Cabinet

15 September 2021

A Patient Group Direction Policy for Durham County Council

Ordinary Decision

Report of Corporate Management Team

Jane Robinson, Corporate Director of Adult & Health Services

Amanda Healy, Director of Public Health, Adult & Health Services

Councillor Paul Sexton, Portfolio holder for Adult & Health Services

Electoral division(s) affected:

Countywide

Purpose of the Report

1 To note the contents of the Patient Group Direction (PGD) Policy in Appendix 2

2 To adopt this Policy.

Executive summary

3 Some services commissioned by Public Health supply medication to service users as part of the service using a PGD.

4 The Council is required to have in place a PGD Policy (Appendix 2) to support this process.

Recommendation(s)

5 Cabinet is recommended to:

(a) note the contents of this report and the PGD Policy in Appendix 2 and the good practice that this policy applies

(b) to adopt this PGD Policy.

Background

6 Some services commissioned by Public Health supply medication to service users as part of the service e.g., the administration of influenza vaccines to Council employees by community pharmacies.

7 When appropriate in line with legislation[1] and national guidance[2], PGDs can be used to supply a medicine. PGDs provide a legal framework that allows some registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber[3].

8 A process defined by legislation and national guidance must be followed, and specific information must be included in a PGD for it to be legally valid. A PGD must be signed by a doctor (or dentist), a pharmacist, and on behalf of the authorizing body.

9 The formal agreement of the authorizing body (via its PGD Approval Group) should be obtained before proceeding to develop or implement a PGD. As in other Councils, the Director of Public Health is the organisation authorization signatory, and the Public Health Senior Management Team is the PGD Approval Group.

10 The PGD policy outlines the process and provides the assurance and governance arrangements for the supply of medicine. It has been developed based on existing good practice and the policy formalises this practice.

11 Examples of use of a PGD include flu immunisation and Hepatitis B vaccine.

Main implications

12 Some services commissioned by Public Health supply medication to service users as part of the service using a PGD.

13 The Council is required to have in place a PGD Policy (Appendix 2) to support this process.

Conclusion

14 Members are asked to support the recommendation to adopt the PGD Policy in Appendix 2.

Background papers

- PGD Policy in Appendix 2.

[1] https://www.legislation.gov.uk/uksi/2012/1916/contents/made
[2] https://www.nice.org.uk/guidance/mpg2 and https://www.sps.nhs.uk/home/guidance/patient-group-directions/
[3] https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them

Author(s)

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Appendix 1: Implications

Legal Implications

In line with Regulation 229 of The Human Medicines Regulations 2012[4] the formal agreement of the authorizing body (via its PGD Approval Group) should be obtained before proceeding to develop or implement a PGD. As in other Councils, the Director of Public Health is the organisation authorization signatory, and the Public Health Senior Management Team is the PGD Approval Group.

Finance

None (this supply route is part of the structure of the commissioned services).

Consultation

With neighbouring Councils for examples of PGD Policies, with the relevant national bodies to source all relevant national guidance.

Equality and Diversity / Public Sector Equality Duty

The Policy allows for the supply of medication to all Public Health commissioned service users as appropriate.

Climate Change

None.

Human Rights

The Policy allows for the supply of medication to all Public Health commissioned service users as appropriate.

Crime and Disorder

None.

Staffing

This supply route is part of the structure of the commissioned services. Staffing training, competency and governance arrangements are a standard part of the PGD implementation process.

Accommodation

None.

Risk

The required PGD Policy is robust in line with legislation and national guidance.

[4] https://www.legislation.gov.uk/uksi/2012/1916/contents/made

Procurement

This supply route is part of the structure of the commissioned services.

Appendix 2: PGD Policy

Policy for the development and authorization of patient group directions

Durham County Council

April 2021 (Review date April 2023)

Background

Patient group directions (PGDs) provide a legal framework that allows some registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber (see PGDs: who can use them). Wherever possible medicines should be administered or supplied on an individual patient basis following the direction of a prescriber for that specifically named patient.

Legislation

PGDs are defined in Health Service Circular (HSC 2000/026) as 'Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment'.

The current legislation for PGDs is included in The Human Medicines Regulations 2012. This legislation was amended in April 2013 to reflect changes to NHS organisational structures in England.

Specific information must be included in a PGD for it to be legally valid, and a PGD must be signed by a doctor (or dentist), a pharmacist, and on behalf of the authorizing body.

Before developing a PGD

Supplying and/or administering medicines under PGD should be reserved for situations where this offers an advantage for patient care without compromising patient safety; where other options for the supply or administration of a medicine have been considered (e.g. a PGD should not be used when it is reasonable to expect that a FP10 or Patient Specific Direction (PSD) (see Specialist Pharmacy Service (SPS) guidance Questions about PSDs) could be written instead, or where a medicine can be supplied / administered by an alternative route e.g. as a General Sales List (GSL) or Pharmacy Only (P) medicine supply); and where there are clear governance arrangements and accountability.

The need for a PGD in a specific clinical situation should be considered locally by reviewing the care pathway and exploring all the options for prescribing, supplying and/or administering medicines e.g., consider investing in the training of additional non-medical prescribers to enable redesign of services if necessary.

The following guidance describes the health professional groups that can operate under a PGD in line with the Human Medicines Regulations 2012; that PGDs are not appropriate for managing long-term conditions or when uncertainty remains about the differential diagnosis; and the medicines that may and may not be included in a PGD:

- Section 1.1 of NICE Medicines Practice Guidance (MPG2)
- SPS guidance When to use a PGD
- SPS guidance Quality PGDs: 7 steps to success
- SPS guidance When PGDs are not required. Guidance on when PGDs should not be used and advice on alternative mechanisms for supply and administration of medicines

: for example, not unlicensed medicines, not a medicine needing frequent dosage adjustments or frequent or complex monitoring, only certain controlled drugs when

clearly justified by best clinical practice (see SPS guidance Supply and/or administration of Controlled Drugs under a PGD), new drugs (black triangle) and off-label use of a licensed medicine only when clearly justified by best clinical practice, and medicines with Risk Minimization Measures (RMM) in place (see SPS guidance Inclusion of medicines with RMM in PGDs).

Obtaining agreement to develop a PGD
The formal agreement of the authorizing body (via its PGD Approval Group) should be obtained before proceeding to develop a PGD (see section 1.2 of NICE MPG2 and SPS guidance Quality PGDs: 7 steps to success).

The PGD Approval Group is a multidisciplinary group that considers proposals to develop a PGD.

Developing a PGD
A named lead author should have responsibility for developing a PGD, supported by a locally determined multidisciplinary PGD Working Group.

A PGD Working Group is a multidisciplinary group established for each individual PGD, that is responsible for developing the PGD and its subsequent review and update. This group should include a doctor (or dentist), a pharmacist and a representative of any other professional group who will practice under the PGD (see section 1.3 of NICE MGP2 and SPS guidance Quality PGDs: 7 steps to success).

The senior doctor should be a doctor who has expert knowledge in the therapeutic field the PGD is addressing. The senior pharmacist should be a pharmacist who has expert knowledge in the therapeutic field the PGD is addressing together with expert knowledge on the development and use of PGDs. The representative of the other professional group(s) should also be a specialist in the particular clinical field being addressed within the PGD. Members of the PGD Working Group should have the appropriate competence as defined in NICE MPG2 Competency Framework: For people developing and / or reviewing and updating PGDs.

A PGD template
Specific information must be included in a PGD for it to be legally valid. National templates are available from NICE PGD template and the SPS – national PGD template to support commissioners to develop PGDs that are in line with current legislation and NICE MPG2.
PGDs should be concise and easy to follow with the appropriate amount of clinical information to ensure that the health professional working under the PGD can deliver safe and effective patient care.

Authorizing a PGD
The NICE PGD template in Appendix 1 includes all signatures that are required by legislation or are considered to represent good practice. Electronic signatures may be used in line with the SPS guidance Questions about electronic systems and PGDs. SPS guidance Authorizing PGDs at organizational level describes the roles and responsibilities of each of the PGD signatories.

Legislation requires that a PGD must be signed by a doctor (or dentist) and a pharmacist and guidance states that they should be involved in the development of the PGD. NICE MPG2 recommends that, although not required by legislation, it is good practice for PGDs to be signed by representative/s of the registered health professional group (s) intended to supply and/or administer the medicine/s under the PGD. Signatures of the doctor(s) and pharmacist(s) are an acceptance of

responsibility for the clinical and pharmaceutical accuracy, and the safety and appropriateness of a PGD in the circumstances in which it will be used. Individuals should have the appropriate competence as defined in NICE MPG2 Competency Framework: For people authorizing PGDs.

In addition the PGD must be authorized by a representative of the relevant authorizing body (see section 1.4 of NICE MPG2 and SPS guidance Quality PGDs: 7 steps to success). An authorizing body is an organisation listed in the Human Medicines Regulations 2012 that is legally able to authorize a PGD to state that the PGD is fit for purpose. The commissioning and/or provider organisation may be an authorizing body.
The representative of the relevant authorizing body signs a PGD to state that the PGD is fit for purpose and hence must have sufficient evidence to be assured that:

- A PGD has previously been agreed as the most appropriate mechanism for supply and administration of the medicine, and there is no opportunity in the care pathway for the medicine to be prescribed in a timely manner.
- Those involved in the clinical authorization of the PGD are competent to do so.
- Local processes and governance arrangements have been followed.
- The views of stakeholders have been considered.
- All legal requirements have been met.

It should be noted that for governance purposes, the signatory should not be involved in developing the PGD, will not practice under the PGD, and should not be required to check clinical content of the PGD in detail but they should be confident that the doctor and pharmacist signatories (and anyone else involved in the development of the PGD) have adequate competency, skills, and experience to carry out the role.

Independent healthcare provider (IHP) organisations outside the NHS e.g., agencies and clinics, police, prison healthcare services, can both develop and authorize PGDs under their own internal governance arrangements for use in their organisation.

However, for the provision of NHS commissioned services only the following organizations are able to authorise PGDs. In the NHS in England, these organizations are:

- clinical commissioning groups (CCGs)
- local authorities
- NHS trusts or NHS foundation trusts
- NHS England
- Public Health England.

Therefore if the organization is an IHP, it cannot authorize its own PGDs in order to provide NHS and public health commissioned services, and needs authorization from the commissioner of the service (see SPS guidance Authorization of IHP PGDs for NHS and public health commissioned services).

Finally, an individual health professional must be authorized in writing to use the PGD by a senior person. For each PGD, the provider organization should identify a senior responsible person from within the service to authorize named, registered health professionals to practice under the PGD. Each individual member of staff working to a PGD must sign the PGD 'Individual Authorization' page. The senior responsible person must ensure that only staff that are competent to work under the PGD are signed up to it (i.e., as described in NICE MPG2 Competency Framework: For health professionals using PGDs).They must also sign the 'Individual Authorization'. Providers should maintain an up-to-date list of the names of the healthcare professionals who have been authorized to operate under a PGD.

Monitoring and review of PGDs
Each PGD must have an expiry date. This will normally be two years from the development of the PGD or from the last review date (see PGDs: who can use them) and NICE recommend a maximum of three years.

PGDs can be used past their expiry date, so long as they have been risk assessed for continued use with patient safety as the main concern. An extension letter must be sent to all providers that are using any PGDs that have been extended in this way. The extension of an expiry date on a PGD without full review and re-authorization should be exceptional practice e.g., during organizational transition and should be for an agreed and limited period of no longer than one year. In line with the recommendations made in NICE MPG2 the total valid period of a PGD should not exceed three years from the date the PGD was authorized (see SPS guidance Extension of expiry date of a PGD).

All clinicians involved in the development and review of PGDs are expected to work within the NICE MPG2 Competency Framework: For people developing and / or reviewing and updating PGDs and in line with NICE MPG2 section 1.6 and SPS guidance Quality PGDs: 7 steps to success when reviewing and updating PGDs.

Reviewing a PGD requires a very similar process to developing a PGD (see SPS guidance Reauthorizing and re-signing of a PGD following amendments/changes). The relevant PGD Approval Group is responsible for ensuring that PGDs are reviewed in a timely manner and for identifying appropriate persons to form the PGD Working Group. When reviewing the PGD, determine whether the PGD remains the most appropriate option to deliver the service.

When a PGD is reviewed all the changes made must be highlighted when submitting to the PGD Approval Group for re-authorization. Major changes to an existing PGD should be highlighted within a covering letter when distributed to providers.

PGDs should also be reviewed, prior to the expiry date, with any:

- Changes in legislation
- Important new evidence or guidance that changes the PGD, such as new national guidance
- New information on drug safety
- Changes in the summary of product characteristics
- Changes to the local formulary.

Health professionals using PGDs
The use of a PGD does not remove the inherent professional obligation and accountability of a registered healthcare professional as defined by their registration body. It is the responsibility of each professional to ensure that they understand the use, dose, adverse effects, cautions and contraindications of each medicine they supply or administer. Professionals must continue to use their professional judgement in each individual situation.

Health professionals may only supply or administer medicines under a PGD as named individuals. There must be comprehensive arrangements for the security, storage and labelling of all medicines. The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicines, including those supplied under PGDs. A patient information leaflet should be made available to patients treated under PGDs.

Health professionals using PGDs are expected to work within the NICE MPG2 Competency Framework: For health professionals using PGDs and in line with NICE MPG2 section 1.5.

Durham County Council procedures

Approval for the development of a new PGD within a public health commissioned service must first be sought from the Durham County Council (DCC) PGD Approval Group. The Public Health Pharmacy Adviser will provide assurance to the DCC PGD Approval Group and the Director of Public Health (DPH) for the development of a new PGD.

DCC is the appropriate authorizing body for PGDs developed for public health services commissioned by DCC:

- Where the commissioned provider is not legally able to be an authorizing body (e.g., an IHP). The Public Health Pharmacy Adviser will provide assurance to the DCC PGD Approval Group, and the DPH will act as the authorizing signatory.
- For PGDs developed by DCC public health. The Public Health Pharmacy Adviser act as the lead clinical pharmacist signatory and will provide assurance to the DCC PGD Approval Group. The DPH will act as the authorizing signatory.

Commissioned providers who are also authorizing bodies (e.g., acute trusts) will be required by DCC to develop and authorize all PGDs required to deliver commissioned public health services (once approval to develop a new PGD has been sought from the DCC PGD Approval Group). Providers that can legally authorize their own PGDs should assure DCC that they:

- Have a robust governance process in place for the development, authorization, implementation, and monitoring of PGDs, which meet statutory and regulatory requirements and that these processes are included in a PGD Policy.
- Maintain a register of all healthcare professionals competent and registered to deliver the PGD.
- Maintain a database of all PGDs and a record of all changes and versions of the PGD.
- Have a medicines policy for the safe and secure handling of medicines, which includes the supply and storage of medicines.

This DCC PGD Policy describes:

1. The responsibilities of the DPH and the Public Health Pharmacy Adviser.
2. The role and responsibilities of the DCC PGD Approval Group.
3. The process for the development and authorization of a PGD by DCC public health for a commissioned public health service.
4. The arrangements whereby DCC authorizes the use of PGDs within commissioned public health services where the provider organization is unable by law to authorize PGDs within their own organization.

Director of Public Health

The DPH is the designated signatory for the authorizing body (DCC), is responsible for ensuring effective implementation of this PGD Policy, and has the following responsibilities:

- Has overall responsibility for ensuring that the PGDs that support DCC commissioned public health services are developed in line with current

legislation and national guidance (e.g. in line with SPS guidance Quality PGDs: 7 steps to success) and within robust governance arrangements.
- Where necessary, acts as the authorized signatory for PGDs and ensures that there are processes in place to ensure that PGDs are authorized in accordance with current legislation, national guidance and within robust clinical governance procedures.
- Has responsibility for providing assurance of competence of the pharmaceutical, medical and other clinician expertise involved in the DCC public health development of PGDs (see NICE MPG2 Competency Framework: For people developing and / or reviewing and updating PGDs).
- Ensures they have the necessary knowledge, skills and expertise needed for authorizing PGDs (see NICE MPG2 Competency Framework: For people authorizing PGDs).

Public Health Pharmacy Adviser

The Public Health Pharmacy Adviser provides assurance to the DCC PGD Approval Group and the DPH that the PGDs that support DCC public health commissioned services are developed in line with current legislation and national guidance, and within robust clinical governance frameworks. Key responsibilities include to:

- Seek approval of the PGD Approval Group for the development of a new PGD within a commissioned public health service.
- Lead on the process for the development of a PGD by DCC for use in a commissioned public health service.
- Lead on the process whereby DCC authorizes the use of PGDs within commissioned public health services where the provider organization is unable by law to authorize PGDs within their own organization (i.e., IHPs).
- Ensure that appropriate DCC organizational records are maintained to include, as appropriate (see Section 1.8 of NICE MPG2):
    1. PGD Approval Group decisions (Appendix 2 and 3 – information also includes members of the PGD Working Groups).
    2. A list of all PGDs in use within commissioned public health services, including their review / expiry date.
    3. Master authorized copies of all PGDs.
    4. Expired versions of all PGDs (see SPS guidance Retaining PGD documentation . Copies of expired PGD master documents will be kept as for all other patient records. For adults all PGD documents must be kept for a minimum of 8 years, and those that apply to children must be kept for 25 years).
- For PGDs written by DCC, ensure that all providers can submit copies of the PGD Individual Authorization Forms on request.
- Ensure that that this role is carried out in line with the required competence (see NICE MPG2 Competency Framework: For people developing and / or reviewing and updating PGDs).

The DCC PGD Approval Group

The role of the PGD Approval Group is to provide evidence to the DPH to demonstrate that PGDs are developed in line with legal requirements in The Human Medicines Regulations 2012, NICE MPG2 2017 recommendations, and robust clinical governance procedures.

The Public Health Senior Management Team (SMT) will act as the PGD Approval Group. The role of this Group, in line with the recommendations in section 1.2 of NICE MPG2 and SPS guidance Quality PGDs: 7 steps to success is to:

- Ensure that PGDs used to support DCC commissioned services meet the necessary legal requirements, national guidance recommendations, and have followed robust governance procedures.
- Decide on the membership of the PGD Working Group for DCC developed PGDs.
- Ensure decision-making is robust and transparent with final decisions on proposals formally recorded and communicated to appropriate stakeholders.
- Ensure a robust and transparent appeals process.

Public health commissioned services that identify a need for a new PGD must obtain approval for its development by submitting a PGD development proposal request to the PGD Approval Group (see Appendix 2).
Appendix 2 contains the application form, a checklist for Public Health SMT to consider, and a record of the decisions made. The information in Appendix 2 supports Public Health SMT in its role as the PGD Approval Group to meet its responsibilities in line with the recommendations in of section 1.2 of NICE MPG2 and SPS guidance Quality PGDs: 7 steps to success.

A DCC PGD Working Group
For a PGD that will be developed by DCC for a public health commissioned service, the DCC PGD Approval Group will approve members of a PGD Working Group as part of the application process to develop a new PGD in Appendix 2.

Section 1.3 of NICE MPG2 recommends to: Ensure that a named lead author has responsibility for developing a PGD, supported by a locally determined multidisciplinary PGD Working Group. Include a doctor (or dentist), pharmacist and representative of any other professional group(s) using the PGD. Any of these professionals may be the lead author as agreed by the group.

The senior doctor should be a doctor who has expert knowledge in the therapeutic field the PGD is addressing. The senior pharmacist should be a pharmacist who has expert knowledge in the therapeutic field the PGD is addressing together with expert knowledge on the development and use of PGDs. The representative of the other professional group(s) should also be a specialist in the particular clinical field being addressed within the PGD. All PGD Working Group members should have the appropriate competence to carry out their expected role as defined in NICE MPG2 Competency Framework: For people developing and / or reviewing and updating PGDs.

Draft PGDs should be sent to representatives of the professional groups who will be operating under the PGD for comment and for identification of potential issues that may arise when PGDs are implemented.

A list of members of the PGD Working Group and any minutes and / or version controls of the PGD development must be kept. See SPS guidance Questions about electronic systems and PGDs for electronic solutions that can be used to write and agree a PGD.

The PGD Working Group is also responsible for ensuring that the PGD is updated as appropriate.

PGDs that are developed (or require a review) by DCC or by IHPs for public health commissioned services, must obtain approval for the PGD by submitting the draft PGD and the Approval form for a new PGD / existing PGD revision to the PGD Approval Group (see Appendix 3).

Appendix 3 contains the application form, a checklist for Public Health SMT to consider, and a record of the decisions made. The information in Appendix 3 supports Public Health SMT in its role as the PGD Approval Group to meet its responsibilities in line with the recommendations in the SPS guidance Quality PGDs: 7 steps to success.

National resources / templates used

Patient Group Directions: Who can use them. MHRA. Last updated Dec 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them

Patient Group Directions. NICE MPG2. Last updated March 2017. https://www.nice.org.uk/guidance/mpg2

Patient Group Directions. NICE MPG2. Last updated March 2017. Tools and Resources. https://www.nice.org.uk/guidance/mpg2/resources:

- Commissioning support: PGD template
- Competency Framework: For people developing and / or reviewing and updating PGDs
- Competency Framework: For people authorizing PGDs
- Competency Framework: For health professionals using PGDs.
- Case scenarios: PGDs

National PGD website at https://www.sps.nhs.uk/articles/what-is-a-patient-group-direction-pgd/ and https://www.sps.nhs.uk/home/guidance/patient-group-directions/:

- When to use a PGD (Last updated March 2021)
- Authorizing PGDs at organizational level (Published Sept 2020)
- Authorization of IHP PGDs for NHS and public health commissioned services (Published Sept 2020)
- Questions about signatories of PGDs (Published Sept 2020)
- Retaining PGD documentation (Published Sept 2020)
- Questions about electronic systems and PGDs (Published Sept 2020)
- Quality PGDs: 7 steps to success (Last updated March 2021)
- Questions about PSDs (Published Sept 2020)
- Supply and/or administration of Controlled Drugs under a PGD (Last updated March 2021)
- When PGDs are not required. Guidance on when PGDs should not be used and advice on alternative mechanisms for supply and administration of medicines (Last updated March 2021)
- Inclusion of medicines with RMM in PGDs (Last updated March 2021)
- PGDs and NHS prescription charges. (Last updated March 2021)
- SPS – national PGD template (Last updated April 2021)
- Reauthorizing and re-signing of a PGD following amendments/changes (Last updated March 2021)
- Extension of expiry date of a PGD (Last updated March 2021)

Appendix 1: NICE MPG2 template PGD

Insert logo of authorising body
Additional organisational logo(s) as agreed locally

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

Patient Group Direction

for the supply and/or administration[5] of

Name of medicine

by registered health professional group(s) for

Condition/situation/patient group

in location/service/organisation

Version number:

Change history

Version number	Change details	Date

[5] Delete as appropriate

PGD development

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

PGD authorization

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

PGD adoption by the provider[6]

Name	Job title and organization	Signature	Date
Signatures to be determined locally, if relevant			

Training and competency of registered health professionals

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

[6] Delete section if not relevant

Clinical condition

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

Details of the medicine

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

Patient information

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

Appendices

Appendix A Key references

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

Appendix B Health professionals' agreement to practise

Insert statement to be signed by individual health professionals agreeing to practice under the PGD.

For example:

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

Name of health professional	Signature	Senior representative authorizing health professional	Date

Other appendices may be added as agreed locally.

Appendix 2: DCC PGD Approval Group: Request for the development of a new PGD

The following document should be completed prior to the development of a full PGD for use in a DCC public health commissioned service. This form captures the information required by section 1.2 of NICE MPG2 and SPS guidance Quality PGDs: 7 steps to success.

Title of PGD:

Name of service in which the PGD is to be used:

Organisation delivering the service (Is this organisation also the authorising body?):

Setting and circumstances in which the PGD is to be used, and its position within the care pathway:

Condition to be treated (considering patient inclusion and/or exclusion criteria):

Benefits and advantages of using a PGD over other methods of supply or administration (e.g., prescribing, patient specific direction, training of additional non-medical prescribers):

Any potential risks to patient safety:

Professional group(s) to be included in the PGD:

Training needs of the HCPs:

How will competency be assessed, who will authorize HCPs to practice under the PGD, and who will keep and maintain the list of authorized prescribers?

Medicines to be included in PGD (medicine(s) to be supplied and/or administered, including dosage, quantity, formulation and strength, route and frequency of administration, duration of treatment and whether it is included in the local formulary):

Details of how the medicine will be funded, purchased and securely stored (and if applicable, the arrangements for packaging and labelling, and collection of prescription charges):

Other resources needed to deliver the service:

A timescale for developing the PGD:

Name the healthcare professionals who will form the PGD Working Group:

	Name	Job title
Member		
Doctor		
Pharmacist		
Clinician practising under the PGD		
Other		

If applicable, name the professionals who will authorize the PGD:

	Name	Job title
Member		
Lead doctor		
Lead pharmacist		
Lead clinician practising under the PGD		
Organizational authorization		
Other		

Proposer (manager or clinical lead):

I can confirm that:

- An organizational PGD policy is in place.
- The service has considered whether a PGD is appropriate by considering other potential options for supply and the SPS guidance When to use a PGD.
- The PGD content will comply with the specific information which must be included in a PGD for it to be legally valid, and with the NICE MPG2 Commissioning support: PGD template. and the SPS – national PGD template
- The process for developing the PGD will comply with NICE MPG2 and SPS guidance Quality PGDs: 7 steps to success.
- The professionals that will be involved in developing, authorizing, monitoring, reviewing, and updating the PGD will have the necessary competencies as described in NICE MPG2 Competency Framework: For people authorizing PGDs and Competency Framework: For people developing and / or reviewing and updating PGDs.
- The professionals that will be involved in using the PGD will work according to the guidance in NICE MPG2 section 1.5 and will have the necessary competencies as described in NICE MPG2 Competency Framework: For health professionals using PGDs.
- The organization will maintain a register of all healthcare professionals competent and registered to deliver the PGD.
- The organization has a medicines policy for the safe and secure handling of medicines, which includes the supply and storage of medicines.

Name: Title: Signature: Date:

Please send to completed form to PublicHealth@durham.gov.uk

For completion by the DCC PGD Approval Group

Checklist for the PGD Approval Group to consider for request to develop a new PGD to support a DCC commissioned service in line with the necessary legal requirements, national guidance recommendations, and robust

governance procedures (section 1.2 of NICE MPG2 and SPS guidance Quality PGDs: 7 steps to success)

Consideration	Public Health Pharmacy Adviser comments	Additional Public Health SMT comments
Have all options for other routes of supply / administration been considered? e.g., training of further non-medical prescribers?		
Does use of this PGD align with the public health commissioned service framework?		
Will use of a PGD compromise patient safety in any way?		
Is the medicine appropriate for use under a PGD? Are appropriately registered health professionals available to use the PGD, and have training and competency needs been addressed?		
Are there other resources needed to deliver the PGD within an appropriate timeframe e.g., finance and commissioning implications?		
Are there suitable governance and accountability arrangements in place for developing, authorizing, using, monitoring, reviewing, and updating the PGD?		
What are the arrangements for the security, storage, packaging and labelling of medicines where applicable, and collection of prescription charges where applicable (see SPS guidance PGDs and NHS prescription charges).		

Date of PGD Approval Group meeting:

The request to develop this PGD for use within DCC public health commissioned services has / has not been (please delete as appropriate) **approved for development for the following reasons:**

Approval has been granted on the condition that the following requirements or restrictions are included in the PGD:
e.g., minimum qualifications / training requirements; maximum doses or lengths of treatment; criteria for patients to be excluded from the PGD.

The proposer has 28 days to appeal the decision of the PGD Approval Group in writing, or to re-submit an amended application with the recommended changes.

Appendix 3: DCC PGD Approval Group: Approval form for new PGD / existing PGD revision (please delete as appropriate).
This form captures the information required by SPS guidance Quality PGDs: 7 steps to success.

Please attach a copy of the draft PGD with this approval form.

Title of PGD:

Name of service in which the PGD is to be used:

Organisation delivering the service (Is this organisation also the authorising body?):

Setting and circumstances in which the PGD is to be used, and its position within the care pathway:

Condition to be treated (considering patient inclusion and/or exclusion criteria):

Benefits and advantages of using a PGD over other methods of supply or administration (e.g., prescribing, patient specific direction, training of additional non-medical prescribers):

Any potential risks to patient safety:

Professional group(s) to be included in the PGD:

Training needs of HCPs:

How will competency be assessed, who will authorize HCPs to practice under the PGD, and who will keep and maintain the list of authorized prescribers?

Medicines to be included in PGD (medicine(s) to be supplied and/or administered, including dosage, quantity, formulation and strength, route and frequency of administration, duration of treatment and whether it is included in the local formulary):

Details of how the medicine will be funded, purchased and securely stored (and if applicable, the arrangements for packaging and labelling, and collection of prescription charges):

Other resources needed to deliver the service:

Name the professionals in the PGD Working Group:

	Name	Job title
Member		
Doctor		
Pharmacist		
Clinician practising under the PGD		
Other		

Name the professionals who will authorize the PGD:

	Name	Job title
Member		
Lead doctor		
Lead pharmacist		
Lead clinician practising under the PGD		
Organizational authorization		
Other		

Has final draft of PGD been agreed with the relevant stakeholders / representatives of the professional groups who will be operating under the PGD?

If PGD has been revised, please describe main amendments made to the original PGD:

Once the PGD has been approved:

1. Who is responsible for keeping the master copy of the authorised PGD?
2. How will individual authorised practitioners access the most current versions of authorised PGDs?
3. Who is responsible for monitoring and reviewing the use of the PGD e.g., in line with any significant changes to clinical practice?
4. When is the next PGD review date?

Proposer (manager or clinical lead):
I can confirm that:

- An organizational PGD policy is in place.
- The service has considered whether a PGD is appropriate by considering other potential options for supply and the SPS guidance When to use a PGD.
- The PGD content complies with the specific information which must be included in a PGD for it to be legally valid, and with the NICE MPG2 Commissioning support: PGD template. and the SPS – national PGD template
- The process for developing the PGD has complied with NICE MPG2 and SPS guidance Quality PGDs: 7 steps to success.
- The professionals involved in developing, authorizing, monitoring, reviewing, and updating the PGD have the necessary competencies as described in NICE MPG2 Competency Framework: For people authorizing PGDs and Competency Framework: For people developing and / or reviewing and updating PGDs.
- The eligible and trained health professionals using the PGD will work according to the guidance in NICE MPG2 section 1.5 and will have the necessary competencies as described in NICE MPG2 Competency Framework: For health professionals using PGDs.

- The organization will maintain a register of all healthcare professionals competent and registered to deliver the PGD.
- The organization has a medicines policy for the safe and secure handling of medicines, which includes the supply and storage of medicines.

Name: Title: Signature: Date:

Please send to completed form to PublicHealth@durham.gov.uk

For completion by the DCC PGD Approval Group

Checklist for the PGD Approval Group to consider for a new / revised PGD in line with the necessary legal requirements, national guidance recommendations, and robust governance procedures (SPS guidance Quality PGDs: 7 steps to success)

Consideration	Public Health Pharmacy Adviser comments	Additional Public Health SMT comments
Have all options for other routes of supply / administration been considered? e.g., training of further non-medical prescribers? Is this route of supply still the appropriate option?		
Does use of this PGD align with the public health commissioned service framework?		
Will use of a PGD compromise patient safety in any way?		
Is the medicine appropriate for use under a PGD? Are appropriately registered health professionals available to use the PGD, and have training and competency needs been addressed?		
Are there other resources needed to deliver the PGD e.g., finance and commissioning implications?		
Are there suitable governance and accountability arrangements in place for developing, authorizing, using, monitoring, reviewing, and updating the PGD?		
What are the arrangements for the security, storage, packaging and labelling of medicines where applicable, and collection of prescription charges where applicable (see SPS guidance PGDs and NHS prescription charges).		

This version of the PGD for use within DCC public health commissioned services has / has not been (please delete as appropriate) **approved.**

If not approved, state reasons why:

Date of PGD Approval Group meeting:

The service lead has 28 days to appeal the decision of the PGD Approval Group in writing, or to re-submit an amended PGD with the recommended changes.