenance of the PGDs and their training, implementation, and audit/review. Furthermore, the correct application and documentation of PGDs in clinical practice is a very time-consuming activity. These factors mean that PGDs should only ever be considered where they offer benefits to patients clinical care and then only as a secondary option (rather than a substitute) to prescriptions by medical, independent, or supplementary prescribers.

This policy and associated procedures aim to ensure that patient group directions are only employed in line with legislation and national guidance whilst ensuring that patients have safe and timely access to the medicines they need.

## 2. Purpose and Outcomes

To only consider PGDs where prescriptions (Patient Specific Directions) cannot be obtained from a competent medical or non-medical prescriber.

To add scrutiny to the application and approval of PGDs such that they are reserved for limited situations by defined and appropriately trained staff groups to provide an advantage for patient care without compromising patient safety. To provide evidence of this by outlining clear governance arrangements and accountability.

To ensure PGDs are not employed where the Human Medicines Regulations 2012 provide alternative exemptions for the supply or administration of medicines by other means (e.g. midwives exemptions / paramedic exemptions).

## 3. Definitions Used

**Appropriately labelled pack**

In cases of supply (rather than administration), the pack to be issued under a PGD will need to be labelled to reflect the dose exactly as authorised in the PGD, as if it were being dispensed against a prescription. Separate requirements exist for prescription-only medicines (POMs) and for pharmacy (P) and general sales list (GSL) medicines. In practice, medicines supplied for use under a PGD are often in packs that are pre-labelled by a licensed manufacturing unit. These labels include all the standard labelling requirements, leaving a space on the pack for the patient's name and date of dispensing to be added at the time of supply. This is sometimes known as over-labelling.

**PGD Suites**

In most circumstances a PGD document will now contain a single medicine (although there may be multiple formulations e.g. capsule and liquid antibiotics). Historically, some specialities may have had a suite of medicines within one single document which is tailored to their clinical practice. This practice has mostly ceased as it created duplication of medications used by multiple areas in similar, or the same, ways. However, suites will still be supported where this helps provide clarity to the practitioner working under the PGD. For example, when a course of treatment involves multiple concurrent medicines (e.g. MRSA decolonisation) or where there are 1st/2nd line options to consider. Suites may be necessary where there are multiple medicines within a drug class such as options for iodinated contrast media or options for bowel cleansing.

## 4. Key Responsibilities/Duties

**PGD Working Group** - A locally determined multidisciplinary group established for each individual PGD. The PGD working group is responsible for: appraising the appropriateness of incorporating a PGD in to a clinical pathway; making a formal proposal for the PGD to the PGD Governance Group; writing the PGD template if approval is given to develop the PGD; reviewing the PGD including any intermittent clinical audits or advising on alternative staff to undertake this. The group members are responsible for ensuring clinical appropriateness and accuracy of the PGD template.

**PGD Governance Group** - A multidisciplinary group that considers, authorises or declines proposals to develop a PGD to deliver a service. The group will agree any monitoring or audit programme required for implementation with the PGD Working Group.

The group will not routinely scrutinise the clinical content which remains responsibility of the PGD Working Group and overseen by the authorised signatories. However, the Governance Group will check that the scope of the proposed PGD, including inclusion/exclusion and referral pathways, is appropriate and that the PGD will only be used by adequately experienced and trained staff.

**Medicines Safety Officer**

Main contact for professional queries related to PGD legislation. Chairs the PGD governance Group. This role can provide the UHDB organisational authorisation signature for final submissions.

**Medicines Safety and Clinical Governance Support Officer**

Main contact for process and administrative queries relating to PGDs including the governance process.

**Chief Pharmacist (Controlled Drugs Accountable Officer)**

Chief Pharmacist role can provide the UHDB organisational authorisation signature for final submissions or delegate to suitably trained deputies. Must provide support to any new proposals for controlled drugs in any of the CD schedules 1 – 5 as part of their CDAO role.

**Divisional Nurse Directors**

Support dissemination of this policy and support arrangements for staff training for PGDs. Provide representatives for the PGD Governance Group and contacts for any urgent proposals to be considered.

**Medical Director(s), Divisional Medical Directors, Clinical Directors (and assistants)**

Required as signatories for the final PGD prior to publication. An appropriate signatory will be required based on scope of the PGD (i.e. MD for trust-wide application; DMD for cross-specialty within division etc See Appendix 3).

**Chief Nurse**

Executive sponsor to the policy. Required as signatory for cross-divisional or multi-agency PGDs.

## 5. Policy for Patient Group Directions

### 5.1 Considering the need for a patient group direction

5.1.1 PGDs must be used only by named and authorised registered health professionals who can legally supply and/or administer medicines using a PGD in line with the Human Medicines Regulations 2012 (see Appendix 2).

5.1.2 When considering a PGD, convene a Local PGD Working Group involving:

- A lead nurse (or relevant professional who can work under PGD) for that area
- A Pharmacist – Contact the Divisional Lead Pharmacist (who may assign a deputy or relevant specialist pharmacist for that area)
- A consultant for the specialty.

5.1.3 As a group, use the NHS Specialist Pharmacy Service PGD resources[1] to consider whether a PGD is necessary. Explore all the available options for supplying and/or administering medicines in a specific clinical situation. This should include consideration of existing medical and non-medical prescribers. Consider whether 1 option or a range of options is appropriate. Consider if the PGD is only needed in the short term (e.g. to allow service redesign, resource requests, training for additional non-medical prescribers).

Advice and Tools hosted by Specialist Pharmacy Service (SPS)[1] will help the local team navigate the main points within the legislation.

5.1.4 Contact the Medication Safety Officer or Support Officer for advice via UHDB.PGDgovernance@nhs.net if your planned PGD will breach any of the following recommendations from the NICE guideline:

[1] https://www.sps.nhs.uk/articles/when-to-use-a-pgd-2/

- Do not use PGDs for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.

- Do not make dose adjustments to a medicine supplied under a PGD when the medicine is already in the patient's possession (i.e. a PGD is not a legitimate means for a non-prescriber to adjust a patient's existing dosage regime).

- Do not include a medicine needing frequent dosage adjustments or frequent or complex monitoring in a PGD (for example, coumarin anticoagulants or insulin).

- Do not use PGDs for medicines when exemptions in legislation allow their supply and/or administration without the need for a PGD. The main exemptions are:

    - Midwives Exemptions - See Appendix 4 policy extension for medicines which can be administered or supplied by midwives. UHDB clinical systems are configured to allow role-based access to medication functionality for midwives who are auhthorised to work under these exemptions.

    - Paramedics exemptions - Note that paramedics exemptions are not routinely supported for clinical practice within UHDB services. The exemptions exist to facilitate access in the absence of medical and nursing support "in the field" during community based first-response. Any proposals to use a paramedic exemption within the Trust can be submitted to the PGD governance group via the Medication Safety Officer for consideration. Paramedics working in acute services can be trained to work under PGDs or where scope allows, train as non-medical prescribers to undertake advanced prescribing practice.

    - Medicinal products for parenteral administration in an emergency (Schedule 19, Human Medicines Regulation 2012)

    - Written Instructions - Under the Human Medicines Regulations 2012, Occupational Health Services (OHS) are exempt from the restrictions that apply to prescription only medicines. Medicinal products can be supplied or administered in the course of the OHS by a registered nurse acting in accordance with the written and signed instruction of a doctor. Following Covid-19 the written instructions for influenza or Covid vaccines can be followed by some professions in addition to registered nurses. The Medication Safety Officer and support officer provide templates and governance oversight to OH for Written Instructions. Written Instructions are not interchangeable with PGDs although the written format and governance do follow the principles in this policy.

5.1.5 Antibiotics can be included in PGDs but must not jeopardise local and national strategies to combat antimicrobial resistance and healthcare associated infections. Ensure that an antimicrobial is included in a PGD only when:

    - Clinically essential and clearly justified by best practice guidance

- For systemic (enteral or parenteral) antibiotics: A local specialist in microbiology has agreed that a PGD is needed (note that the PGD Governance Group will seek approval from a representative of the Antimicrobial Stewardship Group prior to approval and so staff developing PGDs - *the PGD working group* - are encouraged to scope this with a microbiologist or antimicrobial pharmacist during the proposal phase and document this on the form).

### 5.1.6 PSDs and Protocols where a PGD cannot be legally implemented or is inappropriate in accordance with national/NICE guidelines

A Patient Specific Direction is a directive from a prescriber for a specific patient. In most cases, under UHDB Medicines Policy, a prescription from a medical or non-medical prescriber will be required to fulfil best practice requirements of a PSD.

There are some circumstances where simple medication pathways are consistent and could be safely delivered by following a framework that meets the minimum standards we would otherwise include in a PGD. The Pharmacy BU and PGD governance group can review and advise when it might be appropriate to include a PSD as part of a referral letter or clinical-systems pathway **from a prescriber** that directs staff to further assess/administer/supply "as per protocol". Where agreed formally by the PGD governance group, such locally agreed "Protocols" can be developed following a Trust approved template, and in alignment with the same governance and authorisation principles within this policy.

Examples:

a) Unlicensed medicines that cannot legally be included on a PGD.

   A PSD from a prescriber is required to approve the use of the unlicensed medicine (see Unlicensed Medicines Policy). However, where a non-prescribing practitioner may then add safety and value to the process by performing the final assessment and decision to supply or administer, a protocol may be deemed appropriate by the PGD Governance group.

b) Some clinical pathways exist where the staff member is not listed as one that can work under a PGD but they are trained and competent to prepare, administer or supply that medication. A PSD can fulfil the legal authorisation for that practitioner to then proceed with the assessment, counselling, supply, or administration following the full protocol which mirrors the PGD governance framework.

## 5.2 Obtaining agreement to develop a patient group direction

### 5.2.1 Role of the Local PGD Working Group

After establishing a case of need and following section 5.1 above, complete the PGD Proposal form following all guidance notes (indicated in red italics on the template) to ensure alignment with legislation and national guidance. Once complete, submit to UHDB.PGDgovernance@nhs.net so that the request can be added to the next PGD

Governance Group agenda (any clinically or operationally urgent PGDs should be discussed with the Medication Safety Officer to consider options for expediting sign-off).

A representative from the PGD Working Group is encouraged to attend the review meeting to answer any questions arising from the PGD governance Group.

The PGD Working Group have opportunity to appeal any proposals rejected by PGD Governance Group as outlined on the PGD Decision form (included at the end of the proposal paperwork).

#### 5.2.2 Role of the PGD Governance Group

Review proposals for PGDs in accordance with the Terms of Reference for the group published on the PGD pages of the intranet.

Provide a formal response to the proposal using the PGD Decision Form (included at the end of the proposal paperwork) which will either confirm approval to proceed to developing the PGD, or rejection with documented reasoning.

Refer any appeals made by the PGD Working Group so they can be considered by the Drugs & Therapeutics Group.

### 5.3 Developing patient group directions

**NOTE/ The development of the PGD template itself should not commence until the proposal has received a positive decision from the PGD Governance Group.**

#### 5.3.1 Developing the PGD (role of the PGD Working Group)

The PGD should be authored by a registered professional who is trained to operate under PGDs and has clinical and operational knowledge of the area.

In most cases this will be the relevant professional from the PGD working group but it can be delegated providing the PGD working group are available to advise.

Use the standard UHDB template (which can be obtained by contacting UHDB.PGDgovernance@nhs.net) which will ensure that the format is consistent across the organisation and will guide you to include all legally required information in line with the Human Medicines Regulations 2012.

Ensure that all aspects covered in the proposal are included in the final template (and take in to account any approval notes provided on the decision form from the PGD governance Group).

Liaise with the consultant and pharmacist in the PGD working group to agree content of the clinical sections 4 – 6 of the PGD including:

- Ensure PGDs are consistent with the relevant summary of product characteristics (MHRA website or https://www.medicines.org.uk) unless the medicine is being used off-label in which case relevant national guidance should be followed (and referenced).

- Use the best available evidence, such as NICE guidance and other sources of high-quality information when developing PGDs. Include key references which have been used in developing the PGD

### 5.3.2 Draft for Submission (Role of the Clinical Pharmacist in the PGD Working Group)

The draft should always be checked by the clinical pharmacist in the PGD Working Group prior to submission. This pharmacist will final check the clinical content and references in section 4 – 6, if they have not previously reviewed this as part of 5.3.1.

The clinical pharmacist must ensure that an antimicrobial pharmacist/microbiologist has checked all systemic antibiotic PGD templates for consideration of alignment with current (or pending) guidelines and any additional training that may be required. The name and job title of the antimicrobial advisor must be documented in the relevant section of the PGD template.

Liaise with divisional pharmacists, as necessary, to ensure the stock/product arrangements are in place ready for publication.

Submit the final draft electronically to UHDB.PGDgovernance@nhs.net as soon as the PGD working group have agreed all content in principle - **Signatures are NOT required at this stage and will be coordinated following review by one of the UHDB authorised Trust signatories.**

Note: It is recommended that the pharmacist themselves submit the final draft. This will help avoid any delays by providing assurance to the UHDB authorised Trust signatories that the clinical pharmacist is satisfied with the content and prepared to provide the pharmacist signature (legal requirement).

### 5.3.3 Check of final draft by UHDB Organisational Authorisation Signatory

Authorised Trust Signatory (Medication Safety Officer, Chief Pharmacist or Deputies) will check:

- All sections have been completed
- All medications are licensed
- No CDs have been included unless authorised in the proposal (and therefore by the PGD Governance group and CD Accountable Officer)
- Any off-label or black triangle medicines have been appropriately referenced with the best practice guidance agreed during proposal
- For new PGDs: that the Training and Documentation elements of the proposal have been transferred accurately to the final PGD template.
- For new PGDs: that any recommendations made on the PGD decision form have been adopted

Any matters for clarification will be referred back to the PGD Working Group for review and resubmission.

### 5.4 Authorising patient group directions

#### 5.4.1 Signatures for UHDB Patient Group Directions

A single hard copy or PDF will be sent to the following recipients for signing or eSignature:

- The pharmacist from the PGD working group: who signs to confirm the clinical content of the PGD on behalf of the PGD Working Group.
- A registered professional who can operate under PGD (as a minimum this should be matron level or equivalent as outlined in appendix 3)
- A medical doctor (consultant grade with sufficient remit in accordance with the guidance in appendix 3)
- The UHDB organisational authorisation signatory (Pharmacist: Medication Safety Officer, Chief Pharmacist or deputies).

#### 5.4.3 Authorising Patient Group Directions used by Independent Healthcare Providers ("third-party" providers) delivering UHDB services

It is essential that one of the UHDB Organisational Authorisation Signatories is consulted (via UHDB.PGDgovernance@nhs.net) in all cases where it is planned for external agencies to use their own PGDs to deliver UHDB services. Non-NHS organisations can develop and approve PGDs and train their own staff to use them, but in order for them to be used in delivery of care to NHS patients they must be reviewed, approved and signed by the NHS provider Trust.

#### 5.4.4 Authorising Patient Group Directions written by jointly commissioned services

A memorandum of understanding (MOU) or contract should be agreed before any PGD processes begin and this should be considered as part of the tender process. A MOU should clearly state all the responsibilities involved in PGD development and use: from writing and authorising PGDs to adoption and implementation and should consider factors such as review, document management and any training requirements including which organisation will be responsible for each function.

This must be agreed and recorded in each authorising organisation at Board level to ensure that the activity is accepted within each organisation's clinical governance framework. This is in accordance with national guidance from the Specialist Pharmacy Service.

At the time of publication there is agreement between UHDB and Derby Community Healthcare Services for the following joint services to be delivered:

a) Derbyshire Integrated Sexual Health (GUM) - PGDs developed and approved following DCHS governance pathway for use by either organisation. They are hosted on Koha to support UHDB staff with currency and compliance.

b) Speech & Language Therapy - Videofluoroscopy - PGDs developed and approved following UHDB governance pathway.

### 5.4.5 Publication

***The following actions will be facilitated by members of the PGD Governance Group:***

The signed hard-copy (or digital copies with eSignatures) will be held by pharmacy.

For ePMA enabled areas: The PGD Governance Group consider whether ePMA / IT teams need to update ePMA systems to facilitate PGD access to the relevant drugs and formulations (this does not include allocation of security rights to individual staff members as they have not yet been trained).

Add an 'uncontrolled when printed' note to the web PDF to discourage the practice of holding local hard copies (see 5.5, staff should access this information via a web format wherever possible).

Final version PDF will be sent to the clinical librarian who uploads to Koha web directory. This does not need to be a scanned copy of the signed version as there is a governance controlled process in place to ensure that the librarians will only upload requests received from the PGD Governance Group (i.e. PGD Governance chair, secretary or joint email account).

Email clinical managers for the areas using the PGD so that training and authorisation can commence using the approved templates on Koha web directory.

## 5.5 Using Patient Group Directions

### 5.5.1 Before practising under a PGD

Health professionals should ensure that all of the following apply:

- have undertaken the core PGD training via *My Learning Passport.*
- have read and understand the context and content of the PGD (always using the uploaded version on the Koha web portal). This includes:
    - Understanding of clinical content
    - Confirmation they have requisite role, experience or qualifications defined
    - Completion of any additional extended training defined (Section 3 of PGD)
- have signed the *Registered Health Professional Authorisation Sheet* (Section 7, final page, of the published PGD on Koha)
- have been assessed as competent and authorised to practise (by senior signature) included on the *Registered Health Professional Authorisation Sheet*
    - This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD. This

must be held or archived for 8 years for adult PGDs and 25 years for paediatric PGDs.

- are using a copy of the most recent and in date final signed version of the PGD (access via Koha online portal)

### 5.5.2 When practising under a PGD

Health professionals must:

- **Not** delegate their responsibility to administer or supply the medicine to any other staff member (including other registered professionals). The activities within a PGD must be discharged by the same practitioner throughout the process.
- Ensure that they can determine that the patient meets the inclusion criteria as set out in the PGD
- Ensure that they can determine that no exclusion criteria apply
- Discuss alternative options for treating the patient's condition, when appropriate
- assess each individual patient's circumstances and preferences
- Recognise when signposting or referral to another health professional or service is needed, as specified in the PGD
- Understand relevant information about the medicine(s) included in the PGD, such as:
  - how to administer the medicine
  - how the medicine acts within the body
  - dosage calculations
  - potential adverse effects and how to manage them
  - drug interactions, precautions and contraindications
  - storage requirements, including maintenance of the 'cold chain' for refrigerated items
  - follow-up arrangements
  - be able to advise the patient or their carer about the medicine(s), as appropriate.

### 5.5.3 Supply of medications to a patient to self-administer or take home

When supplying a medicine(s), provide an appropriately labelled pack (see definitions). Health professionals (other than pharmacists) should **not** split or modify packs in any way.

Ensure that the patient receives a manufacturer's patient information leaflet with each medicine.

### 5.6 Reviewing and updating patient group directions (role of PGD Working Group)

PGDs will be reviewed and updated every 3 years except:

- Those containing CDs (2 years)
- Those containing systemic antimicrobials (2 years or earlier if there is a change to trust antimicrobial guidelines)

- Those containing black triangle medicines (2 years)

### 5.6.1 Reflection on the use of the PGD

6 months prior to the review date, the PGD Governance group will contact the original authors (PGD Working Group) and ask for confirmation of the names of relevant PGD professional, doctor and pharmacist who need to be involved in the review. These staff will be sent

- a word version of the existing PGD version for modification
    - For areas who hold suites of PGDs (see definitions section), the entire suite will be sent for an overall service review.
- A copy of any relevant original proposals that outline rationale and monitoring arrangements
- For ePMA (electronic prescribing) areas and where possible only: a report outlining usage data for the PGDs listed

The working group should meet to review the following:

- Any audit results as per section 6 – If not yet completed, arrange for these to be done in accordance with original proposal
- Datix incidents for the clinical area related to the PGD or medication in use (search for incidents involving the specific medications from that PGD in that location OR do a freetext search for *PGD* or *Patient Group Direction* in the incident description for that location)
- Discuss any changes that have occurred in the clinical pathway or underlying clinical guidelines
- Discuss any change to the licensing of any of the medications in the PGD or PGD suite.

**Follow one of the processes 5.6.2 or 5.6.3:**

### 5.6.2 New proposals (significant changes)

A new proposal to PGD Governance Group only needs to be made in the following circumstances:

- there are new medication(s) to add to a PGD suite
- Changes to the licensing of the medication now make it off-license when it was previously being used as per license. Or where MHRA or national safety alerts have been issued against the medicines for this indication.
- Change of CD schedule since last review (rare)

### 5.6.3 Updates of existing medications

PGD Governance Group will send a word template of the current in-use PGD.

Use 'Track Changes' to update the names of the PGD Working Group and then work through each section to evidence the changes made ready for re-authorisation. Any rationale for changes can be provided by review comments.

The PGD Working group should summarise changes made in the change history section on the PGD template and update the references.

Once the group are in agreement, the clinical pharmacist can complete a clinical check (as per 5.3.2) and then forward to the PGD Governance group to progress steps 5.3.3 and section 5.4.

### 5.6.4 Re-authorising PGDs after amendment

All amendments made to a PGD, including minor ones require a PGD to be reauthorised. Even where review of a PGD results in no changes it must still be reauthorised and re-dated accordingly.

Reauthorising requires the agreement of, and re-signing by, the development signatories (i.e. the doctor, pharmacist and member of professional group using the PGD) and UHDB organisational authorisation signatory.

### 5.6.5 Extension of a PGD

Once beyond PGD expiry date, PGDs are no longer supported by the original signatories, including the corporate authorisation signature.

These PGDs will be removed from Koha once expired although some medicines may remain available in ePMA systems if they are used by multiple areas. Therefore all staff who are authorised to work under PGD must be informed by their professional leads when PGDs are out of date (Individual staff records are held by individual departments in accordance with this policy).

This policy is aligned with recommendations of the NHS Specialist Pharmacy Service:

PGDs do not have a definitive lifespan in legislation, however NICE guidance and UHDB policy is limited to 3 years (2 years for CDs and antibiotics; earlier if clinical changes are envisaged at the point of being authored and authorised). If exceptional circumstances prevent a document being reviewed before its expiry, areas may submit formal applications for extension to the PGD Governance Group. Contact uhdb.pgdgovernance@nhs.net if you require an application form and note that national guidance prevents any extensions of more than 12 months and not all applications will be approved).

Consideration should always be given by divisional management teams for suspending expired PGD use, taking in to account operational impact and alternative legal mechanisms available to facilitate supply or administration of medicines (in most cases, a prescription from medical or non-medical prescriber is the only option).

Any divisional consideration to continued use of the PGD in expired format should be risk assessed. Update uhdb.pgdgovernance@nhs.net if this is the case. All staff using the PGD must be informed of any local decisions to continue use beyond expiry. Staff may require reassurance that this is formally documented and supported by their division but may also choose to exercise their professional judgment in respect of continuing to work under an expired PGD (consider how vicarious liability will be offered for any activity outside of NICE guidance and trust policy).

**5.7 Training and competency**

| **Staff Type** | **Minimum Requirement** | **Additional notes** | **Recommended development (CPD)** |
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| All staff who will be supplying and administering medicines under PGD | Read section 5.5. of this policy (will be included in My Learning Passport Training / declaration).<br><br>Complete all training and requirements outlined in 5.5.1 before a PGD can be used to supply or administer. | - | NICE – Competency framework for professionals USING PGDs |
| Local Authorising manager or Assessor (who signs the final part of the registered professional authorisation form. This form is found in section 7 of each individual PGD) | Read and apply this policy<br><br>Completed any core training for PGDs via My Learning Passport | If also practising under the PGD themselves:<br><br>Complete all training and requirements outlined in 5.5.1 before a PGD can be used to supply or administer. | NICE – Competency framework for professionals USING PGDs |
| PGD Working Group members | Read and apply this policy | | NICE – Competency framework for people DEVELOPING / UPDATING PGDs |
| Organisational authorisation | Read and apply this | - | - |

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| signatories (MSO, Chief Pharmacist & Deputies) | policy.<br><br>NICE - Competency framework for people AUTHORISING PGDs | | |
| Additional Signatories (Registered professionals and doctors signing on behalf of the trust) | Read and apply this policy. | - | NICE - Competency framework for people AUTHORISING PGDs |

### 5.7.1 Bank or Agency Staff Training

Registered bank or agency staff may use UHDB PGDs provided they undertake **UHDB** core PGD training, including all essential-to-role training as outlined in the UHDB PGD policy. The bank or agency staff must then be trained and authorised on the individual UHDB PGD(s) in accordance with UHDB policy.

In the case of Agency staff, the learning team can register them to allow access to *My Learning Passport* for a finite time period. If it is not known how long the agency staff are contracted for, consider requesting up until the next review date on any active PGDs they are using and then liaise further with learning team to extend as necessary.

### 5.7.2 NHS staff delivering UHDB services, employed by other organisations

Contact the Medication Safety Officer who will confirm whether the core training from their employer organisations is equivalent to UHDB training. In all cases the staff must then be trained and authorised on the individual UHDB PGD(s) in accordance with UHDB policy.

## 5.8 Organisational governance

- The PGD governance group are responsible for considering the need for unscheduled review of a PGD, when the need for this has been identified in response to:
    - changes in legislation (highlighted to the group by Chief Pharmacist or Medication Safety Officer)
    - important new evidence or guidance that changes the PGD, such as new NICE guidance
    - new information on drug safety (to be highlighted to the PGD Governance group by Medication Safety Officer via Medicines Safety Group from sources such as MHRA Drug Safety updates and NHSI Patient Safety Alerts)

- Significant changes in the summary of product characteristics, license or availability circulated by MHRA recalls or 'Dear Doctor' circulars (to be highlighted to the group by the Medication Safety Officer following review at the Medicines Safety Group)

## 6. Monitoring Compliance and Effectiveness

| | |
|---|---|
| Monitoring Requirement : | *For a sample of areas operating PGDs:*<br><br>*100% of staff recording PGD administration or supply must have up-to-date authorisation records held by the clinical area/specialty signed by practitioner and their senior professional manager.*<br><br>*100% of staff using PGDs have completed core eLearning training*<br><br>*100% of medications used by practitioners have an in-date PGD for that medicine - in that area - on Koha* |
| Monitoring Method: | eForm developed with guidance notes for distribution to all business units across UHDB who use PGDs. A sample of staff and drugs from each area will be audited only.<br><br>eLearning is monitored centrally via *My Learning Passport* compliance reports.<br><br>The PGD Governance group review currency (expiry dates) of all PGDs at each meeting. These are also shared via divisional contacts and PGD Governance group contacts each month. |
| Report Prepared by: | Data collection within specialties, coordinated by divisional representatives of PGD Governance Group.<br><br>Collated and prepared by Medication Safety Officer. |
| Monitoring Report presented to: | PGD Governance Group |
| Frequency of Report | Annual |

In addition the following interim / operational reports will be provided where appropriate and defined in the PGD proposal by the clinical areas:

- Additional clinical audit led by the PGD working group within the speciality reviewing the PGD may be required according to any detail in the original PGD proposal (e.g. for high risk drugs, or CDs) or at the request of PGD Governance Group

- For systemic antibiotics, the use of the PGD should be audited before each review. The antimicrobial stewardship group should be invited to provide input to the standards that should be included.

- Standards will be routinely set at 100% compliance as a PGD, by definition, does not allow clinical judgment outside of the parameters specified in the published PGD.

## 7. References


NICE. Patient Group Directions (MPG02). Updated 03/2017

Human Medicines Regulations 2012 Schedule 16 Part 4 http://www.legislation.gov.uk/uksi/2012/1916/schedule/16/part/4/made

Human Medicines Regulations 2012 Schedule 16 Part 1 http://www.legislation.gov.uk/uksi/2012/1916/schedule/16/part/1/made

NMC. Practising as a midwife in the UK. Updated Jan 2021.

Practising as a midwife (nmc.org.uk)

## 8. Appendices

**Appendix 1**

The Specialist Pharmacy Service is a national resource providing tools and advice for deciding whether PGDs are a legal or appropriate option for supply or administration.

Find the latest version at www.sps.nhs.uk

**Appendix 2**

List of staff who can operate under PGDs in accordance with Human Medicines Regulation 2012 at the time of publishing this policy. There are ongoing consultations nationally to review Operating Department Practitioners and Pharmacy Technicians ans other consultations may open. Check primary legislation for any amendments/revisions here.

**PART 4 Classes of individuals by whom supplies may be made**

- Pharmacists.
- Registered chiropodists and podiatrists.
- Registered dental hygienist.
- Registered dental therapist.
- Registered dietitians.
- 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 therapists.

**Appendix 3 – Recommended staff roles to act as trust signatories for different types of PGD**

Note: there is a legal requirement for PGDs to be signed by a doctor & pharmacist; policy requirement for additional registered professional.

| Scope of PGD | Doctor | | | | Registered Professional Representing users of the PGD | | | |
|---|---|---|---|---|---|---|---|---|
| | Specialty Consultant | ACD/CD | DMD | MD or nominate ddeputy | Senior Ward sister / service or department clinical manager | Matron or lead professional for the specialty (therapist, dietician | DND or relevant professional lead (chief dietician, therapist etc.) | Chief Nurse or nominated deputy |
| Single ward or department | √ | | | | *Not generally appropriate as this person will often lead PGD development* | √ | | |
| Single clinical Specialty but may incorporate multiple areas e.g. clinic and ward | | √ | | | | √ | | |
| Cross-specialty within same division | | √* | √ | | | √* | √ | |
| Cross-Divisional or Cross-organisation (SLA partnerships and honorary contracts etc. e.g. DCHS staff, DISH service) | | | | √ | | | | √ |
| | *Appropriate to sign-off providing all specialities are within their remit | | | | | | | |

## Appendix 4 - Role specific policy extension - Midwives Exemptions

1. Introduction

An important part of a midwife's role is an understanding of medicines management, particularly what a midwife can and cannot supply and administer without the need of a prescription within their professional role.

2. Aim and Purpose of Midwife role-specific policy extension

To provide clear guidance on medication that can be supplied and administered when there is a Midwives Exemption (ME). These will be used wherever legislation allows in preference to a PGD as per Human Medicines Regulations 2012. A PGD can be considered in accordance with the full UHDB PGD policy and legislation for any medications, indications or regimens not covered by Midwives Exemptions legislation.

3. Abbreviations

| | | |
|---|---|---|
| GSL | - | General Sales List |
| ME | - | Midwives Exemption |
| MHRA | - | Medicines and Healthcare products Regulatory Authority |
| P | - | Pharmacy Medicines |
| PGD | - | Patient Group Direction |
| POM | - | Prescription Only Medicines |

4. Definitions & Classification of Medicines

Midwives exemptions

Registered midwives may supply and administer, on their own initiative, any of the substances that are specified in medicines legislation under midwives exemptions (Summary in Appendix 5), provided it is in the course of their professional practice. They may do so without the need for a prescription or patient-specific direction (PSD) from a medical practitioner.

Registered midwives must only supply and administer those medicines, including analgesics, in which they have received the appropriate training as to therapeutic use, dosage, side effects, precautions, contra-indication and methods of administration.

Pharmacy Medicines (P)

Are a relatively small group of medicines. They can be purchased from a pharmacist without a doctor's prescription. Midwives are reminded that they have access to utilise pharmacy medicines provided it is the course of their professional practice.

General Sales List Medicines (GSL)

Can be bought from a pharmacy, supermarkets and other retail outlets without the supervision of a pharmacist. Sometimes referred to as "over the counter medicines". Midwives are reminded that they have access to utilise GSL medicines provided it is the course of their professional practice.

Prescription Only Medicines (POMs)

Medicines which are prescribed by an appropriate practitioner e.g. Doctor.

4.1 Administration of medicines by student midwives

Student midwives are allowed to administer medicines on the midwives exemptions list (including P and GSL medicines), except controlled drugs, under the direct supervision of a sign-off midwife. Direct supervision means in direct visual contact during which time the midwife observes and takes responsibility for the act of assessment, preparation and administration of medicines by a student midwife.

The Medicines and Healthcare products Regulatory Authority (MHRA) require that the midwife supervising the administration of medicines by a student midwife must have undertaken an approved mentorship programme and be a sign off mentor.

Students are only able to observe the administration of medicines under PGD.

4.2 Record keeping

Midwives Exemptions are to be recorded within the clinical systems in use in that particular area. This will be ePrescribing for inpatient based areas. Digital or paper based health records can be used in ambulatory/domiciliary settings and must be retained for at least 8 years.

The following must all be recorded for Midwives Exemptions:

- Name of the health professional providing treatment
- Patient identifiers
- Patient inclusion or exclusion after assessment
- Details of the medicine provided
- Date the medicine is supplied or administered
- Patient consent or refusal
- Information given to the patient
- Batch number and expiry date must also be recorded for immunisations, vaccinations and blood derived products such as immunoglobins
- State any other agreed records to be kept for audit purposes

For PGDs, the record keeping requirements are defined in each published PGD document.

**Appendix 5 - List of medications on the Midwives' exemption list**

In addition to those listed in parts 1-3 below, all P & GSL medicines can be administered under Midwives Exemptions as per Human Medicines Regulations 2012.

Schedule 17, Part 1 makes the following provision in relation to midwives regarding the sale and supply of certain prescription only medicines:

| Column 1<br>**Persons exempted** | Column 2<br>**Prescription only medicine to which the exemptions apply** | Column 3<br>**Conditions** |
|---|---|---|
| 4. Registered midwives | 4. Prescription only medicines containing any of the following substances—<br>(a) Diclofenac;<br>(b) Hydrocortisone Acetate;<br>(c) Miconazole;<br>(d) Nystatin;<br>(e) Phytomenadione; | 4. The sale or supply shall be only in the ourse of their professional practice. |

Schedule 17, Part 2 lists the exemptions on supply of prescription only medicines:

| Column 1<br>**Persons exempted** | Column 2<br>**Prescription only medicine to which the exemptions apply** | Column 3<br>**Conditions** |
|---|---|---|
| 12. Registered midwives | 12. Prescription only medicines for parenteral administration that contain-<br>(a) Diamorphine<br>(b) Morphine<br>(c) Pethidine hydrochloride | 12. The supply shall be only in the course of their professional practice. |

Schedule 17, Part 3 lists the exemptions from the restriction on administration of prescription only medicines. The following exemptions are listed:

| Column 1<br>**Persons exempted** | Column 2<br>**Prescription only medicine to which the exemptions apply** | Column 3<br>**Conditions** |
|---|---|---|
| 2. Registered midwives and student midwives. | 2. Prescription only medicines for parenteral administration containing any of the following substances but no other substance that is classified as a product available on prescription only-<br>(a) Adrenaline<br>(b) Anti-D immunoglobin<br>(c) Carboprost<br>(d) Cyclizine lactate<br>(e) Diamorphine<br>(f) Ergometrine maleate<br>(g) Gelofusine<br>(h) Hartmann's solution<br>(i) Hepatitis B vaccine | 2. The medicine shall-<br>(a) in the case of Lidocaine and Lidocaine hydrochloride, be administered only while attending on a woman in childbirth, and<br>(b) where administration is-<br>(i) by a registered midwife, be administered in the course of their professional practice;<br>(ii) by a student midwife-<br>(aa) be administered under the direct supervision of a registered midwife; and<br>(bb) not include Diamorphine, Morphine or Pethidine |
| | (j) Hepatitis immunoglobin<br>(k) Lidocaine hydrochloride<br>(l) Morphine<br>(m) Naloxone hydrochloride<br>(n) Oxcytocins, natural and synthetic<br>(o) Pethidine hydrochloride<br>(p) Phytomenadione<br>(q) Prochloperazine<br>(r) Sodium chloride 0.9% | hydrochloride |