journey to change

NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

Public – To be published on the Trust external website

Patient Group Direction (PGD) Overarching Framework

Ref: PHARM-0076-v3

Status: Ratified
Document type: Policy

Contents

1 Introduction

The preferred way for patients to receive medicines is for an appropriately qualified healthcare professional to prescribe for an individual patient on a one-to-one basis. The supply and/or administration of medicines under a Patient Group Direction (PGD) should be reserved for those limited situations where this offers an advantage for patient care, without compromising patient safety.

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

A PGD is defined as the written instruction for the supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. Patients within the group may or may not be known to the service prior to presenting for treatment, depending on the circumstances. In simple terms, a PGD is the supply and/or administration of a specified medicine or medicines, by named authorised health professionals, to a well-defined group of patients requiring treatment for the condition described in the PGD. Any practice requiring a PGD that fails to comply with the criteria outlined in Health Service Circular (HSC) 2000/026 (and any subsequent Statutory Instruments) falls outside of the Law and could result in criminal prosecution under the Medicines Act. 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, effective services for patients.

This policy and its legal framework are needed to enable our trained healthcare professionals to maximise their skills and deliver effective patient and staff care that is appropriate in a pre-defined clinical situation, without compromising patient and staff safety and in some cases the need for hospital admissions. It allows us to offer a significant advantage to patient care by improving access to appropriate medicines and reduces delays in treatment as well as increasing the availability and quality of services when other options for supplying and/or administering medicines are not available.

This policy is critical to the delivery of OJTC and our ambition to co-create safe and personalised care that improves the lives of people with mental health needs, a learning disability or autism. It helps us deliver our three strategic goals as follows:

This policy supports the trust to co- create a great experience for all patients, carers and families from its diverse population by supporting the clinical teams to use PGDs to enable timely assessment and access to PGD specified medications and care that is right for the individual.

This policy supports the trust to co-create a great experience for our colleagues by developing our registered practitioners so that they expand their scope of practice which in turn will enhance patient support and care, giving greater autonomy and job satisfaction.

2 Why we need this policy

2.1 Purpose

Following this policy will help the Trust to:

- Provides a robust framework to ensure that the organisation plans, develops, authorises, adopts and implements PGDs appropriately.
- This document puts PGDs into context so that the organisation can decide whether a PGD is an appropriate means to supply and/or administer medicines.
- By adhering to this policy, the Trust will be able to give assurance that any PDGs introduced within services have been through a structured and considered process before being introduced and that ongoing monitoring of this will happen; including the regular review PGDs and any training requirements for those services.

2.2 Objectives

- PGDs will be made available to teams/services that are approved to use these in a safe agreed way as set out in this document.
- PGD training will be provided to ensure that only appropriately trained staff have access to these medicines for use.
- Safe handling and use of PGDs will be monitored via audits to ensure continued compliance with procedure and policy.

3 Scope

3.1 Who this procedure applies to

The registered health professionals who may supply and/or administer medicines under a patient group direction within TEWV are (only where defined within the specific PGD):

- Nurses
- Dieticians
- Pharmacists
- Occupational therapists
- Physiotherapists
- Speech and language

Healthcare professionals can only act under a PGD as named **and** authorised individuals and must act within their own professional code of conduct and within their own competence.

3.2 Roles and responsibilities

Role	Responsibility
Chief Pharmacist	• Co-ordinate and ensure robust governance arrangements at an organisational level for PGDs within TEWV • To act as lead pharmacist signatory for PGD sign off or to delegate to specialist clinical pharmacist appropriate to the PGD content • To provide a PGD update for the Drug & Therapeutics Committee as needed highlighting any organisational concerns relating to PGD activity • To provide advice and support to all trust services using PGDs
Lead Nurse Medicines Management and Non Medical Prescriber's	• To provided face to face training for all new and out of date PGD trainees and ensure that the staff member is added to ESR to allow team managers to oversee compliance with electronic updates. • To ensure that PGDs are reviewed regularity and up to date. • To undertake and co-ordinate PGD audits and relevant action plans • To only sign off staff who have adequate qualifications, training and competence to act under each relevant PGDs.
Nominated Service Leads for PGDs	• Co-ordinate PGDs at a service level as outlined in this policy
Individual health Professionals using PGDs	• To follow the contents of this policy • To only act within their own level of competence • To work only within the boundaries specified within each PGD • To successfully complete relevant PGD training • To ensure that they maintain relevant PGD training (3 yearly)
Drug and Therapeutic Committee (D&T)	• The chair of the D&T will act as governance signatory for each PGD implemented within TEWV • The D&T will review and approve or reject each PGD application • The D&T will monitor the use of PGDs and ensure appropriate action if there are any concerns identified.

4 The Law

The relevant modifications to the provisions in and under the Medicines Act 1968 are contained in:

- The Prescription Only Medicines (Human Use) Amendment Order 2000 (SI 2000/1917)
- The Medicine (Pharmacy and General Sale - Exemption) Amendment Order 2000 - SI (SI 2000/1919)
- The Medicines (Sale and Supply) (Miscellaneous Provisions) Amendment (No2) Regulations 2000 (SI 2000/1918)

5 What can and cannot be included in a PGD

- More than one medicine can be included on the same PGD, although this is not normal practice and will be avoided unless a clear benefit can be articulated.
- Black triangle (▼) medicines can be included, but only when clearly justified by best clinical practice. The risks vs. benefits of including these types of medicines will be reviewed during the review of the PGD request at the D&T.
- “Off license” / “off-label” use of medicines is allowed unless stipulated otherwise by the MHRA.
- Unlicensed medicines cannot be included on a PGD. This includes
- Imported medicines that do not have a UK product license.
- Administration where two products are going to be mixed together (and one of them cannot be described as a vehicle for administration) as this results in a new unlicensed product.
- “special” manufactured medicines
- Appliances and dressings cannot be supplied under a PGD (protocols or guidelines should be developed for the supply of these products).

Other issues relating to what should and should not be included in a PGD are outlined in appendix 3

6 The Process

The organisational process regarding a PGD has been split for ease into 5 stages:

- Stage 1 Proposal
- Stage 2 Submission of application
- Stage 3 Approval
- Stage 4 Implementation, management and monitoring
- Stage 5 Review and re-submission

Additionally, the organisation may adopt national PGDs for use (e.g. vaccinations). The chair of the D&T will approve adoption of national PGDs.

6.1 Stage 1: Proposal

The proposed use of a PGD should come from recognised service requirements agreed at a service level through multidisciplinary discussions. The proposed use of PGDs must not come from individual practitioners. A nominated service lead should discuss the proposal with the lead medicines management nurse. Before discussing the proposal with pharmacy the nominated lead should ensure the following:

- There is a definite requirement for the medication to be administered or supplied by the service.
- That the use of prescribing is not possible or is impractical to achieve the supply or administration of the drug.
- The medication is not covered by exemptions in legislation which allow it to be supplied and/or administered without the need for a PGD.
- The service has capacity to write, implement and review (including audit) the PGD in line with this policy. The service must be able to allocate a lead author (usually a representative of professional group using the PGD), and a doctor to produce an initial draft of the PGD.
- They have support of the full service (i.e. Trust-wide) where appropriate.

If the proposal is supported at this stage then the nominated service lead should move to stage 2.

6.2 Stage 2: Submission of Application

This stage is required for all new PGDs and applications for existing PGDs to be used in alternate services.

The nominated service lead will complete an application form (appendix 4 or appendix 5 as appropriate). The form outlines all of the requirements of the application and will only proceed for approval if it is fully completed. Key aspects required to support an application are:

- A nominated, competent representative of the health professionals utilising the PGD must be able to write the first draft of the PGD.
- A lead medic will support the application and sign the final PGD.
- Financial implications are addressed and any increase budget requirements are agreed in advance with budget older and (where necessary) finance
- Safe and secure medication handling systems are in place
- Where there is an existing PGD for a requested product & indication, the service must agree where possible to work under that PGD or request alterations specific to the service in question. A new PGD will only usually be authorised if the indications for use are significantly different

The completed application form will be submitted to the chief pharmacist. Once complete this will be submitted for approval to the D&T In some circumstances (depending upon timescales) it may be appropriate for the service to begin drafting the PGD before approval. This may help speed up implementation if the application is accepted.

6.3 Stage 3: Approval

The role of the D&T is to consider the application on the basis of the following:

- Is a PGD the most appropriate method of delivering the “service”?
- Have the risks and benefits to patients been explored?
- Is the drug appropriate for a PGD e.g. is it on formulary, is the suggested use in line with other services, would an alternate drug be more appropriate etc.?
- Are the indications appropriate?
- Is the drug a black triangle (▼) product or is it being used “off – license”?
- Are the characteristics of staff and suggested training / experience appropriate?
- Should any restrictions be placed upon the PGD?
- Should there be a shorter period of review than the standard 2 years?

If the PGD application is approved then the professional secretary of the D&T will contact the service lead asking them to submit a draft of the PGD to the Chief pharmacist. All PGDs written within TEWV must be in the pre agreed format available from Pharmacy. The only PGDs that may not be in the TEWV format are those developed with other organisations or those written at regional or national level.

The submitted draft must have been developed in conjunction with a multi-disciplinary team including the medic.

Legislation specifies that each PGD must contain all of the information stated in appendix 3. The PGD template has been designed to prompt for all of the necessary information.

A pharmacist will be nominated by the Chief pharmacist to review the PGD for accuracy and for any risk management issues. Any outstanding medication supply issues must be considered in this review.

6.3.1 The final PGD must be signed by the following as a minimum:

- Chief Pharmacist
- Medical Director
- Chief Nurse
- Additional signatures from senior representatives from any additional professional group expected to supply or administer under the PGD
- Chair of D&T (which may be one of the above)

It is appropriate for a deputy to sign in place of the identified signatories listed above.

6.3.2 Additional signatures required from some services:

There may be circumstances where PGDs are developed for services in non-NHS areas such as police custody environments. The Medicines and Healthcare Products Regulatory Agency (MHRA) website gives full advice on who is an appropriate authorised signatory. The lead pharmacist will advise. In the case of a PGD in use in a police force in England the chief officer of police for that police force **and** a doctor who is not employed/engaged or providing services to any police force must sign the PGD.

Where a PGD is developed jointly by TEWV and another NHS organisation the standard signatures (detailed above) will be required from the organisation developing / reviewing the PGD and the clinical governance signature of the organisation adopting the PGD.

The exception being where TEWV adopt national PGDs for use (e.g. vaccinations). The chair of the D&T is the only signatory required.

Once all of the signatures are in place the signature sheet will be scanned and a full PDF of the PGD (including signatures) will be added to the pharmacy intranet pages and the service will be notified. The master copy will be held in pharmacy for 8 years from the date of expiry or 25 years if indicated for use in children.

A record of all PGDs will be held by pharmacy. This will include all current and expired PGDs, reference numbers, expiry dates and details of the services in which the PGDs have been disseminated for use.

6.3.3 Appeals:

If a PGD application is rejected by the D&T the relevant Service Lead for PGDs can appeal against this decision. An intention to appeal against the decision of the committee should be made in writing to the Chief Pharmacist within 4 weeks of the decision being made.

Within 3 months the appeal will be heard at a committee meeting where twenty minutes will be allowed to hear the appeal. This would normally comprise a presentation by the appellant followed by questions by the committee.

The appellant will not be present whilst the appeal is discussed and will be informed of the decision by the Chief Pharmacist following the meeting.

6.4 Stage 4: Implementation; Management and Monitoring

A senior person in each service should be designated with the responsibility to ensure that only fully competent, qualified and trained professionals operate within the boundaries of the PGD. This will normally be the service manager, but could be a nominated lead professional for PGDs. The service must be clear on the governance arrangements within the service. Depending upon the size of the service it may be appropriate for service level responsibilities and Standard Operating Procedures (SOPs) to be outlined. These should not recreate this policy, but should instead ensure the service knows who is responsible for:

- Writing, reviewing or applying for PGDs
- Disseminating PGDs
- Authorising individuals to work within the PGD (including assessment of competency)
- Keeping any relevant PGD files up to date
- Audit

All professions must act within their appropriate Code of Professional Conduct and must individually sign up to each PGD that they anticipate working within. When administering or supplying under a PGD they must have the PGD available for reference and must have a British National Formulary (BNF) available too (always available online via BNF (British National Formulary) | NICE).

Service leads must be clear on training mechanisms and assessment of competency.

There must be comprehensive arrangements for the security, storage and labelling of all medicines. These should be supplied in pre-packs from the Trust pharmacy. In particular there must be a secure system for recording and monitoring medicines use from which it should be

possible to reconcile incoming stock and out-goings on a patient by patient basis (see record keeping requirements). Names of the health professionals providing treatment, patient identifiers and medicine provided should all be recorded.

The EC Labelling and Leaflet Directive 92/27 apply to all supplies of medicines, including those supplied under PGDs. A patient information leaflet must be made available to patients treated under PGDs. If these are not available in the medicine box they can be printed from www.medicines.org.uk

6.5 Stage 5: review and re-submission

A PGD will normally be given a maximum 3 year expiry date. In exceptional circumstances an extension letter may be issued for a PGD to ensure continuity of service until a reviewed PGD can be signed off. The letter must be issued by the lead PGD pharmacist or medical director / associate medical director.

The pharmacy database will track all PGD expiry dates. The database will be monitored once a month by pharmacy and 6 months before expiry the service will be emailed the PGD and informed that a review is required. The review should include clinical governance arrangements and an assessment of whether the PGD remains the most effective way of providing the relevant services. Where the PGD is still required, the service lead will be asked to review the PGD ensuring the lead medic / dentist is involved.

Changes to national guidance or changes to the ways in which services are delivered may also trigger a PGD review.

The use of PGDs within a service must be subject to regular review and must be audited by the service every 3 years. The audit does not need to cover every PGD in use, but should be sufficient to assure the D&T that PGDs are being appropriately implemented.

Normally, reviewed PGDs will not require resubmission to the D&T. Instead the D&T will be notified of the reissued PGD as an agenda item at the meeting for information only. The exceptions to this rule will be if any of the following changes are required:

- New or significantly amended indications
- Significant new inclusions, including use of the PGD in new or changed services
- Planned implementation in new staff group

These changes will be submitted to the D&T using the form in appendix 5 submitted along with the revised draft PGD.

There may be other reasons why the lead medicines management nurse also requests resubmission to the D&T. These will be discussed with the service lead and appendix 5 will be completed as above.

The D&T may request an appropriate review of a specific PGD or a range of PGDs at any stage of the process.

The D&T will receive a paper as needed detailing the new PGDs which have been authorised, any extension letters which have been issued and any PGDs which have been made obsolete. The pharmacy intranet pages will have copies of all active PGDs. Any PGDs that are not included on that list will be considered obsolete and must be resubmitted for approval before they are implemented again.

All revised PGDs must follow the full sign off process regardless of how small the changes are.

7 Practical issues relating to the supply or administration of a medicine under a PGD

7.1 Supplied medicines

If a medicine is going to be supplied to the patient to take home, an appropriately labelled pack must be supplied. Usually this will be an original pack, although in certain circumstances pharmacy may supply smaller pack sizes to match the requirements of the service.

If the medicine has a label on then the professional supplying must ensure that any gaps on the label are completed. This will usually include the name of the patient and date of supply.

Additional information may be required if there are blank spaces in the dosage instruction which may include:

- The amount to take (e.g. 2 tablets)
- The frequency to take (e.g. 4 times a day)
- The length of course (e.g. for 3 days)

Additional information may be required for other labels and it is the professionals' responsibility to ensure these are complete. It should be noted that sometimes a label will be on a bottle inside of the outer box. This must be checked before supply. All doses added to the label must be in line with the PGD.

Each pharmacy dispensary is limited (legally) to producing 25 packs for each strength of each medication per month. Replenishing stock may take up to 7 days and staff must use the order template (appendix 7), which should be emailed to the teams allocated Pharmacy:

tewv.pharmacytees@nhs.net – Roseberry Park

tewv.pharmacyyork@nhs.net – Foss Park

tewv.pharmacycdd@nhs – West Park

7.2 Patient advice

A patient information leaflet (PIL) must always be supplied for any medicines to take home. It is good practice to also supply a PIL for drugs immediately administered, but this is not a legal requirement. If the PIL is not available with the product then these can be printed from www.medicines.org.uk

All information advised in the "Patient Advice" section of the PGD must be communicated to the patient. This may include advice such as the disposal of excess medicines.

7.3 Record keeping

All of the records required are outlined on each individual PGD. The professional supplying or administering under a PGD must record the event in line with the requirements on the individual PGD. All staff should complete the PGD template (Appendix 6) to ensure that entries are standardised and contain all the relevant information pertinent to the assessment and decision to supply/administer or not.

Regardless of the system in place, care must be taken to ensure each of these aspects has been recorded.

If a medicines administration chart is in use then the words “As per PGD” should be entered in the prescriber’s signature box. The rest of the drug details should be entered onto the drug chart and administration recorded as per the Medicines Overarching Framework. The extra details required (as above) should be recorded in the patient’s records.

7.4 Clinical judgement

Under no circumstances can any patient be treated for any indication other than those stated on the PGD. The patient must match the inclusion criteria and not match any exclusion criteria. All aspects of the PGD must be followed, including advice that the full dose issued being taken. It is a legal document and there is no room for clinical judgement for those patients who fall slightly outside of the PGD criteria. If a patient does not fit the “patient group” then they should be referred to an appropriate prescriber. A prescription will then be required if the patient does require treatment.

The supply or administration under a PGD cannot be delegated to any other individual regardless of their level of training or profession.

If a medicine is to be immediately administered, it must only be administered by the person who assessed the individual against the PGD criteria.

7.5 Retention of records

For adults, all PGD documentation must be retained for 8 years and for children until the child is 25 years old or for 8 years after a child’s death. In practice pharmacy will retain master versions of the PGD. The service must retain copies of the professionals signed up to a PGD for the aforementioned time periods as well as the records pertaining to supply or administration.

How will learning take place?

Outcomes will be shared via: the pharmacy intranet page, Trust intranet, e-mail forum, education opportunity, change in practice, re-audit, eBulletin

8 Definitions

Term	Definition
▼ Back triangle	The black triangle appearing after the trade name of a British medicine (or vaccine) indicates that the medication is new to the market, or that an existing medicine (or vaccine) is being used for a new reason or by a new route of administration
D&T	Drugs and Therapeutics Committee
MHRA	The Medicines and Healthcare Products Regulatory Agency
PGD	Patient Group Direction
PIL	Patient Information leaflet

9 Related documents

This policy refers to:-

- ✓ Medicines Overarching Framework
- ✓ Medicines - Prescribing and Initiation of Treatment
- ✓ Guidelines for Unlicensed and Off-Label Use of Medicines
- ✓ Medicines Optimisation - interactive guide

10 How this procedure will be implemented

[In this section, write about how the procedure will be disseminated and implemented. Identify any training needs and who is responsible for its delivery.]

• This procedure will be published on the Trust's intranet and external website.
• Line managers will disseminate this procedure to all Trust employees through a line management briefing.
• Those teams wishing to use PGD's will require specific training provided by the lead Medicines management Nurse, this is face to face training for initial authorisation to practice – or for those staff who have gone out of date - and then eLearning which should be completed on a 3yearly basis and managed by individual managers through ESR.

10.1 Training needs analysis

Staff/Professional Group	Type of Training	Duration	Frequency of Training
Registered Nurses in Crisis Teams	Initial Face to Face eLearning update	2.5 hours 1 hour	One off or repeated if out of date 3 yearly
Vaccinators	eLearning modules/updates	2- 3 hours	Annual
Vaccinators	Face to face training	1.5 – 3 hours	Annual

11 How the implementation of this procedure will be monitored

Number	Auditable Standard/Key Performance Indicators	Frequency/Method/Person Responsible	Where results and any Associate Action Plan will be reported to, implemented and monitored; (this will usually be via the relevant Governance Group).
1	Monitored PGD standards are included with Community Medicines Management Assessment (CMMA) which can be found here: CMMA	**Frequency**: Quarterly; **Method**: Crisis teams complete audit and send to Pharmacy; **Responsible**: Audit is Co-ordinated by Pharmacy. Service lead is responsible for completion.	Local action required at the point of assessment. Reports sent by Pharmacy to locality Improvement delivery groups (IDGs)

11.1 Training and Competency

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

The individual PGD will state any additional qualifications required and any specific training required when using the PGD.

Within the Crisis Services, the lead nurse for medicines management is responsible for authorising health professionals to work under a PGD and must ensure that all required training has been completed and that they have an adequate method of assessing competence to use the PGD. The lead nurse is responsible for providing face to face training for all new and out of date PGD trainees. They should also ensure that all trained staff members are added to ESR to allow team managers to oversee compliance with the eLearning updates. The lead nurse will ensure that training is provided for all services wishing to use PGD's and will complete a management and Authorisation certificate for all those staff who successfully complete the training (Appendix 8). Staff will then be entered onto the PGD database, training and education will be notified to add the 3 yearly eLearning updates to the individual's training competencies.

For the authorisation of Vaccinators, again the relevant learning must be completed via the Trust vaccinator programme, evidenced and the individual must be signed off as competent by an authorising manager to confirm this.

NICE has published competency frameworks to support healthcare professionals involved in all aspects of PGD use within organisations.

Three competency frameworks are available.

- Competency framework for people developing and/or reviewing and updating PGDs
- Competency framework for people authorising PGDs
- Competency framework for health professionals using PGDs

The competency frameworks are available to download from the NICE website at Overview | Patient group directions | Guidance | NICE

12 References

This Policy refers to the following guidance, including national and international standards:

Medicines Practice Guideline 2 Patient group directions: Overview | Patient group directions | Guidance | NICE (last updated 27/03/2017)

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

13 Document control (external)

To be recorded on the policy register by Policy Coordinator

Date of approval	19 July 2023
Next review date	19 July 2026
This document replaces	PGD Overarching Framework v2.0
This document was approved by	Drug and Therapeutic Committee
This document was approved	25 May 2023
This document was ratified by	Management Group
This document was ratified	19 July 2023
An equality analysis was completed on this policy on	28 March 2023
Document type	Public

Change record

Version	Date	Amendment details	Status
1	11 Jan 2017	New document	Superseded
1	09 Jan 2020	Review date extended to 01 Apr 2020	Superseded
1	09 Apr 2020	Review date extended to 01 Sept 2020	Superseded
2	14 May 2020	Minor amendments	Approved
3	19 July 2023	Refreshed throughout to reflect job titles and organisational changes. Addition of adoption of national PGDs. Change 1 update on dispensary information Change 2 changes to training and the training matrix Change 3 PGD order form for crisis teams	Ratified

Appendix 1 Equality Impact Assessment Screening Form

Please note: The Equality Impact Assessment Policy and Equality Impact Assessment Guidance can be found on the policy pages of the intranet

Section 1	Scope
Name of service area/directorate/department	Pharmacy
Title	PGD Overarching Framework
Type	Policy
Geographical area covered	Trust wide
Aims and objectives	To provides a robust framework to ensure that the organisation plans, develops, authorises, adopts and implements PGDs appropriately.
Start date of Equality Analysis Screening	24/03/2023
End date of Equality Analysis Screening	28/03/2023

Section 2	Impacts
Who does the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan benefit?	The policy benefits Patients, carers and staff.
Will the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan impact negatively on any of the protected characteristic groups? Are there any Human Rights implications?	• **Race** (including Gypsy and Traveller) **NO** • **Disability** (includes physical, learning, mental health, sensory and medical disabilities) **NO** • **Sex** (Men and women) **NO** • **Gender reassignment** (Transgender and gender identity) **NO**

	• **Sexual Orientation** (Lesbian, Gay, Bisexual, Heterosexual, Pansexual and Asexual etc.) **NO** • **Age** (includes, young people, older people – people of all ages) **NO** • **Religion or Belief** (includes faith groups, atheism and philosophical beliefs) **NO** • **Pregnancy and Maternity** (includes pregnancy, women / people who are breastfeeding, women / people accessing perinatal services, women / people on maternity leave) **YES** • **Marriage and Civil Partnership** (includes opposite and same sex couples who are married or civil partners) **NO** • **Armed Forces** (includes serving armed forces personnel, reservists, veterans and their families) **NO** • **Human Rights Implications NO** (Human Rights - easy read)
Describe any negative impacts / Human Rights Implications	PGDs would currently not be issued within the Crisis services to individuals who are pregnant or breastfeeding due to contraindications and cautions, this would remain the clinical decision of a prescriber.
Describe any positive impacts / Human Rights Implications	More timely responses to care.

Section 3	**Research and involvement**
What sources of information have you considered? (e.g. legislation, codes of practice, best practice, nice guidelines, CQC reports or feedback etc.)	NICE Guidance
Have you engaged or consulted with service users, carers, staff and other stakeholders including people from the protected groups?	NO

If you answered Yes above, describe the engagement and involvement that has taken place	
If you answered No above, describe future plans that you may have to engage and involve people from different groups	Full Trust Consultation and approval at Drug and Therapeutics committee with both patient and carer representation.

Section 4	**Training needs**
As part of this equality impact assessment have any training needs/service needs been identified?	Yes
Describe any training needs for Trust staff	As detailed within the training matrix
Describe any training needs for patients	N/A
Describe any training needs for contractors or other outside agencies	N/A

Check the information you have provided and ensure additional evidence can be provided if asked

Appendix 2 – Approval checklist

To be completed by lead and attached to any document which guides practice when submitted to the appropriate committee/group for consideration and approval.

	Title of document being reviewed:	Yes/No/ Not applicable	Comments
1.	**Title**		
	Is the title clear and unambiguous?	YES	
	Is it clear whether the document is a guideline, policy, protocol or standard?	YES	
2.	**Rationale**		
	Are reasons for development of the document stated?	YES	
3.	**Development Process**		
	Are people involved in the development identified?	YES	
	Has relevant expertise has been sought/used?	YES	
	Is there evidence of consultation with stakeholders and users?	N/A	
	Have any related documents or documents that are impacted by this change been identified and updated?	N/A	
4.	**Content**		
	Is the objective of the document clear?	YES	
	Is the target population clear and unambiguous?	YES	
	Are the intended outcomes described?	YES	
	Are the statements clear and unambiguous?	YES	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	YES	
	Are key references cited?	YES	
	Are supporting documents referenced?	YES	
6.	**Training**		
	Have training needs been considered?	YES	

	Title of document being reviewed:	Yes/No/ Not applicable	Comments
	Are training needs included in the document?	YES	
7.	**Implementation and monitoring**		
	Does the document identify how it will be implemented and monitored?	YES	
8.	**Equality analysis**		
	Has an equality analysis been completed for the document?	YES	
	Have Equality and Diversity reviewed and approved the equality analysis?	YES	confirmed
9.	**Approval**		
	Does the document identify which committee/group will approve it?	YES	
10.	**Publication**		
	Has the document been reviewed for harm?	YES	No Harm
	Does the document identify whether it is private or public?	YES	PUBLIC
	If private, does the document identify which clause of the Freedom of Information Act 2000 applies?	N/A	

Appendix 3 - What can, must and should be included in a PGD

What can, must and should be included in a PGD

It is important that the use of any medicine is consistent with the Summary of Product Characteristics for the relevant products (save in special circumstances) and any relevant authoritative good practice guidance.

- The name of the business to which the direction applies
- The date the direction comes into force and the date it expires
- A description of the medicine(s) to which the direction applies
- Class of health professional who may supply or administer the medicine
- signature of a doctor or dentist, as appropriate, and a pharmacist
- signature by an appropriate organisation
- the clinical condition or situation to which the direction applies
- the clinical criteria under which a person is eligible for treatment
- a description of those patients excluded from treatment under the direction
- a description of the circumstances 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 reactions
- details of any necessary follow-up action and the circumstances;
- A statement of the records to be kept for audit purposes.

Some additional requirements…

Black Triangle ▼ drugs and medicines used outside the terms of the Summary of Product Characteristics

Black triangle ▼ drugs (i.e. those recently licensed and subject to special reporting arrangements 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 clinical practice and that a direction clearly describes the status of the product. 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 the documentation should include the reasons why, exceptionally, such use is necessary.

Controlled Drugs

Only certain controlled drugs are legally eligible to be included in a PGD, in accordance with The Misuse of Drugs Regulations 2001.

Schedule	Controlled drugs that may be considered for inclusion in a PGD	Additional comments
Schedule 2	Morphine Diamorphine	Used by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person (except for treating addiction)
Schedule 3	Midazolam	
Schedule 4	All drugs, including benzodiazepines and ketamine	Anabolic steroids and any injectable preparation used for treating addiction must not be included in a PGD
Schedule 5	All drugs, including codeine	

Other issues

It is not normally advised that a PGD be developed to manage chronic conditions. It is however reasonable to manage certain exacerbations of conditions via a PGD or to supply some immediately necessary medications such as a GTN spray or a salbutamol inhaler.

A PGD may be implemented to adjust the dose of a patient's medication as long as this is defined within the PGD and that the medicine is going to be supplied or administered under a PGD. A PGD does not have the scope to alter the dose of a medicine that has already been supplied.

The following tools are useful in deciding whether a PGD is the best way for your service to supply a medicine:

- To PGD or NOT to PGD? That is the question
- So you think you need a PGD?

The most up to date version of these tools can be found on the national Specialist Pharmacy Services website:

https://www.sps.nhs.uk/

These will be used by the lead medicines management nurse when advising the service and the D&T on the application.

Appendix 4 – PGD Application Form

Service Details
Type of service: Location: Identified PGD Lead : Identified Medic: Supported by (i.e. Lead Psychiatrist, Lead Nurse, General Manager): Forum this has been discussed in (i.e. QAIG, Clinical Network):
Drug details
Name: Form(s) & Strength(s): Dosage details (if different from BNF):
Indications(s)
Inclusion/exclusion criteria – This section should define age ranges and other pertinent patient group details (do not list contra indications)

Further details regarding the treatment

Is the medicine licensed for this indication, dose & route, is it a black triangle (▼) product?

Rational for request

Please provide details of: What other options have been considered, anticipated frequency and service benefits.

Potential Benefits to patient?

Potential risks to patient?

Staff Characteristics

Which professional groups will be utilising the PGD? , are there additional qualifications/training required, how will training be delivered? And are additional resources or equipment required?

Appendix 5 – Changes to existing PGD Application form

Service Details
Type of service: Location: Identified PGD Lead : Identified Medic: Supported by (i.e. Lead Psychiatrist, Lead Nurse, General Manager): Forum this has been discussed in (i.e. QAIG, Clinical Network):
PGD Details
Name of PGD: PGD reference number:
Are you requesting an existing PGD be implemented in an additional service? **YES/NO**
Changes requested to existing PGD
Further details regarding the treatment
Rational for request

Appendix 6 – Electronic record Template

CRISIS PGD PARIS TEMPLATE	
Current situation / presentation:	
Inclusion / exclusion Criteria assessment (please include all rationale for decision):	
PGD issued:→YES →NO (If excluded or declined please seek further medical attention and document in patient record)	
Dose:	**Route:**
Number of treatments:	
Patient advice verbal and written provided (including adverse reactions and possible side-effects):	

Appendix 7 – Crisis Team PGD Order Form

Team {INSERT TEAM NAME}			
Stock holding at each crisis team is 12 of each, stock should be ordered regularly to maintain adequate supplies			
PGD order form			
DRUG	**STRENGTH**	**PACK SIZE**	**QTY REQUIRED**
DIAZEPAM TABLETS	2mg	1	
DIAZEPAM TABLETS	5mg	1	
PROMETHAZINE TABLETS	25mg	1	
ZOPICLONE TABLETS	7.5mg	1	
ORDER BY	**DESIGNATION**		**DATE**
{INSERT NAME}	{INSERT JOB TITLE}		{INSERT DATE}
Email completed form to locality Pharmacy inbox:			
Roseberry Park Hospital email: tewv.pharmacytees@nhs.net Tel: 01642 838131			
West Park Hospital email: tewv.pharmacycdd@nhs.net Tel: 01325 552299			
Foss Park Hospital email: tewv.pharmacyyork@nhs.net Tel: 01904 717780			

Appendix 8 - Authorisation to Practice template (Crisis Teams)

Management and authorisation of Patient Group Direction (PGD)

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

- PGDs do not remove inherent professional obligations or accountability
- PGDs should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. Summary of Product Characteristics) and do NOT replace the need to refer to such sources
- It is the responsibility of each professional to practice only within the bounds of their own competence
- Note to authorising managers: **All nurses authorised to use this PGD must have received training as defined within the PGD and be competent to administer the medicines identified in the PGD.** Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the authorisation sheet showing their authorisation.

Pre-requisition – successful completion of PGD theory e-learning package (100%)		
Successful completion evidenced via certificate: Y/N	Date	Checked and confirmed by: Signature:
PGD specific Face to Face training -		
Completed Y/N	Date	Checked and confirmed by: Signature:

For the administration and/or supply of (trainer to indicate below by deleting non-relevant PGDs and initialling which PGDs are relevant)

PGD	Review date	Trainers initials
Zopiclone 7.5mg tablets: PGD 10	Next review date March 2025	
Diazepam 2 & 5 mg tablets: PGD 32	Next review date March 2025	
Promethazine 25mg tablets: PGD 32	Next review date June 2025	

Name of authorised practitioner		
Authorising Trainer		
Successful completion evidenced via pass of assessment	Date	Checked and confirmed by: Signature:
The above named person is authorised to work within the confines of the indicated PGDs		
Authorising Manager & Designation:	Signature:	
I, the undersigned, have read and understood this PGD. I have attended a specific information and training session/completed the appropriate e-learning package for the implementation of this PGD and can safely implement this PGD		
Signature of named nurse	Date	3 yearly updates will be evidenced on ESR .

authorised practitioner
One copy with PGDs to be retained by authorised practitioner; one copy to PGD file