Leicestershire Partnership NHS Trust

Patient Group Directions Policy for their Development, Approval and Use

This policy describes the processes to be followed in Leicestershire Partnership NHS Trust (LPT) for a structured approach to the development, approval, and use of Patient Group Directions (PGDs).

This policy reflects national standards, definitions and aligns to national guidance as appropriate for the category of care. For the purpose of this policy a Patient Group Direction is a written instruction for the sale, supply and/or administration of medicines to groups of individuals who may not be individually identified before presenting for treatment.

Key words: Patient Group Direction; PGD; Medicines Management, Administration, Supply

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SUMMARY & AIM

Patient Group Directions (PGDs) provide a legal framework that allows registered health professionals, defined within the legislation to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber. 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.

This policy describes the processes to be followed in Leicestershire Partnership NHS Trust (LPT) for a structured approach to the development, approval, and use of Patient Group Directions (PGDs).

KEY REQUIREMENTS

The policy aims to encompass all necessary requirements for the proposal, development, review, approval, and implementation of a PGD.

This policy aims to ensure that all PGDs we develop comply with the law.

PGDs will be consistent with current best practice and will be evidence based.

Particular caution will be exercised in any decision to draw up PGDs relating to antibiotics.

Requests for new PGDs must be submitted to the Medication Risk Reduction Group who are the Trust group which approve PGDs.

Care provided under a PGD must be audited. Practitioners need to be able to access records who have received medication under a PGD so that the appropriateness of the supply or administration can be reviewed.

Once approved, original signed copies of each PGD will be kept by the Head of Pharmacy. An electronic copy of each PGD will be available on Staffnet.

All practitioners using PGDs must be signed up to the current version, in advance of it being used. After the expiry date the PGD is not valid. Medicines must not be supplied or administered on the authority of an expired PGD. All patient group directions will be reviewed every 3 years.

TARGET AUDIENCE:

This policy is applicable to all staff involved in the development, approval, and use of Patient Group Directions (PGDs).

PGDs can only be used by the registered healthcare professionals listed in Schedule 16, part 4 of the Human Medicines Regulations 2012.

TRAINING

Individuals must be competent, qualified, and currently registered members of their professional body.

All healthcare professionals using a PGD must have completed the approved medicines management training. Additional training requirements should be identified when each new PGD is prepared and agreed.

1.0 Quick look summary

Please note that this is designed to act as a quick reference guide only and is not intended to replace the need to read the full policy.

1.1 Version control and summary of changes

Version number	Date	Comments (description change and amendments)
1.0	March 2012	New Policy.
2.0	April 2014	**Definitions that apply to this policy -**rewording to align definitions used within the NICE Medicines Practice Guidelines for Patient Group Directions (2013).
	April 2014	3.1 addition of dental therapists and dental hygienists to health professionals eligible to use PGDs.
	April 2014	Appendix 6 – Addition of NHS Core Principles checklist
3.0	June 2016	4.3.1 Updating of table to reflect changes to which CDs can be included in a PGD.
	June 2016	4.3.2 Updating of this section to establish that PGDs including an antimicrobial must follow the principles of Antimicrobial Stewardship and be supported by the Antimicrobial Working Party to provide the required microbiology input.
	June 2016	7.1 (NEW) Adoption and Use of PGDs developed by other bodies.
	June 2016	13.0 References Updated
	June 2016	Appendix 1: updated version 9.2 (December 2015)
	June 2016	Appendix 5: Addition of training
	June 2016	Appendix 6: Addition of Policy Monitoring Section
	June 2016	Appendix 7: Addition of Due Regard Screening Template
3.1	Sept 2017	Appendix 2 (NEW) Proposal for the Development of a new PGD/Changes to an existing PGD.
4.0	July 2018	Changes to maximum expiry of PGDs from two to three years.
	July 2018	New section 4.3.4 Medicines with “Risk Minimisation Measures”
	July 2018	Appendix 10 (NEW): Privacy Impact Assessment Screening
5.0	July 2021	Section 4.3 PGDs and Unlicensed medicines legal change under Regulation 174 of the Human Medicines Regulations 2012 to allow PGDs for unlicensed medicines which have been given special authorisation by Ministers on a temporary basis, in response the suspected or confirmed spread of pathogenic agents (e.g., Covid-19),
	July 2021	Section 4.3.1 Controlled Drugs (CD) –the following professionals (dietitians, speech & language therapists, dental hygienists, dental therapists) cannot supply any CD under a PGD.
	July 2021	Section 7.3 (NEW) Extension of PGD expiry dates
6.0	October 2024	Section 4.1 Amendment to the Human Medicines Regulations 2012 (HMR 2012) took effect on 26 June 2024 which will enable registered pharmacy technicians to legally supply and administer medicines under a PGD.
	October 2024	General updating and new policy format according to Trust requirements

1.2 Key individuals involved in developing and consulting on the document

Name	Designation
Joanne Charles	Lead Pharmacist – Community Health Services
Tejas Khatau	Lead Pharmacist
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	All members of the Medication Risk Reduction Group – consultation November 2024
	Trust Policy Expert

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1.3 Governance

Level 2 or 3 approving delivery group – Medicines Management Committee

Level 1 Committee to ratify policy – Quality and Safety

1.4 Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account the provisions of the Equality Act 2010 and promotes equal opportunities for all. This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity.

If you would like a copy of this document in any other format, please contact lpt.corporateaffairs@nhs.net

1.5 Due Regard (see also Due Regard Assessment Appendix 7)

LPT will ensure that due regard for equality is taken and as such will undertake an analysis of equality (assessment of impact) on existing and new policies in line with the Equality Act 2010. This process will help to ensure that:

- Strategies, policies and procedures and services are free from discrimination.
- LPT complies with current equality legislation.
- Due regard is given to equality in decision making and subsequent processes.
- Opportunities for promoting equality are identified.

1.6 Definitions that apply to this policy.

Patient Group Direction (PGD)	A PGD is a specific written instruction for the supply and/or administration of named medicines in an identified clinical situation. It applies to groups of patients or service users who may not be individually identified before presentation for treatment
Administer	To give a medicine by either introduction into the body, whether by direct contact with the body or not, (e.g., orally or by injection) or by external application (e.g. application of a cream or ointment)
Supply	To provide a medicine to a patient/carer for administration.
Prescription Only Medicines (POM)	A medicinal product which may normally only be sold or supplied against a signed prescription of an appropriate practitioner as specified in the Prescription Only Medicines (Human Use) Order 1997. There are exemptions to requiring a prescription in some circumstances, such as using a PGD.
Authorised Healthcare Professional	A healthcare professional described within the legislation (HSC 2000/026) who has been given authorisation to work under a PGD
Marketing Authorisation	Medicines that meet the standards of safety, quality and efficacy are granted a marketing authorisation (previously referred to as a "product licence"). The authorisation covers all the main activities associated with the marketing of a medicine. In the UK, a marketing authorisation is granted by the Medicines and Healthcare Products Regulatory Agency (MHRA).
Licensed medicine	A medicine that has a UK marketing authorisation.
Summary of Product Characteristics (SmPC)	The SmPC is written information on a licensed medicine that must contain a range of specified information, such as the indication(s), recommended dose(s), contraindications, and special warnings and precautions for use.
Black triangle medicine (▼)	Black triangle medicines are licensed medicinal products (usually newly introduced medicines) that are being monitored particularly closely by regulatory authorities (described as being under "additional monitoring"). All suspected reactions (including those not considered to be serious) should be reported through the Yellow Card Scheme.
Consent	A patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing. For the consent to be valid, the patient must: • be competent to take the particular decision. • have received sufficient information to take it and not be acting under duress.

2.0 Purpose of this Policy

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

However, it is possible in some circumstances, for medicines, including Prescription Only Medicines (POM), to be supplied or administered in accordance with a "Patient Group Direction" (PGD). A Patient Group Direction (PGD) is a written instruction for the supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. Legislation establishing PGDs was introduced in 2000, and the Health Service Circular is HSC 2000/026 [(1)] provided additional guidance.

This policy describes the processes to be followed in LPT for a structured approach to the development, approval, and use of Patient Group Directions (PGDs). This will ensure that PGDs are presented in a consistent and standard format and that the practice it supports is within the law and has approval of the Trust. It should be read in conjunction with other relevant guidance and policies on prescribing and medicines administration, including the Leicestershire Medicines Code.

The Patient Group Direction Policy:

- Applies to all staff employed by LPT involved in the development, approval, and use of Patient Group Directions for the Supply and/or Administration of Medicinal Products.
- Ensures that PGDs are only developed and used in the organisation where they have been identified as the most appropriate mechanism for patients to receive their medicines.
- Sets the framework in which PGDs are developed and implemented in the Trust.
- Provide standards for the use of PGDs which ensure quality of care and patient safety, including requirements for appropriate training.
- Describes the responsibilities of approved practitioners working under a PGD.

3.0 Policy Requirements

The current legislation governing PGDs is included in The Human Medicines Regulations (HMR) 2012 [(2)], which came into force in August 2012.

Medicines Practice Guidelines issued by NICE during 2013 [(3)] provide good practice recommendations for individuals and organisations using Patient Group Directions, with the aim of ensuring patients receive safe and appropriate care and timely access to medicines, in line with legislation. The supply or administration of medicines under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where there are clear governance arrangements and accountability.

A PGD provides a mechanism for medicines to be supplied and/or administered to patients by a specified range of healthcare professionals, as defined within the legislation, without seeing a prescriber. PGDs are legal documents and must be produced and used correctly to ensure the practitioner is working within the requisite legislation. All PGDs should be underpinned by the best available evidence and must only include medicines with a UK marketing authorisation.

3.1 Which Healthcare Professionals can use a PGD [4] ?

PGDs can only be used by the registered health professionals listed in Schedule 16, part 4 of the HMR 2012.

- Registered Dental therapists and Hygienists.
- Registered Dieticians
- Registered Midwives
- Registered Nurses
- Registered Occupational Therapists
- Registered Optometrists
- Registered Orthoptists
- Registered Paramedics
- Registered Pharmacists
- Registered Pharmacy Technicians (updated legislation approved 26th June 2024).
- Registered Physiotherapists
- Registered Podiatrists and Chiropodists
- Registered Prosthetists and Orthotists
- Registered Radiographers
- Registered Speech and Language Therapists

Individuals must be competent, qualified, and currently registered members of their professional body. No other groups of health care workers such as dentists or nursing associates can use PGDs. The law requires that individual health care professionals who will be using a specific PGD must be named and authorised to practice under a PGD.

3.2 What information must be included in a PGD?

The following information must be included in a PGD [3]

- The name of the body to which the direction applies.
- The date the direction comes into force and the date it expires. **The expiry date for a PGD needs to be decided on a case-by-case basis but should not be more than 3 years from the date the PGD was authorised.**
- The class A description of the medicine(s) to which the direction applies**.** Where the medicine is for children, particular attention will be needed to specify any restrictions on the age, size or weight, and maturity of the child.
- The class of the health professional who may supply or administer the medicine.
- A signature of a doctor or dentist (as appropriate) and a pharmacist.
- The clinical condition(s) covered by the direction (if the patient does not fit the inclusion criteria of the PGD, the PGD must not be used).
- A description of those patients excluded from treatment under the direction.
- A description of the circumstances under which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral.
- 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. Dose adjustment is allowed within a PGD, for medicines supplied or administered under that PGD, as long as a dosage range is specified in the PGD.
- Relevant warnings, including potential adverse reactions.
- Details of any follow-up action and the circumstances
- A statement of the records to be kept for audit purposes.
- Use the best available evidence, such as NICE guidance and other sources of high-quality information when developing a PGD. These should be included as key references or as an appendix to the PGD. The Summary of Product Characteristics (SmPC) must always be consulted in developing a PGD and included in the list of references.
- It is a legal requirement that staff must work to a signed current PGD. After the expiry date a PGD is not valid. Medicines must not be supplied or administered on the authority of an expired PGD.

3.3 Clinical situations in which PGDs should be considered carefully?

- the medicine is an antimicrobial (**see section 3.6**)
- the medicine has a Black Triangle symbol (**see section 3.7**)
- the medicine has any Risk Minimisation Measures (RMM) associated with the marketing authorisation (**see section 3.8)**
- Off label use of a licensed medicine should be exceptional and clearly justified by best clinical practice. Each PGD must clearly state when the product is being used outside the terms of the marketing authorisation and the documentation must include the reasons why exceptional use is necessary.

3.4 The following must not be included in a PGD:

- abortifacients, such as mifepristone
- controlled drugs not permitted by the legislation - under the Misuse of Drugs Regulations 2001, including anabolic steroids and any injectable preparation used for treating addiction. (**see section 3.5**)
- delegation – a PGD cannot be used where there is a delegation of responsibility to supply or administer the medicine.
- dressings or medical devices – PGDs can only be used for medicines with a UK marketing authorisation.
- mixing of medicines – when two or more licensed medicines are mixed, this results in an unlicensed medicine which cannot be used under a PGD.
- radiopharmaceuticals.
- where dose adjustment is required to a medicine already in the patient's possession. PGDs do not give a legal framework for healthcare professionals to adjust a dose of medicine already in a person's possession and must not be used for this purpose.
- medicines which are not approved for use within the Trust.
- unlicensed medicines – these do not have a UK marketing authorisation so cannot be included in a PGD. This includes imported medicines and specially manufactured medicines (**see exception below***).

The following types of treatment are also unsuitable for inclusion in a PGD:

- medicines requiring frequent dose adjustment or complex monitoring, for example anticoagulants or insulin.
- medicines intended for the management of long-term conditions, such as hypertension, or where there is uncertainty about the differential diagnosis.

* **Unlicensed medicines exceptions**.

In November 2020, there was a regulatory update (Regulation 174 of the Human Medicines Regulations 2012) which waived the requirement for a medicine to hold a marketing authorisation when the sale or supply of the medicine is authorised by Ministers, in response the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation. Amendments to this legislation for Covid – 19 vaccines allowed the vaccine to be supplied under a PGD. **At the time of writing this policy, this exemption is not currently in use. All vaccines used in the Covid-19 vaccine programme are now licensed medicines.**

3.5 Controlled Drugs

Schedule	Controlled drugs that may be considered for inclusion in a PGD	Additional comments
Schedule 2	Morphine Diamorphine Ketamine (Schedule 2 from 30th November 2015)	Use by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person (not for treating addiction)
Schedule 3	Midazolam	Following their reclassification as Schedule 3 Controlled Drugs, gabapentin, pregabalin and tramadol may not be included in a PGD
Schedule 4	All drugs **except** anabolic steroids & injectable drugs used for treating addiction.	
Schedule 5	All drugs including codeine	Although nitrous oxide is now a Schedule 5 controlled drug, it does not require a PGD for administration as it is a pharmacy only (P) medicine.

Note: The following registered professions cannot supply or administer any controlled drugs, in any of the five schedules, under a PGD: dieticians, speech & language therapists, dental hygienists, dental therapists.

3.6 Antimicrobials

The inclusion of antimicrobial agents in a PGD must be absolutely necessary and not jeopardise local and national strategies to combat increasing antimicrobial resistance. The principles of the Trust Antimicrobial Stewardship Policy (2024) [5] should be followed to ensure that antimicrobials are utilised in the best possible way in order to maximize effectiveness and minimize resistance.

Ensure an antimicrobial is included in a PGD only when it is:

- clinically essential and justified by best clinical practice. Antibiotic choice should be in line with the Trust Antimicrobial Policy or other guidelines, approved by the Leicester, Leicestershire & Rutland Area Prescribing Committee.
- has the support of a specialist within microbiology, through the Antimicrobial Working Party, and that this support is clearly documented.
- the use of the PGD is monitored and reviewed regularly.

3.7 Black Triangle Drugs (▼)

Black triangle drugs (i.e., those recently licensed and/or subject to additional monitoring arrangements for adverse reactions) may be included in PGDs provided such use is exceptional and justified by current best clinical practice. The black triangle status must be clearly indicated on the PGD.

3.8 Use of Medicines with "Risk Minimisation Measures" (RMM)

As well as information routinely described in the Summary of Product Characteristics (SmPC) , some medicines have extra requirements for additional Risk Minimisation Measures (RMM). Examples can range from extra information for patients, such as an 'alert' card, or checklists for health professionals, to the imposition of a controlled access scheme.

When developing a PGD for a medicine, it is important to determine whether the medicine has any RMM associated with the licence.

In accordance with NICE guidance, medicines needing frequent dosage adjustments, or frequent or complex monitoring should not be included in a PGD. Therefore, a medicine with RMM for close monitoring and supervision of patients may not be suitable for inclusion in a PGD. If a decision is taken to include a medicine with RMM in a PGD, the requirements of the RMM **must be included in the PGD**.

4.0 Duties within the Organisation

- **The Trust Board** has a legal responsibility for Trust policies and ensuring that they are carried out effectively.
- **Trust Board sub-committees** have the responsibility for approving policies and protocols, to assess assurances received related to the implementation of National Guidance and for ensuring that such documents adhere to the current Trust process for the Development and Implementation of Policies.
- **Medication Risk Reduction Group (MRRG)** All proposals for a new PGD or a review of a current PGD must be submitted to the MRRG for approval which has the role and function of a "PGD approval group" (as defined by NICE MPG2 [3]. The MRRG is responsible for providing assurance that PGDs are developed in line with this policy and reports to the Trust Medicines Management Committee.

Proposals will be considered against set criteria [3], which include consideration that:

- 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, 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 training and competency needs are addressed.
- the need for appropriately labelled packs and safe storage can be met.
- adequate resources, such as finance, training, procurement are available for service delivery and decisions are aligned with local policies or formularies.

The MRRG will ensure that:

- any decision to accept or reject a PGD proposal, including the rationale for the decision, is recorded in the minutes, and communicated to the person who submitted the proposal.
- when a proposal for a new PGD is not approved, the applicant is given the opportunity to address any concerns and/or provide additional rationale for use of the PGD. This must be done in writing to the chair of the MRRG.
- when a PGD is approved, the final version is forwarded to the appropriate persons for signature (**see section 4.1**) and that the most up to date version of the PGD is published on the staff intranet.

4.1 The PGD signatories

All authors and signatories must meet the nationally stated competencies for authorising PGDs, which have been published by NICE [7] in conjunction with the Medicines Practice Guidelines on Patient Group Directions [(3)]

The usual signatories for a PGD will be:

- The Medical Director,
- The Head of Pharmacy
- Executive Director of Nursing/AHP's & Quality

Other signatories may be used, where appropriate to the PGD, providing that they are members of the specified professions who will be using the PGD.

In addition, the Head of Pharmacy (or nominated senior pharmacist) will ensure that:

- the medicines content of the PGD is legal and accurate.
- that local formularies and procedures are complied with when considering inclusion of a medicine in a PGD.
- legal and adequate supplies of the medicines (in appropriately labelled packs where relevant) are available for the agreed clinical areas.

Note: If the PGD is for supply or administration of an antibiotic it should also be supported by the local Antimicrobial Working Party. The comments of this group and support for the approval of the PGD(s) must be recorded.

4.2 The Service Lead

Heads of Service have responsibility for implementing this policy within the service for which they have overall responsibility and to ensure adherence to this policy.

It is the responsibility of the Service Lead to ensure that only fully competent, qualified, and trained professionals within their team(s) operate within PGDs. The Service Lead must be assured that the individual meets the requirements regarding training deemed necessary and is competent to use the PGD.

The individual must have evidence of competence, training and continuing education relevant to the clinical conditions/situation to which the Patient Group Directions applies. Before a healthcare professional can supply or administer medicines under a specific PGD they must be “authorised” by their line manager and named in the Patient group Direction held within their area of practice.

The service lead must keep a list/database of all those authorised to practice under a PGD. If a practitioner is no longer authorised to act within the PGD, it is the responsibility of the individual or their line manager to inform the Authorising Manager so that the individual’s name is removed from this list or database.The Service Lead must ensure that any examples of non-adherence to the policy are reported through the incident reporting process.

4.3 Authorised Registered Practitioners

All Authorised Healthcare Professionals who use PGDs are responsible for adhering to the requirements of the policy. They must be registered with their professional body and must always act within their Code of Professional Conduct.

All Authorised Healthcare Professionals must understand and have read the content of each PGD and take responsibility for maintaining their competency and ongoing training requirements to continue to use the PGD safely. They must be named and have evidence of competence, training and continuing education relevant to the clinical conditions/situation to which the Patient Group Direction applies. Any practitioner failing to comply with the criteria within the PGD falls outside of the law.

They must only undertake the role of working to PGDs where they are competent to assess all relevant aspects of the patient’s clinical condition and take responsibility for the supply or administration of medicines and related decisions. Accurate records must be made of the consultation that results in the use of the PGD.

When supplying a medicine, provide an appropriately labelled pack and ensure that the patient receives a patient information leaflet with each medicine. Do not split packs. Clinical judgement cannot be used to supply/administer a medicine outside the criteria in the PGD, including quantities supplied and inclusion/exclusion criteria, e.g. age.

Supply or administration cannot be delegated to any other person under a PGD, because such delegation is not allowed by medicines legislation. The appropriate prescription charge must be collected from patients (who are not exempt) in line with legislation.

5.0 Identifying the need and obtaining agreement to develop a Patient Group Direction

The preferred method for patients to receive medicines is for a prescriber to prescribe for an individual patient based on their clinical need. However, there may be instances where PGDs are more suited to a certain group of patients. For example, in situations where a prescriber is not normally available, where clearly defined instructions, for the supply and administration of medicines, can be produced and where there are volumes of patients who present for treatment (e.g., vaccines)

A PGD is not an authorisation to prescribe. It allows a range of specified health care professionals to supply and / or administer a medicine directly to a patient with an identified clinical condition without them seeing a prescriber. However, the patient presents, the health care professional, working within the PGD, is responsible for assessing that the patient fits the criteria set out in the PGD. Careful consideration needs to be given as to whether a PGD is the most appropriate option for supply and/or administration of medicines. PGDs must be exceptional and lead to improvement in patient care.

A PGD is not meant to be a long-term means of managing a patient's clinical condition. This is best achieved by a health care professional prescribing for an individual patient on a one-to-one basis. The supply and administration of medicines under PGDs should be reserved for those limited situations where this offers an advantage to patient care without compromising patient safety and must be consistent with appropriate professional relationships and accountability. Before development of a PGD, the most appropriate method of supply of the medicine must be identified, including the availability of a budget to support the use of the PGD (service and medicine supplies).

PGDs are not required for the following:

- Dressings, appliances, medical devices, or chemical agents: these are not legally classed as medicines.
- Supply or administration of General Sales List medicines (GSLs)
- Administration of Pharmacy (P) medicines or the administration or supply of a GSL medicine to an individual. A locally produced protocol or SOP should be used instead.
- Administration of medical gases
- Administration of medicines where exemptions apply under the Human Medicines Regulations 2012, such as those parenteral medicines used for the purposes of saving a life in an emergency , including adrenaline and naloxone.

Any service wishing to introduce a PGD must complete **Appendix 1 – Proposal for the Development of a New Patient Group Direction or Change to an Existing PGD (significant amendment only)** and submit the request to the Head of Pharmacy for consideration at the MRRG.

In completing this proposal, the service will need to consider the following:

- Is there a genuine service need?
- Is the patient group appropriate for supply or administration under a PGD (offers an advantage to patient care without compromising patient safety)
- Is this the most effective way of providing the medicine to a patient?
- Is the health care professional identified as potential user of the PGD included in the groups legally entitled to use PGDs and is this medicine appropriate to the scope of practice of this professional group?
- How will the supply of the medicines be obtained and stored and is the supply legal (does it comply with labelling legislation for instance if the supply is provided for administration at home)? What arrangements will apply for the collection of prescription charges **where applicable**?
- Any decisions to accept or reject a proposal, including the rationale for the decision, will be recorded in the minutes of the MRRG.

6.0 Patient Group Direction development and approval

6.1 Proposal to develop a new PGD.

A new Patient Group Direction (PGD) should only be developed following agreement of the Medication Risk Reduction Group (MRRG) as above. The process for drafting and developing PGDs within LPT is outlined below (see also **Appendix 2).**

All PGDs should be developed following the agreed template (**see Appendix 3**) and with appropriate clinical input; for a review of an existing PGD, the author(s) should ensure that the whole PGD is reviewed to ensure the information is still current and applicable.

The final draft of the PGD should be submitted to the MRRG, who will advise on any further amendments. Patient Group Directions for antimicrobial agents must have the support of microbiology specialists via submission to the Antimicrobial Working Party.

Once the MRRG are assured that the PGD is compliant with this policy, the PGD will be forwarded for the appropriate signatures. If the PGD is associated with a clinical protocol, this must have been completed prior to final PGD approval.

Until approved by the MRRG, and signed by the agreed signatories, a PGD or amendments to an existing PGD is invalid. LPT accepts no responsibility for an approved practitioner who acts in accordance with a PGD not approved in accordance with this policy.

The expiry date of all PGDs **must be no longer than three years after the approval date**. The review period may in some cases be shorter to allow for circumstances when the MRRG considers it is appropriate for an earlier review.

6.2 Review of Existing PGDs

Each PGD will have a review date assigned by the Head of Pharmacy (or nominated senior pharmacist) and will alert the lead author of the PGD of the upcoming review date to ensure it is reviewed before the PGD expires. This review date will be a minimum of 3 months prior to the expiry date of the PGD. At the review date, it is important for the service to assess whether there is a continued need for the PGD.

The author(s) should ensure that the whole PGD is reviewed to ensure the information is still current and applicable. If the PGD requires a significant amendment, the author(s) must also complete **Appendix 1 – Proposal for the Development of a New Patient Group Direction or Change to an Existing PGD (significant amendment only).** Once review of the PGD is complete, it should be submitted to the MRRG for consideration and will be signed off following the same process described in section 6.1.

After the expiry date, the PGD is not valid. **Medicines must not be supplied or administered under the authority of an expired PGD.**

6.3 Extension of PGD expiry dates

Extension of expiry dates without review of the PGD is not without risk (e.g., marketing authorisation of medicine may have changed/national or local guidance may have changed) but the Trust may deem this necessary where it is in the interest of patient safety from withdrawing the PGD. Extension of an expiry date should only be in exceptional circumstances within the following criteria:

- Maximum of 6 months extension
- Extended once only
- To be approved by the MRRG and the version with extended expiry signed with the usual signatories.

6.4 The adoption and use of PGDs developed by other authorising bodies

Registered practitioners who are employed by the Leicestershire Partnership Trust may be required to use PGDs that are approved by organisations, such as NHS England to administer medicines or vaccines.

The Leicestershire Partnership NHS Trust has agreed to adopt PGDs, approved by the National or Local Area Team and authorises its staff to use them to administer medicines when the following conditions have been met:

- PGDs are signed by a doctor or dentist and a pharmacist authorised by the authorising body for this responsibility.
- None of the content of the PGD may be changed in this scenario as the signatures for the development of the PGD correspond to the original content.

- It can be demonstrated, for PGDs for antimicrobial agents, that a microbiologist has been involved in the development.
- The PGD has been signed by an appropriate signatory (e.g., Medical Director), on behalf Leicestershire Partnership Trust where specified in the PGD.
- Details of the adopted PGD will be added to the organisation database of PGDs to support governance and enable tracking.

7.0 Patient Group Direction Management and Implementation

This policy will be implemented and disseminated throughout the organisation, in accordance with the post ratification process and will be catalogued in the Trust register of Policies and posted on the intranet document portal.

It is the responsibility of the Service Lead to ensure that staff are familiar and compliant with this policy and have documented evidence of this. The practitioner must read and retain a copy of each PGD they are working to. Staff using a PGD must be competency assessed and signed off by their authorising manager before using a PGD. However 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. Healthcare professionals have the ability to exercise personal and professional judgment as to whether to accept the responsibility that this role will place on them.

The Authorising Manager should retain a list of names of each Authorised Healthcare Practitioners using a PGD which must be made available to the MRRG on request. If a practitioner is no longer authorised to act within a PGD it is the responsibility of the Authorising Manager to remove the individual's name from the relevant list.

8.0 Consent

Clinical staff must ensure that consent has been sought and obtained before any care, intervention or treatment described in this policy is delivered. Consent can be given orally and/ or in writing. Someone could also give non-verbal consent if they understand the treatment or care about to take place. Consent must be voluntary and informed, and the person consenting must have the capacity to make the decision.

In the event that the patient's capacity to consent is in doubt, clinical staff must ensure that a mental capacity assessment is completed and recorded. Someone with an impairment of or a disturbance in the functioning of the mind or brain is thought to lack the mental capacity to give informed consent if they cannot do one of the following:

- Understand information about the decision.
- Remember that information.
- Use the information to make the decision.
- Communicate the decision.

9.0 Education and Training (see also Appendix 4 & 5)

All healthcare professionals who wish to administer or supply medication under any PGD must have completed the approved medicines management training, which includes relevant theory on the use of Patient Group Directions.

Training requirements should be identified when each new PGD is prepared and agreed with the service involved, before seeking approval for the PGD. Individual practitioners should ensure that any training or updates required are identified with their manager.

The preferred method of carrying out competency assessment is supervised practice. Where this is not possible, the following methods should be considered:

The competency document in **Appendix 4** has been designed to provide services with an outline of requirements to be covered in a competency assessment. Services should use the template and adapt with additional questions where applicable to the drug/disease included in the PGD. The competency assessment must be documented and repeated as a minimum in line with renewal of the PGD.

10.0 Monitoring Compliance and Effectiveness

The policy will be monitored through the receipt of the PGD proposals and PGD documents by the Medication Risk Reduction Group (MRRG). Accurate records must be made of PGD consultation and approval as stated in this policy.

Approved versions of PGDs will be stored on:

- The Trust intranet (StaffNet)
- An electronic copy of current and archived PGDs will be retained on the Pharmacy shared drive in accordance with best practice requirements.

Care provided under a PGD must be reviewed. Practitioners must be able to access records of patients who have received medication under a PGD for audit purposes. PGD documentation must be retained in accordance with the Electronic Health Records Policy (including Record Keeping and Management).

The procedure, supporting processes and guidance will be reviewed and revised in line with changes to the UK legislation , relating to PGDs, three years from the date of approval.

Page/Section	Minimum Requirements to monitor	Method for Monitoring	Responsible Individual /Group	Frequency of Monitoring
Section 6.0	PGDs is use within the Trust are compliant with Policy and in date	The MRRG will ensure the review of PGDs & monitor implementation of this Policy	MRRG	As required.

Page/Section	Minimum Requirements to monitor	Method for Monitoring	Responsible Individual /Group	Frequency of Monitoring
Section 9.0	Healthcare professionals using PGDs must have completed the required training, specified in each PGD they are using	Compliance with medicines management training will be monitored via reports issued by Workforce	Service Lead	As required.
Section 4.0	Untoward incidents reported concerning the use of PGDs by healthcare professionals	Incident forms submitted on Ulysses and investigations completed.	Service Lead/MRRG	As required
Section 10.0	Elements of the policy will be audited as agreed within the Annual Quality Schedule.	Audit report and agreed actions.	MRRG	As agreed within the Quality Schedule

11.0 References and Bibliography

1. Department of Health (2000) : HSC 2000/026 – Patient Group Directions (England only)
2. Her Majesty's Government (2012), The Human Medicines Regulations 2012 (SI 2012:1916) as amended.
3. National Institute for Health and Care Excellence. Medicines Practice Guideline (MPG2), Patient Group Directions. First published August 2013, last updated March 2017
4. Medicines and Healthcare Products Regulatory Agency (MHRA) at GOV.UK Patient group directions: who can use them (updated December 2017)
5. Leicestershire Partnership Trust (v. 4.0 (2024)), Antimicrobial Stewardship Policy
6. National Institute for Health and Care Excellence. Competency framework for people authorising Patient Group Directions. Implementing the NICE, good practice guidance on Patient Group Directions (MPG2)
7. National Institute for Health and Care Excellence. Competency framework for health professionals using Patient Group Directions. First published January 2014, last updated January 2018
8. Leicestershire Partnership Trust (v.1.1 (2022) Electronic Health Records Policy (including Record Keeping and Management)

12.0 Fraud, Bribery and Corruption consideration

The Trust has a zero-tolerance approach to fraud, bribery and corruption in all areas of our work and it is important that this is reflected through all policies and procedures to mitigate these risks.

Fraud relates to a dishonest representation, failure to disclose information or abuse of position in order to make a gain or cause a loss. Bribery involves the giving or receiving of gifts or money in return for improper performance. Corruption relates to dishonest or fraudulent conduct by those in power.

Any procedure incurring costs or fees or involving the procurement or provision of goods or service, may be susceptible to fraud, bribery, or corruption so provision should be made within the policy to safeguard against these.

If there is a potential that the policy being written, amended or updated controls a procedure for which there is a potential of fraud, bribery, or corruption to occur you should contact the Trusts Local Counter Fraud Specialist (LCFS) for assistance.

PROPOSAL FOR THE DEVELOPMENT OF A NEW PATIENT GROUP DIRECTION (PGD) OR CHANGE TO AN EXISTING PGD (SIGNIFICANT AMENDMENT ONLY e.g., change of indication, extension to staff groups able to operate under the PGD)

Please complete **Part** 1 of the form below electronically, and once completed, return via e-mail to the Head of Pharmacy. This form will be reviewed by the Medication Risk Reduction Group (MRRG) to assess suitability for the development of a PGD/proposed significant amendment. Please refer to the Trust Policy for Patient Group Directions for further information; if you require further support, please contact the Lead Pharmacist for your service.

PART 1 – (To be completed by the proposer of the PGD)

PGD FOR ……(insert name, strength and form of medicine)

☐ I/we have reviewed the requirements of the policy and a PGD is the most appropriate route to provide this clinical activity

NAME AND POSITION OF PROPOSER – Clinical/Service Lead **Contact details (Tel No/Email)**

NAME AND POSITION OF LEAD AUTHOR(S) RESPONSIBLE FOR THE DEVELOPMENT OF THE PGD (Note: PGDs for antimicrobials must also include the input of a microbiologist) **Contact details (Tel No/Email)**

DEPARTMENT

STATEMENT OF SUPPORT FROM PROFESSIONAL/SERVICE LEAD (if different to above) **NAME, SIGNATURE AND POSITION**: **…… …… ……..**

Date:……

Details of the Proposed Patient Group Direction (PGD) or Existing PGD Requiring Significant Amendment

Is this a new PGD or a significant amendment of an existing PGD? **Please indicate**	☐ New PGD ☐ PGD Amendment* *** For existing PGDs, please complete the sections requiring an amendment. For all other PGDs, ALL sections must be completed.**
Title of PGD	
Names, formulation and dosage of drug(s) to be supplied or administered.	
Indications for this PGD? Specify age group?	
Please list local/national guidance which supports the use of this drug	
Clearly describe – Why there is a need for this PGD within your service.	
How is this medicine currently administered/supplied to the patient? (By following a prescription, patient told to consult the GP etc.)	
What are the benefits to patients of having this PGD?	
What are the benefits to staff having this PGD?	
Which professional group (s) will use this PGD?	
Please describe how you will ensure staff are trained to work safely under this PGD?	
Please describe how the service will ensure the requirements for safe storage, including confirmation that a medical refrigerator is available if the PGD includes a medicine requiring storage between 2-8 C.	
Are there any resource implications? (e.g., cost of drugs/staff training)	
Are there any risks from not developing this PGD?	

PART 2 – (To be completed on behalf of the Medication Risk Reduction Group (MRRG)

PGD TITLE: …….

SERVICE :……..

This PGD was considered by MRRG on ……..(insert date)

which has

☐ **Approved** the Patient Group Direction for development/significant amendment on behalf of the Leicestershire Partnership NHS Trust (LPT)

OR

☐ **NOT** approved for development into a Patient Group Direction on behalf of the Leicestershire Partnership NHS Trust (LPT)

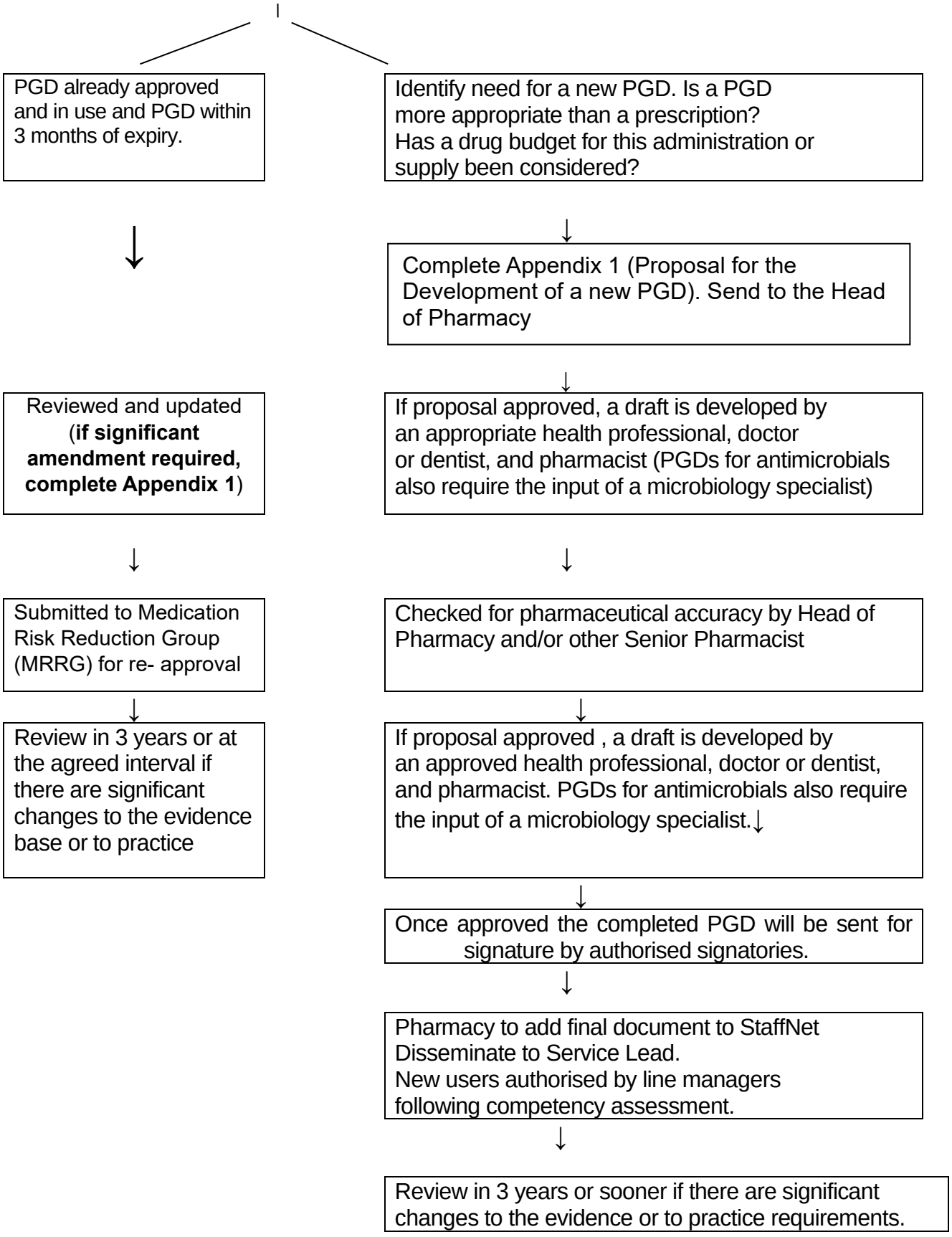
…….. ……

Head of Pharmacy Date

MRRG COMMENTS

Completed form to be returned to the proposer.

Process for Development, Approval and Dissemination of PGDs



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PATIENT GROUP DIRECTION (PGD) FOR

Drug name	CLASS e.g. POM

Clinical Condition

Indication	Need to be specific on the clinical condition to be treated. Is it a licensed indication - check SmPC, BNF.
Inclusion criteria	Follow any clinical guidelines or policies that are available either locally or nationally e.g. SIGN, NICE, local on LMSG Check SmPC. Consult clinicians working in that area.
Exclusion criteria	Check SmPC/published guidelines such as SIGN, NICE, local on LMSG Decide if there are limitations for service i.e. to age or patient groups (e.g. immunocompromised patients). **Lack of consent will always be an exclusion** 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.
Cautions/Need for further advice	• Check SmPC / published guidelines such as SIGN, NICE, Local on LMSG • Pregnancy and breast feeding – explain reason for inclusion, exclusion or caution wherever 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

Leicestershire Partnership NHS
NHS Trust

PATIENT GROUP DIRECTION (PGD) FOR

Drug name	CLASS e.g. POM

Drug Details

Name, form & strength of medicine	References include: BNF/SmPC/ Medicines for Children Use clear format to express strength and form e.g. BNF style: Amoxicillin Capsules 250 mg; Amoxicillin Suspension 250 mg in 5 mL
Route/Method	References: BNF/SmPC /Medicines for Children To avoid errors, state in full and do not use abbreviations e.g. oral not p.o.
Dosage	References: BNF/SmPC/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 pharmacy 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/SmPC/ local and guidelines/ Medicines for Children
Duration of treatment	Decide with service provider and medicine supplier.
Maximum or minimum treatment period	To be decided locally.
Quantity to supply/administer	Depends on above i.e. dosage, frequency and duration.

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PATIENT GROUP DIRECTION (PGD) FOR

Drug name	CLASS e.g. POM

Side effects	Useful references: SmPC/BNF /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 • Consider whether other health promotion material is appropriate e.g. Smoking Cessation clinics

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PATIENT GROUP DIRECTION (PGD) FOR

Drug name	CLASS e.g. POM

Follow up	*Enter details of local policy.*

Referral Arrangements and Audit Trail

Referral arrangements	*As per local arrangements/national guidelines.*
Records/audit trail	The following points have been used in the development of model templates for Emergency/First Contact Services: • Patient's name, address, date of birth and consent given • Contact details of GP (if registered) • 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.

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PATIENT GROUP DIRECTION (PGD) FOR

Drug name	CLASS e.g. POM

Staff Characteristics

Qualifications	Registered professional *[appropriate qualification to be listed]* with a current *[professional]* registration
Specialist competencies or qualifications	• Refer to guidelines relating to this drug e.g. nurses must be trained in anaphylaxis if administering vaccines.
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.

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PATIENT GROUP DIRECTION (PGD) FOR

Drug name	CLASS e.g. POM

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

Authorisation

Lead Doctor	Name: Position: Medical Director Signature:	Date:
Lead Nurse/Allied Health Professional	Name: Position: Executive Director of Nursing/AHP's & Quality Signature:	Date:
Lead Pharmacist	Name: Position: Head of Pharmacy Signature:	Date:
Other signature (where agreed for professional group)	Name: Position: Signature:	Date:

Patient Group Direction Peer Reviewed by

Leicestershire Partnership NHS
NHS Trust

PATIENT GROUP DIRECTION (PGD) FOR

Drug name	CLASS e.g. POM

Name	Position	Date
Medication Risk Reduction Group	The PGD Policy requires all PGDs to be approved by this group	

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PATIENT GROUP DIRECTION (PGD) FOR

Drug name	CLASS e.g. POM

Individual Authorisation

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.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD.

Name of Professional	Signature	Authorising Manager	Date

Appendix 4

PGD Competency Assessment Document – *[insert name of PGD here]*

Name of Healthcare Professional (HCP)		**Line Manager**	
Job Title		**Date**	

Knowledge/competency being assessed	**Question/Statement to assess knowledge/competency**	**Knowledge/competency shown? (or HCP to answer "True" or "False" if written test)**
Understanding of general principals of PGD use and legalities	Examples of suitable questions:	
	• A black-triangle drug can be put on a PGD	
	• Unlicensed medicines can be put on a PGD	
	• A PGD needs to be signed only by a doctor for it to be legal	
	• A PGD needs to be reviewed yearly	
	• HCPs must be competency assessed for each PGD before they can use it	
	• A PGD can only be used by independent prescribers	
	• Health Care Assistants can use PGDs after appropriate training	
	• Administration/Supply can be delegated to another HCP under the terms of a PGD	
Relevant training	**Examples of suitable questions:**	
	• Is the HCP up-to-date with CPR training?	
	• Is the HCP up-to-date with anaphylaxis training?	
Understanding of disease or condition to be managed by the PGD	**Insert questions to test HCPs understanding of:**	
	• Disease/condition	
	• Disease progression	
	• Differential diagnosis	
	• Danger/warning signs	

Understanding of drug contained in the PGD	**Insert questions to test HCP's understanding of:**	
	• Mechanism of action of drug	
	• dose	
	• side effects	
	• interactions	
	• cautions	
	• contra-indications	
Understanding of specific PGD	**Insert questions to test HCP's understanding of:**	
	• Inclusion criteria	
	• exclusion criteria	
	• when to refer	
	• advice to give	
	• documentation	

Final Mark: ____

To be used by the assessor only

List below actions taken where a gap in the HCPs knowledge/competency has been identified:

Gap in knowledge/competency	Action(s) taken (e.g., discussion, reading etc..)

Name of Assessor	
Job Title	
Date	

Appendix 5

Training Needs Analysis

Training topic:	Patient Group Directions	
Type of training: (see study leave policy)	√Mandatory (Trust Medicines Management Training) √Role Essential (additional specific competencies or qualifications according to the PGD. Personal development	
Directorate to which the training is applicable:	Adult Mental Health Community Health Services Families Young People Children / Learning Disability/	
Staff groups who require the training:	Individual healthcare professionals intending to work under a PGD and who are legally authorised in accordance with the Human Medicines Regulations 2012.	
Regularity of Update requirement:	In line with planned review of the PGD or sooner if there is any change to the specific competencies or qualifications specified within the PGD.	
Who is responsible for delivery of this training?	uLearn module (for Trust Medicines Management Training and additional qualifications e.g., anaphylaxis training). Competency Assessment via Supervised Practice (Appendix 5).	
Have resources been identified?	uLearn module	
Has a training plan been agreed?	uLearn module and individual practitioners should ensure that any training or updates required are included in their annual development review.	
Where will completion of this training be recorded?	ULearn Other (please specify)	
How is this training going to be monitored?	Compliance of medicines management training will be monitored by OLM with quarterly flash reports	
Signed by Learning and Development Approval name and date		Date: October 2024

The NHS Constitution

- The NHS will provide a universal service for all based on clinical need, not ability to pay.
- The NHS will provide a comprehensive range of services.

Shape its services around the needs and preferences of individual patients, their families and their carers	**Yes**
Respond to different needs of different sectors of the population	**Yes**
Work continuously to improve quality services and to minimise errors	**Yes**
Support and value its staff	**Yes**
Work together with others to ensure a seamless service for patients	**Yes**
Help keep people healthy and work to reduce health inequalities	**Yes**
Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance	**Yes**

Due Regard Screening Template

Section 1	
Name of activity/proposal	Patient Group Directions Policy for their Development, Approval and Use
Date Screening commenced	October 2024
Directorate / Service carrying out the assessment	Medication Risk Reduction Group (MRRG)
Name and role of person undertaking this Due Regard (Equality Analysis)	Joanne Charles, Lead Pharmacist, Community Health Services on behalf of MRRG
Give an overview of the aims, objectives and purpose of the proposal:	
AIMS: To provide a framework for the development, approval, and use of PGDs for the supply, administration of medicines by Authorised Healthcare Professionals. To improve patient access to medicines and/or reduce clinical risk.	
OBJECTIVES: This policy describes the process to be followed within the Trust for the development and implementation of PGDs to ensure that the practice it supports is within the law and has the approval of the Trust.	

Section 2	
Protected Characteristic	If the proposal/s have a positive or negative impact please give brief details
Age	No negative impacts identified at this stage of screening
Disability	No negative impacts identified at this stage of screening
Gender reassignment	No negative impacts identified at this stage of screening
Marriage & Civil Partnership	No negative impacts identified at this stage of screening
Pregnancy & Maternity	No negative impacts identified at this stage of screening
Race	No negative impacts identified at this stage of screening
Religion and Belief	No negative impacts identified at this stage of screening
Sex	No negative impacts identified at this stage of screening
Sexual Orientation	No negative impacts identified at this stage of screening
Other equality groups?	

Section 3	
Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please tick appropriate box below.	
Yes	**No**
High risk: Complete a full EIA starting click here to proceed to Part B	Low risk: Go to Section 4 √.

Section 4			
If this proposal is low risk please give evidence or justification for how you reached this decision:			
This policy provides the Trust and members of healthcare staff with standards of clinical practice and guidelines for the development, approval and use of PGDs and does not discriminate any patient group.			
Signed by reviewer/assessor	Joanne Charles	Date	October 2024
Sign off that this proposal is low risk and does not require a full Equality Analysis			
Head of Service Signed	Anthony Oxley	Date	October 2024

Data Privacy Impact Assessment Screening

Data Privacy impact assessment (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet Individual's expectations of privacy. The following screening questions will help the Trust determine if there are any privacy issues associated with the implementation of the Policy. Answering 'yes' to any of these questions is an indication that a DPIA may be a useful exercise. An explanation for the answers will assist with the determination as to whether a full DPIA is required which will require senior management support, at this stage the Head of Data Privacy must be involved.		
Name of Document:	Patient Group Directions Policy for their Development, Approval and Use	
Completed by:	Joanne Charles	
Job title	Lead Pharmacist, Community Health Services	**Date** 31st October 2024
Screening Questions	**Yes / No**	**Explanatory Note**
1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.	No	
2. Will the process described in the document compel individuals to provide information about them? This is information in excess of what is required to carry out the process described within the document.	No	
3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document?	No	
4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?	No	
5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.	No	
6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them?	No	

7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.	No	
8. Will the process require you to contact individuals in ways which they may find intrusive?	No	
If the answer to any of these questions is 'Yes' please contact the Data Privacy Team via Lpt-dataprivacy@leicspart.secure.nhs.uk In this case, ratification of a procedural document will not take place until review by the Head of Data Privacy.		
Data Privacy approval name:	**Joanne Charlee**	
Date of approval	**October 2024**	

Acknowledgement: This is based on the work of Princess Alexandra Hospital NHS Trust