Lincolnshire Community Health Services NHS Trust

Policy for the Development and Control of Patient Group Directions (PGDs)

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Lincolnshire Community Health Services Trust

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Version Control Sheet

Version	Section/Para/ Appendix	Version/Description of Amendments	Date	Author/Amended by
1			November 2011	Susan Ferguson
2	Throughout	Updated NHSL to GEM CSU and P&MMT to PMOS	November 2013	Susan Ferguson
	3.2 and Appendix 2	Added requirement for 'Proposal for Development of a New PGD' form and appendix of form template		
	3.3	Added 'PGD Approval Group' into process		
	3.5	Defined multi-disciplinary group as 'PGD Working Group'		
	4.2	Updated to reflect approval through Medicines Management Committee		
	5.3	Updated to reflect NICE Guidance on expiry dates		
	5.6	Added publication of final PGD on LCHS intranet		
	7.1.2	Added requirements of review		
	7.1.3	Updated re: authorisation following review		
	8.1	Clarified monitoring and evaluation of use of PGDs.		
	9.3	Added regarding PGD adoption		
	11	References updated		
	Appendix 1	Updated to reflect changes		

		in body of policy		
	Appendix 3	Added appendix: Criteria for Assessment of Proposals for Development of a New PGD		
	Appendix 4	Incorporation of version control sheet to PGD template		
	Appendix 6	Included assessment of frequency of use		
	Appendix 7	NHSLA Monitoring		
	Appendix 8	Equality Analysis		
2.1		Extension agreed to update new guidelines	November 15 MMC	P Mitchell
2.2		Extension agreed to allow document to be ratified at TB	May 2016	Audit Committee
3	Section 3, 4, 5, 6,10 and 11	New Sections	8th April, 2016	Lorna Adlington
	Section 2, 7, 8, 9, 13, 14, 15, 16, 17 and Appendices	Revised and updated processes		
	References	Updated		
3.1	Section 9 Appendix Seven	Changes to authorisation process. Introduce electronic process.	12th September 2016	Lorna Adlington
4		Optimisation Lead changed to MM throughout		
4	Section 11	Addition , clarification on that all medicines should be supplied in pre-packs; the only exception being stat doses	07.03.18	Helen Oliver
4	Section 18	References checked and updated	07.03.18	Helen Oliver
4	Appendix Seven	New audit form	07.03.18	Helen Oliver

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Contents

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Policy Statement

Background	The purpose of this policy is to set out a generic framework for a co-ordinated approach to the development and control of PGDs in use in Lincolnshire Community Health Services (LCHS) Trust. The policy contains a standard template for all Trust PGDs. Using the framework and template should ensure that PGDs comply with the legislation and are reviewed and updated as required.
Statement	This policy incorporates legislative requirements and good practice.
Responsibilities	Implementation and compliance with the policy will be the responsibility of all staff.
Training	Heads of Service are responsible for arranging the provision of appropriate training to ensure relevant skills, knowledge and competencies are maintained.
Dissemination	Website, Service Leads
Resource implication	This policy has been developed in line with guidelines and legislation to enable the appropriate development and use of PGDs in LCHS and to put in place control mechanisms to ensure governance. There are no additional resource requirements.

1 Introduction

1.1 The preferred way for patients to receive medicines is for a trained health care professional to prescribe for individual patients on a one-to-one basis. An alternative to a prescription for an individual patient is for a prescriber to give a documented Patient Specific Direction (PSD), which instructs another health care professional to supply or administer a medicine to a specified patient.

1.2 A Patient Group Direction (PGD) is a written instruction for the safe, supply and/ or administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment. A PGD is not a form of prescribing.

1.3 The following policy sets out the framework for the development, authorisation, tracking, implementation, review and audit of PGDs within LCHS. The procedural steps are also summarised in flowchart format (Appendix 1).

2. Identification of the need to develop a PGD

2.1 Prior to development of a PGD the need for the PGD must be assessed.

2.2 A log of all PGDs approved for use within LCHS is available from the Medicines Management (MM) Team. Before starting to develop a PGD the Medicines Management Team should be consulted to prevent duplication and ensure standardisation. An existing PGD may be able to be used or adapted for use in the newly identified area of need.

2.3 The majority of clinical care should still be provided on an individual, patient-specific basis. The supply or administration of medicines under PGDs should be reserved for situations where it offers an advantage for patient care, without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability. Managers who wish to set up new systems for supply or administration of medicines have a range of methods to choose from and should select the most appropriate route in each case. The Medicines Management team should be contacted to assist with this decision making and assessment of need. Reference should be made to the relevant legislation and the flowchart, '*To PGD or not to PGD? - That is the question,'* to assist in the assessment of need. Careful consideration should be given as to whether a PGD is the most appropriate option for the supply and / or administration of medicine.

2.4 Any service considering the use of a PGD will need to assess 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?
- Are the health professionals identified as potential users of the PGD included in the groups legally entitled to use PGDs (health care assistants are not included in the legislation) 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 before use and is the supply legal (does it comply with labelling legislation for instance if the supply is provided for administration at home)?
- Consideration should be given to the availability of a budget to support the use of a PGD.
- What arrangements will apply for the collection of prescription charges where applicable?

2.5 For all new services involving medicines, a member of the medicines management team are able to support and advise decision making.

3. Medicines and healthcare products excluded from a PGD

3.1 Legislation requires that the following must not be included in a Patient Group Direction:

- unlicensed medicines, including:
  - the mixing of 2 licensed medicines to form 1 new (unlicensed) product, unless 1 is a vehicle for administration, such as water for injection
  - special manufactured medicines
- dressings, appliances and devices
- radiopharmaceuticals
- abortifacients, such as mifepristone

4. Off Licence Use

4.1 Medicines can be used outside the terms of their Summary of Products Characteristics (SPC) known as 'off licence or off label' use (as opposed to unlicenced), provided such use is supported by best clinical practice, and the Patient Group Direction must state when the product is being used outside the terms of the SPC and why this is necessary (DH 2006).

5. Controlled Drugs

5.1 Only certain controlled drugs are legally eligible to be included in a Patient Group Direction in accordance with The Misuse of Drugs Regulations (2001).

6. Permitted Professional Groups who may use PGDs

6.1 Legislation requires that Patient Group Directions must only be used by the following registered health professionals:

- chiropodists and podiatrists
- dental hygienists
- dental therapists
- dieticians
- midwives
- nurses (not including nurse associates at this time)
- occupational therapists
- optometrists
- orthoptists
- orthotists and prosthetists
- paramedics
- pharmacists
- physiotherapists
- radiographers
- speech and language therapists.

6.2 Individual health professionals must be named and authorised to practice under a PGD. The registered healthcare professional cannot delegate the administration/ supply of a medicine via a Patient Group Direction to another member of staff e.g. a nurse cannot delegate the administration of a vaccine to a healthcare assistant when the instruction to supply is via a Patient Group Direction

7. PGD Approval process

7.1 It is the responsibility of the service requiring the PGD to take the PGD through the development, authorisation, implementation, review and audit stages.

7.2 Following the assessment of need for a PGD a 'Proposal for Development of a New PGD' form (Appendix 2) shall be completed and submitted to the Drug and Therapeutics Group for discussion and consideration.

7.3 The Drug and Therapeutics Committee (DTC) has the role of PGD Approval Group and shall consider all proposals for new PGDs against defined criteria (Appendix 3), inform the Proposer of the new PGD of the decision and consider

appeals against decisions.

7.4 Decisions to accept or reject the proposal, including the rationale for the decision, will be recorded in the minutes and communicated to the person who submitted the proposal.

7.5 Should the proposal for a new PGD not be approved clear feedback should be given to the applicant. If the applicant disagrees with the decision then one appeal will be allowed to address the concerns or provide additional rationale for use. A final decision will be made by the Medical Director should there be a split vote.

8. Development of a PGD

8.1 Once approval for the development of a new PGD has been given, the Medicines Management Team will note the title of the PGD and apply a PGD reference number. Details of the clinical lead (for development) will be required.

8.2 The Medicines Management team will provide a copy of the PGD template for completion.

8.3 All new PGDs should follow the format of the LCHS PGD template (Appendix 4). The template ensures that all PGDs are written in accordance with the relevant legislation (HSC 2000/026) and allows for familiarity and ease of reference by practitioners.

8.4 PGDs must be drawn up by a multi-disciplinary PGD Working Group involving a doctor, a pharmacist and a representative of any professional group expected to administer and/or supply medicines under the PGD. The clinical lead for the PGD will arrange for a draft PGD to be prepared in conjunction with the PGD Working Group.

8.5 Arrangements for the security, storage and labelling of medicines for use under a PGD must be considered at the development phase.

8.6 The PGD and Standard Operating Procedures for the area must ensure that it is possible to reconcile receipts for supply of medicines from the medication supplier with the administration and/or supplies made on a patient by patient basis.

8.7 Once the content of the new PGD is agreed and finalised by the members of the multi-disciplinary group the PGD should be forwarded to the DTC for final approval and comment. Safeguarding and Patient Safety Group will deputise as the authorising subcommittee if required.

8.8 Following the 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 PGD should be signed and authorised. A reviewed PGD should only be shared with the DTC if any changes are considered to be of clinical significance.

8.9 Following approval of the new PGD at the DTC, the clinical lead should arrange for a paper copy of the document to be signed and authorised. The clinical lead for the PGD shall ensure all signatures required for authorisation are obtained

and forward the master copy of the PGD to Medicines Management Team at Beech House. The clinical lead must also forward the final electronic version of the PGD to the Medicines Management Team for electronic filing centrally.

9. Authorisation

Paper Authorisation

9.1 All PGDs must be signed by each member of the multi-disciplinary group involved in the development i.e. a doctor, pharmacist and representative of the professional group(s) expected to supply medicines under the PGD to approve the content.

9.2 All new PGDs must be approved by the Drug and Therapeutics Committee, prior to use within the Trust.

9.3 Following approval, as above, all PGDs must be signed by the designated LCHS Clinical Governance Lead authorising the PGD for use within the organisation.

Electronic Authorisation

9.4 The MHRA (September 2016) have now approved the process of electronic signatures in order to authorise PGDs for use. A process for electronic authorisation is permitted providing the following criteria are met:

- An electronic signature must be linked uniquely to an individual and under their sole control.
- Standards laid down for electronic prescribing should be observed, i.e. the signature should be uniquely linked to the signatory, identifiable and under the individuals sole control – the individuals organisational email address.
- The final document must be securely protected (PDF) so that the signature cannot be lifted from the document.

9.5 A signatory can authorise a PGD by signing into their organisational email address and sending an email to the Medicines Management Team to confirm their authorisation.

9.6 A copy of this email authorisation will be kept with the master copy of the PGD for reference.

9.7 The PGD will state "***signatories have approved this PGD using approved electronic authorisation systems"*** alongside the names and job titles of all involved. The date of authorisation will be annotated under this statement.

9.8 See Appendix Seven for process.

10. Expiry Dates

10.1 Expiry dates of a PGD must be no longer than three years after approval date.

10.2 After the expiry date, the PGD is not valid and medicines must not be supplied or administered against the PGD.

10.3 For those PGDs where the evidence base is subject to frequent change, for example influenza vaccine, a shorter review period should be given. Further advice can be sought from the pharmacist supporting review / development.

11. Supply of Medicines

11.1 All medicines supplied via a Patient Group Direction must be labelled.

11.2 The quantity for supply must match the amount stipulated within the PGD, either supply amount or stat dose.

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

11.3 All medicines should be supplied in pre-packs; the only exception being stat doses.

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11.4 Identify whether patients supplied with a medicine(s) under a Patient Group Direction are exempt from NHS prescription charges. The appropriate prescription charge(s) should be collected from patients who are not exempt.

11.5 There should be a system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and outgoing stock on a patient-by-patient basis. Names of the healthcare professionals providing treatment, patient identifiers and medicines provided should all be recorded.

12. Tracking

12.1 The Medicines Management Team maintain a log of all PGDs authorised for use within the Trust. This log is used to track the status of all PGDs.

12.2 Upon signing the PGD authorising it for use within the organisation the Clinical Governance Lead shall forward the signed master copy of the PGD to the Medicines Management team for safe filing.

12.3 The database details the start date and the expiry date of each PGD. Expiry dates should be determined on a case-by-case basis, with patient safety paramount. Ensure that this date does not exceed 3 years from the date the PGD was authorised.

12.4 A review date, 3 months prior to the expiry date of the PGD, will be assigned. The medicines management team will alert the clinical lead of the upcoming review date.

12.5 The signed master copy will be scanned and distributed to the clinical/implementation lead/s electronically in PDF format ready for local implementation.

12.6 The Medicines Management Team shall publish the final signed version of the PGD's on the intranet, Medicines Management Staff Services page at: https://staff.lincolnshirecommunityhealthservices.nhs.uk/patient-safety/medicines-management/pgds.

12.7 Following implementation the implementation lead shall return the second signature page of the photocopy, containing the signatures of all staff working under the PGD, to the Medicines Management team for secure filing along with the master copy. The photocopy and first signature page should be retained for reference in the clinical area it pertains to, or centrally, according to locally agreed procedures.

13. Implementation

13.1 Implementation of the PGD may be through the Clinical Lead, through Service Leads or other individuals responsible for provision of the service. At implementation this individual should complete the Implementation Lead box at the top of section 7, the signature section, sign and date.

13.2 The implementation lead has responsibility for ensuring that only fully competent, qualified and trained professionals operate within the PGD. The NICE (2014 updated 2017) competency framework for health care professionals using PGDs should be used as a starting point for assessing competency.

13.3 The implementation lead will arrange for any necessary training to meet the required competencies before an individual shall be authorised to work under the PGD.

13.4 The implementation lead may delegate the responsibility for ensuring competency and training to team leaders/line managers. The person responsible for ensuring competency of individual healthcare professionals signing the PGD must complete the authorising person box on the signature page and sign and date against each Healthcare Professional.

13.5 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. Each individual healthcare professional working under the PGD should sign the healthcare professional box and date.

13.6 The implementation lead must ensure that each individual professional working under the PGD signs the Healthcare Professional section of the signature pages and receives a personal copy of the PGD.

13.7 The delegated implementation lead must ensure that a full copy of the PGD is available for reference in each of the clinical areas it pertains to.

13.8 The implementation lead has responsibility for maintaining the list of signatures of the individuals who may work within this PGD and for sending this signature list to the Medicines Management Team for filing with the master copy of the PGD. If additional names/signatures are added to the PGD signature page, an updated original of the signature page must be sent to the Medicines Management

Team for filing with the master copy.

14. Review

14.1 The clinical lead has responsibility for reviewing the PGD prior to the expiry date or as changes are required such as changes to product licence or the way the product is used e.g. immunisation schedule changes or as a result of untoward incidents.

14.2 As part of the review, the clinical lead should consider if the PGD remains the most appropriate option to deliver the service. This should be informed by local monitoring and evaluations, frequency of use of the PGD and views of health professionals working under the PGD. Where possible and where clinically appropriate to gain support for the PGD, the views of relevant stakeholders, such as patients or their carers, should be sought.

14.3 Following review PGDs where there has been significant clinical change to the content must be approved through the Drug and Therapeutics Committee. Where only minor changes are made at review the PGD may be authorised directly by the designated LCHS Clinical Governance Lead authorising the PGD for use within the organisation.

15. Audit

15.1 At regular intervals the clinical lead for the PGD shall undertake monitoring and evaluation of PGD use within the service. The clinical lead may delegate this responsibility to the implementation lead if appropriate. Suggested audit criteria are included in Appendix 5.

15.2 Clinical leads should consider auditing the use of a PGD prior to review. Following the audit, the results should be used to amend the PGD in light of current local practice and processes.

16. Adopting PGDs from other organisations

16.1 On occasion, in the interest of effective use of staff time, clinical and service need and 'not reinventing the wheel', PGDs can be adopted from another organisation. In doing so, the clinical lead for the respective area will liaise with the Medicines Management Team. The decision whether to adopt the PGD will be based upon clinical need and this will be audited to ensure its appropriateness and to prevent proliferation of PGDs within the organisation.

16.2 **Note**: 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.

16.3 Individual services should not adopt PGDs locally. All PGD adoption must occur at organisational level and be approved through the Drug and Therapeutics Committee

16.4 A cover sheet should be affixed to a copy of the master PGD from the other organisation and must contain the signature of the Medicines Management Officer

and Medical Director. A sample cover sheet is available for this purpose (Appendix 6).

16.5 Details of the adopted PGD will be added to the organisation database of PGDs to support governance and enable tracking.

16.6 At the point the original PGD requires reviewing; the review will include the transfer of the PGD to the LCHS template.

17. Reporting

17.1 Bi-annually a report will be provided to the DTC demonstrating activity within the reporting period, to include PGDs being developed, reviewed and archived.

18. References

National Institute for Health and Care Excellence (NICE) Good Practice Guidance, Patient Group Directions, 2 August 2013 (Updated March 2017) Available at:. https://www.nice.org.uk/Guidance/MPG2 Accessed 26.02.18

National Institute for Health and Care Excellence (NICE) Competency framework for healthcare professionals using PGDs. Jan 2014 (Updated March 17) Available at: https://www.nice.org.uk/guidance/mpg2/resources Accessed 26.02.18

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NHS Education for Scotland (NES), Management and Monitoring of Patient Group Directions. Available at: http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/prescribing-and-patient-group-direction/patient-group-directions/guidance.aspx
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Royal College of Nursing, Patient Group Directions: Guidance and information for nurses, July 2004. Available at: https://www.rcn.org.uk/professional-development/publications/pub-001370 Accessed 26.02.18

Royal Pharmaceutical Society of Great Britain, Professional Standards Directorate: Patient Group Directions, A Resource Pack for Pharmacists. Available at: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Prescribing%20competency%20framework/prescribing-competency-framework.pdf Accessed 26.02.18

To PGD or not to PGD? That is the question, Version 9.2: December 2015. Available at https://www.sps.nhs.uk/wp-content/uploads/2017/11/To-PGD-v9.4-November-2017-1.pdf Accessed 26.02.18

19. Flowchart for PGDs

Appendix 1

Development of New PGD

- Assessment of need for a PGD carried out within the service in consultation with MM Team.
- Completion and submission of 'Proposal for development of a New PGD' form.
- Drug and Therapeutics Committee consider / approve the development of a new PGD.
- PGD reference number applied.
- PGD drafted and agreed by multidisciplinary PGD Working Group. The PGD should be drafted by the clinical lead with support from an identified pharmacist.

Review of Existing PGD

- MM Team highlight need to review role of PGD, audit use of PGD and request clinical review of PGD 3 months prior to expiry date.
- The Clinical lead has the responsibility for reviewing the PGD prior to the expiry date or when changes are required.
- Consider if the PGD is the most appropriate option to deliver the service.
- Ensure the whole PGD is reviewed to ensure the PGD is still current and applicable.
- Once reviewed by the clinical lead the PGD will require a review by Pharmacist.

Authorisation

- PGD signed by PGD Working Group to include
  - Doctor
  - Pharmacist
  - Representative of Professional Group(s) operating under the PGD

Tracking

- Allocation of reference number
- PGD entered onto database – reference number, Title, Clinical Lead, Start date, expiry date, review date, signatures
- Receipt of master copy signed by CG lead – kept securely on file
- Electronic copy of signed PGD sent to clinical lead for implementation.
- Read only version posted on the website
- Original hard copies of staff signatures

Implementation – responsibilities of implementation lead for PGD

- Arrange appropriate training
- Ensure staff working within PGD have skills, knowledge and competence
- Ensure staff have access to copy of PGD
- Ensure clinical areas have reference to paper and electronic copies of PGDs
- Clinical guideline development as appropriate
- Ensure staff working to PGD have signed of PGDs
- Copy of signature pages to be stored with master copy of PGD
- When new staff join, send additional

20. Proposal for Development of a New Patient Group Direction (PGD)

Title of PGD	
Name of individual proposing PGD	
Other individuals that will be involved in the developing and authorisation of this PGD	
Organisation delivering the service (if this organisation is not the authorising body)	
Setting / service where this PGD will be used	
Condition to be treated, considering patient inclusion and / or exclusion criteria **Note:** • **PGDs should not be used for managing long-term conditions e.g. hypertension or diabetes, or when uncertainty remains about the differential diagnosis**	
Benefits to patient care	
Potential risks to patient safety	
Details of medicine(s) to be supplied and /or administered, including dosage, quantity, formulation and strength, route and frequency of administration, duration of treatment and whether this is included in the local formulary **Notes:** • **PGDs should not be developed for medicines requiring frequent dosage adjustments or complex monitoring (e.g. anticoagulants or insulin);** • **When PGDs are developed for antimicrobials they must be clinically essential, justified by best clinical practice and in line with local formulary recommendations;** • **PGDs must only include medicines with a UK marketing authorisation;** • **Only certain Controlled Drugs are permitted to be included in PGDs.**	

Health professional groups who would work under this PGD, including training and competency needs	
Current and / or future service provisions for supplying and / or administering the medicine(s), including its position within the care pathway	
Evidence to support the proposal	
Resources needed to deliver the service	
Timescale for developing the PGD	

Once completed please submit for approval to Medicines Management Team

helen.oliver@lincs-chs.nhs.uk or lorna.adlington@lincs-chs.nhs.uk

21. Criteria for Assessment of Proposals for Development of a New PGD

The Drug and Therapeutics Committee (DTC) will consider all proposals for development of a new PGD.

Proposals will only be considered when submitted in the required format (a fully completed standard proposal form).

Proposals will be considered against set criteria 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, such as clinical groups, patients and the public, and the provider or commissioning organisation have been considered
- appropriate registered health professionals are available to use the PGD, and training and competency needs are addressed
- people who are developing, authorising, monitoring, reviewing and updating the PGD are identified, and training and competency needs are addressed
- the need for appropriately labelled packs and safe storage can be met
- adequate resources, such as finance, training, medicines procurement and diagnostic equipment are available for service delivery
- adequate resources are available to ensure that processes are followed within any locally agreed timeframe
- decisions are aligned with local clinical commissioning frameworks.

Decisions to accept or reject the proposal, including the rationale for the decision, will be recorded in the minutes and communicated to the person who submitted the proposal.

Appeal of decisions may be made in writing to the Chair of the Drug and Therapeutics Committee.

Appendix 4 – PGD template

PGD Ref No:

Patient Group Direction for the Supply and/or Administration of

FOR USE IN
(INSERT SERVICES)

Date PGD comes into effect:

Date PGD expires:

Version	Section/ Para/	Version/Description of Amendments	Date	Author/Amended by

1. Clinical condition(s) or situation to which the PGD applies

Clinical situation / condition / indication for which the medicine may be used	
Within or outside terms of Summary of Product Characteristics (SPC)? (if outside state reason for inclusion)	
Black triangle product ▼?	
Clinical criteria for inclusion	
Clinical criteria for exclusion	
Cautions / need for further advice	
Drug interactions	Patients taking the following drugs, highlighted in bold, must be referred to a doctor if available or alternatively to a qualified independent prescriber **(Black spot drug interactions)** [List black spot drug interactions (in bold) as per BNF /Stockley] Seek medical advice if the patient is taking: [List (in normal type) significant drug interactions] Other potential drug interactions [e.g. where patient may need to be warned but medical intervention not required]
Action if excluded	Refer patient to the supervising doctor if available, or alternatively to a qualified independent prescriber or receiving facility as appropriate. Document action in patient's record.
Action if patient declines	Refer patient to the supervising doctor if available, or alternatively to a qualified independent prescriber or receiving facility as appropriate. Document action / refusal in patient's record.

2. Title

Clinical situation / condition / indication for which the medicine may be used	
Within or outside terms of Summary of Product Characteristics (SPC)? (if outside state reason for inclusion)	
Black triangle product ▼?	
Clinical criteria for inclusion	
Clinical criteria for exclusion	
Cautions / need for further advice	
Drug interactions	Patients taking the following drugs, highlighted in bold, must be referred to a doctor if available or alternatively to a qualified independent prescriber **(Black spot drug interactions)** [List black spot drug interactions (in bold) as per BNF /Stockley] Seek medical advice if the patient is taking: [List (in normal type) significant drug interactions] Other potential drug interactions [e.g. where patient may need to be warned but medical intervention not required]
Action if excluded	Refer patient to the supervising doctor if available, or alternatively to a qualified independent prescriber or receiving facility as appropriate. Document action in patient's record.
Action if patient declines	Refer patient to the supervising doctor if available, or alternatively to a qualified independent prescriber or receiving facility as appropriate. Document action / refusal in patient's record.

3.Treatment

Healthcare Professional group/s eligible to work under this PGD Details of professional qualification required	e.g. A nurse with a valid NMC registration or paramedics registered with the Health Professionals Council only employed by or on behalf of Lincolnshire Community Health Services, working within the scope of his/her professional practice.
Specialist qualifications / training / experience relevant to the clinical condition being treated	Have undertaken appropriate training to carry out a clinical assessment of the patient leading to a diagnosis that can be treated according to the indications listed in the PGD. Have undertaken appropriate training for this PGD. Health professionals using PGD's have a responsibility to ensure they are up to date with annual basic life support and anaphylaxis training. Is authorised by name to work under the current version of the PGD, having met the competencies according to the guidance in the NPC, Patient Group Directions December 2009: A practical guide and framework of competencies for all professionals using patient group directions.
Specialist qualifications / training / experience and competence relevant to the medicines being used	In accordance with standards for administration of medicines and competencies within the courses specified above. **It is the responsibility of the individual nurse/paramedic to ensure that s/he has appropriate knowledge of the product and its compatibility with other medical conditions and medications. Refer to the summary of product characteristics (SPC) (http://emc.medicines.org.uk/), package insert or current BNF for further details on the product.**
Name, form and strength of medication(s)	
Legal Classification (POM / P / GSL)	
Dosage to be used, including criteria for variation where a range is permitted. Include maximum total/daily dose.	
Route of administration	
Frequency - is administration allowed on more than one occasion? If yes, define the minimum or maximum interval between doses	
Number of doses to be given	
Advice to be given to patient (include patient information sheet if available)	In line with GMC guidance, consider informing the patient or their carer if use is off-label.
Possible side effects, warnings or adverse reactions	
What follow up treatment is required (if any)	Seek further medical advice if there is no improvement or the symptoms worsen

Facilities needed at the site where direction is in use (eg. Resuscitation equipment)	
Details of records to be kept in order to provide a clear audit trail	Patient's name, address, date of birth and consent given Record Allergies Contact details of GP (if registered) Diagnosis Name, strength, form, quantity, dose, batch number and expiry date of the medicine. Advice given to patient (including side effects) Date and time of administration and / or supply Route of administration Signature, or electronic record, of the person administering or supplying 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) Patients GP to be informed. Record whether the medicines was administered / supplied via a PGD

4. Management and Monitoring

How can the medicine be identified?	Labelling of the medication includes: Name of the drug, strength, dosage form, quantity, batch number and expiry date. If supplying to the patient, on the label of the prepack write the • patient's name • date of dispensing • length of the course (if appropriate) • name of the centre from where it was issued.
Instructions on reporting adverse drug reactions	Use the yellow card system to report adverse drug reactions directly to the MHRA. Yellow cards and guidance on their use is available at the back of the BNF or online at www.yellowcard.gov.uk Contact patient's GP with details of the reaction.
Audit	Audit should take place at regular intervals to ensure good practice. Responsibility for audit lies with the Clinical Lead for the professional group working under the PGD. Examples of suggested audit criteria are included in the Trust's Policy for the Development and Control of PGDs (Appendix 3).

5. References

6. Approval and Authorisation

PGD developed by:	
Name: Doctor Name of Employing Organisation:	Signature: Date
Name: Pharmacist Name of Employing Organisation:	Signature: Date
Name: Clinical Lead for Professional Group working under the PGD e.g. Nurse manager Name of Employing Organisation:	Signature: Date
PGD authorised for use within Lincolnshire Community Health Services by:	
Name: Clinical Governance Lead on behalf of Lincolnshire Community Health Services	Signature: Date

I_____ (NAME) _____ (TITLE e.g.: Service Manager)

of_____ (NAME OF SERVICE e.g. Out of Hour's, Sexual Health) at

_____ (location) give authorisation on behalf of the Healthcare Professional(s) named below, to supply and administer in accordance with this Patient Group Direction and current guidelines. I understand that I am responsible for ensuring only fully competent, qualified and trained professionals who hold current registration with their professional body and will be working within their scope of professional practice will work under this PGD. I understand that I may delegate this responsibility to the Authorising Person named below. I understand that I am responsible for ensuring audit takes place at regular intervals.

Signature _____ Date_____

This Patient Group Direction is to be read, agreed and signed by all eligible Healthcare Professionals who will administer/supply under it. <u>PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.</u> 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 Professional As a registered Healthcare Professional eligible to work under this PGD I have read this PGD and agree to follow the directions contained within it and to administer/supply in accordance with this document and within my scope of professional practice.			**Authorising Person** As the authorising person I am responsible for ensuring that only fully competent, qualified and trained professionals operating within the scope of their professional practice will work under this PGD. I understand that I am also responsible for maintaining a list of names of the individuals who may work within this PGD and for keeping this with the master copy of the PGD. Each individual professional must receive and sign for a personal copy of the PGD.	
Name	**Signature**	**Date**	**Authorising person signature**	**Date**

This signature page to be retained with a full copy of the PGD in the workplace for reference. A photocopy of the signature page should be returned to the Medicines Management Team, via Beech House, for filing with the master copy of the PGD.

Appendix Five

Adoption Template

The following PGD for the ..... was

developed by a multi-disciplinary team in .....(name of organisation) .....and ha

Signature: Name:

Date: Medicine

Signature: Manageme

Date: nt Officer

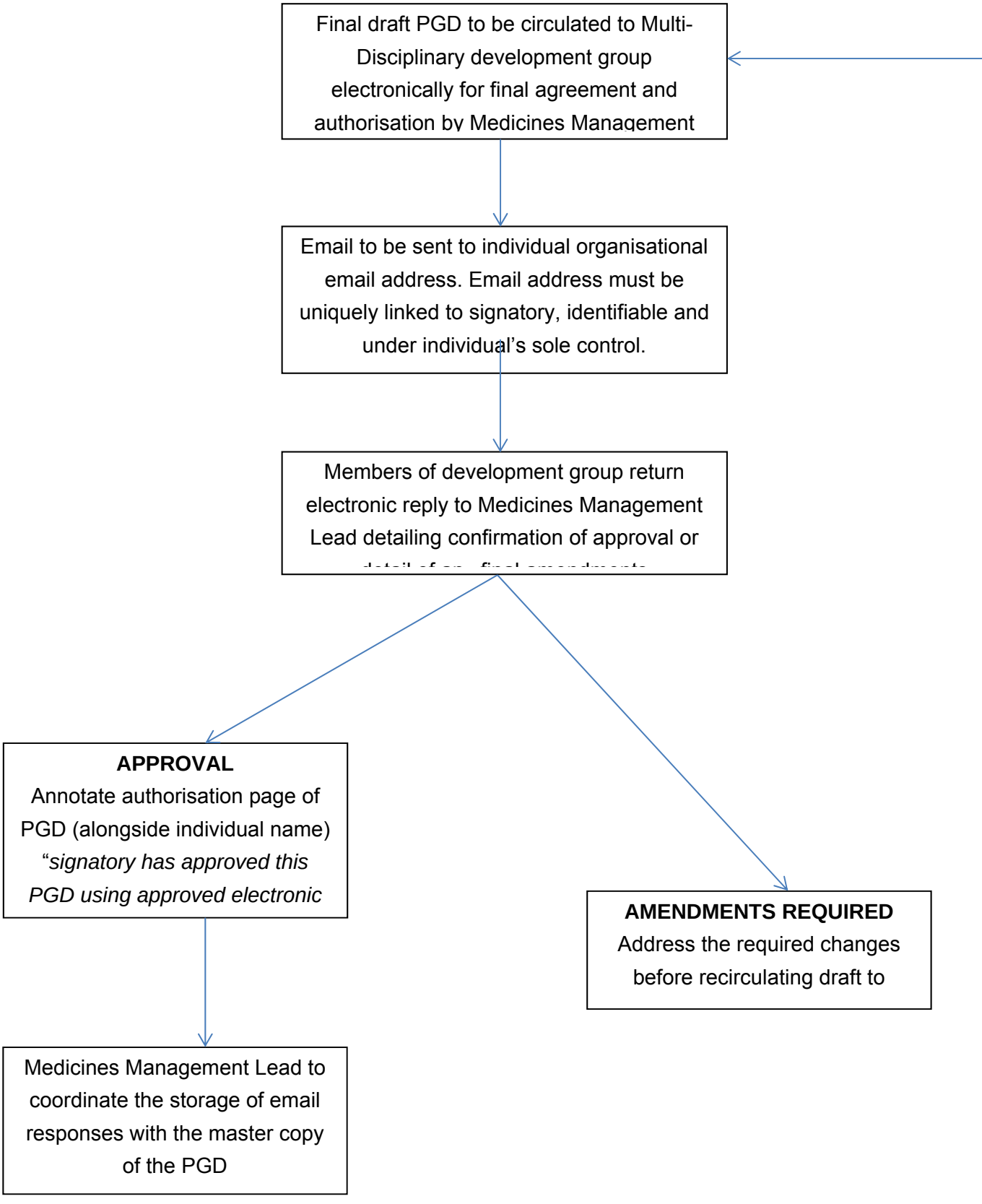
Name:

Clinical Governance Lead on behalf of Lincolnshire Community Health Services Trust Medical Director

Lincolnshire Community Health Services Trust has responsibility for ensuring that only fully competent, qualified and trained professionals operate within this PGD, agrees to maintain a list of names of the individual professionals who may work within this PGD and to keep this list with the master copy of the PGD

Appendix Six

ELECTRONIC APPROVAL PROCESS FOR PATIENT GROUP DIRECTIONS



Appendix Seven

Patient Group Direction (PGD) Audit

This audit relates to PGD Number _____ completed by _____ Team/ Service

Please attach any supporting information, electronically, that may support the PGD review. Do not leave any blanks. When updates are reviewed, suitability to use a PGD in the particular clinical setting/directorate will also be reviewed.

A minimum of ten patient records must be audited six months prior to the PGD expiring.

Records must be selected at random for sampling.

Peer Review from patient records	1	2	3	4	5	6	7	8	9	10
Is the practitioner using this PGD authorised to do so?										
Has administration or supply of the medicine(s) been delegated to another practitioner?										
Does the patient have a known/documented allergy to the medicine(s)?										
Does the patient meet the inclusion criteria?										
Does the patient meet the exclusion criteria/contraindications?										
Was consent obtained and clearly documented? For PGDs referring to Fraser guidelines, was this included in the consent process?										
Are there any drug interactions that were not considered resulting in inappropriate use of the PGD?										
Has the administration been documented clearly on the drug chart/ePMA/patient records? (Dose, route, frequency)										
Is the date and time of the administration and										

supply recorded in the note?										
Are details of the consultation clearly documented in the patient's notes as per requirements outlined in the PGD?										
Is the practitioner using the PGD clearly identifiable from the entry made in the patient's notes?										
Team / Service Lead to complete next section										
Does the PGD lead, hold a list of authorised practitioners permitted to use PGD Number ----------?										
How many practitioners have supplied or administered medication using this PGD since its last review?										
Has the list of practitioners that can use the PGD been reviewed?										
Are signatures up to date?										
Is a copy of the PGD available for reference when the PGD is in use?										
Have all authorised practitioners been competency assessed to use this PGD?										
Are records being completed on the Trust electronic prescribing system?										
Are all medicines being stored in accordance with the PGD?										
Are medicines used for this PGD appropriately labelled as TTO pack?										
Have any issues/concerns been raised regarding any aspect of this PGD?										
Do you still consider this PGD to be clinically required?										

Team /Service Lead Name …….. Date: …….

Signature ……..

Once completed, return via e-mail to helen.oliver@lincs-chs.nhs.uk.

Appendix Eight

Equality Analysis

Introduction

The general equality duty that is set out in the Equality Act 2010 requires public authorities, in the exercise of their functions, to have due regard to the need to:

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

The general equality duty does not specify how public authorities should analyse the effect of their existing and new policies and practices on equality, but doing so is an important part of complying with the general equality duty. It is up to each organisation to choose the most effective approach for them. This standard template is designed to help LCHS staff members to comply with the general duty.

Please complete the template by following the instructions in each box. Should you have any queries or suggestions on this template, please contact Rachel Higgins Equality and Human Rights Lead

Policy for the development and control of Patient Group Directions

A.	Briefly give an outline of the key objectives of the policy; what it's intended outcome is and who the intended beneficiaries are expected to be	The following policy sets out the framework for the development, authorisation, tracking, implementation, review and audit of PGDs within LCHS.		
B	Does the policy have an impact on patients, carers or staff, or the wider community that we have links with? Please give details	This policy applies to all healthcare staff, including bank and agency involved in the administration of medication via a PGD: Nursing staff Emergency Care Practitioners Pharmacy associated staff Allied Health Care Professionals		
C.	Is there is any evidence that the policy\service relates to an area with known inequalities? Please give details	No.		
D.	Will/Does the implementation of the policy\service result in different impacts for protected characteristics?			
		Yes	No	
	Disability		X	
	Sexual Orientation		X	
	Sex		X	
	Gender Reassignment		X	
	Race		X	
	Marriage/Civil Partnership		X	
	Maternity/Pregnancy		X	
	Age		X	
	Religion or Belief		X	
	Carers		X	
	If you have answered 'Yes' to any of the questions then you are required to carry out a full Equality Analysis which should be approved by the Equality and Human Rights Lead - please go to section 2			

The above named policy has been considered and does not require a full equality analysis

Equality Analysis Carried out by:	Helen Oliver
Date:	07.03.18