Livewell Southwest

Development and Ratification of Patient Group Directions Policy

Version No 3:6
Review: July 2017

Notice to staff using a paper copy of this guidance

The policies and procedures page of LSW intranet holds the most recent version of this document and staff must ensure that they are using the most recent guidance.

Author:	**Chief Pharmacist**
Asset Number:	**463**

Reader Information

Title	Development and Ratification of Patient Group Directions Policy v3.6
Asset number	463
Rights of access	Public
Type of paper	Policy
Category	Clinical
Document purpose/summary	To ensure a development and ratification pathway for PGDs that will meet legal and professional requirements An outline of the legal requirements for patient group directions (PGDs) and the agreed ratification pathway for approval of each PGD for use within Plymouth Community Healthcare (LSW). This will ensure that staff using PGDs in the approved manner are indemnified by LSW.
Author	Chief Pharmacist (LSW)
Ratification date and group	Feb 2014, Medicines Governance Group
Publication date	22nd December 2016
Review date and frequency (one, two or three years based on risk assessment)	Must be reviewed at least every two years
Disposal date	The Pharmacy Office will retain a signed copy for the archive in accordance with the Retention and Disposal Schedule, all previous copies will be destroyed.
Job title	Chief Pharmacist (LSW)
Target audience	All staff who are involved in the development, writing, ratification, implementation and use of Patient Group Directions within all clinical service areas of LSW. Note: This policy only applies to qualified registered health professionals, employed by LSW. NHSP staff will need to read each PGD and sign the declarations before they can work to the PGD.
Circulation	Electronic: LSW Intranet and website (if applicable) Written: Upon request to the Policy Ratification Secretary on ☏ 01752 435104
Consultation process	The following were consulted during Jan 2014: Chief Executive Director of Professional Practice and Patient Safety Medical Director Professional Leads Members of Medicines Governance Group Locality Managers and Deputies District Nurse Teams

	Non-Medical Prescribers Nurse Manager, CCASH Chlamydia Screening coordinator Lead Heart Failure Nurse Continence Nurse Adviser Policy Ratification Group Chair and Secretary LSW GP Practice Managers All Ward Managers /Modern Matrons MIU Manager and Clinical Lead Nurse Deputy Director of Governance Communications and Intranet Officer LSW Pharmacists / Pharmacy Technicians Non-Medical Prescribing Lead, NEW Devon CCG
Equality analysis checklist completed	Yes
References/sources of information	NHS Executive (2000) Patient Group Directions HSC 2000/026 2000 Great Britain (1972) Medicines Act 1968 (as amended) The Stationery Office, London Misuse of Drugs Regulations 2001 (Amended 2003) EU Labelling & Leaflet Directive 92/97 Patient Group Directions: A Practical Guide and Framework of Competencies for All Professionals Using Patient Group Directions. Dec 2009. National Prescribing Centre http://www.npc.nhs.uk/non_medical/resources/patient_group_directions.pdf Great Britain (2003) The Prescription Only Medicines (Human Use) Amendment Order 2003 SI No 696 The Stationery Office, London Great Britain (2000) The National Health Service (Charges for Drugs and Appliances) Regulations 2000 (as amended) ISBN 0110989074. The Stationery Office, London NHS Patient Group Directions website: http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/ NICE Good Practice Guidance: Patient Group Directions 2013: http://www.nice.org.uk/mpc/goodpracticeguidance/gpg2.jsp
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Document review history

Version no.	Type of change	Date	Originator of change	Description of change
2	Ratified and published by NHS Plymouth	21.1.10	Policy Ratification Group.	Updated and reformatted
2.1	Draft update	6/1/12	Chief Pharmacist	Updated /reformatted to LSW format
2.2	Updated	3/2/12	Chief Pharmacist	For approval at PMGG. Checklist added for PCT
3	Approved and ratified by PMGG	3/2/12	Chief Pharmacist	Minor changes
3.1	Updated	1/2/13	Chief Pharmacist	Formatted, Signature sheet amended, Appendix C added.
3.2	Updated	April 2013	Chief Pharmacist	Signature sheet amended (Appendix B).
3.3	Updated	Jan 2014	Chief Pharmacist	Updated in line with NICE GPG Aug 2013 and MHRA / DH / NHS England agreement on approval
3.4	Ratified	Feb 2014	Chief Pharmacist	Following approval at MGG
3.5	Extended	June 2016	Information Governance, Records, Policies & Data Protection Lead.	Formatted to LSW and Extended
3.6	Extended	December 2016	Clinical Director of Pharmacy	Extended no changes

Abbreviations	
CCG	Clinical Commissioning Group
GDG	Guidance Development Group (from NICE)
GPG	Good Practice Guidance (from NICE)
MGG	Medicines Governance Group
MHRA	Medicines and Healthcare Regulatory Authority
NICE	National Institute for Health and Care Excellence
LSW	Livewell Southwest
PGD	Patient Group Direction
PRG	Policy Ratification Group
PSD	Patient Specific Direction

Contents

Guidance

1. Introduction

1.1 The preferred way for a patient to receive the medicines they need is for a prescriber to provide care on a one to one basis. Traditionally medicines would be provided by a doctor or dentist but can now be provided by a range of alternatives (see 1.3 below).

1.2 Following the Crown report in 1999 “Review of prescribing, supply and administration of medicines” legal frameworks were developed to allow health professionals to work more flexibly for the benefit of patients.

1.3 The range of options for the supply or administration of medicines now includes:

- Independent prescribing – the prescriber (a doctor, dentist or non-medical independent prescriber) takes responsibility for the clinical assessment of the patient, establishing a diagnosis, the clinical management needed and prescribing.
- Supplementary prescribing – a voluntary partnership between a doctor or dentist and a supplementary prescriber, to prescribe within an agreed patient-specific clinical management plan with the patient's agreement.
- Patient Specific Directions (PSDs) – written instructions, signed by a doctor, dentist, or nonmedical prescriber for a medicine to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis. Writing a PSD is a form of prescribing.
- Patient Group Directions (PGDs) – see section 1.7 for definition.
- Exemptions from medicines legislation, for example:
  - a range of exemptions enable certain groups of health professionals, such as: chiropodists and podiatrists, midwives,
  - paramedics and optometrists, to sell, supply and administer particular medicines directly to patients occupational health schemes.
  - pandemic disease.

These exemptions are distinct from prescribing and the arrangements for PGDs. A full list of exemptions is included in The Human Medicines Regulations 2012.

1.4 **A Patient Group Direction** provides a legal framework that allows some registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber. However, supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care, without compromising patient safety. Legislation establishing PGDs was introduced in 2000 and the Health Service Circular (HSC 2000/026) provided additional guidance. The current legislation for PGDs is included in The Human Medicines Regulations 2012.

1.5 All practice relating to a PGD must follow the criteria described in this policy. Any deviation from this is prohibited and would be contrary to the legal requirements of The Human Medicines Regulations.

1.6 Definition of a Patient Group Direction

A PGD is defined in Health Service Circular (HSC 2000/026) as:

'Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.' This definition should not be interpreted as indicating that the patient should not be identified.

Patients may or may not be known to the service.

PGDs provide a legal framework that allows the supply and/or administration of a specified medicine(s), by named, authorised, registered health professionals, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber. Using a PGD is not a form of prescribing.

1.7 A Patient Group Direction does not give the practitioner authorisation to prescribe. **Other routes providing treatment, such as those listed in 1.3 above may be more appropriate and should be considered (See http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/PGD-Legislation-Guidance/PGD-Website-Tools/To-PGD-or-not-to-PGD-that-is-the-question/).** Registered prescribers should not use patient group directions for the supply of medicines.

1.8 If the current care pathway can include the issue of a written Patient Specific Direction (PSD) by a doctor or non-medical prescriber so that the patient receives the medicine in a timely manner, then a PGD should not be required.

1.9 A P S D is a written instruction from a doctor, dentist or non-medical prescriber for a medicine or appliance to be supplied or administered to a named patient. For example:

- Primary care: a simple instruction in the patient's notes
- Secondary care: instructions on a patient's ward drug chart

1.10 Following the transfer of Plymouth Teaching Primary Care Trust Provider services to Plymouth Community Healthcare C.I.C. there followed a period of uncertainty regarding the authority of LSW to approve its own PGDs. Initially additional authorisation was sought from Plymouth PCT with agreement for the Governance lead of that organisation to countersign.

1.11 With the imminent dissolution of PCTs in April 2013 and still no official authority granted to Social Enterprises to approve PGDs, guidance was sought directly from the MHRA.

1.12 The MHRA responded initially to affirm that LSW is entitled to approve PGDs on the basis that LSW qualifies as an independent medical agency. However as part of its involvement with the NICE Guidance Development Group the MHRA sought a legal opinion on this question. The legal opinion is that for NHS

commissioned services the PGD needs to be finally approved by the commissioner.

1.13 LSW has now received official confirmation that until there is a change in the law to allow us to approve our own PGDs they must be finally approved by the NHS England Area Team Medical Director.

2. Overall aim of the guidance

2.1 The intention of this policy is to provide legal and good practise guidance to assist in the development, approval and review of Patient Group Directions within the Plymouth Community Healthcare CIC based on nationally agreed standards.

2.1.1 The GDG agreed that the purpose of using a PGD was to:

deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety

offer a significant advantage to patient care by improving access to appropriate medicines

provide equity in the availability and quality of services when other options for supplying and/ or administering medicines are not available

provide a safe legal framework to protect patients

reduce delays in treatment

maximise the use of the skills of a range of health professionals.

2.1.2 The good practice recommendations made at national level in the NICE GPG relating to governance and ratification have been adapted to the particular circumstances prevailing within LSW.

3. Objectives that build toward the overall aim of the guidance

3.1 This guidance aims to provide clear and concise instructions for professional leads or managers when considering using a PGD within their service.

3.2 Professional leads or managers should first consider whether a PGD is the appropriate method for service delivery (see section 6.1).

3.3 The guidance details the steps necessary to develop a PGD from scratch (section 6), or to adapt or update an existing document if available (section 7).

3.4 Full explanation is provided of the approval and ratification process, which is summarised in a flow diagram (Appendix A).

3.5 Guidance is also included on the responsibilities of staff that are involved in the development, approval and review of PGDs and for those staff authorised to work under the direction of a PGD.

4. Description of how you will measure its effectiveness

4.1 The PGD must contain an audit process for monitoring including a secure system for the recording of medicine use under the PGD. It must also include the reconciliation of receipts and supplies of medicines on an individual patient by patient basis so that it is possible to identify which patient has had what medicine. The names of the healthcare professional providing the treatment must also be recorded. Evidence of multi-disciplinary audit must be submitted to the Medicines Governance Group within the first year of a PGD being in clinical use.

4.2 The PGD must be reviewed at least every 3 years to ensure compliance with clinical and corporate standards. The review period for each PGD will be individually assessed at each review. Those PGDs which have been in use for many years without significant changes will be given the maximum 3 years. For new PGDs or for those where the evidence base is subject to frequent change (e.g. influenza vaccine) a one year review period will be given. Established PGDs which have required substantial changes at review will be given a review period of 2 years.

The review must be organised by the clinical lead in the area of practice where the PGD is used.

5. Workforce Planning Issues

5.1 Development of PGDs cannot be undertaken until approval to proceed has been received from the MGG (see section 6.1). Once approval to proceed has been received a comprehensive appropriate training and assessment programme must be developed so that staff can be trained to supply and/or administer medicines under the PGD as soon as it is ratified.

6. Framework for Developing Patient Group Directions

6.1 Process for New Applications for PGDs

6.1.1 LSW services wishing to develop a new PGD must apply to the Medicines Governance Group (MGG) for approval before proceeding to develop the PGD.

6.1.2 Applications must be made to the Chair of the MGG via email: steve.cooke1@nhs.net and include all the details listed in 6.1.6 below.

6.1.3 The application will be considered at the next available meeting of the MGG, held on the 1st Friday of the month. The applicant will be asked to attend the MGG meeting to give the full background for the request and to answer any questions.

6.1.4 The decision and the rationale of the MGG will be communicated to the applicant within one month of the MGG meeting (to allow time for any necessary consultation with stakeholders).

6.1.5 If the applicant disagrees with the decision of the MGG then one appeal will be allowed to the MGG, addressing the concerns stated in the rationale. If appropriate the Chair of the MGG may defer the final decision to the Safety, Quality & Performance Committee.

6.1.6 Ensure that the following information is included in proposal documentation for seeking agreement to develop a PGD:

- the title of the PGD
- details of the proposer and other individual people who would be involved in developing and authorising the PGD
- the setting where the PGD would be used
- the condition to be treated, considering patient inclusion and/or exclusion criteria
- Is the medicine to be administered only, or is a supply needed to take home or for further doses?
- 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. **Note: Only licensed medicines included in the local Plymouth & South Devon Formulary will be considered. Please also note the list of exclusions in section 6.4**
- health professional groups who would work under the 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 (including workforce development) needed to deliver the service
- a timescale for developing the PGD

6.1.7 In making their decision the MGG must consider the following:

- whether a current PGD already exists which could be adapted for an alternative clinical situation or client group. Currently ratified PGDs from either LSW, NEW Devon CCG or NHS England might be acceptable for this purpose
- all legal requirements have been met
- robust local processes and clear governance arrangements are in place
- the risks and benefits of all options for supplying and/or administering the medicine(s) have been explored
- the PGD will deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety
- the views of stakeholders, such as clinical groups, patients and the public, and the commissioning organisation have been considered

- appropriate registered health professionals are available to use the PGD, and training and competency needs are addressed
- people who are developing, 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 within an agreed timeframe
- decisions are aligned with local clinical commissioning frameworks

6.2 The PGD Working Group

6.2.1 Once approval has been granted by the MGG for the development of the PGD a PGD working group should be formed.

6.2.2 Ensure that a named lead author has responsibility for developing the PGD, and that the multidisciplinary PGD working group includes one of each of the following staff groups:

- doctor (or dentist)
- pharmacist
- representative of any other professional group(s) using the PGD.

6.2.3 Define the roles and responsibilities for each of the working party members, and consider their training and competency needs.

6.2.4 All legally required information must be included in a PGD. The use of the LSW template is obligatory (see appendix B).

6.2.5 Ensure PGDs are consistent with the relevant summary of product characteristics, unless the medicine is being used off-label or relevant national guidance is being followed.

6.2.6 Use the best available evidence, such as NICE guidance and other sources of high-quality information when developing PGDs. Include key references in an appendix to the PGD.

6.2.7 Liaise with a local specialist in microbiology when developing a PGD that includes an antimicrobial.

6.2.8 Seek views on a draft PGD and agree a final draft PGD with relevant stakeholders, including clinicians before submitting to the MGG for approval.

6.2.9 Patient Group Directions should only be used for the supply and/ or administration of medicines in the following situations: -

- Individualised care cannot be given in a timely fashion
- It offers an advantage for patient care
- It does not expose the patient to any additional risks.

6.2.10 Any extension to professional roles with regard to the administration and supply of medicines must take into account the need to protect patient safety, ensure continuity of care and safeguarding patient choice, confidentiality and convenience. It must also be cost effective and bring demonstrable benefits to patient care.

6.2.11 Any professional working under a Patient Group Direction must only do so within their professional competence and in accordance with professional guidance.

6.2.12 Where a prescriber for an individual patient(s) gives direct instructions, a Patient Group Direction is not required.

6.3 Who Can Operate Under a PGD?

6.3.1 Only the following qualified registered health professionals can supply or administer medicines under a PGD: -

- chiropodists and podiatrists
- dental hygienists
- dental therapists
- dietitians
- midwives
- nurses
- occupational therapists
- optometrists
- orthoptists
- orthotists and prosthetists
- paramedics
- pharmacists
- physiotherapists
- radiographers
- speech and language therapists

They can only do so as named individuals (see p.30)

6.3.2 Professionals using a PGD must be registered (or equivalent) members of their profession and act within their appropriate code of professional conduct.

6.3.3 A multidisciplinary group that includes a doctor (or a dentist) and a pharmacist, must develop PGD's and a named representative from each of the professions involved in the specialist area.

6.4 Restrictions to Medicines included in PGDs

6.4.1 **Legislation requires that the following medicines must not be included in Patient Group Directions:**

- Unlicensed products, 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

- radiopharmaceuticals
- dressings, appliances and devices
- abortifacients, such as mifepristone

6.4.2 **Medicines that may be considered for inclusion in PGDs under specified conditions:**

- Off-label use of medicines used outside the terms of their licensed indications(marketing authorisation), as defined in the Summary of Product Characteristics (SPC) for the product, only when the indication is justified by current best practice and supported by local or national guidelines. In this situation, the PGD must clearly state that the product is being used outside its marketing authorisation licensed indications. It must also state the reasons why its use is necessary. Inform the patient or their carer that the use is off-label, in line with General Medical Council guidance.

- Newly licensed drugs, which are still subject to special monitoring requirements ('Black Triangle Drugs'), except when justified by best clinical practice. The direction should clearly state the status of the product.

- Controlled Drugs - ensure that a controlled drug is included in a PGD only when legally permitted and clearly justified by best clinical practice. The table below defines which CDs can be used in PGDs:

Schedule	**Controlled drugs that may be considered for inclusion in a PGD**	**Additional comments**
Schedule 2	Morphine Diamorphine	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	
Schedule 4	All drugs, including benzodiazepines and ketamine	Anabolic steroids and any injectable preparation used for treating addiction must not be included in a PGD
Schedule 5	All drugs, including codeine	

6.4.3 Anti-microbial agents may be included in a Patient Group Direction only if this will not jeopardise local and national strategies to combat antimicrobial resistance and healthcare-associated infections and it can be demonstrated that:

- Inclusion is clinically essential and clearly justified by best clinical practice, such as Public Health England guidance
- a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented

- use of the PGD is monitored and reviewed regularly.

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

6.4.5 Do not make dose adjustments to a medicine supplied under a PGD when the medicine is already in the patient's possession.

6.4.6 Carefully consider the risks and benefits of including more than 1 medicine in a PGD on a case-by-case basis. Ensure all legal requirements are met for each medicine.

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

6.5 Criteria to be included in the Patient Group Direction

6.5.1 Legislation specifies that each patient group direction must contain the following information:

- the date the direction comes into force and the date it expires
- a description of the medicine and its legal class to which the direction applies
- the clinical situations which the medicine of that description may be used to treat or manage in any form
- the clinical criteria under which a person shall be eligible for treatment
- Whether there are any restrictions on the quantity of medicinal product that may be sold or supplied on any one occasion and, if so, what restrictions
- Whether any class of person is to be excluded from treatment under the PGD and if so what class of person
- a description of the circumstance in which further advice should be sought from a doctor and arrangements for referral for medical advice
- The pharmaceutical form or forms in which medicinal products of that description or class are to be administered
- The strength, or maximum strength, at which medicinal products of that description or class are to be administered.
- details of appropriate dosage and maximum total dosage
- the route of administration
- frequency of administration
- quantity that may be supplied on any one occasion
- , minimum or maximum period over which the medicine should be administered
- relevant warnings, including potential adverse drug reactions
- details of any necessary follow up action and the circumstances
- the name of the clinical area or body in which the direction is applicable

- the class of health care professional who may supply or administer the medicine
- a statement of the records to be kept of the supply and/or administration of medicines under the PGD for audit purposes
- the signature of a doctor, pharmacist and service lead involved in developing the PGD
- the signature of the health care professionals who are authorised to use the direction
- the signature of the Chair of the approving committee (Medicines Governance Group)
- The signature of the Medical Director (LSW)
- The signature of the commissioner of NHS services provided by LSW

6.5.2 The development of a PGD must utilize current evidence and best practice.

6.5.3 The blank LSW pro-forma must be used as a template when developing a PGD. (Appendix B) NB This can be downloaded from LSW Intranet.

6.6 Safe and Secure handling of medication

6.6.1 Medicines named in PGDs for supply or administration to patients must normally be provided by Derriford hospital pharmacy department. Exceptions include immunisations and vaccinations by District Nurses (supplied by GP practices)

6.6.2 Medicines supplied for patients to take home must meet the standards stated in the EC Labelling and Leaflet Directive 92/27 (http://www.ikev.org/docs/eu/392L0027.htm)

6.6.3 It is a legal requirement that a manufacturer's patient information leaflet is offered with every medicine supplied under a PGD. This requirement does not apply to medical gases.

6.6.4 The provision of pre-packed medicines must be arranged with the hospital pharmacy department where appropriate. This must be included in the PGD development process.

6.6.5 For situations where the minimum order quantity of a hospital pre-pack is in excess of the likely usage, LSW Pharmacy Services may provide small quantities of appropriately labelled packs.

6.6.6 Medicines must be ordered, transported, stored and supplied or administered in accordance with the PGD and the LSW Safe and Secure Handling of Medicines Policy and Procedures.

6.6.7 There must be a system in place for recording and monitoring medicines supplied or administered to each individual patient so that all stock can be reconciled. The full name and signature of the health professional providing the treatment, patient identifiers and the medicine provided must

all be recorded. This can be electronic or paper based so long as the necessary details are captured. For inpatients an entry in the appropriate place on the drug chart is sufficient.

6.6.8 Where medication is supplied, there must be a system in place for the collection of prescription charges or confirmation of exemption status, except for medicines that are automatically exempt e.g. oral contraceptives. The charge does not apply to administration of a dose in a clinic or to inpatients, or for medical gases e.g. oxygen, Entonox.

7. Approval, Review and implementation of PGDs

7.1 Approval Process for PGDs (see flow diagram Appendix A)

7.1.1 The process for approval to commence work on a new PGD is detailed in section 6.1

7.1.2 The process for developing a PGD working group is detailed in section 6.2.

7.1.3 When a final draft version of the PGD is ready the author should obtain an access ID number from the secretary to the Policy Ratification Group

7.1.4 The proposed PGD must be circulated to relevant members of the team/service for comments; in the case of unlicensed indication or non standard practice it is also recommended that views should be sought from appropriate individuals in neighbouring organisations so as to demonstrate as wide a consultation as possible. All comments received should be discussed and changes to the document agreed.

7.1.5 The draft PGD; details of the consultation process, responses received and how resolved; and a training needs assessment, should then be sent to the Chief Pharmacist (LSW). The following checks / actions will then take place:

- That the PGD is accurate, legal and that it conforms to the LSW template
- That the consultation process has been appropriate and that any recommendations made have been fully considered
- Ensure that the training needs identified can be delivered
- Inform the professional lead of any deficiencies or changes necessary
- Table the draft PGD for the next meeting (where possible) of the MGG and inform the author of the time and date so that s/he may attend the meeting to present the PGD.

7.1.6 Agreed final version of the Patient Group Direction must be presented to the Medicines Governance Group (MGG) for approval.

7.1.7 If approved by the MGG Chair will inform the author. If amendments are necessary before the document can be approved, the author will be

expected to make the necessary amendments and return the completed document to the MGG Chair.

7.1.8 Electronic signatures for each of the signatories must be provided with the final document (to include the pharmacist, doctor and senior representative of the profession involved in producing the PGD). Each signatory must be confident that training and assessment issues have been properly addressed. The job title of each signatory and the date of signing must be included on the electronic version.

7.1.9 For final ratification the completed signed copy of the PGD will be signed and dated by:

- Chief Pharmacist (LSW)
- MGG Chair (if not the Chief Pharmacist)
- Medical Director (LSW)
- Medical Director, NHS England Area Team (on behalf of the commissioner)

7.1.10 The PGD will be allocated an operational date and expiry date (maximum 2 years) after final ratification.

7.1.11 The final electronic version of the document will be placed on LSW Intranet and public website by the Communications Officer, and the author will be informed that the PGD is ready to use.

7.1.12 An electronic copy of all current and archived PGDs will be retained on the Pharmacy shared drive in accordance with the Retention Schedule.

7.1.13 The Pharmacy Team Administrative Officer (or secretary of the Policy Ratification Group) will maintain an accurate and up to date database of all PGDs to include:

- ID number
- Title
- Author, responsible person and lead responsibility
- Status i.e. draft, ratified etc
- Risk assessment
- Date created, last review and published dates

7.2 Distribution and Implementation of PGDs

7.2.1 The lead person that submitted the PGD will be responsible for ensuring the correct process is followed. (See Flow Chart Appendix A)

7.2.2 A copy of the ratified PGD will be held: -

- by the Clinical Lead in the area of practice
- by each authorised practitioner within the area of practice
- by each author

7.2.3 Practitioners who will be required to use the PGD in the course of their work should be identified. Professional qualifications and experience required by identified individuals (as stated in the PGD) must be checked and confirmed by their manager. All staff using the PGD must be appropriately trained and assessed before signing their agreement form.

7.2.4 The practitioner must read and retain a copy of the PGD. The practitioner must complete the agreement form and return it to their manager/ professional lead for authorisation. For inpatient or clinic situations where multiple practitioners may be authorised to use the PGD, a single copy of the PGD may be kept in the clinic room.

7.2.5 The clinical lead and manager must ensure that all authorised practitioners have completed an agreement form.

7.2.6 Practitioners will only be able to use a PGD in the scope of their practice once an agreement form has been received and authorised by an appropriate manager and clinical lead.

7.2.7 The Authorised Practitioners register / signed agreement form will be held, together with a ratified copy of the relevant PGD, by the professional lead or manager within the area of practice.

7.2.8 If a practitioner is no longer authorised to act within the Patient Group Direction it is the responsibility of that individual's line manager to remove the individual's name from the Authorised Practitioners Register and inform the professional lead of any changes.

7.3 The revision and amendment of approved Patient Group Directions

7.3.1 Any proposed changes to an existing PGD necessitate a re-drafted document to be re-consulted upon then signed and submitted for approval in accordance with the original approval procedure (start at section 7.1.4).

7.3.2 Electronic signatures of doctor, pharmacist and service lead will be needed from those involved in the review..

7.3.3 Until approved, amendments to an existing PGD are invalid and LSW accepts no responsibility for an authorised practitioner who acts in accordance with a PGD not yet approved, or acts in accordance with a superseded PGD.

7.3.4 Once approved, an implementation date should be agreed. After this date, it is expected that the changeover to the amended PGD will be complete.

7.3.5 It is the responsibility of the Manager of the service using the PGD to ensure that: -

- The amended PGD shall be substituted for the previous PGD held in that area.

- The Service Manager retains the authorisation register in accordance with the DoH Records Management: NHS Code of Practice part 2 Retention and Disposal Schedule.
- A nominated member of staff should remove all copies of the old PGD and ensure that the most up to date version is made available.
- All practitioners authorised under the previous PGD are advised of the changes and any additional training required under the new PGD is provided
- All practitioners are provided with a copy of the new PGD and sign a new agreement of authorisation as described in Section 7.2.

8. Responsibilities of Authorised Practitioners, Professional Groups and the LSW Board

8.1 General Information:

8.1.1 It must be acknowledged by all members of staff that the interests and safety of all patients are paramount.

8.1.2 PGDs should specify clear arrangements for professional responsibility and accountability and contribute to effective use of resources.

8.1.3 All authorised practitioners supplying or administering medicines under the PGD must be named and have written evidence of training and continuing education relevant to the clinical conditions/ situation to which the PGD applies.

8.1.4 In clinical areas where PGDs are used, practitioners who may be required to administer or supply medication in accordance with PGDs must be provided with the necessary training to ensure they are able to carry out this role competently and safely. There should be evidence of competency to be discussed at the individual's yearly appraisal and line management supervision.

8.1.5 Where a practitioner, in the course of their work, may be expected to administer and/or supply medication in accordance with PGDs, this should be included in the job description for that post.

8.2 Authorised Practitioners responsibility

8.2.1 All authorised practitioners must only undertake the extended role under PGDs in circumstances where they are competent to assess all relevant aspects of the patient's clinical condition and take responsibility for supply and administration and related decisions.

Note: An authorised practitioner's delegated authority to supply and administer cannot be re-delegated to non-specifically trained healthcare persons.

8.2.2 No authorised practitioner should undertake any aspect of patient care for which they are not trained and which is beyond their professional competence. If the authorised practitioner is in any doubt about their competency they should not administer or supply in accordance with the PGDs and should seek advice from their line manager

8.2.3 The authorised practitioner undertaking this extended role must only do so in accordance with the current PGD(s) in their area of work.

8.3 Responsibilities of PGD Approval Group, PGD Working Group and Authorised Signatories

8.3.1 The PGD Approval Group will consist of the multi-disciplinary members of the Medicines Governance Group. In discharging this responsibility the MGG members must ensure that governance arrangements continue to be firmly established, with clear lines of accountability and the delegated authority of the LSW Board and the authorising body. These should include:

- agreeing and documenting terms of reference
- declaring any conflicts of interests
- setting the agenda of meetings and taking minutes or notes
- prioritising PGD proposals
- establishing reporting arrangements
- engaging stakeholders, such as clinical groups and patients and the public
- liaising with commissioning and finance.
- Members should refer to appendix C for consideration of their required knowledge, skills and expertise and any associated training and competency needs.

8.3.2 The PGD Working Group is separate from, but will need to liaise with, the PGD approval group. It will consist of:

- a lead author*
- a doctor (or dentist)
- a pharmacist
- a representative of any other professional group who will practice under the PGD, such as a nurse

*the lead author may be the doctor (or dentist) or pharmacist but is more likely to be the service lead so that all aspects of the required service can be carefully considered

- Members should refer to appendix C for consideration of their required knowledge, skills and expertise and any associated training and competency needs.

8.3.3 Authorised signatories will include the working group members and the Chief Pharmacist / Chair of MGG, Medical Director for LSW and the NHS England Area Team Medical Director. All should refer to appendix C for consideration of

their required knowledge, skills and expertise and any associated training and competency needs.

8.4 LSW Board Responsibility

8.4.1 LSW assumes vicarious liability for the actions of the authorised practitioner, properly acting in the course of his/her duties and in accordance with the current PGDs in his/her area of practice.

8.4.2 LSW accepts no responsibility for an authorised practitioner who acts in accordance with a PGD not approved by LSW or acts in accordance with a superseded PGD or acts under a PGD in an area of practice to which the PGD does not apply.

All policies are required to be electronically signed by the Lead Director. Proof of the electronic signature is stored in the policies database.

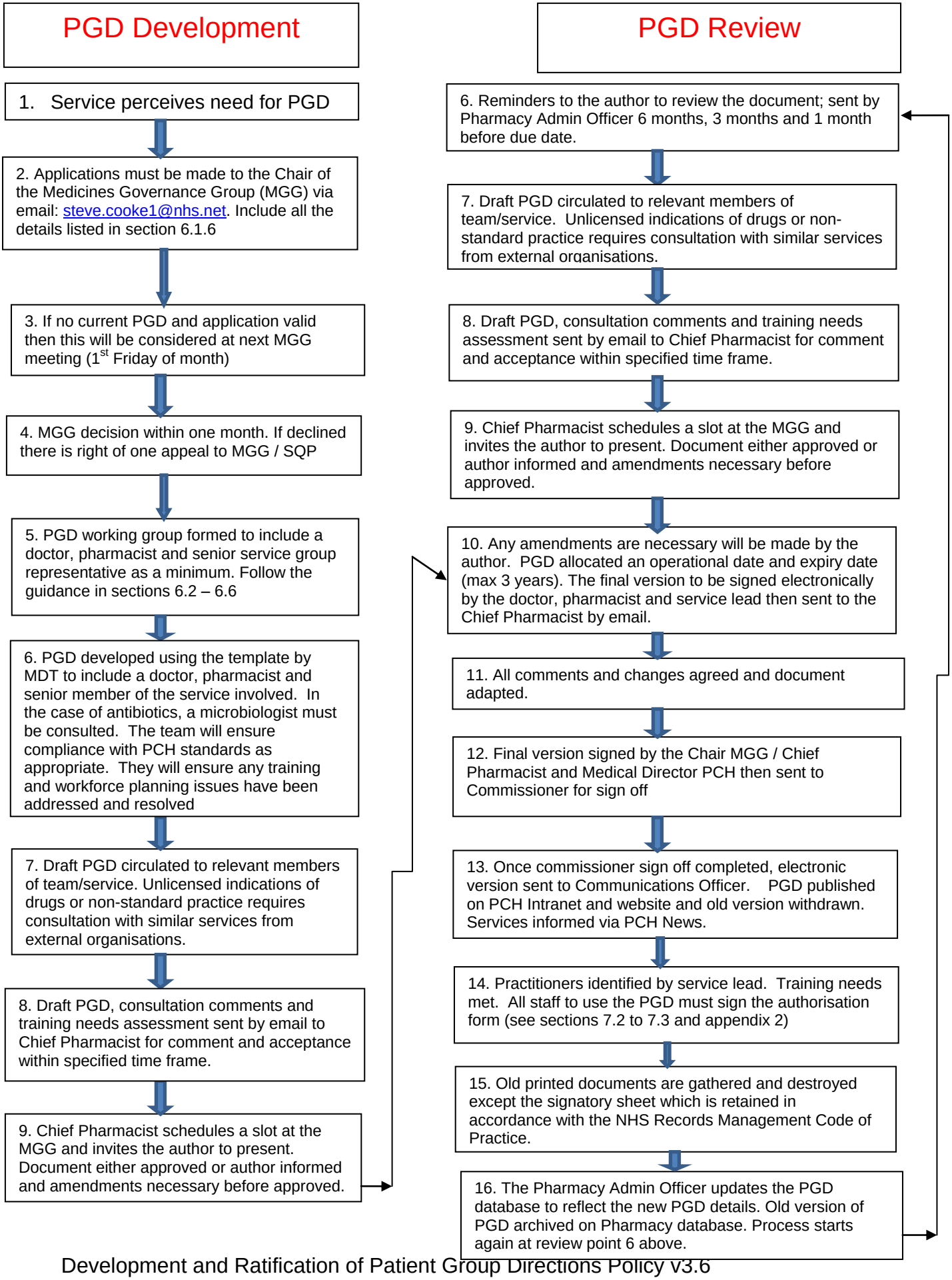
The Lead Director approves this document and any attached appendices. For operational policies this will be the Locality Manager.

The Executive signature is subject to the understanding that the policy owner has followed the organisation process for policy Ratification.

Signed: Medical Director

Date: February 2014

Appendix A: Flowchart of PGD progress for development and review



Appendix B: PGD Template

Livewell Southwest

Patient Group Direction for the Supply / Administration* of……..

Service / Department

Version No

* Can be either or both supply / administration

Notice to staff using a paper copy of this guidance

The policies and procedures page of LSW intranet holds the most recent version of this document and staff must ensure that they are using the most recent guidance.

Author:	Title only.
Asset Number:	To be issued by Policy Ratification Group Secretary

Reader Information

Title	Name and type (in that order) and version number
Asset number	To be obtained from the Policy Ratification Secretary ☏ 01752 435104 – xx35104
Rights of access	Public or Limited
Type of paper	PGD
Category	Clinical
Document purpose/summary	State why you have written it and give very brief description of content. This is to ensure busy people are reading the right document and to assist readers with a visually impairment.
Author	State who is the author/editor of the document
Ratification date and group	(?) Month 200(?) Enter all dates and groups that apply
Publication date	(?) Month 200(?)
Review date and frequency (one, two or three years based on risk assessment)	(?) Month 200(?) Must be reviewed at least every two years
Disposal date	The Pharmacy Office will retain a signed copy for the archive in accordance with the Retention and Disposal Schedule, all previous copies will be destroyed.
Job title	(Title, Directorate)
Target audience	List those that need to work in accordance with these guidelines
Circulation	Electronic: LSW Intranet and website (if applicable) Written: Upon request to the Policy Ratification Secretary on ☏ 01752 435104
Consultation process	Please state what consultation took place in the development of this guidance.
Equality analysis checklist completed	[Yes/No]
References/sources of information	Names of the documents you referenced to write the document References structure is normally Author 1, Initials. and Author 2, Initials. Title of the Book. Edition if not 1st. Town of publication: Publisher, Year of Publication, pp. First relevant page-Last relevant page.
Supersedes document	List any document that it replaces to ensure staff are only using your up to date guidance.
Author contact details	By post: Local Care Centre Mount Gould Hospital, 200 Mount Gould Road, Plymouth, Devon. PL4 7PY. Tel: 0845 155 8085, Fax: 01752 272522 (LCC Reception).

1 Document Version Control

Version no.	Type of change	Date	Originator of change	Description of change
0.1	First Draft	<date>	< title>	<Description>
0.2	Second Draft	<date>	< title>	<Description>
0.3	Third Draft	<date>	< title>	<Description>
1.0	First published version of the document	<date>	< title>	<Description>
1.1	Updated and published	<date>	< title>	<Description>
1.2	Second update and published	<date>	< title>	<Description>

Abbreviations	
CCG	Clinical Commissioning Group
GDG	Guidance Development Group (from NICE)
GPG	Good Practice Guidance (from NICE)
MGG	Medicines Governance Group
MHRA	Medicines and Healthcare Regulatory Authority
NICE	National Institute for Health and Care Excellence
LSW	Livewell Southwest
PGD	Patient Group Direction
PRG	Policy Ratification Group
PSD	Patient Specific Direction

Contents

Guidance

1. Introduction

Reasons that a need for a PGD has been identified at service level

2. Overall aim of the guidance

How the PGD will improve service delivery and benefit patient care

3. Objectives that build toward the overall aim of the guidance

Overview of the patient / client group likely to benefit, the staff groups allowed to operate under the PGD and the protocol to which the PGD relates

4. Description of how you will measure its effectiveness

Arrangements for records, audit and frequency of re-authorisation

5. Workforce Planning Issues

Authority to proceed and an evaluation of the nature and frequency of training including its anticipated impact on current service delivery

6. The Patient Group Direction

Particulars of staff authorised to use this Patient Group Direction and details of training required

The patient must give consent to be treated by an approved written procedure, but without the immediate involvement of a doctor. Verbal consent **must** be documented in the patient record.

Clinical Details	
Clinical Condition / Indication	
Inclusion criteria	
Exclusion criteria	
Cautions/need for further advice	
Action if patient declines	
Action if excluded	

Drug Details	
Name, strength and formulation of medicine	
Legal status of medicine	
Dose to be given	
Method/route of administration	
Frequency of administration	
Number of doses to be given/duration of treatment	
Quantity to supply /administer	
Advice to be given to the patient/carer	<e.g. side effects, any relevant warnings>
Identification & management of adverse reactions	
Arrangements for referral for medical advice (if appropriate)	
Special considerations/ additional information (if appropriate)	

Records	
Documentation to be completed	
Arrangements for audit	

Approval Process

PGD Developed by

Doctor

Name_____ Position_____

Signature _____

Date _____

Pharmacist

Name_____ Position_____

Signature_____

Date_____

Professional group senior representative

Name_____ Position_____

Signature_____

Date_____

Approval by Medicines Governance Group (MGG)

Chief Pharmacist (Chair of MGG)

Name_____

Signature_____

Date_____

Final Approval by Livewell Southwest

Director of Professional Practice, Safety and Quality

Name……

Signature……..

Date……..

Name:

Signature……..

Date……..

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.

Staff Name & Professional Designation	Last anaphylaxis update	PGD training & date	Signature of Practitioner	Authorising Manager	Date

Appendix C

Training and Competency

The GDG agreed that appropriate training, regular re-training and assessment of competency was needed for **all** people involved with PGDs, particularly if and when their roles and responsibilities change. The GDG agreed that, because the use of PGDs has become widely established, there is a need for organisations to review their approach to training.

The GDG concluded that training and assessment of competency is essential to reduce variation and deliver safe and effective services in which PGDs are used. Organisations should establish a training programme that supports all people involved with PGDs. In the absence of a comprehensive suite of nationally produced educational materials, organisations may want to consider collaborating and sharing their existing educational materials to ensure a comprehensive approach.

Knowledge, skills and expertise

The GDG considered that any person involved with PGDs will need knowledge, skills and/or expertise in a number of specific areas as shown in box 7.

Box 7 Knowledge, skills and/or expertise needed by all people involved with PGDs

- Relevant legislation
- Local processes and governance arrangements
- Professional and organisational standards
- Current service provision
- Benefits and risks of all options for supplying and/or administering medicines, including the purpose and intention of PGDs
- Interpretation of medicines information
- Collaborative working
- Ability to use standard software packages and the internet to search for and resource information
- Records management, including version control

The GDG agreed that the additional specialised knowledge, skills and expertise needed by individual people and groups are as listed in table 2.

Table 2 Additional specialised knowledge, skills and/or expertise needed by people in specific roles

Role	Knowledge, skills and expertise
People in a PGD working group[a]	• Evidence gathering and critical appraisal • Clinical and pharmaceutical knowledge, such as drug interactions, contraindications and adverse effects • Authoring clinical content • Medicines management systems, such as safe storage, packaging and labelling
Doctor (or dentist) signing a PGD	• Relevant specialist clinical and pharmaceutical knowledge, including national guidance and policy • Experience of working at a level of responsibility appropriate to the role • Experience of working in a local medicines decision-making group • Understanding of the clinical speciality or service in which the PGD is to be used
Pharmacist signing a PGD	• Relevant specialist clinical and pharmaceutical knowledge, including national guidance and policy • Experience of working at a level of responsibility appropriate to the role • Experience of working in a local medicines decision-making group • Understanding of the clinical speciality or service in which the PGD is to be used • Medicines management systems, such as safe storage, packaging and labelling

Other people signing a PGD (representing any other professional group(s) using the PGD)	• Experience of working at a level of responsibility appropriate to the role • Specialist practitioner in the clinical speciality or service in which the PGD is to be used • Experience of working in a local medicines decision-making group
A person signing PGDs on behalf of the authorising body	• Organisational responsibility for clinical governance • Experience of working in a local medicines decision-making group
People authorising named, registered health professionals to practice under the PGD	• Experience of working at a level of responsibility appropriate to the role in the relevant profession • Experience of working in the clinical speciality or service in which the PGD is to be used • Ability to incorporate relevant professional standards • Ability to incorporate appropriate training and development for the relevant profession
People using PGDs	• Clinical and pharmaceutical knowledge, such as drug interactions, contraindications and adverse effects • Experience of working in the clinical speciality or service in which the PGD is to be used • Medicines management systems, such as safe storage, packaging and labelling
[a] Members of the group should together have the knowledge, skills and expertise needed to undertake all necessary activities.	

Notes: