FREQUENTLY ASKED QUESTIONS (FAQS)

The FAQs are grouped into three sections for clarity:

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.

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