Patient Group Direction Development/Review Process

Background - What is a Patient Group Direction?

A Patient Group Direction (PGD) is 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.

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.

A PGD is not a form of prescribing and where possible, medication should be provided on an individual, patient-specific basis. It is recognised that this may not always be possible and the supply and administration of medicines under PGDs 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.

Scope

In the context of this document the term 'ICB' refers to NHS Derby and Derbyshire Integrated Care Board and the term 'ICS' refers to the Joined Up Care Derbyshire Integrated Care System.

The principles of this document applies to PGDs that have been developed and/or authorised by the ICB for the treatment of NHS patients by healthcare professionals working within the ICS. This includes ICB NHS directly commissioned services.

All staff involved in the development, review and authorisation of these PGDs and operating under PGDs must comply with the principles of this document.

For ICB commissioned services where the provider is unable, by law, to authorise PGDs (see Specialist Pharmacy Service (SPS) Patient Group Directions) eg. urgent care services – the ICB will use this framework to ensure appropriate PGD governance. The ICB Commissioner will then authorise the PGD for use within the commissioned service. The commissioned Independent Health Sector provider (referred to as 'provider' in this document) is responsible for implementation and governance of the PGD.

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

PGD Development

PGD development requires a multi-disciplinary approach, knowledge about PGD legislation and governance as well as clinical expertise and knowledge about the service where the PGD is being considered.

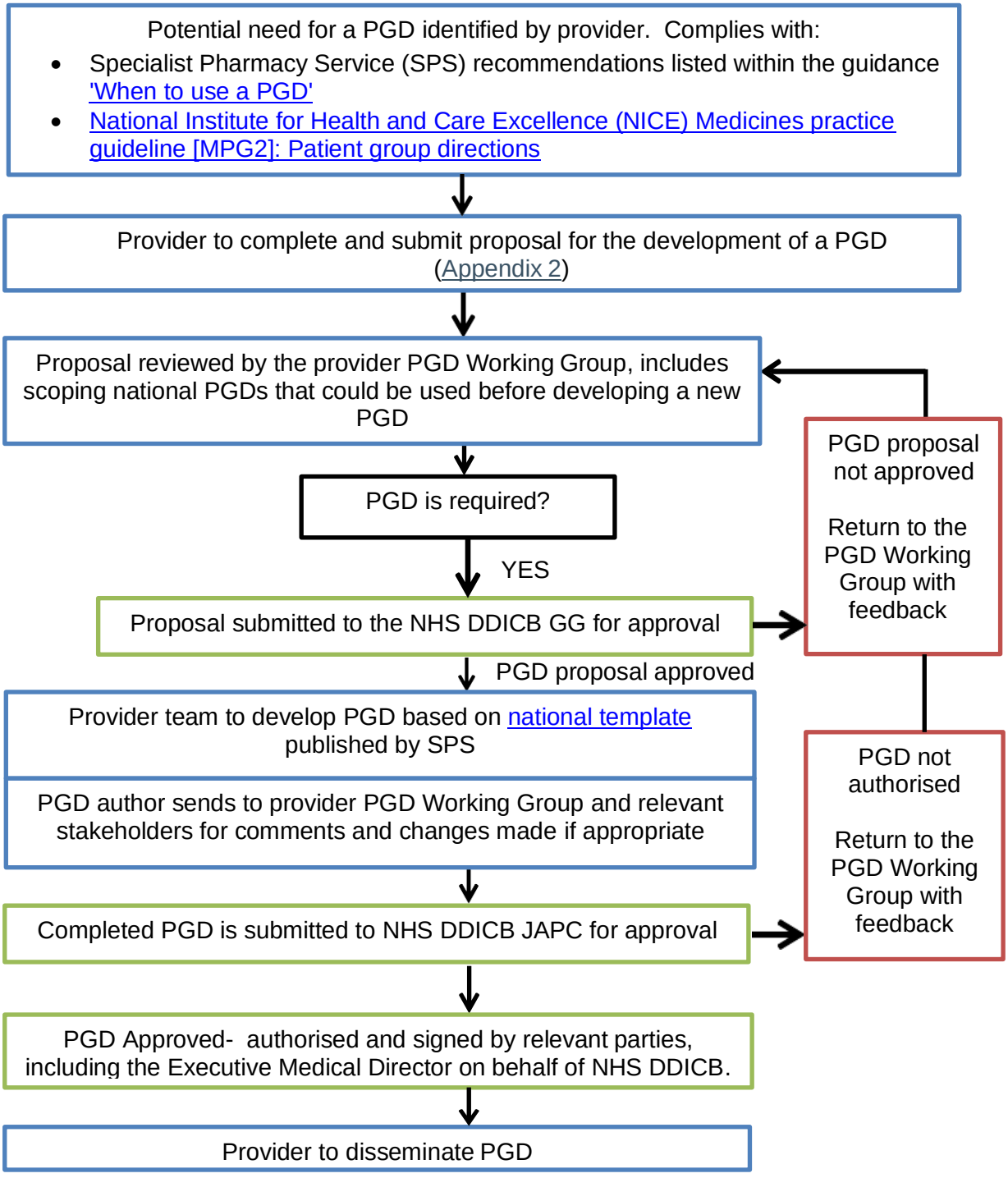
Organisations wishing to use PGDs within services commissioned by the ICB must ensure they comply with the recommendations of the following guidance:

- When to use a PGD- SPS guidance helping to understand the circumstances when PGDs must not be used or are otherwise unsuitable as a mechanism for supply and/or administration
- National Institute for Health and Care Excellence (NICE) Medicines practice guideline [MPG2]: Patient group directions- Covers good practice for developing, authorising, using and updating patient group directions. It also offers advice on deciding whether a patient group direction is needed.

PGD Development for Independent Health Sector Providers ('provider')

1. Overview of process for developing a new PGD

PGD Development flow Chart - Independent Health Sector Providers



Any independent health sector provider developing a PGD should ensure that all the steps listed within Appendix 1: New PGD Development Checklist for Independent Health Sector Provider are followed.

2. Clinical Governance

Note that some providers may have the responsibility for developing, reviewing and implementing PGDs as part of their service specification.

Once there is clear agreement that developing a PGD is appropriate to the particular situation, a multidisciplinary provider PGD working group should established. A named lead author should be identified in this group.

The provider PGD working group should consist of the following members as a minimum requirement, in line with NICE MPG2 guidance:

- Doctor (or dentist)
- Pharmacist
- representative of any other professional group(s) using the PGD

The following individuals should be considered as stakeholders who are consulted for comments on the PGD, if appropriate: (This is not an exhaustive list)

- Public health specialist for the area being covered
- Medical Consultant for the relevant public health area
- Provider
- Commissioner
- Representative of the clinicians using the PGD

For more information on PGD development see the SPS 'How to develop a Patient Group Direction'.

3. PGD Authorisation

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.

The form Appendix 3: Assessment Form for Proposal to Develop PGD should be completed by the ICB Guideline Group (GG). The authorised signatory for signing PGDs on behalf of the ICB is the Director of Medicines Management & Clinical Policies for the ICB. They will sign all PGDs having first established that:

- Local processes and governance arrangements have been followed
- All legal requirements have been met.

Authorised signatories must understand and undertake relevant training to carry out their roles and responsibilities in the authorisation of PGDs. See the following resources for more information:

- SPS: Questions about signatories of PGDs
- NICE: Competency Framework for people authorising PGDs
- SPS: Patient Group Directions and electronic record systems

Further information on responsibilities of signatories see SPS guidance on 'PGD Signatories'.
Roles and responsibilities of the ICB and Independent Healthcare Providers (IHPs) are set out in the SPS advice on the 'Authorisation of IHP PGDs for NHS and local authority commissioned services'.

Note: Electronic signatures may be used in line with MHRA guidance and the SPS guidance 'Questions about electronic systems and PGDs'.

Where a PGD is authorised regionally/ NHSE for use within Derbyshire e.g. for immunisation, these are tabled at JAPC for information/ acknowledgement.

4. PGD Implementation

When supplying and/or administering a medicine under a PGD within services commissioned by the ICB, provider organisations are expected to ensure healthcare professionals follow local organisational policies and act within their code(s) of professional conduct and local governance arrangements. In line with NICE guidance, individuals must:

- Be authorised to work under a PGD
- understand their legal and professional responsibilities.

- have undertaken the necessary initial training and continuing professional development.
- be assessed as competent and be authorised to practice by the provider organisation.
- Understand relevant information about the medicine(s) included in the PGD.

Reauthorisation/ Review of PGD for Independent Health Sector Providers ('provider')

1. Overview of process for reauthorisation/ review of PGD

The named lead author has responsibility for reviewing and updating the PGD, supported by the provider PGD working group. All required governance processes should be met regardless of how small the change.

The expiry date for an individual PGD will be determined on a case-by-case basis but must not exceed 3 years from the date the PGD was authorised, as per NICE MPG2. Work to reauthorise a PGD should start 6 months in advance of the PGD expiry to ensure completion before the PGD expires. JAPC will maintain a record of the status of each PGD, with recorded review of expiry dates as a back up to the provider rolling review programme.

It is the responsibility of the lead author of a PGD to monitor for required changes and prompt unscheduled review. Communication with the ICB regarding any unscheduled review is essential to ensure the ICB authorisation process can be scheduled accordingly.

Any independent health sector provider seeking PGD reauthorisation should ensure that all the steps listed within Appendix 4: Process for Re-authorising/Reviewing a PGD are followed.

Requests to reauthorise PGDs should be submitted to GG using the template in Appendix 5: Application Template for PGD Reauthorisation

2. Audit

PGDs use should be audited as part of a provider organisation's medicines audit programme. The results of audits undertaken should be considered when PGDs are reviewed and updated.

Use of the SPS template audit tool or equivalent is recommended to support provider organisations in auditing aspects of PGD development and use, reflecting the audit recommendations of the NICE PGD guidance.

Reauthorisation/ Review of PGD for GP Practices/ PCN in ICS using PGD

If the ICB develops PGDs for use in commissioned services, then both clinical and authorising signatories will the responsibility of the ICB. See SPS Questions about signatories of PGDs for further information.

All the steps listed within Appendix 6: Process for Re-authorising/Reviewing a PGD should be followed.

Requests to reauthorise PGDs should be submitted to GG using the template in Appendix 5: Application Template for PGD Reauthorisation

Appendix 1: Independent Health Sector Provider- New PGD Development Checklist

For use by independent provider to track progress of new PGD development

New PGD from Independent Health Sector Providers	Tick
Identify a potential need for a PGD; comply with SPS recommendations listed within the guidance 'When to use a PGD', 'How to develop a Patient Group Direction' and the National Institute for Health and Care Excellence (NICE) Medicines practice guideline [MPG2]: Patient group directions	
Complete a "Proposal for the Development of a PGD" (Appendix 2).	
Proposal to be reviewed by the provider PGD Working Group (this includes scoping national PGDs that could be used before developing a new PGD)	
The scope of the PGD proposal is submitted to ICB Guideline Group (GG) for approval GG to use Appendix 3: Assessment Form for Proposal to Develop PGD for Guideline Group to approve or return proposal with feedback.	
If approved, provider team to write the PGD using the national template published by SPS	
PGD author sends to the provider PGD Working Group and relevant stakeholders for comments and changes made if necessary.	
Completed PGD is submitted to the ICB Joint Area Prescribing Committee (JAPC) for clinical sign off	
Following JAPC, the PGD is to be authorised and signed by relevant parties, including the Executive Medical Director on behalf of the ICB.	
Provider is responsible for dissemination, implementation and governance of the PGD.	

Appendix 2: Proposal for the Development of a PGD

For completion by independent provider

Proposal to be reviewed by the provider PGD working group, includes scoping national PGDs that could be used before developing a new PGD. Refer to SPS guidance 'When to use a PGD' and 'How to develop a PGD'.

If approved by provider PGD working group, submit for approval to DDICB ddicb.pharmacy@nhs.net prior to the development of a full PGD

PGD title:				
Proposer				
Name				
Contact details	Tel: Email:			
Position in organisation				
Name and role of senior medical representative backing request (if different from proposer)				
Organisation				
Organisation name				
Service PGD to be used in			Setting(s) PGD to be used in	
Is this a current commissioned service or one under development?	Current		Under development	
Describe current and/or future service provisions for supplying and/or administering the medicine.				
Health professional groups who would work under the PGD				
Lead Author's name and role in organisation				
Is input required from specialist e.g. antimicrobial specialist?	yes no	Name of specialist *(State if ICB support is required to identify specialist)*		
Name and position of individuals who will sign-off PGD	Doctor (or dentist)			
	Pharmacist			
	Representative(s) of HC group using PGD			

Proposed use		
Is the proposed PGD for supply or administration of medicine (tick)?		□ supply □ administration
Condition or health need to be met	Inclusion criteria	
	Exclusion criteria	

Details of medicine(s) to be supplied and/or administered, including (where applicable) • name of medicine, formulation and strength, dosage, quantity, route of administration, frequency, duration of treatment	
Storage requirements of medicine	

Are the medicines licensed in the UK for proposed indication and patient group?	Yes/No
Is this treatment recommended by national or local guidance for the intended use.	Yes/No

Background Information	
Benefits to patient care of using a PGD over other methods of supply or administration e.g. prescribing, patient specific direction.	
Are there any identified potential risks to patient safety by using a PGD	
Is medicine included in the NHSDDICB Prescribing Formulary?	
Supporting information regarding proposal	
Proposed timescale for PGD development	

Governance Assurance	**Tick**
Completed NICE PGD baseline assessment tool provided alongside this form	
Your organisation's PGD policy is provided alongside this form	
Provider's PGD processes comply with NICE MPG2	
Appropriate registered health professionals will use the PGD, and training/competency needs are addressed	
People who are developing, authorising, monitoring, reviewing and updating the PGD are identified, and training and competency needs are addressed	
The need for appropriately labelled packs and safe storage can be met	
There are appropriate monitoring, audit, review and document storage processes in place.	

Appendix 3: DDICB Guideline Group (GG) Assessment Form for Proposal to Develop PGD

The following form should be completed by GG.

PGD proposal		Received from (Organisation)	
Date received		Proposer's name and email address	
Appropriateness of PGD for proposed service/use			
Is a PGD an appropriate mechanism for supply or administration in the service described? *Consider risks and benefits of all options for supplying and/or administering the medicine(s)*			
Does the PGD deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety?			
Do relevant stakeholders, where applicable, agree the proposed PGD is appropriate e.g. antimicrobials?			
Does the medicine have an appropriate status on the NHSDDICB Formulary?			
Appropriate stakeholder engagement or further stakeholders identified?			
Provider has confirmed evidence of governance assurance through completion of Governance Assurance section of Appendix 2: Proposal for the Development of a PGD, including the submission of the following alongside the form: Completed NICE PGD baseline assessment tool Provider organisation's PGD policy			

Appendix 4: Reauthorising/ Reviewing PGD- Independent Health Sector checklist

For use by independent provider to track progress of reauthorisation/ review of PGD

Providers should carefully work through the following questions and provide assurance to JAPC that all criteria has been satisfied.

Refer to SPS guidance 'When to use a PGD' and 'How to develop a PGD'.

PGDs from Independent Health Sector Providers	Tick
1. The need to review an existing PGD that is due to expire or where changes are required is identified by the provider using the PGD.	
2. The PGD lead author, with the support of the PGD working group should: • Consider if the PGD is still an appropriate way of supplying and/or administering the medication before undertaking an update. Is there now an opportunity in the care pathway for the medicine to be prescribed? • Conduct an appropriate literature search to identify new evidence. Ensure that this evidence is evaluated to assess its relevance and validity • Identify any parallel pieces of work being carried out or are ongoing in the organisation that might impact on the PGD e.g. are there any plans for re-design of services? • Demonstrate an ongoing need for the PGD by collating information regarding the frequency of use of the PGD and in what setting. • Provide a summary of incidents relating to the PGD and actions taken. • Ensure that the clinical signatories are still valid	
3. Requests to reauthorise PGDs should be submitted to GG using the template in Appendix 5: Application Template for PGD Reauthorisation to provide assurance to GG/ JAPC that: • Audits have been undertaken to demonstrate compliance with the treatment pathway. • The PGD has been reviewed in accordance with local processes and governance arrangements have been followed. e.g. Has relevant stakeholders, where applicable, such as antimicrobials, agree the proposed PGD is up-to-date? • All legal requirements have been met.	

Appendix 5: Application Template for PGD Reauthorisation

For completion by PGD author with support from PGD working group

Application to be reviewed by the (provider) PGD working group. If approved, submit to DDICB Guideline group/ JAPC via ddicb.pharmacy@nhs.net

Organisation		
Lead for PGD		
Name of PGD*		
Date of Expiry		
Date of review		
The use of this PGD has been reviewed and it is confirmed :		YES/NO
It is still the most appropriate way to supply/administer the medicine in the context of the service it is used within		
Has the clinical content/ reference been reviewed and is up to date		
The number of times the PGD has been used has been reviewed and this indicates:		
there is still a need for it based on frequency of use, OR		
It is used infrequently but is required for urgent treatment		
Audits have been undertaken to demonstrate compliance with the treatment pathway		
Have there been any incidents relating to the PGD? If YES, please describe incident(s) and state what action(s) have been taken after incident(s)		
The PGD has been reviewed in accordance with good practice and the organisation's processes and their governance arrangements have been followed		
All legal requirements have been met		
The clinical signatories are valid		
Signed on behalf of the organisation:		Date
Position:		

Appendix 6: Reauthorisation/review PGD- ICB developed PGD for use in GP practice

For use by ICB team to track progress of reauthorisation/review of PGD

Refer to SPS guidance 'When to use a PGD' and 'How to develop a PGD'.

GP Practices/ PCN in ICS using PGD	
1. The need to review an existing PGD that is due to expire or where changes are required is identified by either the GG or the practices using the PGD. • Ensure that the clinical signatories are still valid	
2. The PGD lead author with the support of PGD working group (GG working group) following consultation with GP practices will consider if: • The PGD is still an appropriate way of supplying and/or administering the medication before undertaking an update. Is there now an opportunity in the care pathway for the medicine to be prescribed? • There are any parallel pieces of work being carried out or are ongoing e.g. are there any plans for re-design of services that could impact on the need for the PGD?	
3. GP Practices/ PCN will, if required • Collate information regarding the frequency of use of the PGD and in what setting. • Provide a summary of incidents relating to the PGD and actions taken. • Provide assurance that audits have been undertaken to demonstrate compliance with the treatment pathway.	
4. PGD lead author with the support of the PGD working group (GG working group) to conduct an appropriate literature search to identify new evidence. Ensure that this evidence is evaluated to assess its relevance and validity	
5. Requests to reauthorise PGDs should be submitted to GG using the template in Appendix 5: Application Template for PGD Reauthorisation to provide assurance to GG/ JAPC that: • The PGD has been reviewed in accordance with local processes and governance arrangements have been followed. • All legal requirements have been met.	