NHS
Sunderland
Clinical Commissioning Group

Policy and process for development and management of PGDs for general practice that require SCCG authorisation

C027

Better health for Sunderland

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Version Control

Version	Date Approved	Committee	Date of next review	CCG Lead
Version 2.0	December 2015	Executive Committee	December 2018	Elizabeth Mallett
Version 2.1	September 2016	Executive Committee	December 2018	Elizabeth Mallett
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Version 3.1	January 2021	Executive Committee Extended for 12 months in light of COVID19	December 2022	Sarrah Seldon

1. Introduction

The lack of a policy for the development and management of Patient Group Directions (PGDs) was identified as a risk when the CCG was asked to provide PGDs for particular drugs in general practices.

It was also identified that the PGDs in use in the Walk-In centres provided by Vocare had not been authorised for use by an accepted authorising body.

The policy and supporting procedures and processes have been developed to meet the needs of general practices in SCCG.

1.1 Status

This policy is a corporate policy.

1.2 Purpose and scope

1.2.1. This document outlines the process to be followed within Sunderland (SCCG) for the development and use of Patient Group Directions (PGDs). It gives practical guidance on the development of a PGD including details of the content, processes, responsibilities, monitoring and implementation, in order that the practice the PGDs support is within the law, and is ready in a form for authorisation.

1.2.2. The policy incorporates the guidance provided in the 1998 Crown Report (Department of Health, 1998) on the supply and administration of medicines under PGD and the legal requirement and guidance set out in HSC 2000/026 (Department of Health, 2000) and the Medicines practice guidelines: Patient Group Directions issued by Medicines and Prescribing at National Institute for Health and Care Excellence (NICE, August 2013).

1.2.3. Only certain organisations are able to authorise PGDs in the NHS in England and these are:

- Clinical Commissioning Groups (CCGs)
- Local Authorities
- NHS Trusts or NHS Foundation Trusts
- NHS England
- Public Health England

1.2.4. Failure to comply with these criteria falls outside of the law and could result in criminal prosecution under the Medicines Act (Department of Health, 1968).

1.2.5. PGDs must ensure that the highest standard of practice is achieved for each clinical situation where they are used. A PGD is not an authorisation to prescribe.

1.2.6. The preferred way for patients to receive medicines is for an appropriately qualified health care professional to prescribe for an individual on a one-to-one basis. Supply and administration of medicines under a PGD is reserved for those limited situations where an advantage to patient care can be demonstrated (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability. A PGD should not be used when it is reasonable to expect that a prescription (FP10) or a PSD (patient specific direction) could be written in advance. PGDs should not be used to circumvent the repeat prescribing systems used in general practice.

1.2.7. This policy outlines the responsibilities of authorised PGD users professional groups and encompasses all the criteria required for the preparation and authorisation of PGDs. **It is important that all people involved in the development of PGDs are aware of the NICE medicines practice guidelines and meet the necessary competencies.**

1.2.8. The qualified registered health professionals who may supply or administer medicines under a patient group direction are: ambulance paramedics; dental hygienists and dental therapists; dieticians; health visitors; midwives; nurses; occupational therapists; optometrists; orthoptists; pharmacists; physiotherapists; podiatrists and chiropodists; prosthetists and orthotists; radiographers; speech and language therapists. They can only do so as named individuals.

1.2.9. This policy applies to PGDs that have been developed and/or authorised by SCCG for the treatment of NHS patients by authorised healthcare professionals working in SCCG member practices and provider organisations directly commissioned by SCCG.

SCCG staff will be responsible for the development and authorisation of PGDs for use in member practices.

All staff involved in the development, review and authorisation of these PGDs must adhere to the policy.

All general practice staff and commissioned service staff providing services under a PGD which has been authorised by SCCG must adhere to this policy.

For SCCG commissioned services where the provider is unable, by law to authorise PGDs - e.g. urgent care services - the PGD must be developed by the commissioned provider. SCCG will then authorise the PGD for use for its commissioned services.

The commissioned provider is responsible for implementation of the PGD.

Table 1. Sunderland Services and Commissioners

			PGD Signatories			
Service	Provider	Commissioning Organisation	Doctor	Pharmacist	Professional Lead	Authorising commissioner
Urgent Care Service	NDUC	SCCG	Medical Director NDUC	Senior Pharmacist NDUC	Senior nurse NDUC	Medical Director or HoMM* SCCG
GP Practices	SCCG GP Practices	SCCG	Medical Director SCCG	Senior Pharmacist SCCG	Senior Nurse SCCG	Medical Director or HoMM SCCG

*HoMM = Head of Medicines Management

PGDs that have been produced and authorised by the NHS England Area Team for use in general practices, including those for the national immunisation schedule are outside the scope of this policy.

2. Definitions

The following terms are used in this document:

A Patient Group Direction (PGD) can be defined as:

"a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by doctors, pharmacists and other appropriate professionals, and approved by the employer, advised by the relevant professional advisory committees. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment."

3. Development and management of PGDs

3.1 Developing a patient group direction (PGD)

3.1.1 Identification of need for a PGD

PGDs for use in SCCG member practices

Requests for new patient group directions must be made by a senior medical representative at the practice using the SCCG PGD application form (Appendix 1). It is recommended that the practice self-assesses the appropriateness of the request using the PGD assessment tool 'To PGD or not to PGD'

Evidence to support the application must be provided, and the application must be signed by the senior medical representative making the request.

The SCCG PGD working group will meet quarterly to consider requests and decide whether the development of a PGD is appropriate using the assessment tool 'To PGD or not to PGD' .

The decision and approval for development will be documented. If the development of the PGD is agreed the applicant will be informed of the expected timescales for the development and authorisation of the PGD.

Special consideration will be given to PGD applications for antimicrobials, off licence, black triangle and controlled drugs. (See sections 3.5-3.9 of this document or NICE MPG2 section 1.1 'Considering the need for a Patient Group Direction').

PGDs for use in commissioned services that require authorisation by SCCG

PGDs for use in the service will be agreed with the SCCG PGD working group. The PGDs will be developed and checked by the service and will be signed by the senior provider/postholders of the service i.e. doctor, pharmacist and representative of the staff using the PGD.
The PGDs will then be submitted to the SCCG PGD working group for authorisation by the medical director or head of medicines optimisation.

3.1.2 Who should be involved?

Legislation does not specify who must be involved in developing PGDs. The Health Service Circular (HSC 2000/026) states that PGDs 'should be drawn up by a multidisciplinary group involving a doctor, a pharmacist and a representative of any other professional group expected to supply medicines under the PGD'. The NICE MPG2 calls this the 'PGD working group'.

For commissioned services –
The responsibility for the membership of the PGD Working Group will lie with the provider organisation, and it should be set up in line with NICE MPG2 recommendations.

For PGDs for use in SCCG member practices -
The SCCG PGD working group will have membership which is consistent with the guidance.

Individual PGDs will be developed by a named lead author and agreed by the PGD Working Group, who will have overall responsibility for clinical content.

Review and renewal of PGDs should be done by the PGD Working Group.

3.1.3 What should be included in a PGD?

a) All legally required information must be included in a PGD. A standard template is used to ensure that the format is consistent across the organisation and is included in this policy (Appendix 2).

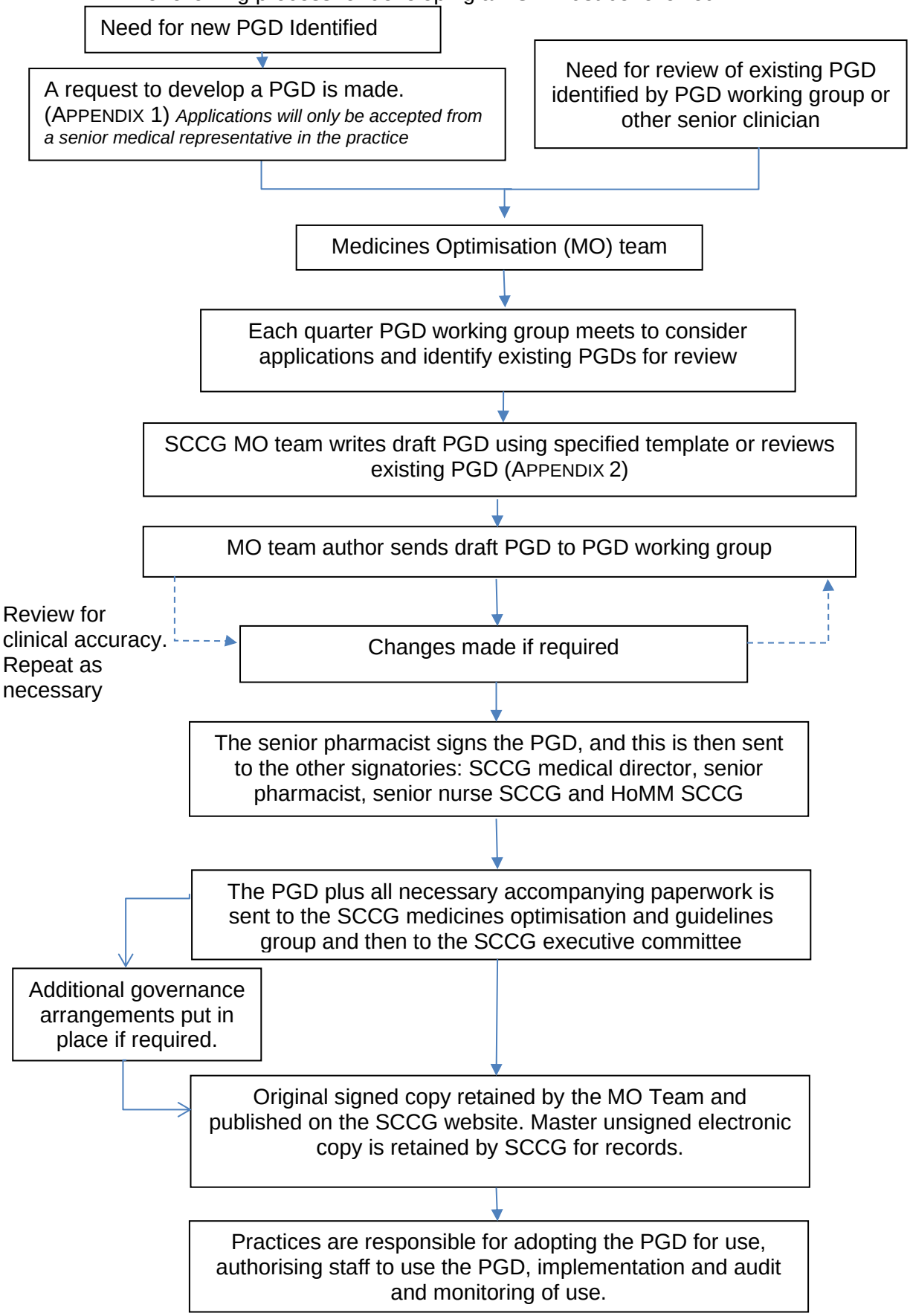
Each section must be completed in the PGD in order to comply with HSC 2000/026: Patient Group Directions (Department of Health, 2000).

b) References – all relevant guidelines and pertinent reference sources must be consulted as part of the development / review. All reference sources must be noted in the PGD.

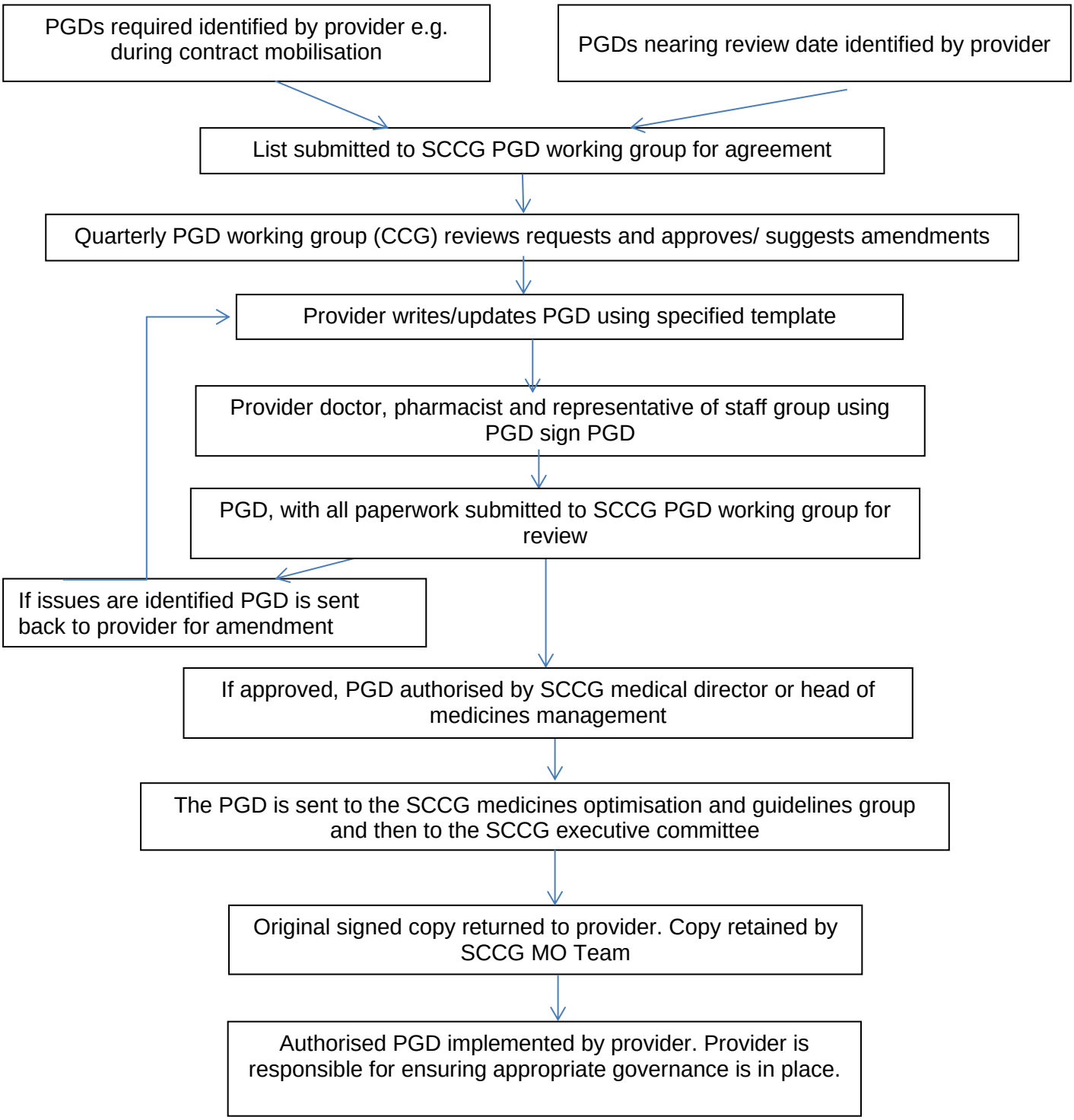
3.1.4 Flowchart for SCCG PGD Development

– for PGDs for use in SCCG member practices

The following process for developing a PGD must be followed.



- for PGDs for use in other services commissioned by SCCG



3.1.5 Approving and ratifying a PGD

SCCG will have a standing PGD working group to handle the development and review of PGDs with specialist contribution when needed.

A copy of each PGD with the recommended paperwork (including details of the any proposed training package and implementation plan) will be submitted to the medicines optimisation and guidelines group and then the SCCG Executive Committee to provide assurance to the Governing Body that the PGD has been developed with appropriate governance in place.

For each PGD, the provider organisation (including each practice) should:

a) Identify a senior, responsible medical representative from within the service to authorise named, registered health professionals to practice under the PGD

b) Ensure that authorised health professionals have signed the appropriate documentation.

3.1.6 Version control

a) During the development process, strict version control must be followed and draft versions must be watermarked on each page as “draft”.

b) A new PGD in development will begin as 0.1

c) Subsequent amended versions will become 0.2, 0.3, 0.4 etc.

d) The first ratified PGD will be version 1.0

e) When a PGD is under review the version changes to 1.1. As different groups are consulted and changes are made, the version changes 1.2, 1.3 etc.

f) The next final reviewed and ratified guideline becomes 2.0, and so on.

3.1.7 Review and revalidation

PGDs must have an expiry date, and must not be used beyond their expiry date, because any supply and/or administration of a medicine(s) would be without legal authorisation. The expiry date for a PGD should be considered and determined on a case-by-case basis with patient safety paramount. NICE recommend that this should be a maximum of 3 years from the date the PGD was authorised (or re-authorised).

SCCG medicines optimisation team will also prompt a review of PGDs in response to:

- changes in legislation
- important new evidence or guidance that changes the PGD, such as new NICE guidance
- new information on drug safety
- changes in the summary of product characteristics
- changes to the local formulary

Any senior medical representative of a member general practice or commissioned

service lead of a provider organisation can request an unscheduled review and updating of a PGD, when the need for this has been identified.

Any proposed changes, including minor amendments, will require the PGD to go through the review process and be re-authorised.

3.1.8 Administration and Dissemination

PGDs for use in general practice - notification of newly published PGDs (new or updated) will be sent to designated individual(s) to co-ordinate distribution to appropriately trained staff. This will usually be the executive practice nurse representative.

It is the responsibility of a senior medical representative in each practice to adopt the PGD by signing it (to be signed on the front page of the document). They must also ensure new staff are authorised to use relevant PGDs. This means that they are responsible for ensuring staff are appropriately trained to use the PGD, and that they have read the PGD and signed to agree to work in line with the requirements.

Copies of this paperwork must be kept in a safe place e.g. in a folder specifically for that purpose and may be required for inspection.

For PGDs for other commissioned providers – the provider is responsible for ensuring appropriate administration and dissemination.
The provider is also responsible for ensuring that staff that need to use the PGD sign it, that they are appropriately trained and that they use the PGD in line with requirements.

3.2 Record Keeping

The following information must be recorded by the practitioner:

- Patient's details: name, condition presented, medical history;
- Patient assessment and diagnosis;
- Contra-indications to any medicines;
- Medicines which have caused allergic reactions or side effects;
- Allergies to the drug and/or excipients;
- Current and recent prescription medication, including over the counter (OTC) medicines and herbal preparations;
- Reasons for exclusion and referral;
- Medicine supplied and/or administered: name; form; strength; quantity; batch number; expiry date; information and advice given;
- Name and/or signature of the health care professional providing treatment and supplying the medicine.

An entry on the computer patient's record on the GP clinical system record under the healthcare professional's individual identification is an acceptable alternative.

All PGD records must be retained as follows:

- For adults, all PGD documentation in a patient's clinical record must be kept for eight years.
- For children, all PGD documentation in a patient's clinical record must be kept until the child is 25 years of age, or for eight years after a child's death.

- If the PGD is for an implant in an adult (for example contraceptive implants or drug eluting coils), then all PGD documentation in a patient's clinical record must be kept for 10 years.
- Staff authorisation records should be kept for eight years after the expiry date of the PGD if the PGD relates to adults only (10 years if it related to an implant) and for 25 years after the expiry date of the PGD if the PGD relates to children.
- The final authorised copy of the PGD should be kept for eight years after the expiry date of the PGD if the PGD relates to adults only (10 years if it related to an implant) and for 25 years after the expiry date of the PGD if the PGD relates to children.
- The main content of a PGD (i.e. an unauthorised final copy), which contains no patient identifiable information or staff authorisation records, may be retained by an organisation for up to 20 years for the purposes of business planning/continuity if there is a reason to do so. An example of this would be as a reference for future PGDs.

For the purposes of the above, PGD documentation includes master authorised (signed) copies of PGDs, lists of authorised practitioners and patient supply/administration records, including electronic records/agreements.

3.3 Security and Storage of Medicines

3.3.1 It is expected that medicines are stored in accordance with current governance recommendations and legislation.

3.3.2 When a POM is supplied, the medicine must be supplied in a pre-pack obtained from an approved supplier. The contents of pre-packs should not be altered to suit individual patients. They should be advised to take the recommend course and return excess doses to their community pharmacy for destruction.

3.3.3 Each pre-pack must be labelled with the following:

- Name of the medicine, form, strength and quantity
- Directions for use, dose and frequency;
- Cautions and advisory labels;
- Additional warning 'to keep out of reach of children';
- Special handling or storage instructions;
- Batch number and expiry date;
- Name and address of the service provider.

At the point of supply the healthcare professional must add both the name of the patient, and the date of issue.

In addition, the manufacturer's patient information leaflet (PIL) must be provided each time a medicine is supplied to comply with European Council Directive 2004/27/EC.

3.3.4 Arrangements for the collection of prescription charges, or identifying clients who are exempt from such charges, need to be in place to comply with NHS Standing Financial Orders.

3.4 Indemnity Insurance

Individual practitioners should have their own professional indemnity insurance and ensure that the insurance provider is aware that they are operating under PGD policy.

Those employed, (as opposed to being self-employed), whether within or outside the NHS, will almost certainly be covered for these purposes. Practitioners, who are members of a professional organisation, or trades union, may also be covered additionally by this body. Most employers provide vicarious liability insurance to cover the acts or omissions of their employees, but practitioners must check that they are covered.

The senior medical representative authorising staff to operate under PGDs within their service should also ensure that their professional indemnity insurance covers their authorising PGDs for use within their service.

3.5 Cautions and Limitations

The assessment tool 'To PGD or not to PGD' should determine whether the use of PGD to administer a particular medicine is appropriate.

3.5.1 A PGD is unnecessary:

- If an exemption exists under the Medicines Act;
- If the medicine involved is on the General Sales List (classified as GSL);
- For medical gases: these are not usually classified as POMs;
- For dressings, appliances, medical devices, or chemical agents: these are not legally classed as medicines.

3.5.2 The NICE medicines practice guideline MPG2 (NICE, 2013) recommends that there are some clinical situations in which alternatives to PGDs should be used, for example:

- For management of long-term conditions, such as hypertension or diabetes;
- Where uncertainty remains about the differential diagnosis, particularly when further investigations or diagnostic tests are needed, for example erectile dysfunction;
- Where the medicine needs frequent dosage adjustments, or frequent or complex monitoring, for example anticoagulants or insulin

3.5.3 Under a PGD you cannot supply or administer:

- unlicensed medicines
- dressings, appliances and devices
- radiopharmaceuticals
- abortifacients, such as mifepristone.
- anabolic steroids, and any injectable preparation used for treating addiction
- Medicines to paralyse muscles which cause wrinkles (e.g. Botox®, Vistabel® or Dysport®)

3.6 Antimicrobials

Particular caution should be exercised in any decision to draw up PGDs relating to antibiotics. Microbial resistance is a public health matter of major importance and great care should be taken to ensure that their inclusion in a direction is absolutely necessary

and will not jeopardise strategies to combat increasing resistance. A local microbiologist should be involved in drawing up antimicrobial PGDs. Any such directions should be consistent with local and regional policies.

3.7 Black triangle drugs and medicines used outside the terms of the license

Black triangle drugs (i.e. those recently licensed and subject to special reporting arrangement for adverse reactions) and medicines used outside the terms of the Summary of Product Characteristics may be included in PGDs provided such use is exceptional, justified by current best practice (e.g. NICE guidance) and that a direction clearly describes the status of the product. Black triangle vaccines used in immunisation programmes may be included in PGDs, provided they are used in accordance with the schedules recommended by the Joint Committee on Vaccination and Immunisation.

3.8 Children

Where the medicine is for children, particular attention will be needed to specify any restrictions on the age, size and maturity of the child. Each PGD should clearly state when the product is being used outside the terms of the SPC and documentation should include the reasons why, exceptionally, such use is necessary.

3.9 Controlled Drugs

The Home Office is responsible for legislation governing the use of all controlled drugs, even when used for medicinal purposes. The Misuse of Drugs Regulations 2001 governs controlled drugs usage and, in October 2003, they were amended to allow some controlled drugs to be supplied and/or administered under a PGD.

The following controlled drugs can be supplied or administered under a PGD:

- Diamorphine & morphine (listed in Schedule 2) but only by nurses and pharmacists for the immediate necessary treatment of a sick or injured person (except for treating addiction).
- Midazolam listed in Schedule 3 of the 2001 Regulations.
- All drugs listed in Schedule 4 of the 2001 Regulations (mostly benzodiazepines), except anabolic steroids and injectables used for treating addiction
- All drugs listed in Schedule 5 of the 2001 Regulations (i.e. low strength opiates such as codeine)

Note: Tramadol, a Schedule 3 controlled drug (CD No Register POM) since June 10 2014, may <u>not</u> be supplied or administered under a PGD.

3.10 Private Practice

SCCG will not support the development of PGDs for privately funded services e.g. some vaccines required for overseas travel. Under the Human Medicines Regulations 2012 (Part 3, Chapter 12, paragraph 230) NHS GP practices are not permitted to use NHS PGDs to administer treatment for non-NHS circumstances, e.g. Hepatitis B vaccine given on a private basis for travel purposes. NHS practices can however use a private PGD, if they have the appropriate policy and procedures in place to develop and authorise their own PGD.

3.11 Adoption

When a PGD is developed and authorised by SCCG for use across multiple GP practices each GP practice needs to adopt the PGD for use in their practice if they wish to use it.

The senior medical representative of the practice is responsible for authorising the health professionals in the practice to use the PGD.

The senior medical representative at the practice (practice PGD signatory) must ensure that the following are in place:

- appropriate training is arranged
- staff working under the PGD have the necessary skills, knowledge and competence
- all staff expected to work within PGD receive the most current full individual copy
- all staff expected to work within the PGD have access to the current full reference copy held on the SCCG website
- any necessary practice/service clinical guidelines to support the PGD are developed
- all staff working within a PGD have signed the PGD 'individual authorisation' as an agreement to practice within the requirements of the PGD and provide assurances that they are trained and competent to do so.
- a process is in place for new staff to progress to working under the PGD as appropriate
- A list is kept by the practice/service of the names of the healthcare professionals who have been authorised to operate under PGDs. SCCG may request details of authorised practitioners.
- The list is updated to reflect both new staff authorised to operate under the PGD and staff no longer authorised to operate under the PGD or no longer working for that service provider.
- a planned programme of audit, monitoring and evaluation of PGD use within the practice/service is undertaken
- PGD review is prompted in good time prior to expiry date

The final authorised copy of the PGD should be kept for eight years after the expiry date of the PGD if the PGD relates to adults only (10 years if it related to an implant) and for 25 years after the expiry date of the PGD if the PGD relates to children.
Staff authorisation records should be kept for eight years after the expiry date of the PGD if the PGD relates to adults only (10 years if it related to an implant) and for 25 years after the expiry date of the PGD if the PGD relates to children.

3.11.1 Training and competence

The senior medical representatives at the practice or commissioned service are responsible for ensuring that all staff using a PGD are competent to assess all relevant aspects of the patient's clinical condition, take responsibility for supply and/or administration of the medicine and make related decisions.

All staff supplying and/or administering medicines under PGDs must have written evidence of competence, training, knowledge, experience and continuing education relevant to the clinical condition/situation to which the PGDs apply.

The practitioner must take personal responsibility for ensuring they maintain their competence and knowledge, and attend additional training when appropriate.

4. Duties and responsibilities

Executive Committee	Responsible for approval of the policy
Chief Officer	The chief officer has overall responsibility for the strategic direction and operational management, including ensuring that CCG process documents comply with all legal, statutory and good practice guidance requirements.
Medicines Optimisation (MO) Team	The MO team are responsible for overseeing the development and updating of this policy and related procedures.
Sunderland CCG	Have a responsibility to ensure that a PGD is authorised within the legal framework and local governance arrangements. SCCG must ensure all authorised PGDs contain the signatures of: • a senior doctor or dentist, • a senior SCCG pharmacist, • a representative of any professional group practising under the PGD • an appropriate person such as a clinical governance or patient safety lead. The doctor (or dentist) and pharmacist signature indicates that the clinical and pharmaceutical content is accurate and supported by the best available evidence. The clinical governance or patient safety lead has designated responsibility for signing PGDs on behalf of the authorising body, having first established that: • local processes and governance arrangements have been followed • all legal requirements have been met. When a PGD is developed and authorised by a commissioning organisation for use across multiple provider organisations – e.g. general practices, it must be adopted for use by each practice that wish to use it. For each PGD, the general practice(s): • must identify a senior medical representative who will be the responsible person from within the practice to authorise named, registered health professionals to practise under the PGD. This would usually be a senior medical representative of the practice, and should be medically trained. • must ensure that authorised health professionals have signed the appropriate documentation • are responsible for providing the necessary training to enable their employee Health Care Professionals to achieve competency to work under the PGD The CCG, as authorising body has responsibility for assessing local needs and developing a communications plan to support the dissemination of PGDs. Final signed versions of PGDs will be published on the SCCG website. Note: Electronic signatures may be used in line with MHRA guidance. However, attaching a scanned picture of a signature is not acceptable.
Provider organisations	Must identify a senior medical representative who will be the responsible person from within the practice to authorise named, registered health professionals to practise under the PGD. This would usually be a senior medical representative of the practice, and should be medically trained. Must ensure that authorised health professionals have signed the appropriate documentation. Are responsible for providing the necessary training to enable their employee Health Care Professionals to achieve competency to work under the PGD. PGDs produced by the providers of commissioned services require the signatures of: • doctor employed by the service • pharmacist employed by the service • representative of the staff group that will use the PGD who is employed by the service • authorised signatory of the CCG as the authorising body.

	The doctor signatory employed by the service is also responsible for: • authorising named registered health professionals to practice under the PGDs • ensuring that the health professionals using the PGD have signed the appropriate documentation • providing the necessary training to enable their employee Health Care Professionals to achieve competency to work under the PGD For further information on PGDs in commissioned services (other than general practices) – see Appendix 4
Senior medical representative within provider organisations	Responsible for adopting PGD for use in their organisation (by signing it on the front page). Must ensure that their professional indemnity insurance covers their authorising PGDs for use within their service. Must accept responsibility for ensuring staff are appropriately trained and competent to use the PGD and that use is in line with the PGD content. Must ensure that all staff using a PGD are competent to assess all relevant aspects of the patient's clinical condition, take responsibility for supply and/or administration of the medicine and make related decisions Must ensure all relevant practice staff are fully aware of the content of the Patient Group Directions. Must ensure that the audits are completed and that practitioners are working in accordance with the PGD. Must ensure that the following are in place: • appropriate training is arranged • staff working under the PGD have the necessary skills, knowledge and competence • all staff expected to work within PGD receive the most current full individual copy • all staff expected to work within the PGD have access to the current full reference copy held on the SCCG website • any necessary practice clinical guidelines to support the PGD are developed • all staff working within a PGD have signed the PGD 'individual authorisation' as an agreement to practice within the requirements of the PGD and provide assurances that they are trained and competent to do so. • a process is in place for new staff to progress to working under the PGD as appropriate • a list is kept by the practice of the names of the healthcare professionals who have been authorised to operate under PGDs. SCCG may request details of authorised practitioners. • the list is updated to reflect both new staff authorised to operate under the PGD and staff no longer authorised to operate under the PGD or no longer working for that service provider. • a planned programme of audit, monitoring and evaluation of PGD use within the service is undertaken PGD review is prompted in good time prior to expiry date
Authorised practitioners	All healthcare professionals signing up to PGDs are responsible for: a) Following NICE guidance and guidance from other relevant national clinical organisations including the Department of Health, MHRA and BNF. b) Referring to the Summary of Product Characteristics (SPC) or other reference sources for additional information where directed to this in the PGD. c) Complying with the PGD. d) Reporting any accidents, incidents and near misses in relation to their use of the PGD.

	e) Completing relevant training and ensuring that they are competent to work under each PGD. If the authorised practitioner is in any doubt about their competency they should not administer and/or supply in accordance with the PGD and should seek advice from their relevant professional body, or the clinical lead for the service. A practitioner authorised to work under a PGD cannot delegate the responsibility to another person. Practitioners should have a signed copy of the current PGD available for reference when supplying and/or administering a medicine. Practitioners should keep a record of the supply and/or administration made under a PGD. This should be made available for audit purposes when necessary. Must have written evidence of competence, training, knowledge, experience and continuing education relevant to the clinical condition/situation to which the PGDs apply. Must take personal responsibility for ensuring they maintain their competence and knowledge, and attend additional training when appropriate.
All Staff	All staff, including temporary and agency staff, are responsible for: • compliance with relevant process documents. Failure to comply may result in disciplinary action being taken. • co-operating with the development and implementation of policies and procedures and as part of their normal duties and responsibilities. • identifying the need for a change in policy or procedure as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager accordingly. • identifying training needs in respect of policies and procedures and bringing them to the attention of their line manager. • attending training / awareness sessions when provided.

5. Implementation

5.1 This policy will be available to all staff for use in the development and use of patient group directives within Sunderland.

5.2 All directors and managers are responsible for ensuring that relevant staff within their own directorates and departments have read and understood this document and are competent to carry out their duties in accordance with the procedures described.

5.3 SCCG will ensure that the PGD policy has been issued and implemented as follows:

a) A variety of dissemination methods are in place to make sure that general practice staff are aware of, have access to and comply with, the PGD policy.

b) All policies are held on the SCCG website to which all practices have access. Staff should always consult the internet for the latest version.

c) All SCCG approved PGDs will be held on the SCCG website.

d) The senior medical representatives in each practice are responsible for ensuring all relevant practice staff are fully aware of the content of the Patient Group Directions Policy.

6. Training Implications

It has been determined that there are no specific training requirements associated with this policy/procedure.

7. Related Documents

7.1 Other related policy documents

7.2 Legislation and statutory requirements

Department of Health (2000). HSC 2000/026: Patient group directions. London: Crown Copyright. Available at: http://www.dh.gov.uk/en/PublicationsAndStatistics/LettersAndCirculars/HealthServiceCirculars/DH_4004179

7.3 Best practice recommendations

NICE. Patient Group Directions. Medicines Practice Guideline (MPG2). (August 2013, updated March 2017). Accessed November 2018. Available at: https://www.nice.org.uk/guidance/mpg2
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8. Monitoring, review and archiving

8.1 Monitoring

The Executive Committee will agree a method for monitoring the dissemination and implementation of this policy. Monitoring information will be recorded in the policy database.

No deviation from this policy will be allowed. Any PGD that has been developed independently of this policy will not be authorised for use by SCCG.

8.1.1 Audit

As stated in HSC 2000/026, care provided under a patient group direction must be audited.

It is a legal requirement as per HSC 2000/026 to keep records of administration and/or supply under PGD for audit purposes.

The records of administration or supply against each PGD must be audited annually by each practice so that the appropriateness of the supply or administration (or of not supplying or administering a medicine) can be reviewed.

It is the responsibility of the signatory senior medical representative or delegated other member of the practice to ensure that the audits are completed and that practitioners are working in accordance with the PGD.

See Appendix 3 for audit templates.

The results of the audit should be shared within the practice and reported to the SCCG medicines optimisation and guidelines group on request.

For new staff, the use of PGDs should be audited six months after commencing the post.

The audit must include:

- Reason for administering or supplying under PGD;
- Record of assessment criteria (e.g. appropriate history taking required for decision making);
- Reason for not making supply/administering and action taken;
- History of allergy recorded in notes;
- Advice given: verbal and written.

The results must highlight areas of best practice as well as areas of concern and identify any areas of training and development need.

8.1.2 Incident reporting

Compliance with this policy will be monitored using an analysis of incidents and complaints where there has been a failure to follow procedure.

Quarterly medication error/incident reports will be reviewed by the Quality and Safety Committee.

Action plans to manage improvement in compliance will be developed where necessary.

Key findings of both audit and monitoring of compliance will be reported quarterly to the Quality and Safety Committee.

8.2 Review

8.2.1 The Executive Committee will ensure that this policy document is reviewed in accordance with the timescale specified at the time of approval. No policy or procedure will remain operational for a period exceeding three years without a review taking place.

8.2.2 Staff who become aware of any change which may affect a policy should advise their line manager as soon as possible. The governing body will then consider the need to review the policy or procedure outside of the agreed timescale for revision.

8.2.3 For ease of reference for reviewers or approval bodies, changes should be noted in the 'document history' table on the front page of this document.

NB: If the review consists of a change to an appendix or procedure document, approval may be given by the sponsor director and a revised document may be issued. Review to the main body of the policy must always follow the original approval process.

8.3 Archiving

The Executive Committee will ensure that archived copies of superseded policy documents are retained in accordance with Records Management: NHS Code of Practice 2009.

9. Equality analysis

An Equality Impact Assessment (EIA) is a process of analysing a new or existing service, policy or process. The aim is to identify what is the (likely) effect of implementation for different groups within the community (including patients, public and staff).

We need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Equality Act 2010
- 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

This is the law. In simple terms it means thinking about how some people might be excluded from what we are offering.

The way in which we organise things, or the assumptions we make, may mean that they cannot join in or if they do, it will not really work for them.

It's good practice to think of all reasons why people may be excluded, not just the ones covered by the law. Think about people who may be suffering from socio-economic deprivation or the challenges facing carers for example.

This will not only ensure legal compliance, but also help to ensure that services best support the healthcare needs of the local population.

Think of it as simply providing great customer service to everyone.

As a manager or someone who is involved in a service, policy, or process development, you are required to complete an Equality Impact Assessment using this toolkit.

Policy	A written statement of intent describing the broad approach or course of action the Trust is taking with a particular service or issue.
Service	A system or organisation that provides for a public need.
Process	Any of a group of related actions contributing to a larger action.

STEP 1 - EVIDENCE GATHERING

Name of person completing EIA:	**Sarrah Seldon**
Title of service/policy/process:	**Policy and process for development and management of PGDs for general practice that require SCCG authorisation**

Existing: √ **New/proposed:** □ **Changed:** □

What are the intended outcomes of this policy/service/process? Include outline of objectives and aims

This document outlines the process to be followed within Sunderland (SCCG) for the development and use of Patient Group Directions (PGDs). It gives practical guidance on the development of a PGD including details of the content, processes, responsibilities, monitoring and implementation, in order that the practice supported by the PGD documentation is within the law, and is ready in a form for authorisation.
The policy and supporting procedures and processes have been developed to meet the needs of general practices in SCCG.

Who will be affected by this policy/service /process? (please tick)

√ **Staff members**
√ **Other**

If other please state:

GPs, nurses, patients

What is your source of feedback/existing evidence? (please tick)

□ **National Reports** □ **Staff Profiles**
□ **Staff Surveys** □ **Complaints/Incidents**
□ **Focus Groups** √ **Previous EIAs**
□ **Other**

If other please state:

Evidence	What does it tell me? (about the existing policy/process? Is there anything suggest there may be challenges when designing something new?)
National Reports	
Staff Profiles	
Staff Surveys	
Complaints and Incidents	
Staff focus groups	
Previous EIA's	**The previous equality analysis screening tool was scored as having a neutral impact on each of the following equality groups: age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation, carers.**
Other evidence (please describe)	

STEP 2 - IMPACT ASSESSMENT
What impact will the new policy/system/process have on the following staff characteristics: (Please refer to the 'EIA Impact Questions to Ask' document for reference)
Age A person belonging to a particular age
Disability A person who has a physical or mental impairment, which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities
Gender reassignment (including transgender) Medical term for what transgender people often call gender-confirmation surgery; surgery to bring the primary and secondary sex characteristics of a transgender person's body into alignment with his or her internal self perception.
Marriage and civil partnership Marriage is defined as a union of a man and a woman (or, in some jurisdictions, two people of the same sex) as partners in a relationship. Same-sex couples can also have their relationships legally recognised as 'civil partnerships'. Civil partners must be treated the same as married couples on a wide range of legal matters
Pregnancy and maternity Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the period after the birth, and is linked to maternity leave in the employment context.
Race It refers to a group of people defined by their race, colour, and nationality, ethnic or national origins, including travelling communities.
Religion or belief Religion is defined as a particular system of faith and worship but belief includes religious and philosophical beliefs including lack of belief (e.g. Atheism). Generally, a belief should affect your life choices or the way you live for it to be included in the definition.
Sex/Gender A man or a woman.
Sexual orientation Whether a person's sexual attraction is towards their own sex, the opposite sex or to both sexes
Carers A family member or paid helper who regularly looks after a child or a sick, elderly, or disabled person

STEP 3 - ENGAGEMENT AND INVOLVEMENT
How have you engaged with staff in testing the policy or process proposals including the impact on protected characteristics?
This is a review of an existing policy; there was already a policy with a completed EIA in place.
Please state how staff engagement will take place:

STEP 4 - METHODS OF COMMUNICATION

What methods of communication do you plan to use to inform staff of the policy?
x Verbal – through focus groups and/or meetings **Verbal - Telephone** **Written – Letter** **Written – Leaflets/guidance booklets** **x Email x Internet** **Other**
If other please state:

STEP 5 - SUMMARY OF POTENTIAL CHALLENGES

Having considered the potential impact on the people accessing the service, policy or process please summarise the areas have been identified as needing action to avoid discrimination.

Potential Challenge	What problems/issues may this cause?
1 none	
2	
3	

STEP 6- ACTION PLAN

Ref no.	Potential Challenge/ Negative Impact	Protected Group Impacted (Age, Race etc)	Action(s) required	Expected Outcome	Owner	Timescale/ Completion date

Ref no.	Who have you consulted with for a solution? (users, other services, etc)	Person/ People to inform	How will you monitor and review whether the action is effective?

SIGN OFF

Completed by:	**Sarrah Seldon**
Date:	**22/11/2018**
Signed:	**Sarrah Seldon**
Presented to: (appropriate committee)	**SCCG Executive Committee**
Publication date:	

Application for development of a PGD

Practice name*:…….
Name and signature of senior medical representative completing the application*:……
Date:……..

Note - fields marked with an asterisk must be completed by the applicant.

PROPOSED USE	
PGD being requested (include details of the condition and medicine(s))*	
Specify the patient group you want to treat *	
Why is a PGD needed? *	
Is the medicines licensed in the UK for the proposed indication? *	
What assessment and monitoring of patient is required? *	
BACKGROUND INFORMATION	
Alternative treatment options	
Legal classification of the medicine	
Storage requirements*	
EVIDENCE OF CLINICAL EFFICACY	
Is this a standard treatment for the condition and patient group? *	
SAFETY DATA	
Contraindications	
Cautions	
Interactions with other drugs	
Side Effects	
Pregnancy and Breast Feeding	
Paediatric Use	
OTHER INFORMATION	
Dosage	
Excipients (of note)	
ASSESSMENT OF THE OPERATIONAL IMPLICATIONS AND STAFF RESOURCES*	
ASSESSMENT OF THE COST IMPLICATIONS	
REFERENCES	

SCCG PGD Template

NHS Sunderland Clinical Commissioning Group

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their practice to use it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the supply and/or administration[1] of

Name of medicine

by registered health professional group(s) for

Condition/situation/patient group

in location/service/organisation

Version number:

Change history

Version number	Change details	Date

[1] Delete as appropriate

PGD development

Name	Job title and organisation	Signature	Date
Lead author			
Lead doctor (or dentist)			
Lead pharmacist			
Representative of other professional group using PGD			
Other members of the PGD working group			

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor (or dentist)			
Senior pharmacist			
Senior representative of professional group using the PGD			
Person signing on behalf of authorising body			

PGD adoption by the GP practice

A senior medical representative at the practice must adopt the PGD for use in the practice and sign to accept responsibility for ensuring staff are appropriately trained and competent to use the PGD and that use is in-line with the PGD content.

Name	Job title and organisation	Signature	Date

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	
Initial training	
Competency assessment	
Ongoing training and competency	

Clinical condition

Clinical condition or situation to which this PGD applies	
Inclusion criteria	
Exclusion criteria	
Cautions (including any relevant action to be taken)	
Arrangements for referral for medical advice	
Action to be taken if patient excluded	
Action to be taken if patient declines treatment	

Details of the medicine

Name, form and strength of medicine *Include ▼for black triangle medicines*	
Legal category	
Indicate any off-label use (if relevant)	
Route/method of administration	
Dose and frequency	
Quantity to be administered and/or supplied	
Maximum or minimum treatment period	
Adverse effects	
Records to be kept	

Patient information

Written information to be given to patient or carer	
Follow-up advice to be given to patient or carer	

Appendices

Appendix A Key references

1. E.g. NICE guidance and the Summary of Product Characteristics
2.

Appendix B Health professionals' agreement to practise

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

Name of health professional	Signature	Senior medical representative authorising health professional	Date

Patient Group Direction Audit Forms

Patient Group Direction Audit Form 1 for use of SCCG member practices

Form for the audit of compliance with PGDs

Senior medical representative name			
Practice name			
Date of audit			
Tick as appropriate. If 'no', state action required	**Y**	**N**	**Comments**
For all PGDs:			
Do the managers listed on the PGD or PGDs hold a current list of authorised staff?			
Are all staff authorised to work under the PGD or PGDs members of one of the health professions listed in the PGD?			
Are you confident that all medicines supplied or administered under the PGD or PGDs are stored according to the PGD where this is specified?			
Do the staff working under the PGD or PGDs have a copy of the PGD which has governance sign off and is in date and, available for reference at the time of consultation?			
Where the medicine requires refrigeration. (Delete if not required).			
Is there a designated person responsible for ensuring that the cold chain is maintained?			
Is there a record that the fridge temperature has been monitored to required levels?			
The questions below refer to the two audit forms which follow:			
Was all the information completed on audit form 2 for staff records?			
Was all the information completed on audit form 3 for patient records?			

Patient Group Direction Audit form 2

Form for audit of completion of staff records for the following PGDs

	PGD drug name / number	Strength and formulation
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Staff ID	**Training specific to each PGD for which the staff member has signed up for, is up to date. (Yes or No)**	**Member of staff is a member of one of the health professions listed in the PGD(s) (Yes or No)**	**Name of staff member is on the master list of staff authorised to work under the PGD(s) and entry is dated (Yes or No)**	**Staff member eligible to authorise staff has signed the PGD(s) (Yes or No).**	**Comments.**
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Patient Group Direction Audit Form 3
Form for audit of completion of Patient Records for supply or administration under a PGD

Practice name and address	Number of times medicines given under PGD	Total number of PGD audits done	Total compliant	Total non-compliant

Signature of senior medical representative: _____
Date:_____

Details of non-compliant administration:

Reference	**Date**	**PGD number/ medication given**	**Description of Non compliance**	**Action**	**Open or closed**

Appendix 4

Commissioning of services that use Patient Group Directions

As part of any procurement process, potential new providers will be asked to provide details of any PGDs that will be used in service delivery and details of their internal arrangements/policies for the development and implementation of PGDs. When evaluating potential providers an assessment should be made of the appropriateness and robustness of its arrangement for PGDs.

As part of the mobilisation of the new provider, discussions will be needed to determine if the provider is able to authorise their own PGDs or if the CCG will need to authorise these. For example:

- NHS trusts – these are able to authorise PGDs in their own right and the CCG will only need to be provided with copies of the PGDs
- A CQC registered independent medical agency which has robust in-house processes for development and management of PGDs – the CCG is required to authorise the PGDs they will be using.

PGDs that need authorisation to support the mobilisation of a new contract or updated documents from existing providers must be provided at least 20 working days ahead of contract initiation/PGD expiry, to ensure that PGDs can be checked and authorised. Standard inclusions within specifications are suggested as follows:

- PGDs to be used in delivery of this contract will be specified within the tender response
- PGDs will be developed and used by the provider in line with legislation/best practice guidance and the provider will have a policy in place that describes their arrangements for the development and use of PGDs.
- PGDs to be used by this service will need to be authorised for use by an appropriate body. If the provider is not an authorised body, the CCG will authorise the PGDs for the service.
- The provider will be responsible for internal management, monitoring and review of PGD.
- The provider will be responsible for ensuring medicines supplied under PGD are purchased and handled in line with current medicines legislation and any medicine supplied to patients will be supplied in accordance with EC labelling and leaflet directive 92/27
- The provider will have a robust policy in place for the safe and secure handling of medicines.
- If any injectable medicines are administered using a PGD the provider will have in place a policy and procedures detailing their arrangements for management of anaphylaxis.
- The provider is responsible for ensuring all staff who sign to work under a PGD must be appropriately trained and competent.
- The provider must ensure governance arrangements should include a process for reporting patient safety incidents relating to PGD use.
- Disposal of any out of date medicines must be arranged by the service in line with Waste Regulations and by contractors licensed to handle pharmaceutical waste.
- Medicines must be stored according to manufacturer’s instructions in secure, lockable cabinets, medicines fridges with full records maintained of ordering, receipt and disposal. Arrangements should be in place to ensure suitable monitoring of temperature.

- Medicines used within the service must be ordered from an authorised wholesaler. If medicines are to be supplied to patients to take home they should be supplied in a form equivalent to a dispensed supplied i.e. be labelled with instructions for use, supplier name, patients name and date of supply. They must also include a product information leaflet.

As part of the procurement, the following is recommended to be requested:

- Provider should detail PGDs to be used in delivery of service
- Provider to supply copy of their Policy for development and management of PGDs
- Provider to supply copy of their Safe and Secure Handling of Medicines Policy
- Provider to supply their management of anaphylaxis guidance – if injectable medicines administered under PGD.