

# Patient Group Directions Policy for their Development, Approval and Use

This policy describes the legal basis for the use of Patient Group Directions (PGDs) and provides a framework for the development, approval and use of PGDs in the supply and/or administration of medicines by Authorised Healthcare Professionals.

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## Version Control and Summary of Changes

Version number	Date	Description of change and amendments
1.0	March 2012	New Policy
2.0	April 2014	<b>Definitions that apply to this policy</b> – 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 Patient Group Directions
	April 2014	13.0 References updated
	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 may 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 authorising bodies.
	June 2016	13.0 References Updated.
	June 2016	Appendix 1: version 9.2 (December 2015) to replace version 8.2 (August 2013)
	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	September 2017	New Appendix 2 (to meet the requirement of NICE Medicines Practice Guideline (MPG2) Patient Group Directions : Proposal for the Development of a new PGD/Changes to an Existing PGD
	September 2017	General updating to include reference to the above & adjust numbering of appendices
4.0	July 2018	Policy reviewed against requirements NICE Medicines Practice Guideline (MPG2) Patient Group Directions with minor updating to sections 4.3, 5.0, 7.0. Change of maximum expiry of PGD from two to three years
		New section 4.3.4 Medicines with “Risk Minimisation Measures” (RMM)
		New Appendix 10 – Privacy Impact Assessment Screening
5.0	July 2021	General updating of references and minor editing
		<b>Section 4.3 PGDs and Unlicensed medicines</b> – 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),
		<b>Section 4.3.1 Controlled Drugs</b> – clarification that the following registered professions (dieticians, speech & language therapists, dental hygienists, dental therapists) cannot supply or administer any controlled drug under a PGD:
		<b>Section 7.3 New Section</b> - Extension of PGD expiry dates

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## 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 advances 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.

## Due Regard

An analysis on the impact on equality' (Due Regard) has been included in the development of the policy, please refer to **Appendix 10**.

This policy ensures Patient Group Directions (PGDs) are only used for patient benefit to improve access to medicines, that they are legally valid and that they are written by practitioners with appropriate support/evidence, based on an appropriate literature search. Clear guidance will ensure there is clarity about processes for the development and review of PGDs.

All PGDs will include a description of the circumstances in which medical advice should be sought and arrangements for managing patients who may be excluded from treatment under the PGD, where patient safety concerns have been identified or where the patient is unable to give consent.

All PGDs contain a description of the information to be provided to the patient or carer about the treatment administered or supplied under a PGD. This will include the manufacturer's Patient Information Leaflet where a supply is made.

Registered healthcare professionals working to PGDs must undertake appropriate training for working under PGDs and appropriate training to carry out the clinical assessment of patients leading to a diagnosis that requires treatment according to the PGD under which they are working.

## Definitions and Abbreviations that apply to this Policy

<b>Patient Group Direction (PGD)</b>	A PGD is a specific written instruction for the supply and/or administration of named medicines in an identified clinical situation. It is drawn up locally by the appropriate healthcare professionals, and approved by the employer, advised by the relevant professional advisory committees. It applies to groups of patients or service users who may not be individually identified before presentation for treatment
<b>Administer</b>	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)
<b>Supply</b>	To provide a medicine to a patient/carer for administration* * There is no legal distinction between 'dispense' and 'supply' although there are considerable differences in practice. The act of dispensing includes supply and also encompasses a number of other cognitive functions (e.g. checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly of the product). In common usage, 'dispense' is usually reserved to the activity of pharmacists and 'supply' can be used for nurses, pharmacists and other healthcare professionals.
<b>Prescription Only Medicines (POM)</b>	A medicinal product which may normally only be sold or supplied against a signed prescription of an appropriate practitioner i.e. doctor, dentist, or qualified and registered nurse, pharmacist, optometrist or allied health professional prescriber 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.
<b>Authorised Healthcare Professional</b>	A healthcare professional described within the legislation (HSC 2000/026) who has been given authorisation to work under a PGD
<b>Marketing Authorisation</b>	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).
<b>Licensed indication</b>	A medicine that has a UK marketing authorisation.
<b>Summary of Product Characteristics (SmPC)</b>	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.
<b>Black triangle medicine (▼)</b>	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.

## 1.0 Purpose

The Patient Group Direction Policy:

- Ensures that Patient Group Directions (PGDs) are only developed and used in the organisation where they have been identified as the most appropriate mechanism for patient's 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.

## 2.0 Summary

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.

## 3.0 Introduction

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<sup>1</sup> provided additional guidance.

Medicines Practice Guidelines issued by NICE during 2013<sup>2</sup> 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 and administration of medicines under PGDs should be reserved for situations where this method offers advantages for patients without compromising safety.

This policy is to support the introduction and use of Patient Group Directions within the Leicestershire Partnership Trust (LPT). It should be read in conjunction with other relevant guidance and policies on prescribing and medicines administration, including the Leicestershire Medicines Code.

This 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.

## 4.0 Statutory Requirements

The current legislation governing PGDs is included in The Human Medicines Regulations 2012<sup>3</sup>, which came into force in August 2012.

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.

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.

### 4.1 Which Healthcare Professionals can use a PGD<sup>(4)</sup>?

- Registered Dental therapists and Hygienists
- Registered Dieticians
- Registered Midwives
- Registered Nurses
- Registered Occupational Therapists
- Registered Optometrists
- Registered Orthoptists
- Registered Paramedics
- Registered Pharmacists
- 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 (or equivalent) members of their professional body. No other groups of health care workers such as dentists, nursing associates or pharmacy technicians 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.

## 4.2 What information must be included in a PGD?

The following information must be included in a PGD <sup>(3)</sup>

- 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.**
- 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.

### 4.3 Clinical situations in which PGDs should be considered carefully?

- under the Misuse of Drugs Regulations 2001, only certain Controlled Drugs can be supplied or administered under a PGD (**see section 4.3.1**)
- the medicine is an antimicrobial (**see section 4.3.2**)
- the medicine has a Black Triangle symbol (**see section 4.3.3**)
- the medicine has any Risk Minimisation Measures (RMM) associated with the marketing authorisation (**see section 4.3.4**)
- 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 (“product licence”) and the documentation must include the reasons why exceptional use is necessary, with reference to the supporting evidence or guidance.

#### The following **must not** be included in a PGD:

- radiopharmaceuticals.
- abortifacients, such as mifepristone.
- anabolic steroids and any injectable preparation used for treating addiction
- 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 diabetes, or where there is uncertainty about the differential diagnosis
- where dose adjustment is required to a medicines already in the patient’s possession
- medicines which are not approved for use within the Trust

#### Unlicensed Medicines

The PGD legislation **does not** allow for unlicensed medicines without a marketing authorisation to be supplied or administered under a PGD. This includes

- the mixing of 2 licensed medicines to form 1 new (unlicensed) product unless one is a vehicle for administration, such as water for injections.
- specially manufactured medicines
- imported medicines

#### Exception to the rule above.

In November 2020, there was a regulatory update (specifically Regulation 174 of the Human Medicines Regulations 2012) which waives the requirement for a medicine to hold a marketing authorisation when the sale or supply of the medicine is authorised by Ministers, on a temporary basis, in response the suspected or confirmed spread of pathogenic agents (Covid-19), toxins, chemical agents or nuclear radiation. **Amendments to this legislation allow a medicine under regulation 174 to be supplied under a PGD.**

### 4.3.1 Controlled Drugs

Schedule	Controlled drugs that may be considered for inclusion in a PGD	Additional comments
Schedule 2	Morphine Diamorphine  Ketamine (Schedule 2 from 30 <sup>th</sup> November 2015)	Use by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person (except for treating addiction)
Schedule 3	Midazolam	Tramadol, a Schedule 3 CD since June 10 <sup>th</sup> 2014, may not be included in a PGD.
Schedule 4	All drugs <b>except</b> anabolic steroids and injectable drugs used for treating addiction.	
Schedule 5	All drugs including codeine	

**Note:** The following registered professions cannot supply or administer any controlled drug under a PGD: dieticians, speech & language therapists, dental hygienists, dental therapists.

### 4.3.2 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 (2017) <sup>5</sup> 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 and Guidance for Primary Care <sup>6</sup> or other guidelines, approved by the Leicestershire Medicines Strategy Group.
- 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.

### 4.3.3 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.

#### 4.3.4 Use of Medicines with “Risk Minimisation Measures” (RMM)

Risk Minimisation Measures (RMM) is a regulatory requirement for some medicines, and is a critical part of the product licence (marketing authorisation) to help maintain a favourable benefit-risk profile. As well as information on contraindications, warnings/precautions and possible side effects routinely described in the Summary of Product Characteristics (SmPC) , some medicines have an extra requirements for additional 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. In line with this, 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**. As well as routine reference to the important particulars of the SmPC and PIL, the relevant sections of the PGD template should make specific reference to the key points of the RMM where applicable.

Further details of medications with associated RMM can be found at <https://www.medicines.org.uk/emc/rmm-directory>

#### 5.0 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 Patient Group Direction (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 <sup>2</sup>). 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 <sup>2</sup>, 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, medicines procurement and are available for service delivery
- decisions are aligned with any 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 5.4**) and that the most up to date version of the PGD is published on the staff intranet.

## **5.4 The PGD signatories**

All authors and signatories must meet the nationally stated competencies for authorising PGDs, which have been published by NICE <sup>7</sup> in conjunction with the Medicines Practice Guidelines on Patient Group Directions <sup>2</sup>

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.

## 5.5 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.

## 5.7 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. This evidence should be held in the practitioner’s portfolio or Continuing Professional Development record, and documented through their appraisal process. 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, as described in the relevant PGD template.

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. 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.

## **6.0 Identifying the need and obtaining agreement to develop a Patient Group Direction**

The preferred and main 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.

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). 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 guide is available to support staff in determining if a PGD is required “To PGD or not to PGD” (Appendix 1) <sup>8</sup>**

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
- 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 2 – 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**?

## **7.0 Patient Group Direction Development and Approval**

### **7.1 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). The process for drafting and developing PGDs within LPT is outlined below. See also **Appendix 3** for a summary of the process. Decisions to accept or reject a proposal, including the rationale for the decision, will be recorded in the minutes of the MRRG.

All PGDs should be developed following the agreed template (**see Appendix 4**) 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 have assurance 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 of the PGD.

## 7.2 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 2 – 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 7.1.

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

## 7.3 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 usual signatories (Senior Doctor, Senior Pharmacist and Nurse Lead) must sign the updated version with extended expiry.

## 7.4 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 only
- 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

## **8.0 Patient Group Direction Management and Implementation**

This policy will be implemented and disseminated throughout the organisation, in accordance with the post ratification process, following approval by the Trust Patient Safety Group 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. It should be noted that 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/database of names of all the Authorised Healthcare Practitioners signed up to each 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 or database.

## **9.0 Education and Training (see also Appendix 6)**

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, in line with the NICE competency framework for health professionals using PGDs, 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:

- Role play between healthcare professional and assessor;
- Written test.

The competency document in **Appendix 5** 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. Accurate records must be made of PGD consultation and approval as stated in this policy.

The MRRG maintain a log of all PGDs authorised for use within the Trust. This log is used to track the status of all PGDs, including review and expiry dates. Approved versions of the 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 <sup>11</sup>.

Care provided under a PGD must be reviewed. <sup>2</sup> Practitioners must be able to access records of patients who have received medication under a PGD for audit purposes so that the appropriateness of the supply or administration (or of not supplying or administering a medicine) can be reviewed. PGD documentation must be retained in accordance with the Record Keeping and Care Planning Policy.

It is the responsibility of all service leads to implement appropriate actions through cascade mechanisms or team meetings to facilitate reflection on current practice and to monitor progress against actions for all new or revised PGDs. Ongoing review arrangements should include an assessment of whether the PGD remains the most effective way of meeting both patient and service needs.

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.

## 11.0 Links to Standards/Performance indicators

Target/Standards	Key Performance indicator
This policy supports the CQC Fundamental Standards of Quality and Safety	Regulation 9 - Person-centred care. Regulation 10: Dignity and respect Regulation 11 – Need for consent. Regulation 12: Safe care and treatment
The policy has been reviewed in line with the Medicines Practice Guidelines (MPG2), issued by NICE (published August 2013, last updated March 2017 )	LPT Policy (v. 3.1 2017) Dissemination, implementation & monitoring of National Institute of Health and Care Excellence (NICE) Guidance and other Nationally Agreed Best Practice

## 12.0 Review

The Medication Risk Reduction Group will review the policy every 3 years or sooner where a change to legislation, national policy or guidance occurs.

## 13.0 Guidance and References

1. Department of Health (2000) : HSC 2000/026 – Patient Group Directions (England only) [http://webarchive.nationalarchives.gov.uk/20120503185443/http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4012260.pdf](http://webarchive.nationalarchives.gov.uk/20120503185443/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf)
2. National Institute for Health and Care Excellence. Medicines Practice Guideline (MPG2), Patient Group Directions. First published August 2013, last updated March 2017 <https://www.nice.org.uk/guidance/mpg2>
3. Her Majesty's Government (2012), The Human Medicines Regulations 2012 (SI 2012:1916) as amended.
4. Medicines and Healthcare Products Regulatory Agency (MHRA) at GOV.UK Patient group directions: who can use them (updated December 2017) <https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them>
5. Leicestershire Partnership Trust (v. 2.0 (2017)), Antimicrobial Stewardship Policy <https://www.leicspart.nhs.uk/wp-content/uploads/2021/01/Antimicrobial-Stewardship-Policy-exp-Jun-21.pdf>
6. Leicester, Leicestershire and Rutland Antimicrobial Policy and Guidance for Primary Care (last reviewed May 2021) <https://267lv2ve190med3l1mgc3ys8-wpengine.netdna-ssl.com/wp-content/uploads/2015/05/LLR-Antimicrobial-Policy-and-Guidance-for-Primary-care-.pdf>
7. 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) <https://www.nice.org.uk/guidance/mpg2/resources>
8. To PGD or not to PGD? That is the question. A Guide to choosing the best option for individual situations (Version 10, January 2018 , links updated March 2021. available at <https://www.sps.nhs.uk/wp-content/uploads/2020/12/To-PGD-v10-March-21.pdf>
9. National Institute for Health and Care Excellence. Competency framework for health professionals using Patient Group Directions. First published January 2014, last updated March 2017 <https://www.nice.org.uk/guidance/mpg2/resources>
10. Leicestershire Partnership Trust (v.4.0(2018) Record Keeping and Care Planning Policy <https://www.leicspart.nhs.uk/wp-content/uploads/2021/04/Record-Keeping-and-Care-Planning-Policy-exp-Dec-21.pdf>

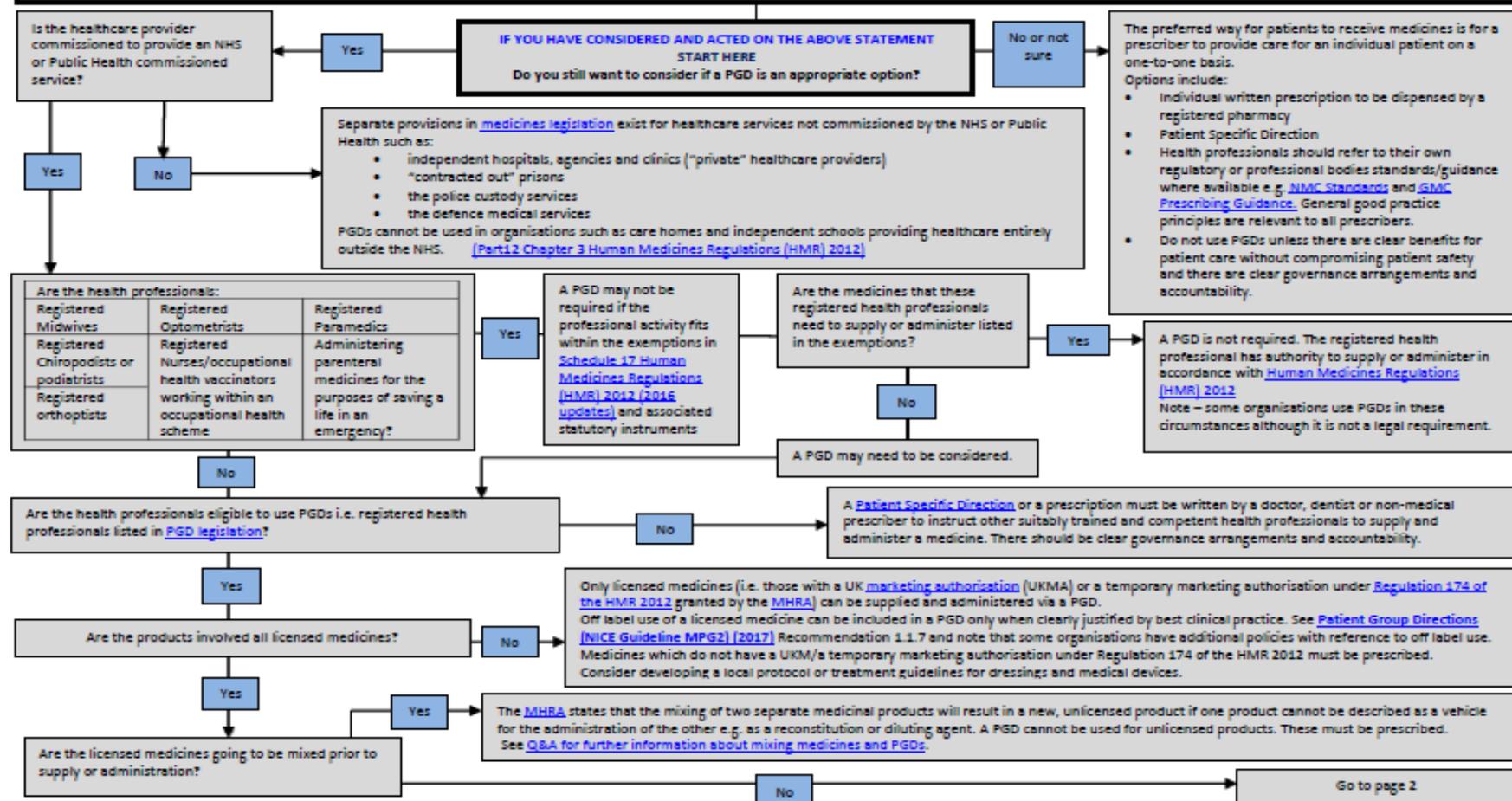
## Appendix 1

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

This diagram is designed to take you through a process to aid decision making and help you consider whether a Patient Group Direction (PGD) is appropriate for an area of practice that involves the supply or administration of medicines. The diagram also has links which signpost to legislation, national guidelines [Patient Group Directions \[NICE Guideline MPG2\] \(2017\)](#) and [Specialist Pharmacy Website \(SPS\) Patient Group Directions \(PGD\) resources](#).

#### BEFORE YOU START

We recommend that you have a multidisciplinary discussion to carefully consider if there is, or could be, an opportunity in the care pathway to use a prescription or a written [Patient Specific Direction](#) by a doctor or non-medical prescriber. [Patient Group Directions \[NICE Guideline MPG2\] \(2017\)](#) states that you should consider investing in the training of additional non-medical prescribers to enable redesign of services if necessary.



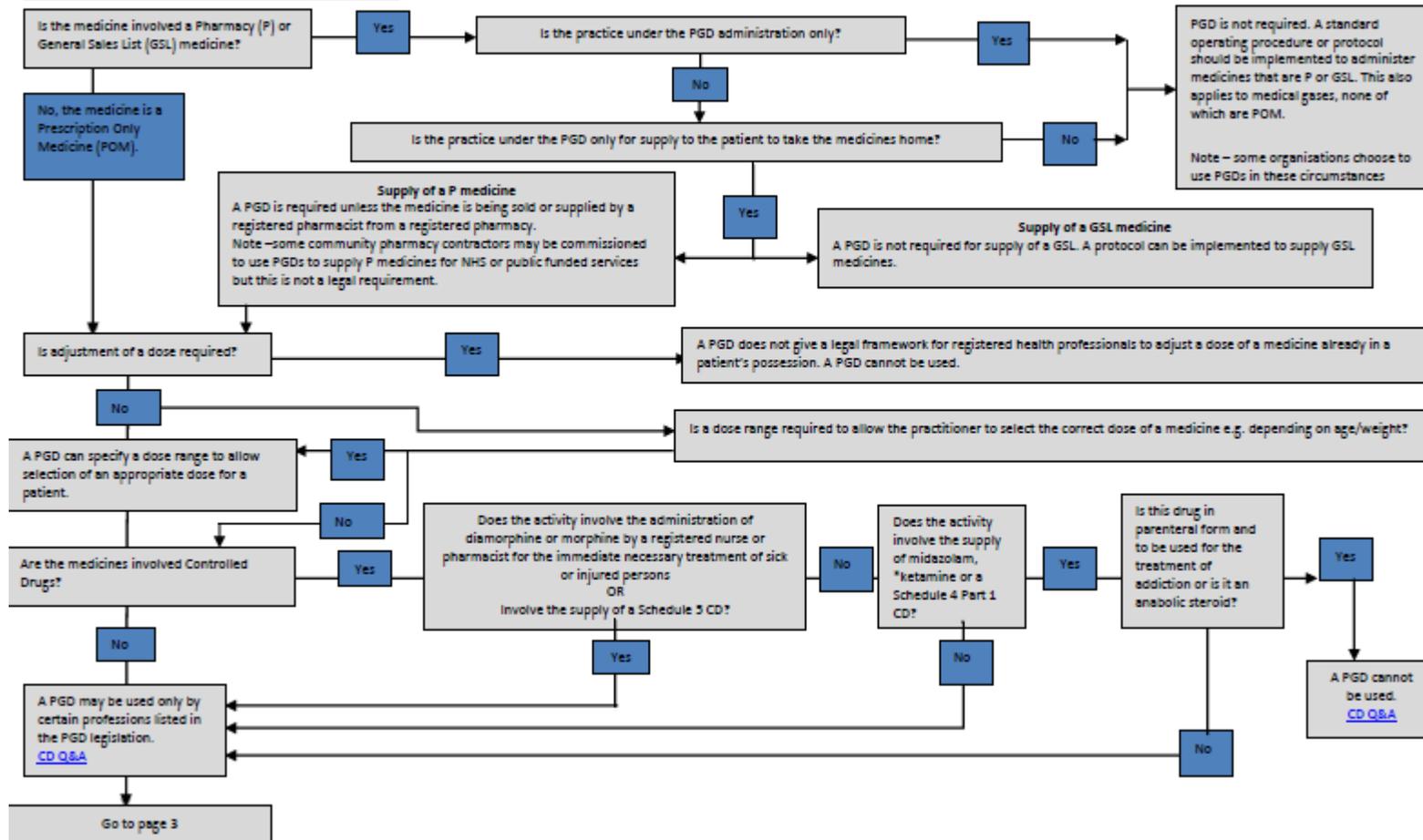
To PGD or not to PGD Version 10. Update of links. Published by SPS PGDs (England) January 2018. **THIS VERSION IS FOR ENGLAND ONLY.** Review due end 2021 (or earlier subject to legislation or other guidelines changes). If you are referring to a hard copy of this document – please check the SPS website (England) [www.sps.nhs.uk](http://www.sps.nhs.uk) to make sure that you are using the most recent version.

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

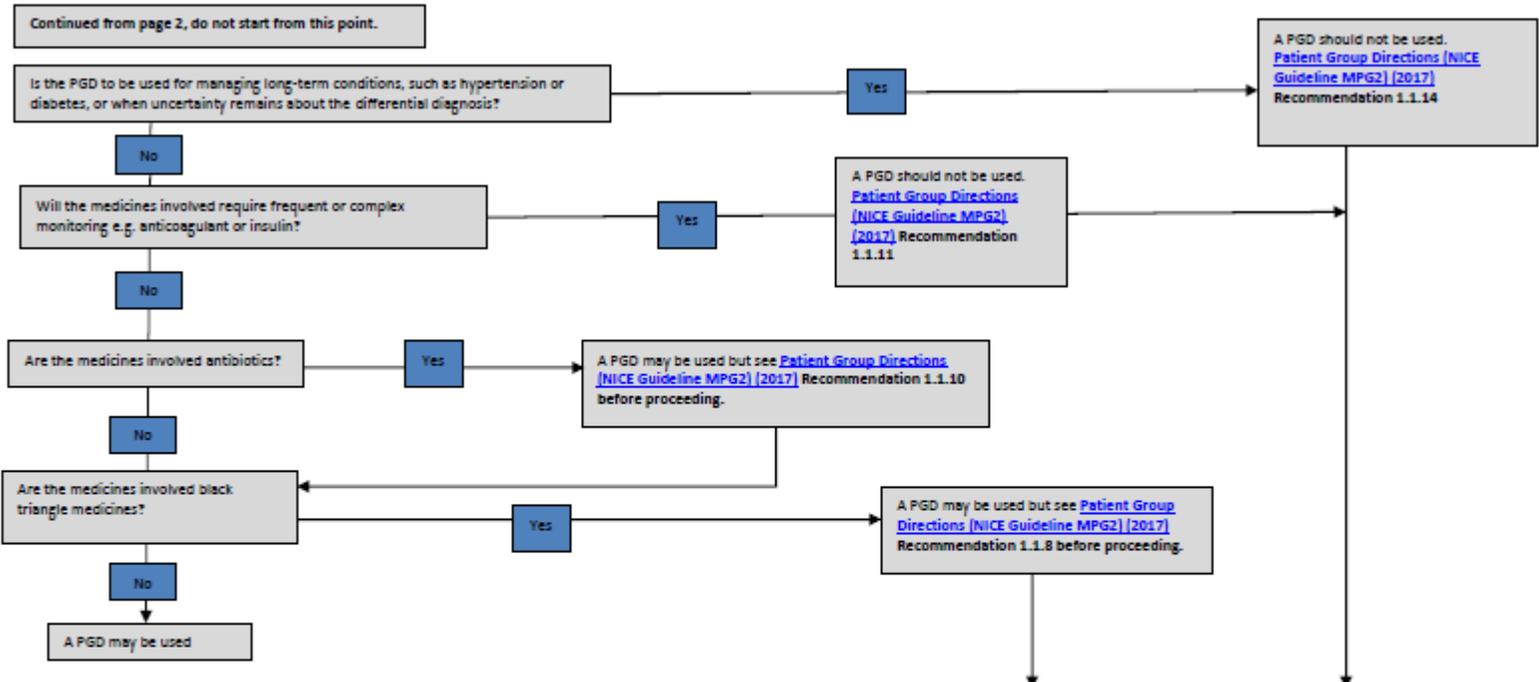


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This chart may not cover all situations proposed for using PGDs. The proposed activity should meet the principles stated in [Patient Group Directions \(NICE Guideline MPG2\) \(2017\)](#) *Supply or administration of medicines under PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.*

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

- [PGD Q&A – abortifacients](#)
- [PGD Q&A - labelling of POMs supplied under PGD](#)
- [PGD Q&A - delegation](#)
- [PGD Q&A – trainee supervision](#)
- [Quality PGDs -7 Steps to success](#) and other resources such as [PGD Q&As on the SPS website](#)
- [Patient Group Directions \(NICE Guideline MPG2\) \(2013\) Pathway](#) and [Tools and Resources](#)
- [PSR multi-disciplinary e learning package](#)
- [Your local Medicines and PGD Policies](#)

To PGD or not to PGD Version 10. Update of links. Published by SPS PGDs (England) January 2018. **THIS VERSION IS FOR ENGLAND ONLY.** Review due end 2021 (or earlier subject to legislation or other guidelines changes). If you are referring to a hard copy of this document – please check the SPS website (England) [www.sps.nhs.uk](http://www.sps.nhs.uk) to make sure that you are using the most recent version.

## Appendix 2

### 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 applied the flowchart 'to PGD or not to PGD', (Appendix 1) and available at: [www.pgd.nhs.uk/](http://www.pgd.nhs.uk/), to this clinical situation 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:**.....

## Appendix 2

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

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

## Appendix 2

**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

.....

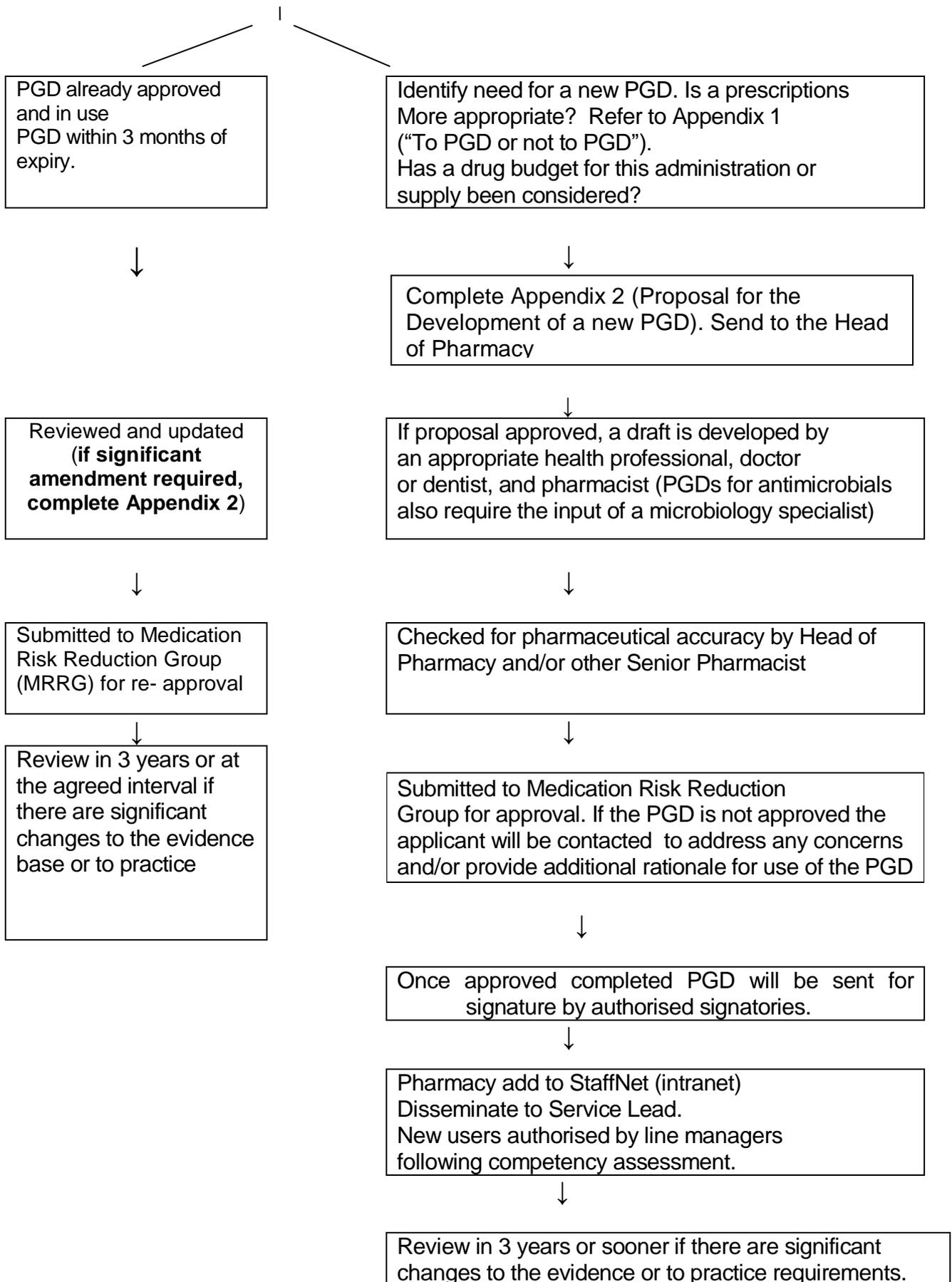
Date

**MRRG COMMENTS**

**Completed form to be returned to the proposer**

## Appendix 3

### Process for Development, Approval and Dissemination of PGDs



## PATIENT GROUP DIRECTION (PGD) FOR

<b>Drug name</b>	<b>CLASS e.g. POM</b>
------------------	-----------------------

**Clinical Condition**

<b>Indication</b>	Need to be specific on the clinical condition to be treated. Is it a licensed indication - check SmPC, BNF.
<b>Inclusion criteria</b>	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.
<b>Exclusion criteria</b>	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). <b>Lack of consent will always be an exclusion</b> Explain reason for exclusion if necessary e.g. <ul style="list-style-type: none"> <li>• Patients on methotrexate – reduced excretion, increasing risk of toxicity</li> <li>• Provide cut off points for exclusion e.g. not just “children” but for example “children under two years old”</li> <li>• 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.</li> </ul>
<b>Cautions/Need for further advice</b>	<ul style="list-style-type: none"> <li>• Check SmPC / published guidelines such as SIGN, NICE, Local on LMSG</li> <li>• Pregnancy and breast feeding – explain reason for inclusion, exclusion or caution wherever possible.</li> <li>• Interactions – list ones that are clinically significant and relevant to this PGD and provide advice if possible e.g.: <ul style="list-style-type: none"> <li>○ 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</li> </ul> </li> </ul>
<b>Action if patient declines or is excluded</b>	Enter details of action to be taken according to local policy

## PATIENT GROUP DIRECTION (PGD) FOR

<b>Drug name</b>	<b>CLASS e.g. POM</b>
------------------	-----------------------

**Drug Details**

<b>Name, form &amp; strength of medicine</b>	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
<b>Route/Method</b>	References: BNF/SmPC /Medicines for Children To avoid errors, state in full and do not use abbreviations e.g. oral not p.o.
<b>Dosage</b>	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.
<b>Frequency</b>	References: BNF/SmPC/ local and guidelines/ Medicines for Children
<b>Duration of treatment</b>	Decide with service provider and medicine supplier.
<b>Maximum or minimum treatment period</b>	To be decided locally.
<b>Quantity to supply/administer</b>	Depends on above i.e. dosage, frequency and duration.
<b>Side effects</b>	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.
<b>Advice to patient/carer</b>	<ul style="list-style-type: none"> <li>• Manufacturer's Patient Information Leaflet</li> <li>• Any further instructions to aid compliance</li> <li>• Storage or expiry details</li> <li>• Practical advice on self-care if appropriate</li> <li>• Advice on recognising side effects and what to do</li> <li>• Advice on where to seek help if treatment fails or condition worsens</li> <li>• Consider whether other health promotion material is appropriate e.g. Smoking Cessation clinics</li> </ul>

Appendix 4

PATIENT GROUP DIRECTION (PGD) FOR

<b>Drug name</b>	<b>CLASS e.g. POM</b>
------------------	-----------------------

<b>Follow up</b>	<i>Enter details of local policy.</i>
------------------	---------------------------------------

**Referral Arrangements and Audit Trail**

<b>Referral arrangements</b>	<i>As per local arrangements/national guidelines.</i>
<b>Records/audit trail</b>	<p>The following points have been used in the development of model templates for Emergency/First Contact Services:</p> <ul style="list-style-type: none"> <li>• Patient's name, address, date of birth and consent given</li> <li>• Contact details of GP (if registered)</li> <li>• Diagnosis</li> <li>• Dose and form administered</li> <li>• Batch and expiry details</li> <li>• Advice given to patient (including side effects)</li> <li>• Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment</li> <li>• Details of any adverse drug reaction and actions taken including documentation in the patient's medical record</li> <li>• Referral arrangements (including self-care)</li> <li>• 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.</li> </ul>

**Staff Characteristics**

<b>Qualifications</b>	<i>Registered professional [appropriate qualification to be listed] with a current [professional] registration</i>
<b>Specialist competencies or qualifications</b>	<ul style="list-style-type: none"> <li>• Refer to guidelines relating to this drug e.g. nurses must be trained in anaphylaxis if administering vaccines.</li> </ul>
<b>Continuing training &amp; education</b>	<i>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.</i>

Appendix 4

PATIENT GROUP DIRECTION (PGD) FOR

<b>Drug name</b>	<b>CLASS e.g. POM</b>
------------------	-----------------------

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**

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

**Patient Group Direction Peer Reviewed by**

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

Next review date: dd/mm/year  
 Expiry date: dd/mm/year

Ref: drug\_DRAFT version/date

**PATIENT GROUP DIRECTION (PGD) FOR**

<b>Drug name</b>	<b>CLASS e.g. POM</b>
------------------	-----------------------

**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 5

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

<b>Name of Healthcare Professional (HCP)</b>		<b>Line Manager</b>	
<b>Job Title</b>		<b>Date</b>	

<b>Knowledge/competency being assessed</b>	<b>Question/Statement to assess knowledge/competency</b>	<b>Knowledge/competency shown? (or HCP to answer “True” or “False” if written test)</b>
Understanding of general principals of PGD use and legalities	<b>Examples of suitable questions:</b>	
	• 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	
Relevant training	<b>Examples of suitable questions:</b>	
	• 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	<b>Insert questions to test HCPs understanding of:</b>	
	• Disease/condition	
	• Disease progression	
	• Differential diagnosis	
	• Danger/warning signs	

## Appendix 5

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

Final Mark: \_\_\_\_

## Appendix 5

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..)

<b>Name of Assessor</b>	
<b>Job Title</b>	
<b>Date</b>	

## Training Requirements

Training Required	YES	NO
<b>Training topic:</b>	Patient Group Directions	
<b>Type of training:</b> (see study leave policy)	<input checked="" type="checkbox"/> Mandatory (Trust Medicines Management Training) <input checked="" type="checkbox"/> Role specific (Additional specific competencies or qualifications according to PGD) <input type="checkbox"/> Personal development	
<b>Division(s) to which the training is applicable:</b>	<input checked="" type="checkbox"/> Adult Mental Health & Learning Disability Services <input checked="" type="checkbox"/> Community Health Services <input type="checkbox"/> Enabling Services <input checked="" type="checkbox"/> Families Young People Children <input type="checkbox"/> Hosted Services	
<b>Staff groups who require the training:</b>	<i>Please specify...</i> Individual healthcare professionals intending to work under a PGD and who are legally authorised in accordance with the Human Medicines Regulations 2012.	
<b>Regularity of Update requirement:</b>	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.	
<b>Who is responsible for delivery of this training?</b>	uLearn module (for Trust Medicines Management Training and additional qualifications e.g., anaphylaxis training). Competency Assessment via Supervised Practice (Appendix 5).	
<b>Have resources been identified?</b>	uLearn module	
<b>Has a training plan been agreed?</b>	uLearn module and individual practitioners should ensure that any training or updates required are included in their annual development review.	
<b>Where will completion of this training be recorded?</b>	<input checked="" type="checkbox"/> uLearn <input checked="" type="checkbox"/> Other (please specify)	
<b>How is this training going to be monitored?</b>	Compliance of medicines management training will be monitored by OLM with quarterly flash reports	

## Appendix 7

Duties outlined in this Policy will be evidenced through monitoring of the minimum requirements.

Where monitoring identifies any shortfall in compliance the group responsible for the Policy (as identified on the policy cover) shall be responsible for developing and monitoring any action plans to ensure full compliance.

Ref	Minimum Requirements	Evidence for Self-assessment	Process for Monitoring	Responsible Individual / Group	Frequency of monitoring
	PGDs in use within the Trust are compliant with this Policy and within date.	Section 7.0	The PGD Review Group will organise the review of PGDs due to expire and monitor implementation of the PGD Policy	Medication Risk Reduction Group (MRRG)	As required.
	Registered nurses or other appropriate healthcare professionals must have completed the approved medicines management training and any additional specialist competencies or qualifications, specified in the PGD which they are working under.	Section 9.0	Compliance of medicines management training will be monitored via monthly flash reports issued by Workforce.	Service Lead	As required.
	Untoward incidents reported concerning the use of PGDs by appropriate healthcare professionals.	Section 5.0	Incident forms submitted and investigations completed.	Service Lead/MRRG	As required.
	Elements of this policy will be audited as agreed within the Annual Quality Schedule	Section 10.0	Audit report and agreed actions	Medication Risk Reduction Group (MRRG)	As agreed within the Quality Schedule

## 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

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

## Appendix 9

### CONTRIBUTION LIST

Key individuals involved in developing the document

Name	Designation
Joanne Charles	Lead Pharmacist – Community Health Services

### Circulated to the following individuals and groups for consultation

Name	Designation
Anthony Oxley	Head of Pharmacy
Tejas Khatau	Lead Pharmacist - Families, Young People and Children's Services
Medication Risk Reduction Group	Circulated to all members of the group at the meeting on July 15 <sup>th</sup> 2021
Medicines Management Committee	Circulated to all members of the group at the meeting on August 18 <sup>th</sup> 2021

## Due Regard Screening Template

Section 1			
Name of activity/proposal		Policy for the Development, Approval and Use of Patient Group Directions	
Date Screening commenced		June 2021	
Directorate / Service carrying out the assessment		Joanne Charles on behalf of the Medication Risk Reduction Group	
Name and role of person undertaking this Due Regard (Equality Analysis)		Joanne Charles, Lead Pharmacist, Community Health Services	
<b>Give an overview of the aims, objectives and purpose of the proposal:</b>			
<b>AIMS:</b> To provide a framework for the development, approval and use of PGDs in the supply/administration of medicines by Authorised Healthcare Professionals To improve patient access to medicines and/or reduce clinical risk.			
<b>OBJECTIVES:</b> This policy describes the process to be followed within the Trust for the development and implementation of Patient Group Directions (PGD) 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			
<b>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.</b>			
<b>Yes</b>		<b>No</b>	
High risk: Complete a full EIA starting click <a href="#">here</a> to proceed to Part B		Low risk: Go to Section 4.	√
Section 4			
<b>If this proposal is low risk please give evidence or justification for how you reached this decision:</b>			
This policy provides the Trust and members of healthcare staff with fixed standards of clinical practice and guidelines for the development, approval and use of patient group directions and does not discriminate any patient group.			
<b>Signed by reviewer/assessor</b>	Joanne Charles	<b>Date</b>	TBC
<i>Sign off that this proposal is low risk and does not require a full Equality Analysis</i>			
<b>Head of Service Signed</b>		<b>Date</b>	

## Appendix 11

### DATA PRIVACY IMPACT ASSESSMENT SCREENING

<p><b>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.</b></p> <p><b>The following screening questions will help the Trust determine if there are any privacy issues associate with the implementation of this 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.</b></p>			
<b>Name of Document:</b>		<b>Patient Group Directions - Policy for their Development, Approval and Use</b>	
<b>Completed by:</b>		Joanne Charles	
<b>Job title</b>		Lead Pharmacist, Community Health Services	<b>Date</b> 8 <sup>th</sup> July 2021
		<b>Yes / No</b>	<b>Explanatory Note</b>
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 themselves? 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	
<p><b>If the answer to any of these questions is 'Yes' please contact Data Privacy Team via <a href="mailto:Lpt-dataprivacy@leicspart.secure.nhs.uk">Lpt-dataprivacy@leicspart.secure.nhs.uk</a></b>  <b>In this case, ratification of a procedural document will not take place until approved by the Head of Data Privacy.</b></p>			
<b>Data privacy approval name:</b>			
<b>Date of approval</b>			

Acknowledgement: Princess Alexandra Hospital NHS Trust