South East Coast Ambulance Service NHS
NHS Foundation Trust

Proposal, Development, Approval, Implementation and Review of Patient Group Directions (PGDs)

Standard Operating Procedure (SOP)

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1 Scope

1.1. Introduction

1.1.1 A PGD is the supply and/or administration of a specified medicine or medicines, by a named authorised health professional, to a well-defined group of patients requiring treatment for the condition described in the PGD.

1.1.2 The supply and/or administration of a medicine under a PGD is NOT a prescription or prescribing.

1.1.3 It is important that all staff involved with PGDs understand the scope and limitations of PGDs, as well as the wider context into which they fit to ensure safe and effective services for patients. This Standing Operating Procedure (SOP) encompasses the requirements for the proposal, development, approval, implementation, use and review of a PGD.

1.1.4 It provides a governance framework to ensure that development and practice of PGDs complies with the relevant legislation (i.e. The Human Medicines Regulations 2012) and relevant guidance for PGDs (i.e. NICE Medicines Practice Guideline (mpg2) Patient Group Directions (2013))

1.1.5 The SOP also provides practical guidance and a standard approach to PGDs to ensure quality of care and patient safety. By following the procedures contained in this SOP, it should ensure that all PGDs developed are appropriate, necessary, conform to National and South East Coast Ambulance Service NHS Foundation Trust (SECAmb) standards and that relevant aspects of the PGD use are considered (e.g. funding, training, storage, procurement, logistics, etc.).

1.2. Scope of SOP

1.2.1 This SOP is aimed at all registered health care professionals (e.g. paramedics, registered nurses) involved in the assessment of the need for, development and approval of, and the use of PGDs in SECAmb.

1.2.2 The SOP does not provide full details of the legal frameworks and national guidance for PGDs but does provide signposting to resources

2 Procedure

2.1. General principles

2.1.1 Any registered health care professional within SECAmb using a PGD must work with a PGD that has been developed and authorised by SECAmb. Clinical practice which does not comply with the criteria regarding PGD development, approval and use, will fall outside of the Law and could result in criminal prosecution under the Medicines Act 1968 and subsequent amendments.

2.1.2 Any extension to professional roles with regard to administration and supply of medicines must take into account the need to protect patient safety, ensure continuity of care and safeguard patient choice and convenience. It also has to be cost effective. PGDs should only be developed where there are clear benefits of improved patient care or organisational advantages, without any reduction in the quality of patient care and where use of a PGD is consistent with appropriate professional relationships and accountability (see Clinical Standards Scope of Practice Policy).

2.1.3 As specified in the regulations, only qualified, registered, health professionals can supply or administer medicines under a PGD. They can only do so as named individuals and cannot delegate the supply and administration of a medicine under a PGD. Instructions by a prescriber for individual patients DO NOT need a Patient Group Direction (as this is a Patient Specific Direction (PSD) i.e. prescribing).

2.1.4 Any registered health care professional working under a PGD must only do so within their professional competence and in accordance with their professional guidance.

2.2. Considerations for the need for a PGD

2.2.1 A PGD should only be developed, after careful consideration of all the potential methods of supply and/or administration of medicines. This should include how a patient will receive their medicines and whether a PGD is safe, legal and cost effective. Useful tools for use when considering whether a PGD should be developed include:

- ‘So You Think You Need A PGD?’
- ‘To PGD or not to PGD?’
- ‘Supply and Administration of Medicines: Are PGDs the Safest Route for Your Service?

2.2.2 The above tools are available on the National Health Service PGD website (see reference section for link).

2.2.3 PGDs are intended to allow improved access to medicines, particularly in the “see and treat” services, where there is a complete episode of unscheduled care.

2.2.4 PGDs have very specific limitations to their use as well as advantages. Points to consider include (see also Appendix A):

- Are the medicines involved well established? Only medicines with a UK Marketing Authorisation can be supplied and/or administered under a PGD. Use of medicines outside of the Marketing Authorisation, i.e. off label, under certain circumstances is allowed in PGD legislation but must be clearly justified by best clinical practice, supported by national guidance and have Trust approval. Any off-label use must be clearly stated in the PGD.

- Unlicensed medicines cannot be supplied or administered under PGD.

- The act of supply and/or administration cannot be delegated under a PGD.

- Do the conditions and treatments of the service provided fit pre-determined criteria? If not, then a PGD is not appropriate.

- PGDs are not suitable for situations or areas with a high usage of temporary staff.

- PGDs are not suitable where it will be difficult to monitor the use of the PGD.

- Significant dedicated resource is required from a number of highly qualified, competent registered health care professionals who should work as a multi-disciplinary team to propose, develop and review PGDs.

- What are the current competencies of registered health care professionals and is there appropriate training available to enable them to become authorised to use individual PGDs?

- Has funding been agreed for the purchase of medicines (if applicable)?

- Do you need to administer only, or do patients require a supply? If supplying then labelling and packaging must be considered.

- What links/referral routes are in place with other providers/prescribers?
- Are any controlled drugs involved? (Restrictions apply – see Appendix A).
- Is there sufficient demand or need for a PGD?

2.3. **Outline of the stages for the Proposal, Development, Approval, Implementation and Review of PGDs**

2.3.1 There are five stages to be considered in this SOP;

- Stage 1 – Proposal
- Stage 2 - Development and submission
- Stage 3 – Approval
- Stage 4 – Implementation, management and monitoring
- Stage 5 – Review and re-submission

These stages are summarised in the following flow chart and in more detail, at the beginning of each section.

South East Coast Ambulance Service NHS
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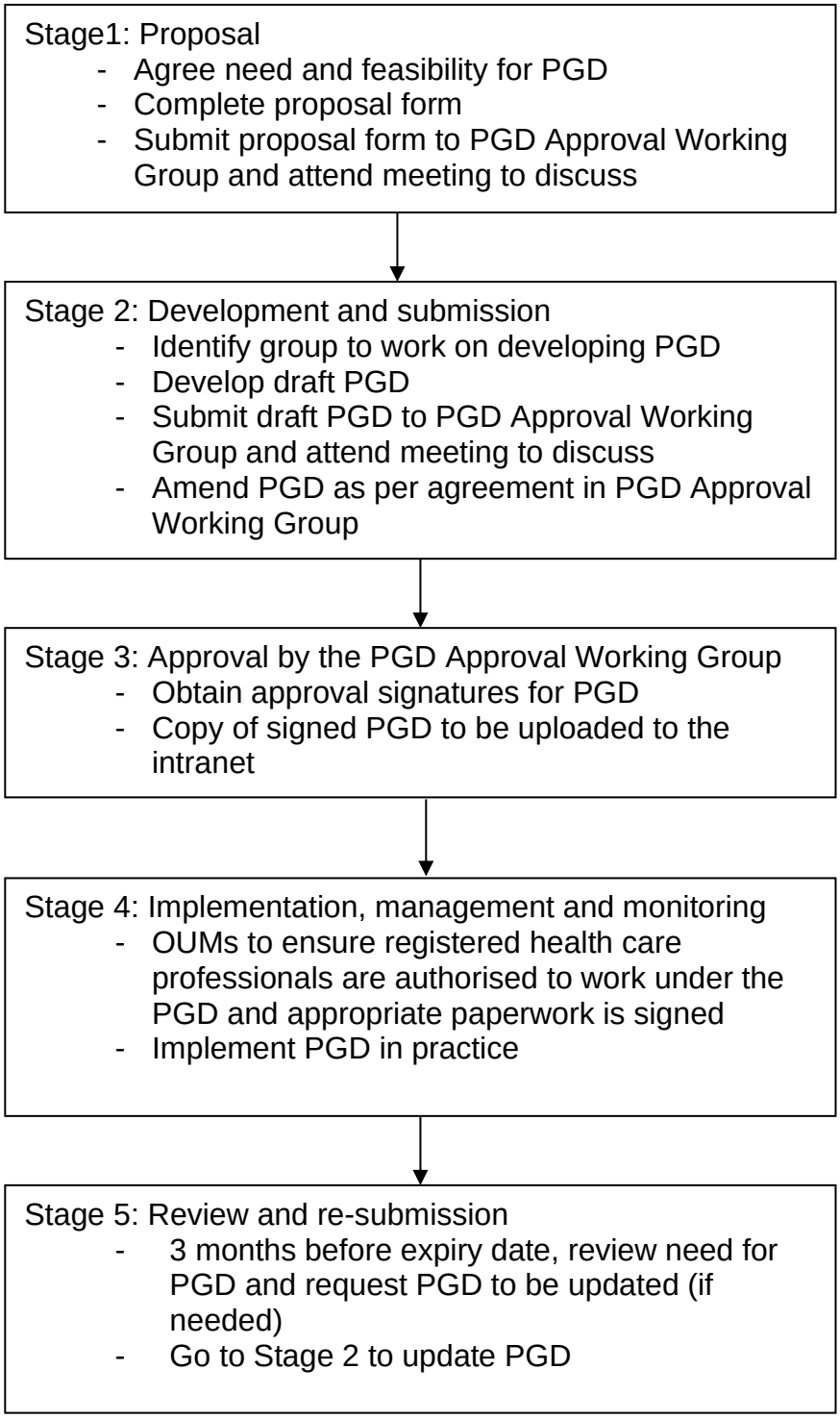
Stages for the Proposal, Development, Approval, Implementation and Review of PGDs - flow chart (overview summary of stages)

- **Each stage is explained in more detail in the following sections**



2.3.1.1 **STAGE 1: PGD proposal**

2.3.1.1.1 Before a PGD is written, a proposal must be developed to support the case that a PGD is the most appropriate method to administer and / or supply the medicine. Section 6 *References* includes some tools and resources that may help with decision making.

2.3.1.1.2 Potential quantities of medicines to be used and availability/costs of appropriately labelled packs must be calculated and the financial viability of the PGD must be confirmed in these circumstances.

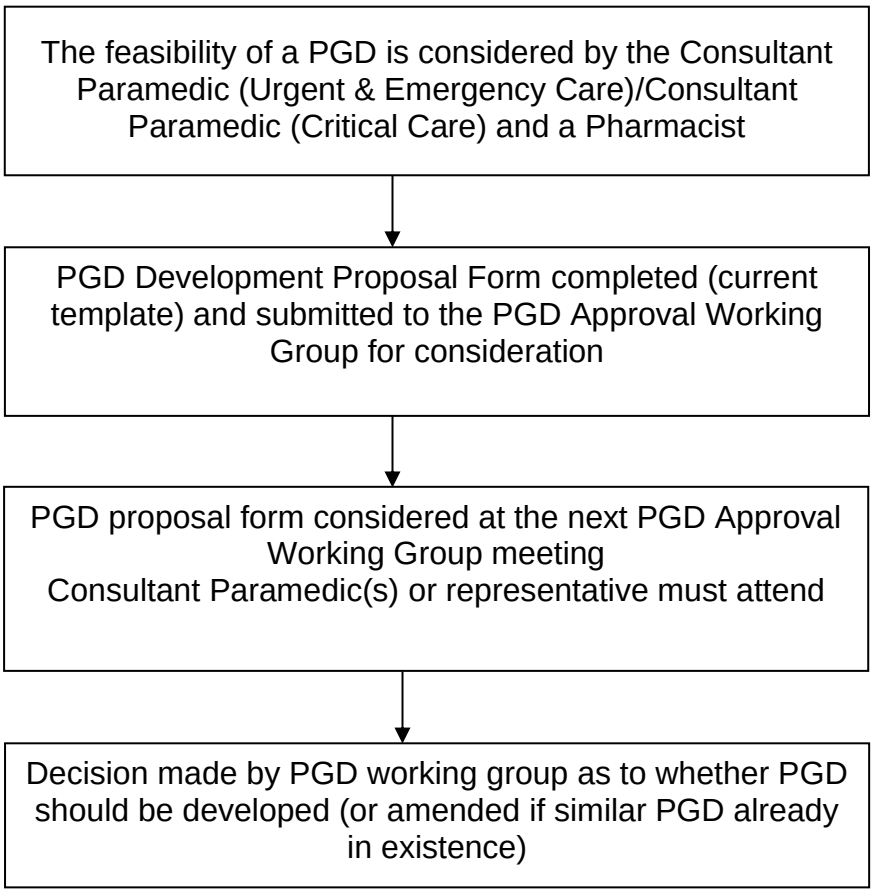
2.3.1.1.3 If a PGD is still deemed appropriate, the PGD Development Proposal Form must be completed (see Appendix B). The completed form must be submitted to the PGD Approval Working Group for consideration. Any PGD Development Proposal Form that has not been fully completed will be returned to the proposer for completion.

2.3.1.1.4 The PGD proposal form will be considered at the next available PGD Approval Working Group meeting, where the PGD Proposer/nominated lead author will be expected to attend to answer any questions on the PGD proposal and will present relevant evidence in support of the proposed PGD. This evidence must be of the highest standard, free from bias and support national guidance. Unless there is extenuating circumstances, if a member of the proposing team is not available, the request for the PGD will be deferred until they are able to attend.

2.3.1.1.5 The PGD Proposer / nominated lead author during the Proposal Stage must have a clear understanding and knowledge of the process for PGD development and implementation in the Trust, as well as an awareness of the law relating to PGDs. They will be a lead health care professional for the management and monitoring of the PGD once implemented. The proposer can be the lead author.

2.3.1.1.6 The following flowchart is a summary of actions required during the proposal stage.

Stage 1 PGD proposal flow chart



2.3.1.2 **STAGE 2: Development and submission**

2.3.1.2.1 PGDs must comply with all criteria specified below, as well as taking into account the approval procedure and individual responsibilities.

2.3.1.2.2 All PGDs will be allocated a unique reference code and version number and this will be stated on the first page and all footers of the PGD document (e.g. PGD-CCP001 v 1).

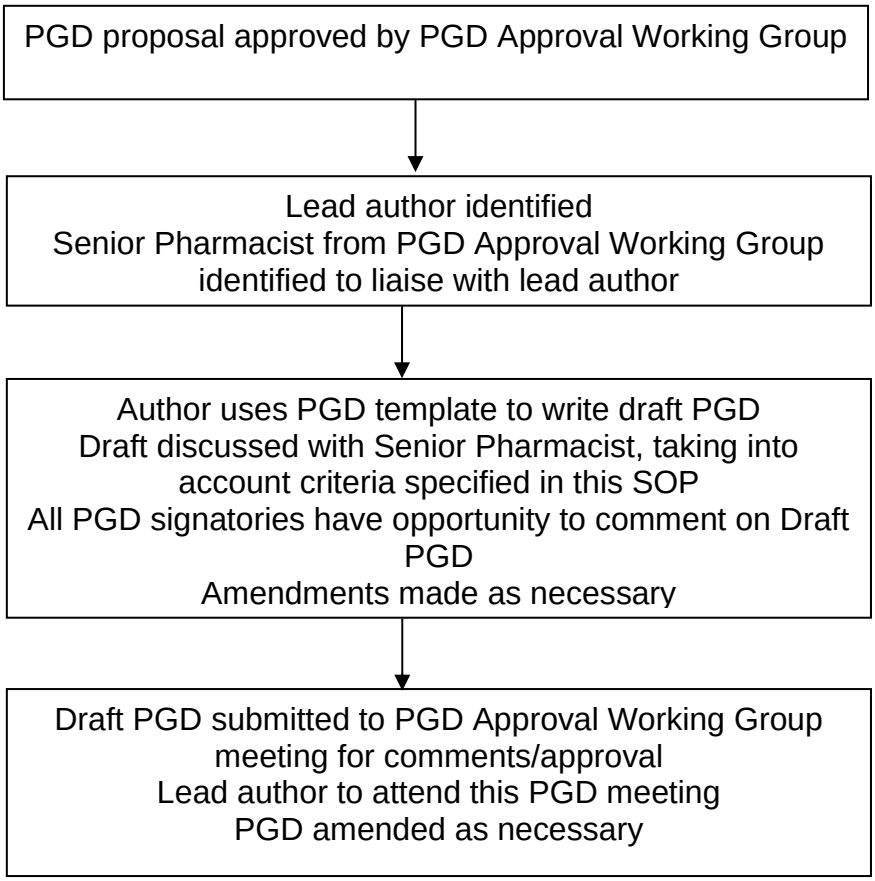
2.3.1.2.3 Usually a PGD document will be prepared for each single drug. More than one medicine can be included in a PGD, but all the requirements of the legislation must be included for each drug.

2.3.1.2.4 The contents of a PGD must include details as specified on the template PGD (available on the intranet)

2.3.1.2.5 It is the responsibility of the Consultant Paramedic (Urgent & Emergency Care)/Consultant Paramedic (Critical Care) to oversee the development of a PGD.

2.3.1.2.6 The following flowchart is a summary of actions required during the development and submission stage.

STAGE 2: Development and submission flow chart



2.3.1.3 **STAGE 3: Approval**

2.3.1.3.1 A PGD is not legal or considered to be approved for use until approval has been obtained from all those authorising the PGD and all the PGD signatories have signed the master copy.

2.3.1.3.2 Once all the authorisation signatures have been obtained, the PGD will be given a “Valid from” date of usually 4 to 8 weeks following approval, to allow any training to take place, for all PGD users to be signed up as authorised to use the PGD and to ensure access to the relevant medicines.

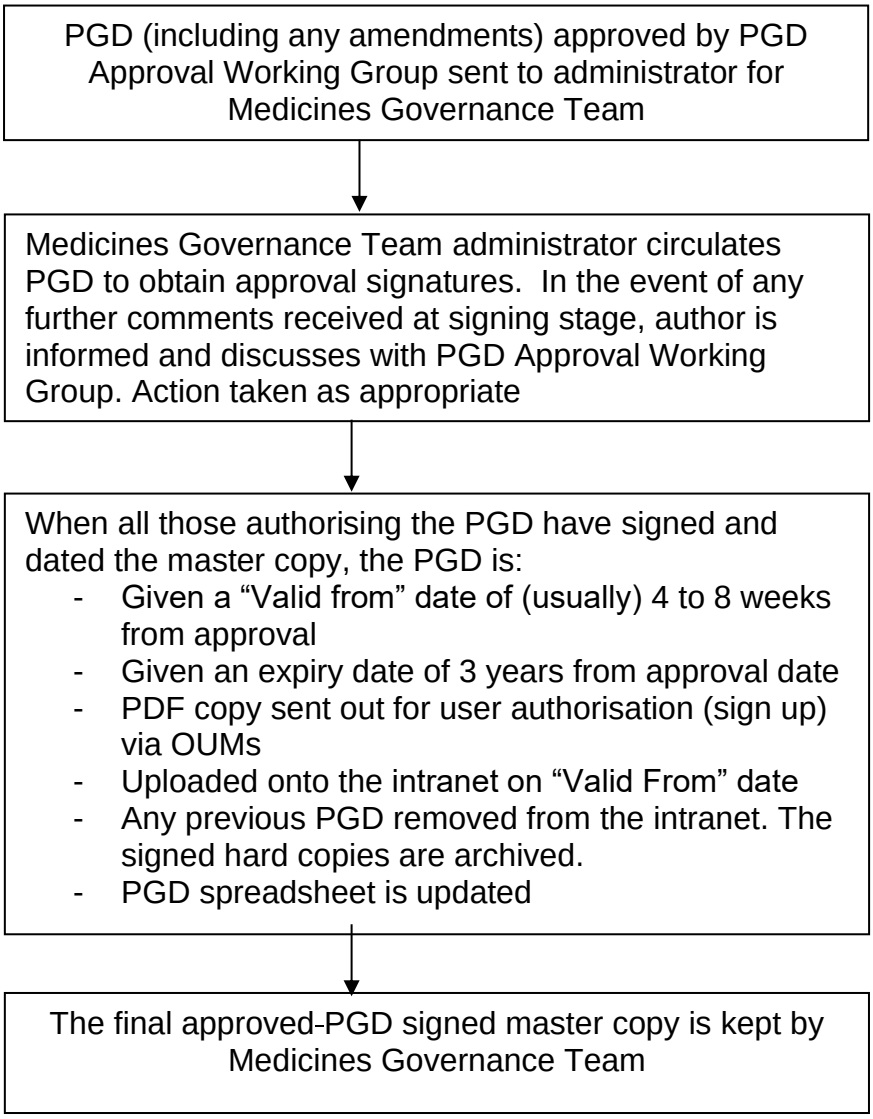
2.3.1.3.3 The Operational Unit Managers (OUMs), will be informed by the Medicines Governance Team when the final document has been approved and then, when this has been uploaded onto the intranet for

implementation. The OUMs will cascade this information to the Operational Team Leaders (OTLs).

2.3.1.3.4 Once the "Valid from" date has been reached, this PGD will immediately supersede any previous PGD version. The OUMs must ensure that any hard copies of the approved PGD shall be substituted as soon as possible for any previous PGD versions and a copy of the previous PGD is promptly placed in an archive file. This task can be delegated to the OTLs but the OUMs will retain overall responsibility.

2.3.1.3.5 **Only one version of a PGD can be in use at any one time within SECAmb.**

STAGE 3: Approval flow chart



2.3.1.4 **STAGE 4: PGD implementation, management and monitoring**

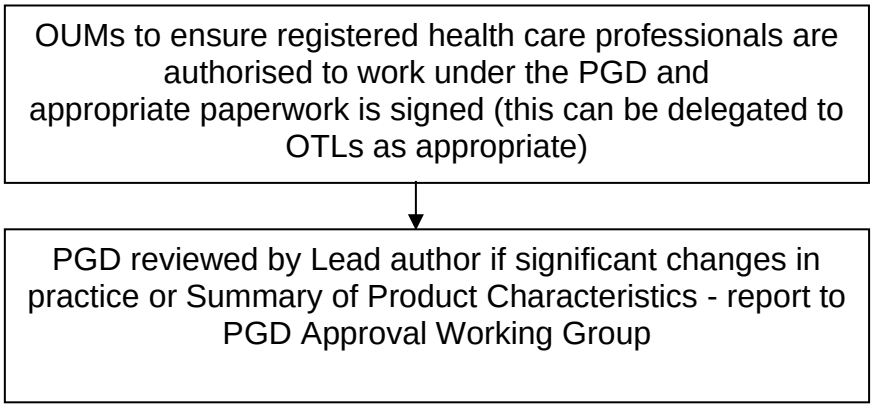
2.3.1.4.1 The OUMs must ensure that practitioners are authorised to work under the PGD and appropriate paperwork is signed (This may include electronic signature)

2.3.1.4.2 The OUMs must ensure the removal of names of any authorised practitioners from the service authorisation form that specifies who can work under the PGD for any of the following:

- Failure to provide relevant CPD evidence when requested e.g. for compulsory training.
- Failure to remain actively registered with their professional body.
- Where individual is under investigation for alleged poor professional standards.
- Professional voluntary request for removal.
- Practitioner leaves the Trust.

2.3.1.4.3 The following flowchart is a summary of the implementation, management and monitoring stage.

STAGE 4: PGD implementation, management and monitoring flowchart



2.3.1.4.4 **Training and Competency of Practitioners working under PGDs**

2.3.1.4.4.1 SECAmb is currently going through a journey where existing medicines systems and processes are being reviewed with the aim of improving these and moving towards a consolidation stage. General PGD training is currently available with mandatory PGD training and competency

assessment being planned (See Risk Register entry no. 268 on training and competency of registered health care professionals working under PGD).

2.3.1.4.4.2 All registered health care professionals working under PGD must self-declare that they are competent to use each PGD, that they are signed up as authorised to use. Self-declaration includes that they have the necessary clinical skills and knowledge for treatment of the conditions included and use of medicines involved in each PGD and that they have completed all relevant training as specified in each PGD.

2.3.1.4.4.3 Any registered health care professional working under a PGD must only do so within their professional competence and in accordance with their professional regulatory body.

2.3.1.4.4.4 Each PGD must detail any qualifications, training and competences required for staff to be authorised to work under the PGD.

2.3.1.4.4.5 The use of PGDs must also be consistent with appropriate professional relationships and accountability, i.e. registered health care professionals must act within their own expertise and competence with responsibility for keeping themselves up to date.

2.3.1.4.4.6 Registered health care professionals should be aware of any changes to the recommendations for the medicine listed and if necessary, bring these to the attention of the PGD Approval Working Group.

2.3.1.4.5 **General PGD training**

2.3.1.4.5.1 Training on general PGD information (not clinical) is available on the intranet in the form of a slide set with questions.

2.3.1.4.5.2 Each PGD user should have viewed, understood and answered the questions correctly in the General PGD Training slide set on the intranet. This is included in individual self-declaration of competence to use PGDs.

2.3.1.4.6 **Record keeping**

2.3.1.4.6.1 All registered health care professionals are required to keep accurate, legible, unambiguous and contemporaneous records of a patient's care, as specified in the PGD and in line with professional regulatory body standards.

2.3.1.4.6.2 **PGD documentation should be kept in line with Trust procedures. This may be as a Patient Clinical Record (PCR) or an ePCR (electronic Patient Clinical Record). A central archive of the signed**

master copy of each final approved PGD must be kept by the Medicine Governance Team.

2.3.1.4.6.3 Each OUM must keep archived copies of PGDs that practitioners have signed as authorised to use. Practitioners may keep copies of any PGD documents they have used for future reference; however, the PGDs must be clearly identified when no longer valid.

2.3.1.4.7 **Security, storage, and labelling of medicines included in PGDs**

2.3.1.4.7.1 There must be a system in place for secure storage and transport of medicines, according to the 'Summary of Product Characteristics' (SPC) of the product and the Medicines Policy. This includes maintenance of the 'cold chain' i.e. there is a system in place ensuring that any items requiring refrigeration are stored within $+2^0$C to $+8^0$C at all times.

2.3.1.4.7.2 There must be a system in place for recording and monitoring medicines supplied or administered to each individual patient.

2.3.1.4.7.3 Where medicines are supplied to patients, they should be in original packs or pre-packs made by a pharmacy, labelled according to legal requirements and must contain a patient information leaflet.

2.3.1.5 **Stage 5: Review and re-submission**

2.3.1.5.1 Approved PGDs, are allocated a unique reference number and given an expiry date of 3 years after the date of PGD approval.

2.3.1.5.2 The reviewed and approved PGD must be allocated a new expiry date and reference number as required in law.

2.3.1.5.3 A PGD may require review and re-approval earlier due to:

- Gaps in service delivery e.g. other registered health care professionals required to be included in the PGD scope e.g. Nurses.
- Guideline or SPC changes e.g. significant change in the SPC.
- Any change in pack size, availability or brand of medicine to be supplied.
- Any change in use of the medicine e.g. need to include/exclude a patient group.

2.3.1.5.4 If there are any changes to a PGD, it will need to be re-authorised before it can be used.

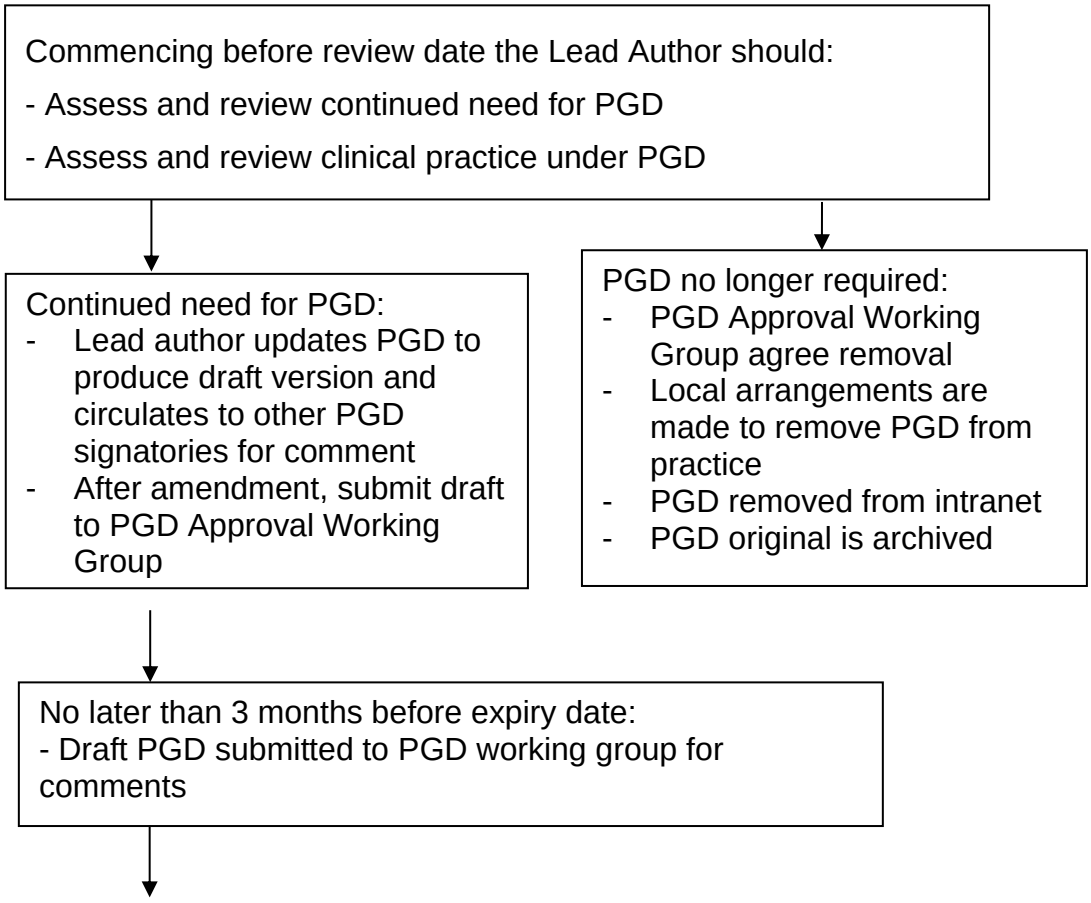
2.3.1.5.5 In very exceptional circumstances, the PGD Approval Working Group may be requested to consider an extension period of the expiry date. This must be supported by reasons for the delay in re-submission of the PGD and substantial evidence that there have been no major changes to clinical practice under the PGD. Any expiry date extension granted by the PGD Approval Working Group will be on condition that the PGD is under review and will be submitted in an agreed timeframe.

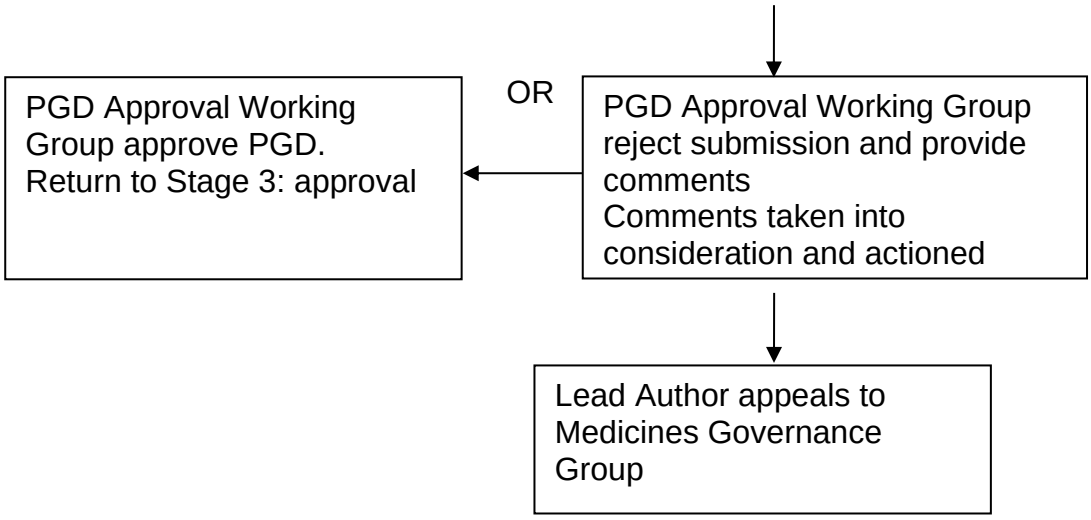
2.3.1.5.6 This process must be supported by an extension letter referencing the PGD being extended, the extension period and the reasons for the extension. The letter must be signed and dated by all signatories required for PGD approval before the expired/ extended PGD can be used. A copy of the extension letter must be added to the intranet with the PGD and a hard copy must be attached to all hard copies of the PGD in use.

2.3.1.5.7 All registered health care professionals authorised to use the PGD must be informed of the extension and the process to be followed.

2.3.1.5.8 See below for a flow chart summary of actions required for review and re-submission.

Stage 5: Review and re-submission flow chart





2.4 **PGD Audit**

See Appendix C for an example of a PGD Audit template that could be used to audit a PGD.

2.5 **Adopting Nationally Approved PGDs**

2.5.1 PGDs which have been developed and approved nationally e.g. influenza vaccine PGD from Public Health England, can be adopted for use in SECAmb following discussion and agreement by the PGD Approval Working Group.

2.5.2 These PGDs have already been developed, approved and signed off by a senior doctor, senior pharmacist and professional Lead from a national body but in order to be authorised for use in SECAmb, the following must be obtained:

- Name, job title and signature of the Governance Lead authorising the PGD on behalf of SECAmb (Organisational authorisation signature). This is a legal requirement
- Name, job title and signature of SECAmb PGD Approval Working Group Chair (on behalf of the PGD Group where the PGD was agreed for adoption).
- Name and signature of SECAmb Medical Director.

2.6 **Withdrawal of a PGD**

2.6.1 A PGD may be withdrawn before it has reached the expiry date due to:

- A change in information that would warrant the withdrawal of the PGD
- An error is made in the production of the PGD that would necessitate the withdrawal (e.g. incorrect dose information).
- Removal of that medicine from the formulary e.g. change to a different medicine (and different PGD)

2.6.2 If a PGD needs to be withdrawn, the process in Appendix D: Guidance on Withdrawal of a PGD, should be followed.

2.7 **Awareness, Training and Implementation**

2.7.1 Staff involved in the handling of medicines must be appropriately trained with regard to safety and security of medicines. Registered health care professionals must not work under a PGD unless they are competent to do so.

2.7.2 When a PGD is approved, there will be a period of time from when the PGD was approved and the "Valid from" date of usually 4 to 8 weeks following approval, to allow any training to take place, for all PGD users to self-declare themselves as competent to use the PGD and to ensure access to the relevant medicines.

2.8 **Definitions**:

Patient Group Direction (PGD)	A specific written instruction for the supply and / or administration of named medicine in an identified clinical situation. It is developed by a multi-disciplinary team (including a doctor, pharmacist and representative of any professional group expected to work under the PGD). It must have been approved as specified in this document. It applies to groups of patients who may not be individually identified before presentation or treatment.
Patient Specific Direction (PSD)	An instruction from a prescriber to administer a medicine to an individually named patient where the

	patient has been individually assessed by that prescriber.
UK Marketing Authorisation	By law, before a medicine can be placed on the market, it must be given a marketing authorisation (product licence) by a medicines regulator. The UK regulator is the Medicines and Healthcare products Regulatory Agency (MHRA).
Marketing Authorisation (Licensed) Indication	Treatment purpose for which a product may be used under the terms of the marketing authorisation granted by the Licensing Authority.
Off Label use	Using a UK licensed medicine outside the terms of its marketing authorisation, such as outside the defined indications, doses or routes of administration.
General Sales List (GSL) medicine	A medicine that can be sold in general retail outlets (such as supermarkets) without the supervision of a pharmacist. These medicines must be intact in original packaging and often have restricted pack sizes e.g. Paracetamol packs containing 16 tablets. A PGD is not required for administration or supply of a GSL medicine (a protocol can be used to ensure a governance framework) but can be used if decided by the Trust.
Pharmacy (P) medicine	Any medicinal product other than those designated as GSL or POM products. Pharmacy medicines can be sold or supplied from registered pharmacy by or under the supervision of a pharmacist, subject to certain exceptions. A PGD is required for supply of Pharmacy (P) medicines. A PGD is not required for administration of Pharmacy (P) medicines (a protocol can be used to ensure a governance framework) but can be used if decided by the Trust.
Prescription-Only-Medicine (POM)	A medicinal product which may only be sold or supplied against the signed prescription of an appropriate prescriber e.g., UK registered doctor, dentist, independent or supplementary prescriber and some nurses specified in the Prescriptions Only Medicines (Human Use) Order 1997. The exceptions to this are for emergency medicines used for the purpose of saving a life (see Appendix A) and exemptions to Medicines Act for podiatrists.

	In addition, a PGD can be used for administration and/or supply of certain Prescription Only Medicines in accordance with legislation (see also PGD above)

3 Responsibilities

3.1. PGD Signatories (i.e. signing the PGD as approved for use)

3.1.1 Senior Representative of Profession using the PGD (Consultant Paramedic/ Consultant Paramedic Critical Care)

Is responsible for ensuring that:

- Development of PGDs is overseen
- Relevant PGDs are reviewed in a timely manner
- Systems for review of adverse events and patient complaints relating to the use of PGDs are in place.
- There is an individual keeping track of the PGDs in use in their area.
- All PGDs in use in their area are up to date and valid. PGDs have a specific review date and are reviewed at a maximum of every 3 years, or earlier if required.
- All authorised practitioners have access to a copy of the PGD (as well as any associated reading material).
- The responsibilities of this role can be delegated, as appropriate.

3.1.2 Senior Doctor (Medical Director)

- Is aware of responsibilities and duties as stated in this Trust SOP for the proposal, development, review, approval and implementation of PGDs, as per NICE guidance.
- Ensures that there has been full and careful consideration of all the potential methods of supply and/or administration of medicines, before agreeing to the PGD proposal.
- Is responsible for the provision of medical advice and support, including advice on the feasibility of the PGD with reference to the most appropriate options for clinical care and associated clinical guidelines.

- Establishes that the clinical and pharmaceutical content is accurate and supported by the best available evidence.
- Takes joint responsibility and accountability with the Senior Pharmacist for the accuracy of both the clinical and pharmaceutical content of the PGD.
- Approves the PGD.
- Considers any changes in related local/national policies or guidelines and flags the need for review (or withdrawal from practice) of the PGD with the lead author and PGD Approval Working Group.

3.1.3 **Senior Pharmacist (Chief Pharmacist)**

- Is aware of responsibilities and duties as stated in this Trust SOP for the proposal, development, review, approval and implementation of PGDs, as per NICE guidance.
- Ensures that there has been full and careful consideration of all the potential methods of supply and/or administration of medicines, before agreeing to the PGD proposal.
- Establishes that the clinical and pharmaceutical content is accurate and supported by the best available evidence.
- Takes joint responsibility and accountability with the Senior Doctor for the accuracy of both the clinical and pharmaceutical content of the PGD.
- Approves the PGD.
- Considers any changes in related local/national policies or guidelines and flags the need for review (or withdrawal from practice) of the PGD with the lead author and PGD Approval Working Group.
- Is responsible for ensuring that the most up to date version of the PGD and associated document(s) is posted on the South East Coast Ambulance Service NHS Foundation Trust intranet.
- Organises the storage of the original signed hard copies of the PGDs

3.1.4 **Organisational Authorisation signatory (Director of Quality and Safety)**

- Is responsible for authorising all PGD documents to authorise their use in South East Coast Ambulance Service NHS Foundation Trust (SECAmb).
- When signing a PGD on behalf of SECAmb, has established that local processes and governance arrangements have been followed for PGDs and governance framework is in place
- All legal requirements have been met

3.2. Operational Unit Managers (OUMs)

OUMs are responsible for:

- Alerting users of the PGD to any version changes.
- Keeping a clear record of all users who have self-declared as competent and are signed up as authorised to use each PGD. PGD records should be available to audit at any time.
- Ensuring that any hard copies of PGDs that have been superseded are substituted (and archived) as soon as possible for the current approved PGD
- Keeping archived copies of PGDs that practitioners have signed as authorised to use

3.3. Individual Responsibilities for PGD Users

Authorised registered health care professionals (Paramedics, Paramedic Practitioners, Critical Care Paramedics and Nurses)

- All authorised registered health care professionals administering and/or supplying medicines under PGD must be named and have evidence of competence (self-declaration), training, knowledge, experience and continuing education relevant to the clinical conditions/situation to which the PGD applies.

- If a registered health care professional becomes authorised to work under PGD, it is the responsibility of that practitioner to ensure that the authorisation form has been signed.

- The authorised registered health care professional must only supply or administer medicines under PGD in accordance with the appropriate current PGD documentation. Only SECAmb approved PGDs may be used by SECAmb authorised registered health care professionals – use of PGDs approved by other organisations is not legal practice and is strictly forbidden.

- All registered health care professionals must be aware of their roles and responsibilities under the current legislation and adhere to the safe practices outlined in the SECAmb Medicines Policy.

- Any registered health care professional working under a PGD must only do so within their professional competence and in accordance with their code of Professional Conduct.

- Any errors and incidents relating to administration and supply of medicines using a PGD by an authorised practitioner should be reported in the usual manner.

4 Audit and Review

4.1 The PGD Approval Working Group will:
Review this SOP, once every three years or sooner, should there be a change to relevant legislation, new codes of practice or national standards.

4.2 Provide a summary of the main actions of the PGD Approval Working Group to the Medicines Governance Group.

4.3 Keep a record of any PGD Development Proposal forms that are incomplete or inappropriately completed on submission. This information will be used to amend the forms if required.

4.4 Ensure that all PGDs produced under this SOP meet the standards set out in legislation. How the principles of the document will be audited (include frequency and what action will be taken if non-compliance is identified) and who will review the document to ensure it is meeting its aims and objectives.

5 References

National Institute for Care and Health Excellence (NICE) Patient Group Directions Overview. Available at: http://pathways.nice.org.uk/pathways/patient-group-directions *(accessed 05.10.17).*

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National Health Service PGD Website: 'So You Think You Need A PGD?' / To PGD or not to PGD?' / "Are PGDs the Safest Route for Your Service? / Is a PGD appropriate?" Available at: http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/About-us/ *(accessed 05.10.17).*

6 Glossary

P	Paramedic
PP	Paramedic Practitioner
CCP	Critical Care
OUM	Operational Unit Manager
OTL	Operational Team Leader
RN	Registered Nurse
HCPC	Health and Care Professions Council

NMC	Nursing and Midwifery Council
SPC	Summary of Product Characteristics

Appendix A: Medicines which should not (or need not) be included in PGDs or have restricted use in PGDs

(see individual bullet points for special circumstances):

- Unlicensed medicines (i.e. does not have a licence (Marketing Authorisation) in the UK)
- Black triangle medicines (i.e. those recently licensed and subject to special reporting arrangements for adverse reactions) should only be included in PGDs in exceptional circumstances, justified by current best clinical practice or national guidance. The PGD should clearly describe the status of the product.
- Off-label use i.e. medicines used outside the terms of the Marketing Authorisation (as seen in the summary of product characteristics (SPC)) should only be included in PGDs in exceptional circumstances, justified by current best clinical practice or national guidance. The PGD should specify that the medicine is being used outside of the terms of the SPC and why this use is necessary.
- Controlled drugs (CDs) have restricted use in PGDs. The following CDs can be used:
    - Diamorphine and Morphine (Registered nurses only)
    - Ketamine (schedule 2)
    - Midazolam (schedule 3)
    - Schedule 4 CDs (but not anabolic steroids)
    - Schedule 5 CDs
- Antimicrobials are restricted for use only where a local antimicrobial specialist (e.g. Consultant microbiologist) is involved in drawing up a PGD that includes any antimicrobial to ensure that strategies to reduce resistance are not jeopardised.
- Medicines included in Schedule 17 in the Human Medicines Regulations 2012 allows paramedics registered with the HCPC to administer those medicines by injection for the immediate, necessary treatment of sick or injured persons (therefore PGD not needed for paramedics using those medicines) if competent to do so)
- Medicines included in Schedule 19 in the Human Medicines Regulations 2012 can be administered by injection by anyone for the purpose of saving a life (therefore a PGD is not needed in those circumstances)
- General Sales List (GSL) medicines (PGD not needed for administration or supply, consider using a protocol or guidelines to ensure use is within a governance framework).
- Pharmacy (P) Medicines for administration only (not supply) – (PGD not needed, consider using a protocol or guidelines to ensure use is within a governance framework)
- Appliances and dressings (cannot be supplied and administered under PGD, as PGDs only apply to licensed medicines). For appliances and dressings, use a protocol or guidelines.

- Administration of radiopharmaceuticals must not be included in PGDs

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Appendix B - Patient Group Direction (PGD) Development Proposal Form

This form must be completed and submitted for approval by the SECAmb PGD Approval Working Group prior to development of any new PGD.

Title of proposed PGD:

……

Name of proposer and job title/role: ……

Please give details of the situation requiring a PGD:

……

……

……

Drug to be supplied / administered that the PGD is required for (one drug per form) including strength, form & route (where appropriate):

……

Is drug approved for use in SECAmb (in drug formulary)? YES / NO / UNSURE
(Delete as appropriate)

Indication / Clinical situation for its use:

……

Does a PGD for this drug currently exist in the Trust? YES / NO / UNSURE
(Delete as appropriate)

Staff group wishing to use the PGD: P/ PP/ CCP/ RN
(Delete as appropriate)

……

Benefits to patient care offered by using PGD:

……

……

Potential risks to patient safety:

……..

……..

Please supply supporting evidence for the use of the PGD requested (e.g. where the PGD is used in other pre-hospital settings)

……

……

Please note: PGD proposer must attend the PGD Approval Working Group to discuss this proposal

Outcome will be recorded in the PGD Approval Working Group Minutes.

Please return this form to Medicines Governance Team Administrator for submission to and consideration by the PGD Approval Working Group.

Appendix C: Patient Group Direction (PGD) Audit Report

PGD Audited (name & ref):

Date Audit conducted:
Period of Audit:

Person conducting audit:

Number of issues in audit period:
Total number of uses in 1 year:

Audit sample:

Issue type	Number	Percentage
Prescription (Not SECAmb)		
PSD (Not SECAmb)		
PGD		

PGD Utilised
Total included:

Criteria	Standard set	Number	Standard at audit
1. PGD details			
Is the PGD in date?	100%		
Is a copy of the PGD available on the intranet?	100%		
2. Practitioner details			
Does the practitioner meet the criteria for staff group and qualifications as specified in the PGD?	100%		
Has the practitioner been authorised to work under this PGD?	100%		
3. Clinical condition			
The clinical condition recorded is the same as specified in the PGD?	100%		
4. Treatment			
The medicine given is the same as stated in PGD?	100%		
Has the dose as specified in the PGD been given?	100%		
5. Records made			
Name of the medicine?	100%		
Dose of medicine? (If appropriate)	100%		

Name of manufacturer of medicine?	100%		
Batch number & expiry date?	100%		
Patient consent indicated?	100%		
Name of practitioner?	100%		
Practitioner's signature?	100%		
Date?	100%		
6. Patient information			
Has verbal advice to patient been given and recorded?	100%		

Discussion
Precise on audit findings

Recommendations / Action Plan

- Bullet point any recommendations/Actions

Appendix D - Guidance for withdrawal of a PGD from SECAmb

A PGD may have to be withdrawn due to:

- A change in information that would warrant the withdrawal of the PGD.
- If an error is made in the production of the PGD that would necessitate the withdrawal. (The process for developing PGDs should minimise the risk of an error occurring).
- Removal of that medicine from the formulary e.g. change to a different medicine (and different PGD)

If a PGD needs to be withdrawn, the following actions should be taken:

1. In order to avoid delay, a member of the Medicines Governance Team in the PGD Approval Working Group, who is made aware of the issue, should take the necessary action to withdraw the PGD. If such a person is not available then another PGD Approval Working Group member (e.g. Deputy Chair) should be contacted.

2. Discuss with the relevant Consultant Paramedic in the area where the PGD is being used to agree an action plan, in consultation with SECAmb Medical Director.

3. If agreed in the action plan, email the appropriate OUMs, stating the withdrawal of the PGD and the reason. Explain that any previous PGDs cannot be used instead of the withdrawn PGD and the withdrawn PGD cannot be used in the future. The OUMs should be made aware that it is their responsibility to cascade information to the OTLs and relevant users of the withdrawn PGD.

4. Complete a Trust incident form, if appropriate (e.g. wrong dose in PGD document)

5. Record the details of actions taken. The record should include written confirmation of agreed action points (if verbal follow up in writing) to provide clarity and an audit trail.

6. Organise the development of a replacement PGD, if appropriate.