

Patient Group Direction (PGD): Governance and Approval Framework

TARGET AUDIENCE

All NHS Lanarkshire staff who may author, sign, implement, use, or manage Patient Group Directions, including clinical, managerial, and administrative roles.

WHAT IS A PATIENT GROUP DIRECTION?

A Patient Group Direction (PGD) is a legal, written instruction for the supply and/or administration of medicines to groups of patients who may not be individually identified before presenting for treatment. Only licensed medicines with UK marketing authorisation can be considered for a PGD.

A PGD allows a specified registered health care professional to supply and/or administer a prescription only medicine (POM) directly to a patient with an identified clinical condition without the need for a prescription or an instruction from a prescriber. PGDs can be used for the supply of a Pharmacy Only (P) medicine but not for their administration and PGDs cannot be used for supply or administration of a General Sales List (GSL) medicine.

The supply and/or administration of medicines under a PGD cannot be delegated – the whole episode of care must be undertaken by the registered health care practitioner operating under the PGD.

The preferred way for a patient to receive a medicine is for a prescriber to provide care for an individual patient on a one-to-one basis. A PGD should not be used unless there are clear benefits for patient care without compromising patient safety, and there are clear governance arrangements and accountability.

Further detail on all aspects of PGDs can be found at the following website - [Specialist Pharmacy Service \(SPS\): Patient Group Directions and legal mechanisms.](#)

Key links within the Specialist Pharmacy Service guidance on PGDs include:

- [An introduction to PGDs: definitions and examples of use](#)
- [The 7-steps for developing a PGD](#)
- [When PGDs can be used](#)
- [When not to use a PGD](#)
- [PGD signatories - roles and responsibilities](#)

DEVELOPMENT OF A PGD

Before developing a PGD or reviewing an existing PGD, the need for a PGD should be assessed. Consider if there is already an opportunity in the care pathway for the medicine to be prescribed in a safe and timely manner.

A PGD should be developed by a multi-disciplinary group that includes a doctor, a pharmacist and a representative of the professional group expected to supply and/or administer the medicine under the PGD. Knowledge about PGD legislation and governance as well as clinical expertise in the medicines and service where the PGD is being considered is essential. Health professionals involved in PGD development should refer to their own regulatory or professional standards.

It is important to ensure the lead author has the competencies and experience required to write a PGD. They should also ensure all contributing authors are involved at all stages of development, to check for clinical accuracy and validity according to the specialty.

It may be appropriate for the lead author of a PGD to use that PGD if they are a registered and authorised healthcare professional meeting legal and competency requirements. However, being the lead author does not automatically grant permission to use the PGD. The PGD must be signed off by all required clinical and organisational signatories, and the practitioner must be listed and authorised. Lead authors may also support training. ([NICE MPG2 Recommendation 1.1.5](#))

CLINICAL AND ORGANISATIONAL SIGNATORIES

CLINICAL SIGNATORIES should be identified at an early stage, and they should know why they are signing and understand their roles/responsibilities. Clinical Signatories must include:

1. A doctor (or dentist) involved in the development of the PGD
2. A pharmacist involved in the development of the PGD
3. A signatory who is a representative of the registered health professional group expected to supply and/or administer the medicine under the PGD

Where the representative of the registered health professional group is a pharmacist, it would be good practice to involve an additional pharmacist with expertise in the specific clinical area of practice who would use the PGD.

ORGANISATIONAL SIGNATORIES may vary depending on the type of PGD – further details can be found under the relevant PGD category later in this guidance. The clinical governance or patient safety lead involved in the organisational authorisation of the PGD should not be involved in developing the PGD and will not practice under the PGD. Organisational Signatories can include:

- Executive Medical Director
- Director of Pharmacy or Associate Director of Pharmacy
- Executive Nurse Director

Additionally, for Immunisation PGDS

- Associate Primary Care Medical Director / Chair Vaccine Services Clinical Governance Committee
- Immunisation Coordinator
- Lead Pharmacist for Public Health

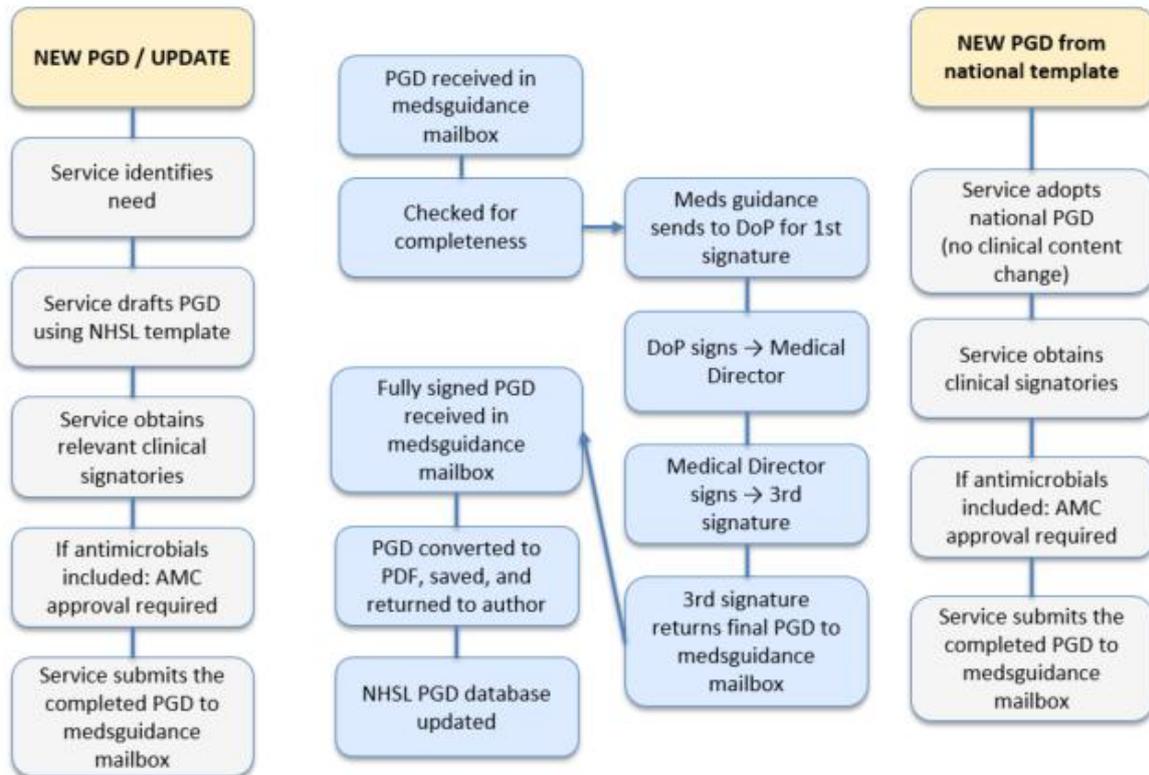
A standard NHS Lanarkshire PGD template is available ([RDS link](#)) and should normally be used for the development of locally authored PGDs. Where a national template is issued (e.g. by Public Health Scotland or UKHSA), the national version may be adopted, with organisational signatories added if required.

All PGDs, whether developed using the local template or adopted from a national template, must be fully signed, with each required signature clearly dated, and submitted to medsguidance@lanarkshire.scot.nhs.uk for organisational approval and governance oversight.

Useful Links:

- [NHS Lanarkshire PGD template](#)
- [SPS guidance on electronic record systems](#)

NHS LANARKSHIRE PGD DEVELOPMENT AND APPROVAL PROCESS



[Appendix 4. NHSL PGD Pre-Submission Checklist](#) provides a structured summary of the key requirements authors and clinical signatories should confirm before sending a PGD for organisational approval.

The [Frequently Asked Questions](#) (see page 10) offer additional clarification on common issues and are a useful reference during drafting and submission.

ACUTE & PRIMARY/COMMUNITY CARE PGDS

The NHS Lanarkshire PGD Template, for use in all sectors including primary/community care and acute, can be found [here](#).

The PGD must be signed by a doctor (or dentist) and a pharmacist who have been involved in the development of the PGD. It is also good practice for PGDs to be signed by representative(s) of the registered health professional group intended to supply and/or administer the medicine under the PGD. Where the representative of the registered health professional group is a pharmacist, it would be good practice to involve an additional pharmacist with expertise in the specific clinical area of practice who would use the PGD.

In primary care where there is no clearly relevant specialist pharmacist e.g. physiotherapy, please contact the Medicine Policy and Guidance Team for further advice.

CLINICAL SIGNATORIES include:

- Lead Author
- Doctor/Dentist
- Pharmacist
- Relevant healthcare professional

Please note; the lead Author may be the same individual as one of the other 3 named producers of the PGD.

If the PGD contains antimicrobials it must be approved by the NHS Lanarkshire Antimicrobial Committee prior to health board sign off.

The finished PGD is then sent to the Medicines Policy and Guidance Team medsguidance@lanarkshire.scot.nhs.uk to obtain the following:

ORGANISATIONAL SIGNATORIES:

- Medical Director or Associate Medical Director
- Director of Pharmacy or Associate Director of Pharmacy
- Executive Nurse Director

COMMUNITY PHARMACY PGDS

The current list of approved PGDs for community pharmacy within NHS Lanarkshire can be found here <https://www.communitypharmacy.scot.nhs.uk/nhs-lanarkshire/pages/pgds/> and includes PGDs for the treatment of a range of conditions including herpes zoster, bacterial skin infections, impetigo, urinary tract infection and seasonal allergic rhinitis.

Most of the community pharmacy PGD's are developed from national templates with final approval sought locally in each health board. The process within NHS Lanarkshire for approval is coordinated by the Lead Pharmacist for Community Pharmacy Services.

Community Pharmacy (Pharmacy First) PGDs are not required to be approved by any additional committees in NHS Lanarkshire because they are developed from national templates. The exception is any PGDs that include antibiotics will be approved by the NHS Lanarkshire Antimicrobial Committee.

The national PGD is then sent to the Medicines Policy and Guidance Team medsguidance@lanarkshire.scot.nhs.uk to obtain the following:

ORGANISATIONAL SIGNATORIES:

- Medical Director
- Director of Pharmacy
- Associate Director of Pharmacy or Lead Pharmacist for Pharmacotherapy and Community Pharmacy Services

Once signed the final copy of the PGD is saved in the NHS Lanarkshire PGD database and sent to the Lead Pharmacist for Community Pharmacy Services who is then responsible for dissemination to community pharmacies and for uploading them to the above community pharmacy Scotland website.

Any PGDs used in community pharmacy which are NHS Lanarkshire board authored, e.g. Levonorgestrel for emergency hormonal contraception, should go through the same development steps detailed for PGDs used within primary care.

Public Health Scotland develops specimen national PGD templates for specific vaccines to assist NHS Boards. Further information can be found here: [Public Health Scotland – PGDs](#).

It is not expected that the contents of the national PGD templates will be altered, however if changes are required, they must be approved by the Area Oversight Vaccination and Immunisation Group prior to organisational approval.

These national immunisation PGDs require to be approved and signed by the following CLINICAL SIGNATORIES:

- Lead Medical Clinician for Vaccine Services
- ⊖ Lead Pharmacist for Public Health
- Lead Nurse for Vaccine Services

The national PGD is then sent to the Medicines Policy and Guidance Team medsguidance@lanarkshire.scot.nhs.uk to obtain the following ORGANISATIONAL SIGNATORIES:

- ⊖ Medical Director or Associate Primary Care Medical Director
- Director of Pharmacy or Associate Director of Pharmacy
- Clinical Governance Lead

Once signed the final copy of the PGD is saved in the NHS Lanarkshire PGD database and sent to the Immunisation Coordinator for dissemination.

The Vaccine Service also uses National Protocols for Influenza and COVID vaccinations. These cannot be modified at Health Board level so there is no local sign off but the process for dissemination and publication is the same as for PGDs.

Detailed operational processes for the development and management of immunisation PGDs are set out in the *'NHS Lanarkshire Public Health Patient Group Direction Development Standard Operating Procedure including vaccination and immunisation, national protocols and CBRN PEP'*.

The UK Health Security Agency (UKHSA) issues nationally developed Patient Group Directions (PGDs), such as those for ciprofloxacin, doxycycline, and potassium iodate, primarily to support Chemical, Biological, Radiological, Nuclear (CBRN) incident response. These PGDs are national documents and are intended to be adopted by NHS Boards without local amendment.

NHSL Process

1. Notification

When UKHSA publishes or updates a PGD, the Public Health Team will circulate it to all relevant stakeholders.

2. Review

The Lead Pharmacist for Public Health (or deputy) will review the PGD content and raise any concerns directly with UKHSA as appropriate.

3. Approval

NHS Lanarkshire does not sign individual UKHSA PGDs. Instead, an NHSL agent authorisation form (cover sheet) is used to authorise practice for each agent.

When a new pharmaceutical agent or indication is introduced, the Lead Pharmacist for Public Health will complete an updated agent authorisation form and submit to the NHS Lanarkshire Medicines Policy and Guidance team.

The Medicines Policy and Guidance team will:

- circulate the agent authorisation form and UKHSA PGD to the required organisational signatories
- confirm that the UKHSA PGD content is acceptable for use within NHS Lanarkshire
- advise the Lead Pharmacist for Public Health of the outcome.

The agent authorisation form, together with the UKHSA PGD, constitutes the full authorisation framework used within NHS Lanarkshire.

4. Recording

The UKHSA PGD and the associated NHSL agent authorisation form will both be added to the central database. For operational use, NHSL authorises staff via the agent authorisation form, while the clinical detail and UKHSA governance requirements remain within the UKHSA PGD. Together, these documents constitute the complete authorisation package.

Updates will be included in the PGD report to the Area Drug and Therapeutics Committee (ADTC).

The Public Health department will inform relevant stakeholders, including acute site leads, to ensure resilience documentation is updated accordingly.

Potassium Iodate

Although a PGD is not legally required for potassium iodate (as it is a P medicine and may be used under other legislative routes), NHS Lanarkshire will utilise the UKHSA protocol and the NHSL agent authorisation form to ensure suitably qualified staff can administer it without delay.

ACCESS AND STORAGE OF PGDS

Currently PGDs are being catalogued in a database and final copies of PGDs are stored by the Medicines Policy and Guidance Team.

A central database is under development by the Medicines Policy and Guidance Team to allow oversight and to send reminders and alerts when PGDs are nearing expiry. PGDs generally have a 3-year expiry with a review date set for 6 months before expiry date.

The responsibility of the content of the PGD will rest with the signatories and not the Medicines Policy and Guidance Team.

ESCALATION AND REPORTING PROCESS

Where concerns, delays, or risks are identified in relation to any PGD, the following escalation process will apply:

1. **Medicines Policy and Guidance Team:** initial review and attempts to engage with authors/stakeholders.
2. **Area Drug and Therapeutics Committee (ADTC):** escalation point for further guidance, decision-making, and next steps.
3. If an issue warrants wider senior-leadership awareness beyond the ADTC membership, the relevant Executive Directors will be notified.

ADTC will also receive a monthly PGD activity report, produced by the Medicines Policy and Guidance Team, to support governance oversight.

MONITORING, REVIEWING & EVALUATING PGD USE IN PRACTICE

When a PGD is due for review, the ongoing need for the PGD must be assessed, as the preferred route for individuals to receive medicines is via a prescriber providing care on a one-to-one basis (e.g. via a prescription or a Patient Specific Direction).

Each PGD has an expiry date. Three months prior to the expiry date, the lead author will be notified by the team overseeing the PGD database to initiate the review. Even if no amendments are required, the PGD must follow the full authorising process. The review and re-authorisation must be fully completed before the existing PGD expires. The use of an expired PGD is not legally permitted.

AUDIT

There are 4 stages to the ongoing audit of PGDs within NHS Lanarkshire. Further information can be found in Appendix 3.

- A. Governance – Process Oversight
- B. Governance – PGD Content
- C. Clinical Patient Factors/clinician decision factors
- D. Operational – Staff Factors/Service Level Factors

FREQUENTLY ASKED QUESTIONS

The FAQs are grouped into three sections for clarity:

Understanding the Basics

Who Can Use or Author PGDs

Governance, Review and Quality Assurance

UNDERSTANDING THE BASICS

1. What is a PGD?

A Patient Group Direction (PGD) is a legal framework that allows registered, authorised healthcare professionals to supply and/or administer a specific medicine to groups of patients without a prescription. It is not optional guidance; it is a legally binding document.

2. Is a PGD the same as a protocol?

No. A PGD is a legal mechanism with strict criteria. A protocol is clinical guidance and carries no legal authority to supply/administer medicines.

3. What medicines can be in a PGD?

Only licensed medicines may be included. PGDs can authorise the supply and/or administration of Prescription Only Medicines (POMs) and supply only of P medicines. GSL medicines cannot be included.

4. When should a PGD be used?

Where it offers an advantage for patient care without compromising safety, and where it is not practical to issue individual prescriptions. Treatment pathways are clearly defined, and the medicine and its use are well-established and low risk.

5. When is a PGD *not* appropriate?

If there is an opportunity within the care pathway for medicines to be safely prescribed on an individual patient basis by a qualified prescriber.

PGDs must not be used for:

- Unlicensed medicines
- Dressings or medical devices
- Unauthorised off-label use of a licensed medicine
- Unlicensed use of a licensed medicine
- Individualised dosing or dose adjustments (PGDs must specify a fixed dose or a clearly defined dose range and cannot be used to titrate or change doses already supplied)
- Repeat or ongoing treatment
- Mixing of medicines
- Covering service gaps from a lack of prescribers or inadequate staffing

6. Can a PGD be used in more than one location?

Yes. A single PGD may be used in any suitable location unless the PGD specifies a named setting. If a location is stated (e.g. “for use in the Minor Injuries Unit”), it can only be used there.

WHO CAN USE OR AUTHOR PGDS

7. Who can work under a PGD?

Only the specific professional groups listed in the PGD (e.g. registered nurses, midwives, physiotherapists, pharmacists) can work under it. You must have read, understood and personally signed the PGD to confirm your authorisation before using it. If you haven't completed the required training and signed the PGD yourself, you cannot use it.

8. Why do I need to sign to work under a PGD?

By signing, you confirm that you:

- understand the PGD
- accept responsibility for practising under it
- are competent to assess patients against the inclusion/exclusion criteria
- will keep to the legal requirements

If you sign but do not follow the PGD correctly, you are personally accountable.

9. Why should the service delivering the care be the authors of the PGD?

PGDs must be written by healthcare professionals with appropriate clinical expertise. The service delivering the care is responsible for the clinical pathway, the patient population, and the risks involved, so they are best placed to:

- Ensure the PGD reflects current clinical practice
- Determine what is clinically appropriate for that patient group
- Identify the correct inclusion/exclusion criteria and red flags
- Align the PGD with local competency, training and supervision
- Make sure the document supports safe and practical delivery in their setting
- Take responsibility for clinical governance and risk around the PGDs use

The Medicines Policy and Guidance Team provides governance, oversight and support, but the clinical content must come from the service that delivers care.

10. What specific expertise should be involved in signing off a PGD?

The doctor and pharmacist signatories are responsible for the final content. They must ensure the PGD is clinically accurate, evidence-based, legally compliant and consistent with:

- The Summary of Product Characteristics (SPC)
- Relevant local and national guidelines/policies
- Current best evidence

They may also seek input from specialists in the relevant condition or medicine.

11. What happens if one of the authoring or developer signatories leaves NHS Lanarkshire?

When a signatory signs a PGD, they do so in line with the responsibilities of their role as agreed by their organisation. If a signatory later leaves NHS Lanarkshire, the PGD does not need to be re-signed.

12. What is the difference between the signatories on a PGD?

Developmental signatories draft and/or review the PGD content. They understand the clinical pathway, patient group, and how the medicine is used in practice.

Clinical signatories (doctor and pharmacist) provide professional approval, confirming the PGD is accurate, evidence-based, safe and legally compliant.

Organisational signatories (e.g. Medical Director, Director of Pharmacy, Executive Nurse Director) give the formal organisational authorisation.

13. Can locum, bank or agency staff use PGDs?

Yes, provided they:

- Belong to a professional group listed in the PGD
- Are trained and competent
- Are locally authorised to work under the PGD
- Have signed the PGD before use

If these conditions are not met, they must not use the PGD.

14. What happens if a staff member has not completed the required PGD training?

They cannot use the PGD until they have completed the required training, competency assessment and signed the PGD. Services are responsible for ensuring that only staff who have met these requirements are authorised to work under the PGD.

GOVERNANCE, REVIEW AND QUALITY ASSURANCE

15. Who is responsible for reviewing and updating PGDs?

The PGD author(s) are responsible for reviewing content, relevance and clinical accuracy. The Medicines Policy and Guidance Team oversees the governance process.

Healthcare professionals using the PGD are responsible for ensuring they are working from the most current approved version.

16. Why are PGDs so strict?

Because PGDs bypass normal prescribing. Without strict legal checks, there is a risk of:

- Unsafe supply
- Misdiagnosis
- Missed red flags
- Inappropriate repeated use of the PGD
- Legal liability for the individual and organisation

The legal framework protects patients, staff and the organisation.

17. What should I do if I think a PGD is unclear, incorrect, or hard to use?

Raise this with your line manager in the first instance. If the issue remains unresolved, contact the lead author. You can also seek advice from the Medicines Policy and Guidance Team. Please note that changes can only be made through the formal review and authorisation process.

18. How long is a PGD valid for?

Most PGDs are valid for up to 3 years, but the expiry date is stated on each PGD document. Services must ensure they do not use a PGD after its expiry date.

19. How early should services start planning a PGD review?

Ideally 3-6 months before expiry. This allows time for clinical updates, stakeholder input and formal approval. Late submission may result in gaps in service provision if the existing PGD expires.

20. Can a PGD still be used if the medicine is temporarily unavailable?

No, PGDs cannot be informally adapted. If a medicine is unavailable, follow any board issued guidance on alternatives. Do not substitute another medicine without formal approval.

21. Are there standard templates services can use when developing a PGD?

Yes, the NHSL template can be found [here](#). Minor amendments may be made where clearly justified.

22. Where can I find further information on developing or signing off a PGD?

There is very helpful guidance in the SPS website - [Patient Group Directions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice.](#)

23. Who do I contact for information about the availability or status of a PGD in NHS Lanarkshire?

Email: medsguidance@lanarkshire.scot.nhs.uk

APPENDICES

1. GOVERNANCE INFORMATION FOR GUIDANCE DOCUMENT

Lead Author(s):	Medicines Policy and Guidance Team
Endorsing Body:	ADTC
Version Number:	3
Approval Date:	21/01/2026
Review Date:	21/01/2029
Responsible Person (if different from lead author):	

CONSULTATION AND DISTRIBUTION RECORD

Contributing Author(s):	
Consultation Process / Stakeholders:	<ul style="list-style-type: none"> • Heads of Pharmacy at Hairmyres, Monklands and Wishaw Hospitals • Primary Care Central Prescribing Team • Margot Russell - Director NMAHP Practice Development • Dr Henry A. Prempeh - Immunisation Coordinator • Dr Chris Deighan - Executive Medical Director • Graeme Bryson – Director of Pharmacy • Barry Melia – Lead Pharmacist for Public Health
Distribution:	ADTC

CHANGE RECORD

Date	Lead Author	Change	Version
27/12/2024	Medicines Policy and Guidance Team	Review, revise and update of policy in line with contemporary professional structures and practice Clarity around submission and update process Inclusion of governance process	2
23/09/2025 27/11/2025	Medicines Policy and Guidance Team	Added section on adoption of UKHSA PGDs Added section on escalation and reporting processes Added additional FAQs Removed mandatory submission checklist and reformatted as a pre-submission checklist	3

2. PGD RECORD MANAGEMENT

The National Institute for Health Care Excellence (NICE) sets out what is required for the maintenance and storage of PGD records. Full information can be found here:

<https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations#organisational-governance>

RESPONSIBILITY OF SERVICE USING PGD

- Signatures of people signing a PGD
- A list of named, registered health professionals authorised to practise under each PGD used within the service
- Training records
- Reporting of patient safety incidents, such as medication errors, near misses and suspected adverse events for board scrutiny

RESPONSIBILITY OF THE MEDICINES POLICY AND GUIDANCE TEAM

- A list of all PGDs in use within the organisation, including their review date and expiry date
- Master authorised copies of PGDs. Final authorised copies of PGDs are to be kept for a specific number of years after expiry depending on the patient group and the content of the PGD:
 - If relates to adults only: 8 years after expiry
 - If relates to adults only AND it relates to an implant: 10 years after expiry
 - If it relates to children: 25 years after expiry
 - Further information can be found here: [Retaining legal mechanism documentation - Specialist Pharmacy Service](#)
- Terms of reference and minutes or notes of the Medicines Clinical Oversight Board pertaining to PGDs
- Expired versions of PGDs
- Results of monitoring and evaluation

3. PGD AUDIT

PGD AUDIT – PART A – GOVERNANCE: PROCESS OVERSIGHT

RESPONSIBILITY OF THE MEDICINES POLICY AND GUIDANCE TEAM

This will be completed annually by the Medicines Policy and Guidance team and reported to the Medicines Clinical Oversight Board

	Questions	Yes/No	
A1	Does NHS Lanarkshire have a PGD oversight group or similar?		
A2	Are there records of terms of reference and minutes or notes by the group?		
A3	Does the PGD oversight group or similar report into the organisation's clinical governance framework?		
A4	Is there current PGD guidance?		
A5	Does the current PGD guidance include:		
	A5.1	Considering the need for a PGD and obtaining agreement to develop a PGD	
	A5.2	Developing and submitting a PGD including review of need for a PGD/alternative mechanisms for administration/supply	
	A5.3	Authorising a PGD	
	A5.4	Authorising named, registered health professionals to use a PGD	
	A5.5	Training and competency	
	A5.6	Audit, review and updating a PGD (including review of continued need for PGD)	
A6	Is there a current and up-to-date list of all the PGDs in use within the organisation, including their review/expiry dates?		
A7	Are all master authorised copies of all current PGDs held by NHS Lanarkshire?		
A8	Are master copies of all expired versions of the PGDs held by the NHS Lanarkshire?		
A9	Is there an audit timetable for PGD audits within each service?		
A10	Are there any PGD related risks on the risk register?		

RESPONSIBILITY OF THE MEDICINES POLICY AND GUIDANCE TEAM

This is an overarching review of all PGDs in use within an organisation. This will be completed by the Medicines Policy and Guidance team annually and reported to the Medicines Clinical Oversight Board.

The information will be compiled using the NHS Lanarkshire PGD Submission Governance Tool which is completed by the PGD author and is submitted with the PGD at the point of organisational signatories. The NHS Lanarkshire PGD Submission Governance Tool can be found in appendix 4.

	Questions		Yes/No
B1	Number of PGDs currently in use within the primary care in NHS Lanarkshire		
B2	Do all medicines administered/supplied under a PGD have a UK Marketing Authorisation?		
B3	Have all medicines which have a current "black triangle" status been clearly indicated on the relevant PGD?		
B4	Is any off-label use clearly indicated on the relevant PGD?		
B5	Is there evidence that all antimicrobial PGDs have had an input from the local microbiology specialist?		
B6	Are there any PGDs that have been developed and used for the management of long-term conditions?		
B7	Are any of the medications included in PGDs for administration of a GSL, P or medicines exempt under schedule 17 or 19 of the Human Medicines Regulations (HMR) 2012?		
B8	Are any of the medications included in PGDs for supply of a GSL, P or medicines exempt under schedule 17 of the HMR 2012?		

PGD AUDIT – PART C – CLINICAL PATIENT FACTORS / CLINICAL DECISION FACTORS

TO COMPLETE AT INDIVIDUAL PGD LEVEL EITHER IN A SINGLE SERVICE OR CLINICAL AREA

This is to be completed by retrospective review of clinical records every 3 years on a rolling basis or sooner if indicated. The information collated can then be used to assess the ongoing need for the PGD at the point of review. This information will be submitted to the Medicines Policy and Guidance team and presented to the Medicines Clinical Oversight Board.

	Questions	Yes/No
C1	Is the clinical indication (which is listed in the PGD's inclusion criteria) stated in the patient's record?	
C2	Is there a record of all of the following: patient's full name, date of birth, registered GP (where applicable)	
C3	Is there a statement in the patient's record that supply and/or administration of the medicine was made using a PGD?	
C4	Is there a record of written or verbal information/advice that was given to the patient when supplying/administering any medicine under the PGD?	
C5	Is there a record of the patient's consent?	
C6	If the patient was excluded, is the reason recorded?	
C7	If the patient was excluded, is there a record of action taken?	
C8	If the patient refused treatment, is there a record of advice provided on alternatives/risk of no treatment?	
C9	Is there a register or other record of stock received and issued to patients under this PGD?	
C10	Does the Patient Record contain details of the medicine supplied or administered (name, strength, dose, quantity, route)?	
C11	For vaccines, (or other medicines in line with local procedure) is both the batch number and expiry date recorded?	
C12	For injectable or topical medicines and implants is the site of administration recorded?	
C13	Is the date of supply or administration recorded?	
C14	Are all medicine packs supplied in their original pack (or a licensed pre pack) when supplied under a PGD? (i.e. packs not split)	
C15	Do all medicines supplied under any PGD have appropriate instruction labels on the pack including the health boards name, address and contact details?	
Name of PGD review:		
number of records reviewed and rationale for sample size:		

PGD AUDIT – PART D – OPERATIONAL – STAFF FACTORS/SERVICE LEVEL FACTORS

TO BE COMPLETED AT INDIVIDUAL SERVICE LEVEL

This should be completed annually and is the full responsibility of each individual service who utilises PGDs.

	Questions	Yes/No
D1	Do staff always have access to a copy of the latest version of the PGD they are working under available for reference at the time of the consultation?	
D2	Have all staff working under the PGD signed the latest version of that PGD?	
D3	Are all staff working under the PGD competent to work under that PGD?	
D4	Are all staff authorised to work under the PGD employed as one of the registered health professions listed in the PGD?	
D5	Is there an up-to-date list held within the service, of all staff authorised to work under each PGD in use?	
D6	Have all staff completed the necessary training and continuing professional development specified in the PGD/s they are authorised to work under?	
D7	Is there an up-to-date record within the service of all staff who have attended any required specific PGD training?	

Comments	
Completed by	
designation	
date	

4. NHSL PGD PRE-SUBMISSION CHECKLIST

For authors to self-check before submitting a PGD for organisational approval. This does not need to be returned.

No.	Pre-Submission Check
1	Is the PGD written on the current NHSL PGD template or authorised national template, with all mandatory sections completed (including clinical signatures and signature dates)? <i>Note: the current NHSL PGD template can be found here, within the Medicines Guidance toolkit on the RDS website.</i>
2	Is the intended care setting, service pathway and eligible patient group clearly defined and aligned with local service delivery?
3	For UKHSA PGDs: Has the Lead Pharmacist for Public Health (or deputy) reviewed the PGD and completed the NHSL agent authorisation form?
4	Is the change record updated and accurate?
5	If the PGD replaces an earlier one, has the previous PGD number been included?
6	Do all medicines included in the PGD hold a valid UK Marketing Authorisation?
7	Does the PGD include any medicines with current "black triangle" status, and are these clearly identified? <i>Black triangle medicines are newly licensed, subject to enhanced monitoring, and identified by an inverted black triangle (▼) in the BNF and SmPC.</i>
8	Does the PGD include any off-label use of a licensed medicine, and is this clearly stated with supporting evidence? <i>Note: off-label use of a licensed medicine may only be included in a PGD when clearly justified by best clinical practice.</i>
9	Does the PGD include any antimicrobials and if so, has Antimicrobial Committee (AMC) approval been obtained?
10	Is the PGD not intended for the routine management of a long-term condition? <i>PGDs must only be used for episodic, predictable presentations and not ongoing treatment.</i>
11	Are all medicines included appropriate for a PGD (i.e., only medicines that legally require a PGD for supply and/or administration)? <i>This excludes GSL medicines and other products that can already be supplied or administered under usual pharmacy routes or existing Medicines Act exemptions.</i>
12	Has any placeholder text (e.g., 'DRUG NAME') been replaced with the actual medicine name, strength and formulation?
13	Is the "Management of PGD" table completed, including Clinical Specialty or Directorate/Division, Base and Locality/HCSP/Ward/Department? <i>Location should be as specific as required by the PGD.</i>
14	Are the registered professions who may use the PGD clearly stated and compliant with legal PGD legislation (not job title)? <i>For example, a PGD cannot refer to "emergency care practitioner" to cover multiple professions.</i>
15	Have training, competency, supervision and assessment requirements been clearly stated?
16	Are Registered Healthcare professionals' user signatures not pre-completed? <i>Signatures must only be added after the individual has read the PGD and confirmed they are competent to practise under it.</i>
17	Are exclusion criteria and the appropriate action or referral pathway for patients not suitable for treatment under the PGD clearly stated?
18	If applicable, has the PGD number been added? <i>(The PGD number section may be left blank if the PGD is new or has not previously had a number)</i>