Medicines Management, Management of Patient Group Directions requiring authorisation by NHS Shropshire Telford and Wrekin

Version	**1.0**
Author Title:	Shola Olowosale, Elizabeth Walker
Responsible committee / individual:	Quality & Performance Committee / ICB Chief Medical Officer Deputy Director, Medicines Management Team
Date ratified:	29/09/2023
Review date:	29/09/2025
Target audience:	Organisations delivering NHS services commissioned by NHS STW.

Version	Type of Change	Date	Description of Change
0.1	Draft	June 2023	

Contents

Acknowledgements To Birmingham and Solihull ICB who wrote the original policy upon which this is based.

1. Purpose

1.1. This policy outlines the processes to be followed by Shropshire Telford and Wrekin Integrated Care Board (STW ICB) to fulfil requirements for assessment of need, development of and authorisation of Patient Group Directions (PGDs) for use in commissioned services.

1.2. The policy defines STW ICB's expectations of Independent Healthcare Providers (IHPs) when considering the development PGDs requiring authorisation by STW ICB for use in commissioned services.

1.3. This policy also provides guidance to support with the assessment of need, development, authorisation, monitoring and review of PGDs for use in ICB commissioned services.

1.4. This policy applies to STW ICB and those providing ICB-commissioned NHS services.

2. Introduction

2.1. A Patient Group Direction (PGD) is a legal mechanism under which certain healthcare professionals can administer and/or supply named medicines to individuals who meet defined criteria without the need for a Patient Specific Direction, prescription or a legal exemption in Human Medicines Regulations 2012.

2.2. A PGD is not necessary and should not be used when there is an opportunity in the care pathway for the medicine to be safely prescribed on an individual basis by a qualified prescriber. Most of the clinical care involving supplying and/or administering medicines should be undertaken on an individual, patient-specific basis where this does not compromise individuals' timely access to care.

2.3. 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. Cross organisational working may be required.

3. National guidance on use of PGDs

3.1. Organisations wishing to use PGDs within services commissioned by STW ICB must ensure they comply with the National Institute for Health and Care Excellence (NICE) Medicines practice guideline [MPG2]: Patient group directions (1)

3.2. The guideline provides good practice recommendations for individuals and organisations involved with PGDs, with the aim of ensuring patients receive safe and appropriate care and timely access to medicines, in line with legislation.

3.3. NICE guidance is written in the context of the NHS in England, including independent organisations or contractors who are commissioned to provide NHS services.

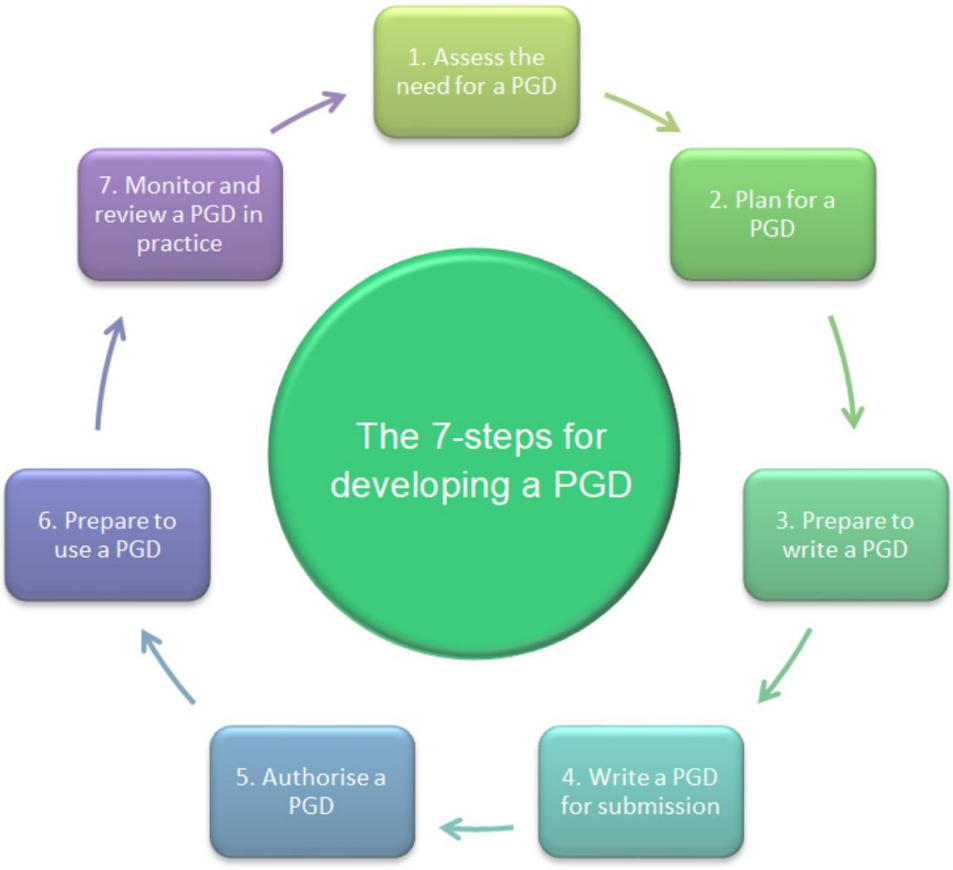
3.4. Specialist Pharmacy Services (SPS) provide guidance on all stages of PGD development, use and monitoring, which is referred to throughout this policy.

Specialist Pharmacy Service (SPS) Patient Group Directions (2)

3.5. The Medicines and Healthcare Products Regulatory Agency regulates medicines in the UK and provides guidance on the use of PGDs.

Medicines and Healthcare products Regulatory Agency (MHRA) Patient group directions: who can use them

3.6. STW ICB expects providers to consider the seven steps for developing a PGD, developed by SPS (2).



SPS: How to develop a Patient Group Direction

4. STW ICB PGD Authorisation Group

4.1. The STW ICB PGD Authorisation Group has responsibility for:

- assessing proposals for PGD development and approving or declining the proposal for PGD development.
- authorisation of PGDs to be used in ICB-commissioned NHS services.
- formally adopting the use of PGDs authorised by another NHS organisation within ICB-commissioned NHS services, where a legal framework exists to do so.

4.2. The PGD Authorisation Group members are:

- Deputy Director Pharmacy and Medicines Optimisation
- Senior Prescribing Advisor Medicines Governance
- ICB Chief Medical Officer (CMO) or agreed deputy.
- ICB Chief Nurse or agreed deputy.

4.3. The STW PGD Authorisation Group is a sub-committee of the NHS Shropshire, Telford and Wrekin System Quality & Performance Committee (SQPC)

4.4. The STW PGD Authorisation Group is chaired by the Deputy Director, Medicines Management, or an agreed deputy.

4.5. The Terms of Reference and final minutes of meetings will be stored in the MM team SharePoint site.

4.6. Only those organisations listed in legislation can authorise their own PGDs for NHS commissioned services. Other organisations, e.g. independent healthcare providers or Primary Care Networks, will need PGDs to be authorised by the ICB as the commissioner of the service within which the PGD will be used.

4.7. Organisations identifying a need to develop and use a PGD that requires authorisation by STW ICB must, before developing the PGD, formally agree with the ICB:

- the need for a PGD
- roles and responsibilities of the provider PGD multi-disciplinary team
- timescales for development / authorisation

4.8. The proposal for agreement should be submitted to the STW ICB PGD Authorisation Group using the form in Appendix A, via stw.motqueries@nhs.net. Emails should be sent for the attention of Senior Prescribing Advisor Medicines Governance and email title should be PGD proposal. This email can be used to request contact to discuss proposed PGDs before submitting for formal consideration.

4.9. Evidence to support the need for a PGD must be provided, and the proposal must be signed by the senior medical representative making the request.

4.10. The organisation's PGD policy, detailing how the organisation complies with NICE Medicines practice guideline: PGDs (1), must be provided alongside the PGD proposal form (or assurance that a previously supplied version is still in use).

4.11. The proposal form includes an assurance declaration from the executive board or equivalent of the requesting organisation that (a) the PGD development process complies in full with NICE Medicines practice guideline: PGDs (1) and that (b) those authorising are competent to the standards in the relevant competency framework provided by NICE.

4.12. If required, a meeting will be held between the STW ICB PGD Authorisation Group member(s) and provider representative(s) to discuss the proposal.

4.13. Decisions to accept or reject a proposal for PGD development will be included in the minutes of the relevant STW PGD Authorisation Group meeting, including the rationale for the decision. The completed PGD proposal assessment form (Appendix 2) will be stored with the minutes in the PGD section of the STW MMT SharePoint site.

4.14. The decision will be communicated in writing by the PGD Authorisation Group to the person who submitted the proposal, within 14 days of the decision being made. Relevant stakeholders will also be informed.

4.15. Appeals will be accepted where the proposer feels the processes outlined in this policy were not followed. Any appeal should be made in writing to stw.motqueries@nhs.net within 28 days of receiving the decision. Emails should be sent for the attention of Senior Prescribing Advisor Medicines Governance and email title should be PGD proposal appeal.

5. STW ICB PGD Development Group

5.1. The STW ICB PGD Development Group has responsibility for:

- screening proposals for PGD development before consideration by the PGD Authorisation Group
- development of PGDs, only where identified by the ICB as being key to service delivery prior to the commissioning process. In all other instances the provider will develop the PGD.

5.2. The PGD Development Group may include:

- Deputy Director, Pharmacy & Medicines Optimisation
- Senior Prescribing Advisor Medicines Governance/Partnerships and Place (Pharmacist)
- ICS Community Pharmacy Clinical Lead
- Senior Medicines Technician Medicines Governance
- Other members of the MM team as appropriate
- Co-opted clinicians as needed (doctor (or dentist), nurse, other as appropriate).

5.3. Where appropriate the ICB will utilise existing commissioning support arrangements with Midlands and Lancashire Commissioning Support Unit for the development of PGDs.

6. Assessment of need

6.1. When commissioning a new service, the requirement for development and implementation of PGDs will be considered as early as possible in the commissioning process.

6.2. The ICB will not routinely authorise PGDs for supply or administration of a medicine where a suitable alternative legal mechanism exists. PGDs should only be developed after careful consideration of the legal classification of the medication and all the potential methods of supply and/or administration of medicines, including prescribing by doctors, dentists or independent or supplementary prescribers and consideration of the legal exemptions that may be applicable.

6.3. PGDs should only be used for limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.

6.4. A PGD is not required:

- If an exemption exists under the Human Medicines Regulations 2012
  - Schedule 17 - specified registered professionals can administer or supply certain specified medicines within their scope of practice and competency;
  - Schedule 19 – certain parenteral medicines by anyone for the purpose of saving life in an emergency e.g. adrenaline for anaphylaxis)
- Supply or administration of a medicines on the General Sales List (GSL)
- For administration of a P medicine (or supply from a registered pharmacy or midwife/exemptions exist)
- For medical gases if GSL/P

6.5. PGDs cannot be used for the following:

- For long-term management of a patient's clinical condition such as in chronic or long-term conditions
- For dressings and medical devices (not medicines with UK marketing authorisation)
- For supply or administration of abortifacients (Abortion Act 1967)
- For training or as part of training
- For unlicensed medicines, including when two or more licensed medicines are mixed as this results in an unlicensed medicine e.g. via syringe drivers.
- For supply or administration of radiopharmaceuticals (Administration of Radioactive Substances Regulations 1978)
- Where there is delegation of responsibility to supply or administer the medicine
- Where dose is not stable and requires adjustment

6.6. Other special considerations

Certain medicines require special consideration before inclusion in a PGD and some are restricted by legislation.

- **Off-label use:** In exceptional circumstances, and justified by best practice, licensed medication can be used outside the terms of its product license ('off label' use) and as such may be included in a PGD whereby there are national recommendations or guidance on the use. *Note* unlicensed medicines are covered in section 6.5.

SPS - Off-label medicine use under a Patient Group Direction

- **Black Triangle▼ medicines:** Black triangle medicines will only be considered when clearly justified by best clinical practice. Treatment guidelines must be followed and the PGD must clearly state the status of the product.
- **Controlled Drugs:** The use of controlled drugs is regulated under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001. PGDs for controlled drugs will only be considered where the professionals who will use the PGD are listed in the PGD legislation. Only certain controlled drugs can be included in a PGD according to The Misuse of Drugs Regulations (2001).

SPS - Supply and/or administration of Controlled Drugs under a Patient Group Direction

- **Antimicrobial drugs:** Since antimicrobial resistance is a major public health concern, antimicrobials should only be included in a PGD when clinically essential and clearly justified by best clinical practice. The development team must include a specialist in microbiology in the development, where an antimicrobial PGD is being considered. The NHSE and NHS Improvement AMR Programme Board's Framework for risk assessment of infection management patient pathways encompassing supply of antimicrobials under a PGD should be reviewed where supply or administration of antimicrobials under a PGD is being considered. A copy of this document can be provided by the ICB on request.

- **Occupational Health use:** While the ICB is not responsible for authorising PGDs for occupation health use, providers should note that PGDs are often not an option for supply or administration of medicines for Occupational Health reasons, and where they are an option, exemption in Schedule 17 of The Human Medicines Regulations 2012 means they are not required. SPS has provided information about the use of alternative mechanisms for common scenarios.

SPS - PGDs and Occupational Health Services

6.7. Further reading

SPS: When to use a PGD

SPS: When Patient Group Directions are not required

SPS: Advice on supply and administration

7. Development of PGDs

7.1. PGDs for use by organisations to deliver NHS services commissioned by STW ICB will be developed by the service where possible.

7.2. In limited circumstances (see section 5.1.2) the STW ICB PGD Development Group or MLCSU may develop the PGD.

7.3. As per NICE guidance (1), a provider PGD working group, responsible for developing and subsequent review of the PGD, should be established for each individual PGD.

7.4. Whilst the responsibility for the membership of the provider PGD Working Group will usually lie with the provider organisation, the ICB requires that:

- Membership reflects recommendations of NICE guidance (1), including appropriate input from relevant primary care practitioners.
- Each PGD has a named lead author.
- Where appropriate, input is sought from external stakeholders e.g. antimicrobial specialist.
- The PGD working group complies with the recommendations of the NICE competency framework for people developing, reviewing or updating PGDs and provides the requested information for assurance purposes, including:

    - The organisations PGD policy
    - An up-to-date copy of the completed NICE PGD baseline assessment tool
    - A completed copy of the relevant NICE Competency Framework Documents for those individuals developing and signing off the PGDs from the provider organisation.

NICE: Tools and resources, patient group directions (competency frameworks, baseline assessment tools)

7.5. The STW ICB PGD Development Group will also reflect the requirements expected of provider groups in 7.4

7.6. Specific information must be included in the PGD for it to be legally valid.

7.7. PGDs must be consistent with the relevant summary of product characteristics, unless the medicine is being used off-label or relevant national guidance is being followed. Use the best available evidence, such as NICE guidance and other sources of high-quality information when developing PGDs. Include key references in an appendix to the PGD.

7.8. Template PGDs provided by SPS or NICE should be used/adapted where available. 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.

7.9. PGDs will be checked and signed by the senior postholders of the service i.e. doctor* (or dentist)*, pharmacist* and representative of the staff# using the PGD (* legal requirement, #good practice and ICB requirement).

7.10. Each signatory must understand their roles and responsibilities in the development of the PGD as set out in the NICE competency framework supporting implementation of NICE MPG: PGDs (1). The ICB will require assurance of competence for all signatories for each PGD authorised

7.11. Electronic signatures may be used in line with the Specialist Pharmacy Service 'Questions about electronic systems and PGDs'.

7.12. Finalised PGDs will be submitted to the STW ICB PGD Group for authorisation (see section 4 for details).

7.13. See section 8 for the use of PGDs where complex commissioning arrangements are in place.

8. Authorisation of PGDs

8.1. Where legislation allows, NHS provider organisations will authorise their own PGDs for use in ICB commissioned services. Assurance around the governance of this process will be provided via the ICB's contract assurance processes.

8.2. Independent healthcare providers (IHPs) cannot authorise their own PGDs for NHS commissioned services so will need authorisation from the ICB as the commissioner of the service within which the PGD will be used. PGDs are not lawful unless authorised by a body noted in legislation as being able to do so (note on legislation: Primary Care Trusts have been superseded by ICBs).

8.3. Within STW ICB, the authorising signatories for PGDs are:

- Chief Medical Officer
- Chief Nursing Officer
- Deputy Director, Pharmacy and Medicines Optimisation

8.4. The ICB will consider the knowledge, skills and expertise of those who developed the PGDs and will seek assurance that all those involved with development and use of the PGD are aware of their responsibilities and can demonstrate their competency as per NICE competency Frameworks (see section 7.4).

8.5. The individual signatory within the ICB will sign to state that a PGD is fit for purpose and 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.
- there is no opportunity in the care pathway for the medicine to be consistently prescribed in a timely manner.
- those involved in the clinical authorisation of the PGD are competent to do so.
- local processes and governance arrangements have been followed.
- the views of all stakeholders have been considered.
- all legal requirements have been met.

Note: The signatory on behalf of the ICB is not required to check clinical content of the PGD in detail but will request information to provide assurance that the doctor (or dentist) and pharmacist signatories (and anyone else involved in the development of the PGD) have adequate competency, skills and experience to carry out the role (see section 7.4).

8.6. Authorised signatories must understand and undertake relevant training to carry out their roles and responsibilities in the authorisation of PGDs.

SPS: Questions about signatories of PGDs

NICE: Competency Framework for people authorising PGDs

SPS: Patient Group Directions and electronic record systems

8.7. Roles and responsibilities of the ICB and IHPs are set out in the SPS advice on the authorisation of IHP PGDs for NHS and local authority commissioned services.

SPS: Authorisation of IHP PGDs for NHS and public health commissioned services.

8.8. Electronic signatures may be used in line with the Specialist Pharmacy Service 'Questions about electronic systems and PGDs'.

9. Complex commissioning arrangements

9.1. Shropshire, Telford and Wrekin ICB will consider entering into an agreement with a provider and other ICB commissioners of a service, to ensure the PGD authorisation process is not overly onerous, while still complying with relevant guidance and legislation. This could involve:

- Acting as the Lead Commissioner and authorising PGDs for use in services commissioned by the ICB, which are then formally adopted by other ICBs under a Memorandum of Understanding (MOU), or
- Formally adopting, for use in services commissioned by the ICB, PGDs that have been authorised by another NHS body acting as Lead Commissioner, under an MOU.

9.2. Clear lines of responsibility must be determined prior to the development of a PGD for use in the delivery of a commissioned service.

9.3. Where a service is commissioned by more than one ICB, a lead commissioner should be identified, which should take responsibility for supporting the development of PGDs for use within the commissioned service.

9.4. Where multiple provider organisations are involved in delivering a service, a lead provider will be identified.

9.5. The initial agreement, laid out in a Memorandum of Understanding (MOU), should define all the responsibilities involved in PGD development and use, from writing and authorising PGDs to adoption and implementation and should consider factors such as review, document management and any training requirements including which organisation will be responsible for each function.

9.6. The need for a MOU should be identified at the initial stages of PGD development and all parties should agree the details of the MOU before progressing the development of a PGD.

9.7. Where a lead organisation is identified to act on behalf of other provider or commissioner organisations it is essential that all involved organisations have the necessary governance processes in place to ensure any action undertaken by the lead organisation are formally noted. This should be reflected in the MOU.

9.8. Where STW ICB acts as a Lead Commissioner (LC), the STW ICB PGD Authorisation Group will support the development of, review and agree, with appropriate legal advice, the MOU for development, authorisation and use of a PGD within a commissioned service.

9.9. Where STW ICB is not the LC, the STW ICB PGD Authorisation Group will review and agree, with appropriate legal advice, the MOU for use of a PGD within a commissioned service.

9.10. The STW ICB PGD Authorisation Group will require assurance of the LC's governance process, including:

- LC's PGD policy
- Details of the person authorising the PGD on behalf of the LC.

SPS: Patient Group Directions in Complex Commissioning Scenarios

SPS: Authorisation of Independent Healthcare Provider (IHP) PGDs for NHS and public health commissioned services

10. Use of PGDs

10.1. For PGDs developed by the ICB:

10.2. Notification of newly published PGDs (new or updated) will be sent to designated individual(s) [depending on service] to co-ordinate distribution to appropriately trained staff.

10.3. For PGDs authorised for other commissioned providers:

10.4. The provider is responsible for ensuring appropriate administration and dissemination.

10.5. It is the responsibility of a senior medical representative in the provider organisation to adopt the PGD by signing it.

10.6. When supplying and/or administering a medicine under a PGD within services commissioned by STW 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 (1), individuals must:

10.7. Be authorised to work under a PGD.

10.8. understand their legal and professional responsibilities.

10.9. have undertaken the necessary initial training and continuing professional development .

10.10. be assessed as competent and be authorised to practice by the provider organisation.

10.11. Understand relevant information about the medicine(s) included in the PGD.

10.12. A senior person should be responsible for ensuring that only fully competent, qualified and trained health professionals are authorised to use the most recently approved version of the PGD.

NICE: Competency Framework for health professionals using PGDs

10.13. An e-learning programme is available for all professionals, to understand how to make sure that PGDs are developed, authorised and used safely.

E-learning for Health: multi-disciplinary PGD e-learning programme

11. Review

11.1. 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 (1).

11.2. The STW ICB PGD Group has responsibility for maintaining a list of and monitoring the review date of PGDs that the ICB has (a) produced and authorised or (b) authorised for use in commissioned services.

11.3. Routine review:

- It is the responsibility of the lead author of a PGD to initiate the review process in sufficient time (at least 6 months prior to PGD expiry) to ensure the process can be carried out without interrupting continuity of care.

11.4. Unscheduled Review:

- Anyone who is involved with clinical practice under the PGD, or who is a clinical signatory, should be alert for the need for an unscheduled review of the PGD.
- This may be as a result of a change in the licence of the product/new national guidelines or other important new evidence which requires changes in clinical practice under the PGD.
- 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.

11.5. The PGD lead author has accountability for:

- leading the review process
- determining whether the PGD remains the most appropriate option to deliver the service.
- reviewing the results of the audit/s of the PGD use that have been undertaken or incidents related to use of the PGD.
- appraising the current evidence base and national/local guidance, stakeholder views and update the PGD accordingly.

11.6. All routine and unscheduled reviews and/or proposed changes to PGDs will be required to go through the review process and be re-authorised by the ICB.

11.7. The expiry date of a PGD will only be extended in exceptional circumstances.

11.8. The STW ICB PGD Group will maintain a record of the status of each PGD, with annual recorded review of expiry dates as a back up to the rolling review programme.

11.9. Re-authorised PGDs will be emailed to the provider PGD Lead by the ICB PGD authorisation Group as soon as they are available.

11.10. It is the responsibility of the provider to inform the ICB if the provider organisation 'PGD Lead' changes.

> SPS: Reauthorising and re-signing of a Patient Group Direction (PGD) following amendments/changes

12. Monitoring and audit

12.1. PGD 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.

12.2. 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 (1).

> SPS: Patient Group Direction SPS Template Audit Tool

12.3. NICE PGD guidance provides additional specific advice on the auditing of PGDs for the supply or administration of antimicrobials.

12.4. Provider organisations are expected to review patient safety incidents relating to PGD use, which should be reported in line with national patient safety reporting systems. Incidents should inform review of PGD use.

12.5. All adverse drug reactions should be reported in accordance with the MHRA Yellow Card system

12.6. STW ICB PGD group will require information from audit and review processes when re-authorising PGDs for continued use in commissioned services.

13. Record keeping

13.1. The STW ICB PGD Group will keep a master copy of all ICB-authorised PGDs used within commissioned services, including those authorised by another lead ICB under a MOU in complex commissioning arrangements.

13.2. The final authorised copy of the PGD should be kept for 8 years after the expiry date of the document if it relates to adults only (10 years if relates to an implant) and for 25 years after the expiry date if it relates to children.

13.3. An unauthorised final copy, which contains no individual identifiable information or staff authorisation records, may be retained for up to 20 years for purposes of

business planning/continuity if there is reason to do so (i.e. reference for future PGD development).

13.4. Provider organisations using PGDs are expected to ensure that appropriate organisational records are maintained, stored securely and archived, in line with NICE guidance (1) and relevant legislation.

SPS: Retaining legal mechanism (e.g. PGD, Written Instruction, National Protocol) documentation

SPS: Patient Group Directions and electronic record systems

14. Other considerations

14.1. Providers must consider process requirements including providing an appropriately labelled pack and manufacturer's patient information leaflet and assessing whether prescription charges are required in line with the National Health Service (Charges for Drugs and Appliances) Amendment (No. 2) Regulations 2000.

15. Bibliography

1. (NICE), National Institute for Health and Care Excellence. Medicines practice guideline [MPG2]: Patient group directions. [Online] 2017. [Cited: 09 11 2022.] https://www.nice.org.uk/guidance/mpg2.

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3. The Human Medicines Regulations 2012. [Online] [Cited: 09 11 2022.] http://www.legislation.gov.uk/uksi/2012/1916/regulation/229/made. 1.

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Appendix 1: proposal to develop 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?	*curr ent*		*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 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				
Is the medicine licensed in the UK for proposed indication and patient group				

Is this treatment recommended by national or local guidance for the intended use.	
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 STW Integrated Care System Formulary?	
Storage requirements of medicine	
Supporting information regarding proposal	
Proposed timescale for PDG development *Proposals will be considered at the next routine PGD Authorisation Group meeting, at least* 4 weeks following submission. Please indicate if a more urgent response is required with rationale.* **meetings routinely held quarterly*	
Please supply your organisation's **PGD policy** and completed **NICE PGD baseline assessment tool** alongside this form.	

ICB use only	*PGD proposal reference number:*	
	Date received:	

Appendix 2: Assessment form for proposal to develop PGD

This form should be completed by the STW PGD Authorisation Group.

PGD proposal application number		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 STW Formulary?	
Governance assurance	
PGD policy and NICE PGD baseline assessment tool provided and give assurance that: • Providers 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.	

Date considered at PGD Authorisation Group	
Decision	
Date and method communicated to provider.	