

PATIENT GROUP DIRECTIONS

**To be read in conjunction with the Medicines Policy
and the Controlled Drugs Policy**

(Medicines Management Reference MO2)

Policy

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1.0 INTRODUCTION

- 1.1. This document outlines the process to be followed within the Trust for the development and implementation of Patient Group Directions (PGDs) to ensure that the practice it supports is within the law and has the approval of the Trust.
- 1.2. Modifications to the Medicines Act 1968 in 2000 formalised previous practices where supply and / or administration of medicines to certain patients under what were previously known as 'group protocols' the legal term for such became 'Patient Group Directions'.
- 1.3. The Human Medicines Regulations 2012 (as amended) consolidated the law concerning medical products for human use, including a majority of the legislation pertaining to PGDs, replacing most of the Medicines Act 1968 and a number of statutory instruments.
- 1.4. Patient Group Directions are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.
- 1.5. PGDs provide a legal framework that allows the supply and/or administration of a specified medicine(s), by named, authorised, registered health professionals, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber. Using a PGD is not a form of prescribing.
- 1.6. The purpose of using a PGD is to:
 - deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety
 - offer a significant advantage to patient care by improving access to appropriate medicines
 - provide equity in the availability and quality of services when other options for supplying and / or administering medicines are not available
 - provide a safe legal framework to protect patients
 - reduce delays in treatment
 - maximise the use of the skills of a range of health professionals.
- 1.7. This policy applies to all Trust staff who may:
 - assess the need for a Patient Group Direction within their service
 - develop a Patient Group Direction legally supply or administer medicines under a Patient Group Direction.

2.0 DEFINITIONS

2.1 **Patient Group Direction** is defined under Health Service Circular (HSC 2000/26) and can be defined as:

“a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is developed locally by doctors, pharmacists and other appropriate professionals, approved by the employer and 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.”

2.2 A Patient Group Direction is NOT an authorisation to prescribe. It is NOT Non-medical Prescribing.

2.3 A PGD must not be confused with a written direction as defined under the Medicines Act 1968 and the Prescription Only Medicine (Human Use) Order 1997 (SI 1997/1830) which is a Patient Specific Direction (PSD).

2.4 An authorised practitioner can be defined as:

A registered professional who is legally allowed to supply or administer medication under a Patient Group Direction, who has completed the Trust approved PGD training package, been assessed as competent in both the legal aspects of PGDs and the individual PGD as well as being authorised by their line manager to use an individual PGD.

2.5 The roles and functions of the ‘PGD working group’, as defined under the relevant NICE Medicines Practice Guidance, is undertaken by the PGD Review Group and is a locally determined multidisciplinary group established for each individual PGD. The PGD Review Group is responsible for developing the PGD and its subsequent review and updating.

2.6 The roles and functions of the ‘PGD approval group’, as defined under the relevant NICE Medicines Practice Guidance, is undertaken by the Medicines Oversight Group and is a locally determined multidisciplinary group that considers and ratifies a proposed PGD on behalf of the Trust.

3.0 DUTIES AND RESPONSIBILITIES

3.1 The **Trust Board** has a duty to care for patients receiving care and treatment from the Trust and has overall responsibility for procedural documents and delegates responsibility as appropriate.

3.2 The **Lead Director** is the **Chief Medical Officer** with devolved responsibility for the implementation of this policy.

3.3 The **Medical Director for Integrated and Community Care** has delegated authority from the Chief Medical Officer to act as the authorising signatory for approved PGDs to validate organisational approval.

3.4 The **Medical Director for Integrated and Community Care** is the nominated senior doctor employed by the Trust and is one of the final statutory authorising signatories for approved PGDs.

- 3.5 The **Chief Pharmacist** or their nominated senior pharmacist employed by the Trust is responsible as one of the final statutory authorising signatories for approved PGDs.
- 3.6 The **Consultant Medical Microbiologist** is the microbiologist approved by the Trust for statutorily required contribution to development of PGDs for antimicrobial agents and as one of the final authorising signatories for approved PGDs for antimicrobial agents.
- 3.7 The **Identified Lead (Author)** will be responsible for producing written drafts of the document and for consulting with others and amending the draft as appropriate.
- 3.8 **Service Directors / Senior Managers** have responsibility for implementing this policy and for ensuring high standards of clinical healthcare within the service for which they have overall responsibility and to ensure adherence to this policy.
- 3.9 **Line Managers** will ensure that staff adhere to this policy and are appropriately trained and competency assessed according to the policy.
- 3.10 Before a healthcare professional can supply or administer medicines under a specific patient group direction they must be “authorised” by their **line manager** and named in the patient group direction held within the area of practice.
- 3.11 To authorise a healthcare professional to use a PGD the **line manager** must:
- agree to operate in this extended role
 - have completed the Trust Patient Group Direction training
 - have written evidence of competence, training, knowledge, experience and continuing education relevant to the clinical conditions/situation to which the Patient Group Direction applies.
- 3.12 **All staff including temporary staff** are individually responsible for their actions including complying with this policy and undertaking any training and competency assessments in line with this policy.
- 3.13 It must be acknowledged by all members of staff that the interests and safety of every patient are paramount.
- 3.14 The extended role, with regard to administration and supply under PGDs, is not compulsory and each practitioner has the ability to exercise personal and professional judgement as to whether to accept the responsibility that the extended role will place upon them.
- 3.15 All **authorised practitioners** must only undertake the extended role under PGDs in circumstances where they are competent to assess all relevant aspects of the patient’s clinical condition and take responsibility for supply, administration and related decisions.
- No **authorised practitioner** should undertake any aspect of patient care for which they are not trained and which is beyond their professional scope of practice. If the authorised practitioner is in any doubt about their competency they should not administer or supply in accordance with the PGDs and should seek advice.

- The **authorised practitioner** undertaking this extended role must do so in accordance with the appropriate current PGD.
- All **authorised practitioners** must act within their Professional Code of Conduct, be trained and assessed as competent in the use of PGDs.

NOTE: An authorised practitioner’s delegated authority to supply and administer under a PGD cannot be re-delegated.

- 3.16 The **appropriate professional lead** is responsible for ensuring that only fully competent, qualified and trained healthcare professionals operate within a PGD.
- 3.17 **PGD authors** are responsible for ensuring that they have the appropriate training and theory competency to undertake this role. This requires completion of the Trust PGD Training Package and the theory component of the PGD Competency Assessment.
- 3.18 The **Patient Group Direction Review Group** has the role and function of a ‘PGD working group’ (as defined by NICE MPG2) and are responsible for the management of the review and updating of PGD process.
- 3.19 The **Medicines Oversight Group** acts on behalf of the Trust Board to ratify a PGD after all the legal requirements for authorisation have been made and act as the ‘PGD approval group’ (as defined by NICE MPG2).

4.0 PROCESS DESCRIPTION

4.1 Appropriate Use of PGDs

- 4.1.1 The majority of clinical care should be provided on an individual patient specific basis. The supply and administration of medicines under Patient Group Direction should be reserved for those limited situations where this offers an advantage to patient care without compromising patient safety and be consistent with appropriate professional relationships and accountability (NICE Medicines Practice Guidance (MPG2): Patient Group Directions (Aug-13) as amended).
- 4.1.2 PGDs apply only to licensed medicines. Appliances and dressings can not be supplied or administered under a PGD. Although not legally required the Trust may, in exceptional circumstances, make a clinical governance decision to develop a PGD for:
- a medical device where that device contains a medicinal product
 - administration of a GSL (General Sales List) or P (Pharmacy only) medicine or a medical gas
 - supply of a GSL medicine.
- 4.1.3 The following drugs should **not** be included in Patient Group Directions:
- medicines unlicensed in the UK
 - radiopharmaceuticals
 - medicines which are not approved for use within the Trust

- **administration or supply** of Schedule 2 or 3 Controlled Drugs (for exceptions see 4.1.4)
 - where exemptions from medicines legislation obviate the need for PSDs or PGDs
- 4.1.4 The following drugs can be included in Patient Group Directions in the circumstances outlined below:
- new drugs under intensive monitoring and subject to special adverse drug reaction reporting requirements ('Black Triangle drugs' ▼) – use must be supported by current best clinical practice. The PGD must state that a black triangle medicine is included and should refer to any supporting guidelines / written evidence
 - medicines being used outside their licensed indications ('off-label indications') only when the indication is justified by current best practice as described in other Trust documentation, NICE guidance, or other nationally recognised guidance.
 - morphine and diamorphine injection (Schedule 2 CDs) – **administration** by a nurse or pharmacist for the immediate necessary treatment of sick or injured persons
 - midazolam (Schedule 3 CD) and schedule 4 Part 1 CDs – oral preparations only, not an anabolic steroid and not for the treatment of addiction.
- 4.1.5 The inclusion of antimicrobial agents in a Patient Group Direction must be absolutely necessary and not jeopardise strategies to combat increasing resistance. A Consultant Microbiologist must be part of the multidisciplinary group developing the Patient Group Direction where it includes antimicrobial therapies.
- 4.2 All registered health care professionals groups that are authorised under Schedule 16 Part 4 of the Human Medicines Regulations 2012 (as amended) are permitted to supply or administer medicines under a Patient Group Direction as part of their clinical activities for the Trust when all other legal and Trust requirements have been met.
- 4.3 UK legislation may be amended in the future to include further qualified healthcare professional groups and this policy will be deemed to have been extended to include these groups
- 4.4 Healthcare professionals (see paragraphs 4.2 and 4.3) may only supply or administer medicines under a Patient Group Direction when individually authorised in writing according to Trust PGD authorisation procedures.

4.5 Developing Patient Group Directions

4.5.1 PGDs will only be developed, in addition to conditions set out in Section 4.1 above, for medicines meeting at least one of the following criteria:

- The medicinal product is approved for use for the proposed indication and in the proposed patient group in the Somerset Prescribing Formulary,
or
- The medicinal product is approved for use for the proposed indication and in the proposed patient group by Somerset Partnership NHS Foundation Trust Medicines Oversight Group
or
- Evidence can be presented that use of the medicinal product for the proposed indication and in the proposed patient group is accepted good practice

4.5.2 Anyone wanting to develop a Patient Group Direction (PGD) within their locality / speciality must first discuss the implications with their locality / speciality clinical lead and / or service manager, including potential training issues and costs.

4.5.3 A proposal form (Appendix A) should be completed or an equivalent summary of all the information required in Appendix A and submitted to the Chief Pharmacist (see Appendix A for details) for consideration.

4.5.4 Once approval for development of the PGD has been granted the lead author should draft a PGD for consideration by the PGD Review Group.

4.5.5 If a proposal for the development of a PGD is rejected by the PGD Review Group the proposer has the right of appeal to the PGD Review Group providing:

- Appeals are made within 30 calendar days of receipt of notification of the rejection of the proposal, *and*
- Appeals must provide additional supporting evidence to address the reasons given for the original rejection.

The appeal will be heard at the next scheduled meeting of the PGD Review Group provided the meeting is not within 14 calendar days of receipt of the appeal.

4.5.6 The PGD Review Group (see 3.18 for details of group role and responsibilities) is a multidisciplinary group including a senior doctor or dentist, a senior pharmacist, a senior nurse, who will review the PGD with an invited representative of each of the professional groups involved in the specialist area concerned. The PGD Review Group may review the PGD by virtual means if needed.

4.5.7 Once the completed PGD has been reviewed and approved as 'fit for purpose' by the PGD Review Group the PGD will be forwarded to the Medicines Oversight Group for ratification.

4.6 **Content of Patient Group Directions**

4.6.1 It is a legal requirement that each patient group direction **must** contain the following information:

- the name of the clinical area in which the direction is applicable
- the date the direction comes into force and the date it expires
- a description of the medicine to which the direction applies
- the class of health care professional who may supply or administer the medicine
- the signature of a doctor or dentist, as appropriate, and a pharmacist who are responsible for the direction
- the signature of senior manager on behalf of the authorising body (the Trust)
- the clinical condition to which the direction applies
- a description of those patients excluded from treatment under the direction
- a description of the circumstance in which further advice should be sought from a doctor or dentist, as appropriate, and arrangements for referral
- details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered
- relevant warnings, including potential adverse drug reactions
- details of any necessary follow up action and the circumstances
- a statement of the records to be kept for audit purposes.

4.6.2 The current Trust template must be used for developing PGDs (available on the Patient Group Directions intranet page).

4.7 **Medicines Management Arrangements**

4.7.1 There must be comprehensive arrangements for the supply, security, storage and labelling of all medicines.

4.7.2 There must be a system for recording and monitoring medicine use under a Patient Group Direction to enable all stock receipts and all issues to individual patients to be reconciled.

4.7.3 When administering medicines under a PGD when RiO electronic prescribing and medicines administration (EPMA) is in use in the clinical setting the administration must be recorded using the unscheduled administration function (accessible via the Medicines Administration screen) (see relevant [How Do I? guide](#) for further details.)

4.7.4 Single dose medicines which are not injectables and which are supplied by a healthcare professional under PGD and then immediately self-administered

or administered by another person, such as a carer or healthcare worker, in the same room or clinic do not require labelling.

- 4.7.5 A healthcare professional operating under the PGD may be permitted to attach a label including the patient's name, the date supplied and the address of the clinic from which it was supplied but including no dosage instructions to the product at the time of supply only if all of the following criteria are met:
- a) Where directions supplied with the manufacturer's original packaging are the same as those stated in the PGD for:
 - Oral contraception and injectable contraceptives intended for self-administration that are often prescribed and labelled "To be taken as directed" or "To be administered as directed" with dosage directions included in the Patient Information Leaflet or are pre-printed on to the outer box at time of manufacturer, *or*
 - Other POMs where the directions for use are complex and do not fit on a label e.g. podophyllotoxin or imiquimod
 - b) The patient needs to be fully counselled on the dosage instructions at the time of supply and must be shown where these instructions are located for reference
 - c) The supplying healthcare professional should ensure that they add the label in such a way that it does not obscure other information on the POM pack
 - d) The Chief Pharmacist has approved the practice.

Note: The practice of adding an address label onto the box of a POM by a clinic nurse at the point of supply to a patient under their care, is not considered "manufacturing" or "assembly" as defined by the Medicines Act.

- 4.7.6 Wherever possible, medicines should be supplied in packs supplied by a Trust-approved medicine supplier. Medicine suppliers must hold all the relevant MHRA licenses or relevant exemptions for such a supply function.
- 4.7.7 Legislation requires that a patient information leaflet must be supplied with any medicines supplied to patients to take away for patient self-administration, including those supplied under a PGD.
- 4.7.8 Patient information leaflets are not required, under the legislation, to be supplied to patients administered medicines directly by a healthcare professional under a PGD, however, it is Trust policy that patient information leaflets should be made available to all patients to whom medicines are administered.
- 4.7.9 Legislation relating to prescription charges and exemptions (including pandemic influenza exemptions) also applies to patients receiving a supply of medicine(s) under a PGD from the NHS. Prescription charges do not apply when medicines are administered under a PGD.
- 4.7.10 There must be a system in place for collection of prescription charges or confirmation of exemption status where applicable.
- 4.7.11 When supplying or administering a medicine under a PGD for an unlicensed use ('off-label') health professionals must, where practicable, inform patients

or carers about the proposed unlicensed prior to supply or administration, in line with the 'prescribing unlicensed medicines guidance' published by the GMC (2013).

- 4.7.12 Staff should ensure the patient is able to understand the information given to them and are able to give their informed consent. This may necessitate the use of a professional interpreter and the translation of written information. A capacity assessment should be considered for those patients who are unable to consent to the procedure and reference should be made to the relevant Trust policy.

4.8 **Approval Procedure**

- 4.8.1 After review by the PGD Review Group, the completed Patient Group Direction must be forwarded to the Trust Medicines Oversight Group for final approval. The Medicines Oversight Group acts on behalf of the Trust Board and this final approval of the Patient Group Direction ensures that legal liability and hence indemnification of staff is given full consideration.
- 4.8.2 In exceptional circumstances PGDs may be approved for use on Medicines Oversight Group Chairman's approval
- 4.8.3 If approved, the PGD document will be signed and dated by the following signatories: a doctor or dentist, a pharmacist, a senior manager nominated by an Executive Director, representative(s) of the professional group(s) for organisational authorisation (see 4.8.4), and a microbiologist if the PGD is for an antimicrobial agent.
- 4.8.4 The following signatories are the approved Trust employees for authorisation of PGDs:

Role	Trust designation
Senior Manager with delegated authority for organisational authorisation	Medical Director for Integrated and Community Care
Governance Lead	
Doctor or dentist	
Pharmacist	Chief Pharmacist or nominated senior pharmacist
Microbiologist (if for an antimicrobial agent)	Approved Consultant Microbiologist

- 4.8.5 The signatories authorise the content of the PGD and are accountable for ensuring that the correct governance procedures have been followed in developing and approving the PGD. The PGD must bear all signatures required to comply with legal requirements.

4.8.6 Appropriate clinical skills, professional and service input will be sought from the relevant service leads, authors or specialists as part of the drafting or review process (and documented in the contributors list) but will not be required to sign the PGD as part of the authorisation process.

4.9 **Authorisation of an individual practitioner to practice under a Patient Group Direction**

4.9.1 A list of individuals' authorised to practice under the relevant PGDs will be maintained on the Trust's [Patient Group Direction Intranet page](#): the "PGD authorised practitioner list".

4.9.2 The individual practitioner and the line manager must complete the "Individual authorisation for use of PGD" form included in the relevant PGD or alternatively the electronic authorisation and notification process on the Trust intranet. The process for completing electronic individual authorisation form can be found at Appendix B.

4.9.3 Individuals will be authorised to practice under the relevant PGD when:

- a) all training and professional registration requirements set out in the PGD have been met *and*;
- b) the relevant line manager has authorised the individual healthcare professional *and*;
- c) details of the individuals authorisation is listed on the "PGD authorised practitioner list" maintained on the Trust intranet.

Relevant practitioners will be authorised temporarily for 14 calendar days after the date of signature of the relevant line manager. Authorisation will only continue if details of the authorisation appears on the "PGD authorised practitioner list".

4.9.4 Practitioners are responsible for ensuring that they only practice under the PGDs for which they are authorised on the "PGD authorised practitioner list"

4.9.5 Line managers are accountable for ensuring practitioners who they manage, only practice under the PGDs for which they are authorised on the "PGD authorised practitioner list".

4.9.6 Line managers are responsible for ensuring that notification of authorisation is completed and submitted.

4.9.7 Each authorised practitioner must have access to a copy of the Patient Group Direction for reference when required.

4.9.8 If a practitioner is no longer authorised to act within the Patient Group Direction, the individual's line manager is responsible for informing the Chief Pharmacist.

4.9.9 The Trust accepts no responsibility for an authorised practitioner who attempts to act under a PGD in an area of practice to which the PGD does not apply and in such circumstances the Trust's vicarious liability may not cover the practitioner.

4.10 **Review of Patient Group Directions**

4.10.1 PGDs will have a target review date set for two years after the effective date.

4.10.2 The content of a Patient Group Direction should be reviewed and re-authorised every two years. All PGDs that are past their stated review date can continue to be used until review for up to one year (i.e. up to three years after the effective date.)

4.10.3 PGDs cannot be used for greater than three-years from the effective date (greater than one year after the stated review date) without completion of the formal review process if such continued use is approved by the Medicines Oversight Group.

4.10.4 The content of a PGD should be reviewed immediately by the authors if there are evidence based changes to clinical practice that affect the PGD, regardless of the review date.

4.10.5 Any proposed changes to an existing PGD must be reviewed by the PGD Review Group and approved by the Medicines Oversight Group in accordance with the original approval procedure. If the proposed changes are authorised the amended PGD will be countersigned.

4.10.6 Once approved by the Medicines Oversight Group the amended PGD will immediately supersede the previous PGD for that area of practice. The **team managers** will ensure that:

- The amended PGD shall be substituted as soon as possible for the previous PGD held in that area
- All copies of the previous PGD are destroyed
- All practitioners authorised under the previous PGD are advised of the changes and any additional training required under the new PGD is provided
- All practitioners are provided with a copy of the new PGD.

4.10.7 Until final approval by the Medicines Oversight Group a PGD is invalid. Where there is an urgent need for rapid approval or where a minor amendment is required a PGD may be approved by Medicines Oversight Group Chairman's approval and the members of the group informed no later than the next scheduled meeting of the Group.

4.10.8 The Trust accepts no responsibility for an authorised practitioner who acts in accordance with a PGD not yet approved, or acts in accordance with a superseded PGD.

4.11 **Adoption of PGDs developed by other authorising bodies**

4.11.1 Clinically authorised PGDs may be adopted for use by Somerset Partnership staff when the following conditions have been met:

- PGDs signed by a doctor or dentist and a pharmacist authorised by the authorising body for this responsibility
- It can be demonstrated, for PGDs for antimicrobial agents, that a microbiologist has been involved in the development

- The authorising body has approved adoption and use of the clinically authorised PGDs by other organisations providing services relevant to use of the PGD
 - The PGD has been reviewed by the PGD Review Group and is deemed to be fit for purpose.
 - The PGD has been approved for use in the Trust by the Medicines Oversight Group
 - The PGD has been signed by the Medical Director for Integrated and Community Care, the Chief Pharmacist and the Governance Lead (see 4.8.4) to demonstrate Somerset Partnership's organisational approval for use.
- 4.11.2 After final approval and adoption of the PGDs developed by other authorising bodies the legal liability and hence indemnification of staff using the adopted PGD is the same as for all other PGDs developed and authorised by Somerset Partnership.
- 4.12 **Adoption of Trust-approved PGDs by other organisations and authorising bodies**
- 4.12.1 Use of clinically authorised PGDs by other organisations and / or authorising bodies results in the extension of the Trusts clinical responsibility and risk to those organisations and / or authorising bodies. Individual clinically authorising signatories will extend their clinical responsibility and risk to those third party organisations and / or authorising bodies.
- 4.12.2 Use of organisationally authorised PGDs by other organisations and / or authorising bodies results in the extension of the Trusts organisational responsibility and risk to those organisations and / or authorising bodies.
- 4.12.3 Clinically authorised Somerset Partnership PGDs may be adopted for use by other organisations that are **not** authorising bodies when the following conditions have been met:
- The organisation is providing services on behalf of Somerset Partnership NHS Foundation Trust
 - The organisation is providing care to patients of Somerset Partnership NHS Foundation Trust
 - Staff in the organisation that will be authorised to provide care under the PGD have the clinical qualifications and completed all the relevant training as defined in the PGD
 - The PGD Review Group have explicitly authorised such use
- 4.12.4 Clinically authorised Somerset Partnership PGDs may be adopted for use by other organisations that **are** authorising bodies when the following conditions have been met:
- The authorising body providing services has authorised the PGDs organisationally and has accepted the organisational responsibility and risk for the PGDs.

- Staff in the organisation that will be authorised have to provide care under the PGD the clinical qualifications and completed all the relevant training as defined in the PGD
- The PGD Review Group have explicitly authorised such use

4.13 Use of PGDs by Trust staff providing services on behalf of other organisations

- 4.13.1 Use of Trust clinically and organisationally authorised PGDs by Trust staff sub-contracted to provide services on behalf of other organisations results in the extension of the Trusts clinical and organisational responsibility and risk to those organisations and / or authorising bodies.
- 4.13.2 Use of Trust clinically and organisationally authorised PGDs by Trust staff sub-contracted to provide services on behalf of other organisations must be explicitly identified as an inclusion of any contractual arrangements otherwise PGDs will be deemed to be excluded.
- 4.13.3 Use of Trust clinically and organisational authorised PGDs by Trust staff sub-contracted to provide services on behalf of other organisations will normally be subject to an annual licensing agreement between the Trust and the sub-contracting organisation.
- 4.13.4 Use of third party clinically and organisationally authorised PGDs not adopted for Trust use (see 4.12 above) by Trust staff sub-contracted to third-party organisations must be approved by the PGD Review Group and the Medicines Oversight Group.

4.14 Appropriation of medicines costs incurred by the Trust as the result of PGD use by third-party organisations

- 4.14.1 Medicines supplied or administered under Trust clinically and / or organisationally authorised PGDs must be supplied in accordance with the requirements defined in the relevant PGD(s) and if supplied at Trust expense costs for the medicines the organisation responsible for the costs must be defined explicitly in any contractual arrangements or otherwise will be rechargeable to the third-party organisation on a pass-through basis with the addition of a discretionary processing fee.
- 4.14.2 Failure to reimburse the Trust for any medicines costs incurred not inclusive of any contractual fees or arrangements within 30 days of invoice will result in immediate removal of any authorisation of the relevant third party organisation to use the Trust clinically and / or organisationally approved PGDs.

5.0 TRAINING/COMPETENCE REQUIREMENTS

- 5.1 All healthcare professionals who wish to administer or supply medication under any PGD must have completed an approved Trust PGD training package and pass the approved competency assessment test.
- 5.2 To be authorised to supply medicines under a specific PGD staff must be assessed and deemed to have the relevant competencies by their line manager. Evidence of the assessment and demonstrated competencies must be held by the line manager.

- 5.3 PGD lead authors should also have completed a Trust-approved general PGD training package and theory competency assessment, but are not required to undertake other individual PGD competency assessments in order to be an author.

6.0 MONITORING

- 6.1 Line managers will review the use of PGDs by individual practitioners at annual appraisal.
- 6.2 The Chief Pharmacist will maintain a list (the “PGD authorised practitioner list”) of:
- PGDs approved for use within the organisation
 - individuals authorised to operate under each PGD
- The “PGD authorised practitioner list” will be available on the Trust intranet.
- 6.3 The Learning and Development Team will maintain details of individual’s completion of Trust PGD training and competency assessments.
- 6.4 The line managers and professional leads will ensure that individuals authorised have been appropriately trained and are competent in the relevant PGD training and competency assessments.
- 6.5 The PGD Review Group will oversee the development of PGDs and review of PGDs due to expire.
- 6.6 The Medicines Oversight Group will monitor implementation of the PGD Policy.

7.0 REFERENCES

British National Formulary (BNF) – current edition.

Care Quality Commission (2017) Nigel's surgery 19: Patient Group Directions (PGDs) / Patient Specific Directions (PSDs) (Available at: <https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-19-patient-group-directions-pgds-patient-specific-directions>)

General Medical Council (2013) Good practice in prescribing and managing medicines and devices (or current version)

MHRA (2009) Patient Group Directions in the NHS

National Prescribing Centre (2009) Patient Group Directions

NICE Medicines Practice Guidance (MPG2): Patient Group Directions (Aug-13) as amended

Specialist Pharmacy Service (2018) What are the legal requirements for labelling a Prescription Only Medicine (POM) issued via a PGD before supply to the patient? (available at <https://www.sps.nhs.uk/articles/what-are-the-legal-requirements-for-labelling-a-prescription-only-medicine-pom-issued-via-a-pgd-before-supply-to-the-patient/>)

The Human Medicines Regulations 2012 (SI 2012/1916) as amended

The Medicines Act 1968 as amended.

The Medicines (Sale and Supply) (Miscellaneous Provisions) Amendment (No2) Regulations 2000 (SI 2000/1918)

The Medicine (Pharmacy and General Sale – Exemption) Amendment Order 2000 (SI 2000/1919)

The Prescription Only Medicine (Human Use) Order 1997 (SI 1997/1830)

The Prescription Only Medicines (Human Use) Amendment Order 2000 (SI 2000/1917)

To PGD or not to PGD? That is the question. A Guide to choosing the best option for individual situations (current version) NHS PGD website.

Cross Reference to Other Procedural Documents

Mental Capacity (Using the MCA) Policy

Medicines Policy

Controlled Drugs Policy

Non-Medical Prescribing Policy

Record Keeping and Records Management Policy

Untoward Event Reporting Policy and Procedure

All current policies and procedures are accessible in the policy section of the public website (on the home page, click on 'Policies and Procedures'). Trust Guidance is accessible to staff on the Trust Intranet.

8.0 DOCUMENT CONTROL

Document Author		Chief Pharmacist – Head of Medicines Management	
Lead Owner		Chief Medical Officer	
This Version	8	Status	Final
Replaces	7		
Approval Date	11 September 2019 12 February 2020	Where	Medicines Oversight Group
Ratification Date	8 November 2019	Where	Policy Review Group
Date of issue	8 November 2019 9 March 2020	Review date	November 2022
Applies to	All registered health care professionals involved in assessing the need for, developing and administering and / or supplying medication under a Patient Group Direction.	Exclusions	

PATIENT GROUP DIRECTION PROPOSAL FORM

Medicine to be supplied or administered:

Before submitting this form, please confirm you have worked through the attached "To PGD or not to PGD" flow chart. YES / NO

If an existing PGD is used in another area, please state which area/group:

Team / Service proposing the PGD: _____

Proposal for multidisciplinary group to develop the Patient Group Direction

Name (PRINT)	Profession
	Lead Health Care Professional
	Pharmacist
	Medical / Dental Practitioner
	Consultant Microbiologist (antimicrobials)
	Other (please specify):

Clinical Condition to which the PGD applies:

Explain the current process in place for prescribing and administration.

How would the introduction of this PGD improve the quality and process of delivering care?

Professional group(s) to whom the PGD will apply:

Agreed with Line Manager

Name:

Job title:

Signature:

Date:

Please submit completed form to the Chief Pharmacist :Address: Medicines Management Team, Cheddon Lodge, Cheddon Road, Taunton, TA2 7AZ (MedicinesManagement@sompar.nhs.uk)

Approval for development by:

Chief Pharmacist:

Approved – Yes / No

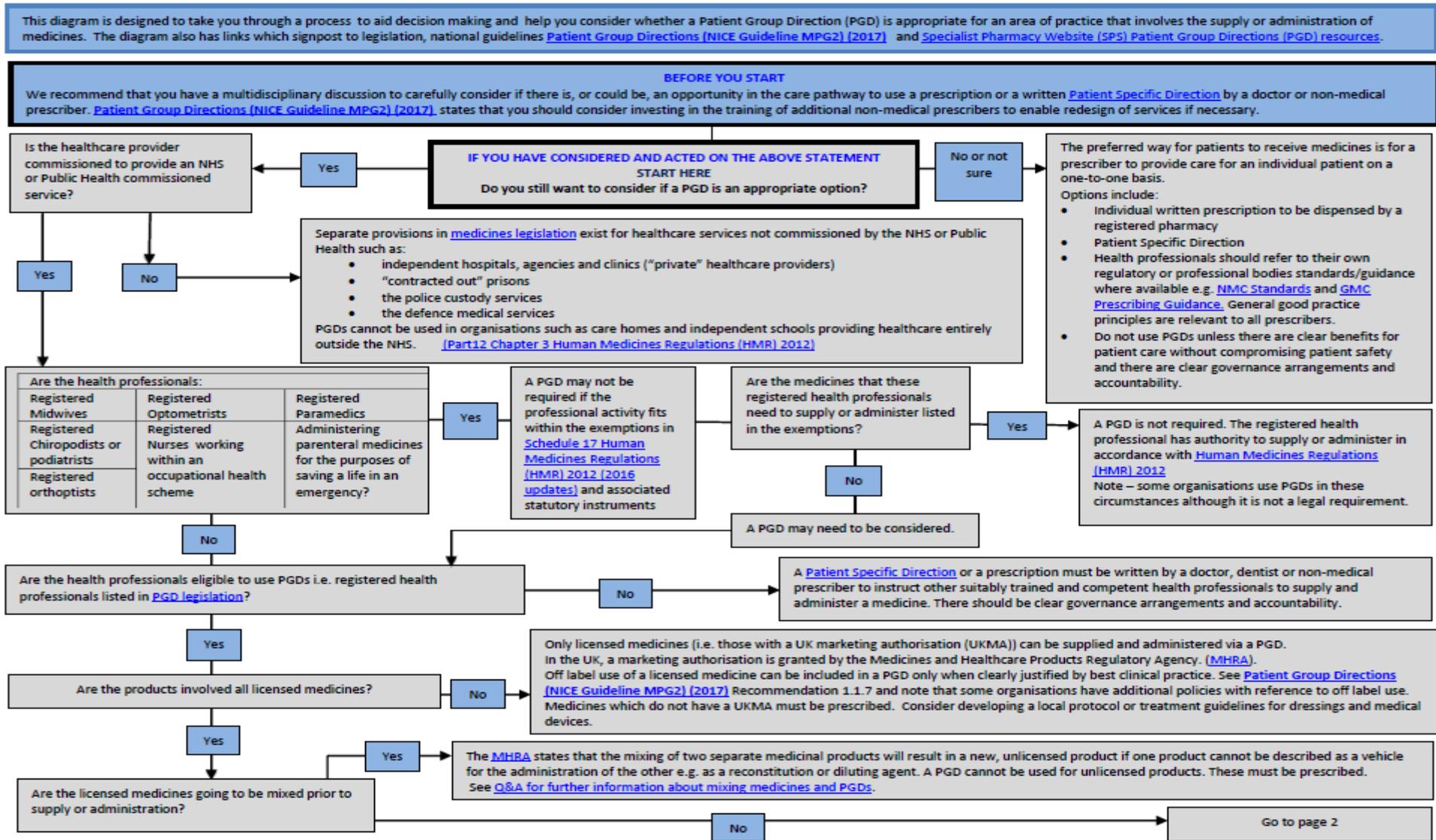
Name:

Signature:

Date:

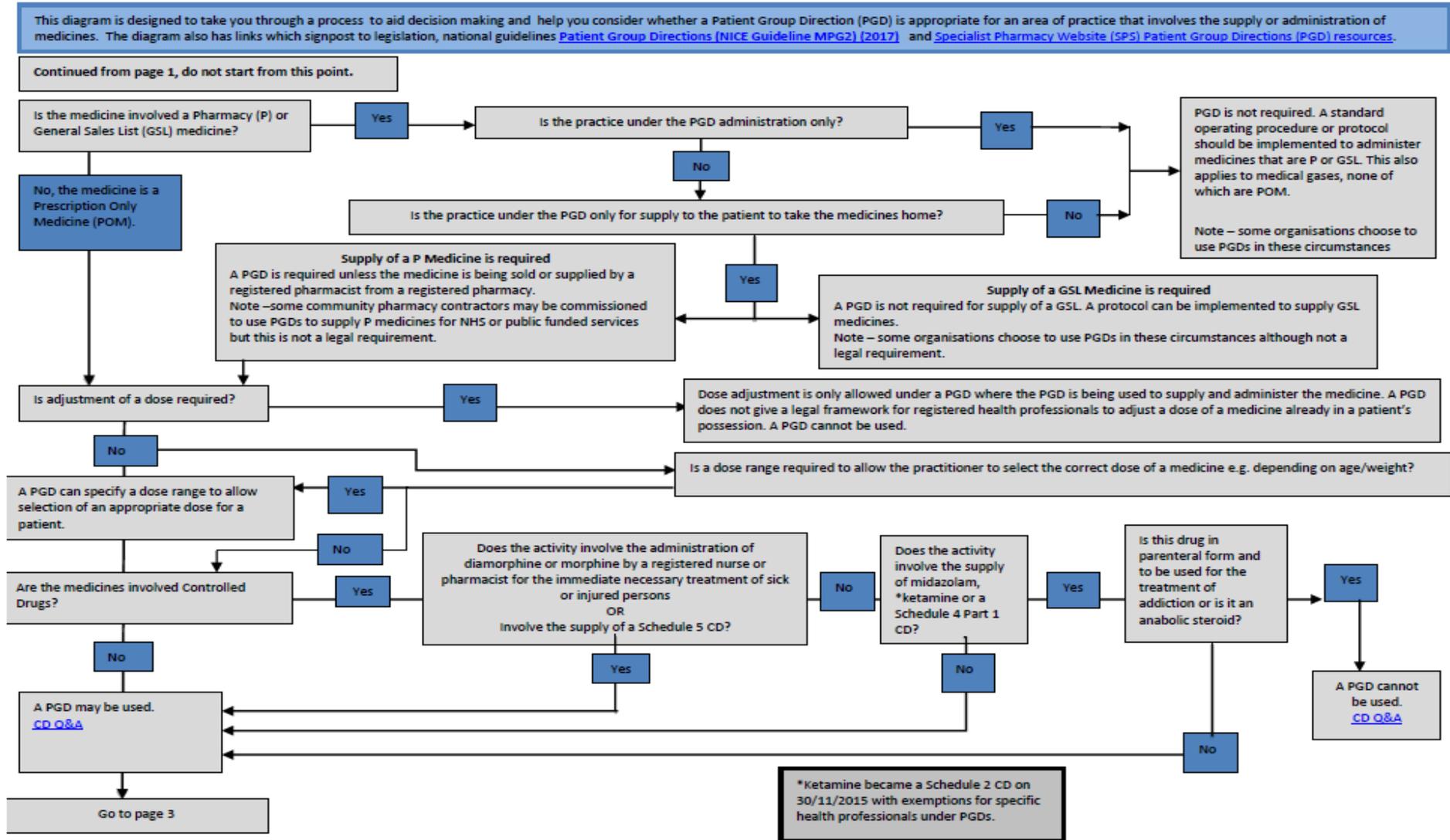
Please check the SPS website (www.sps.nhs.uk) to ensure you are using the most recent version

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



To PGD or not to PGD Version 9.5. Update of links. Published by SPS PGDs (England) January 2018. **THIS VERSION IS FOR ENGLAND ONLY.** Review due June 2018 (or earlier subject to legislation or other guidelines changes). If you are referring to a hard copy of this document – please check the SPS website (England) www.sps.nhs.uk to make sure that you are using the most recent version.

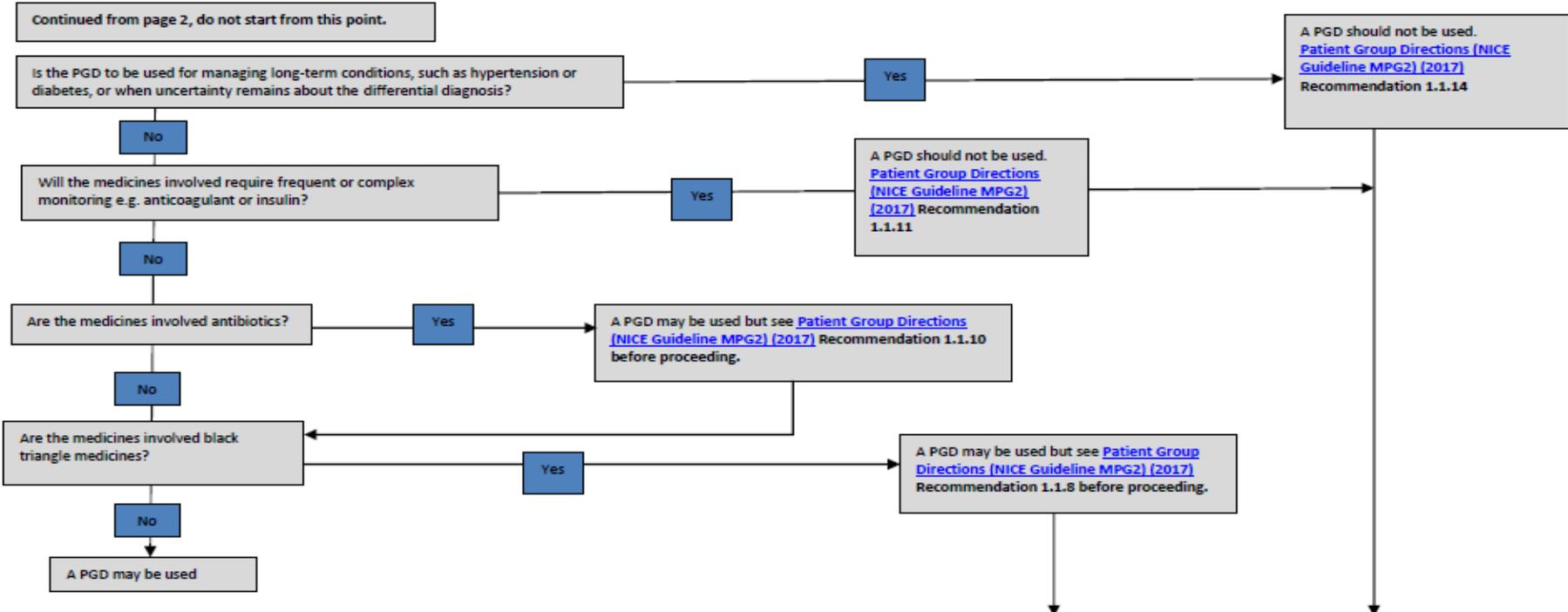
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This diagram is designed to take you through a process to aid decision making and help you consider whether a Patient Group Direction (PGD) is appropriate for an area of practice that involves the supply or administration of medicines. The diagram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



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

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

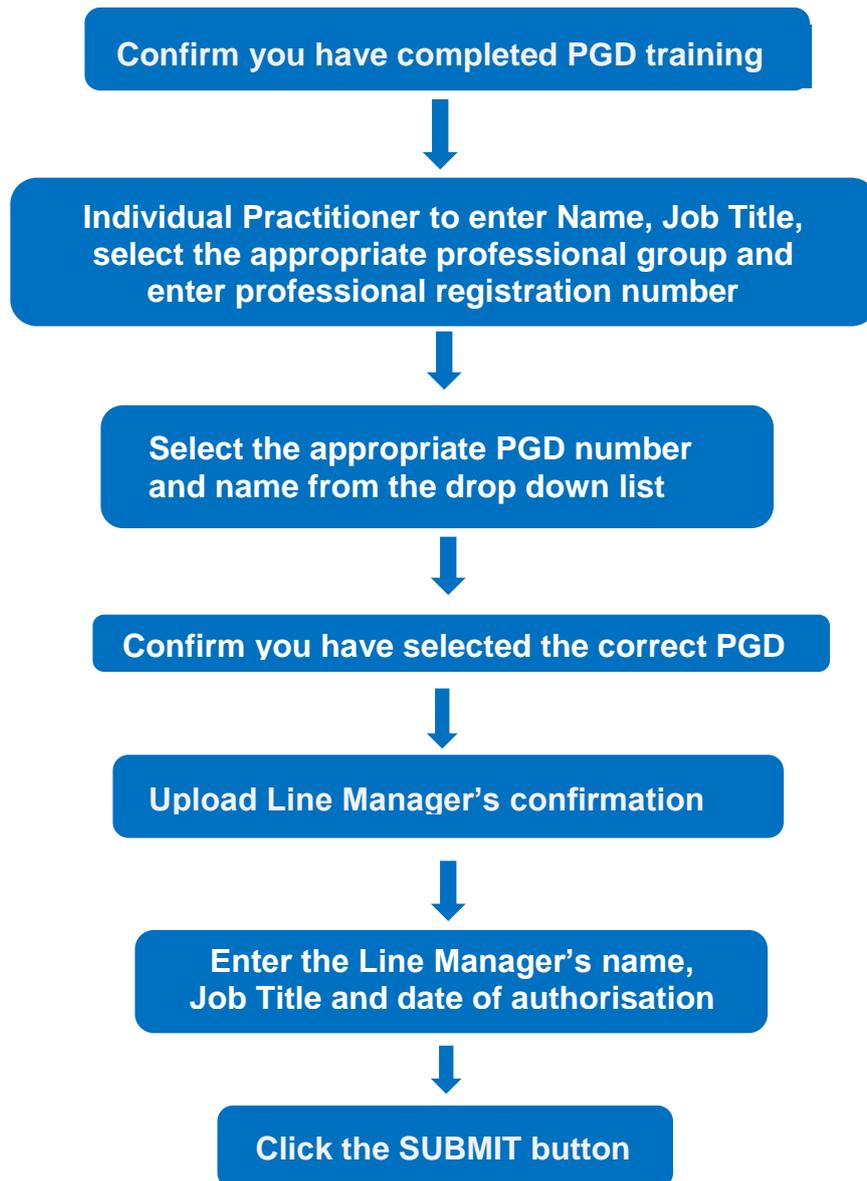
- [PGD Q&A – abortifacients](#)
- [PGD Q&A - labelling of POMs supplied under PGD](#)
- [PGD Q&A - delegation](#)
- [PGD Q&A – trainee supervision](#)
- [Quality PGDs - 7 Steps to success](#) and other resources such as [PGD Q&As](#) on the [SPS website](#)
- [Patient Group Directions \(NICE Guideline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

To PGD or not to PGD Version 9.5. Update of links. Published by SPS PGDs (England) January 2018. **THIS VERSION IS FOR ENGLAND ONLY.** Review due June 2018 (or earlier subject to legislation or other guidelines changes). **If you are referring to a hard copy of this document – please check the SPS website (England) www.sps.nhs.uk to make sure that you are using the most recent version.**

Process for completing electronic individual authorisation form

Go to the Patient Group Directions intranet page
and click on the link to **PGD Individual Authorisation Form**

BEFORE COMPLETING THE FORM, you must have email confirmation from your Line Manager that you are competent to administer under this PGD. The Line Manager's email must contain details of the PGD number, name and version number



The Individual Practitioner will be sent an electronic notification of **temporary** authorisation to practice under the PGD for 14 calendar days (notification includes expiry date).

The Chief Pharmacist will add the details to the "PGD authorised practitioner list" (available on the Patient Group Direction intranet page) within 14 days of receipt of the completed form, from which point the Individual Practitioner has ongoing approval until the expiry date of the PGD.