

## Purpose of this procedure:

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Most of the treatment with medicines must be prescribed on an individual, patient specific basis. There are legal exemptions for certain registered healthcare practitioners to supply / administer specific medicines in the course of their professional practice [The Human Medicines Regulations 2012](#). In addition, there are exemptions for the administration of specific medicinal products in an emergency [The Human Medicines Regulations 2012](#). Within NHS Lothian there is a provision for registered healthcare practitioners to supply / administer certain medicines without the need for a prescription [Medicinal products that do not require a prescription or PGD or PSD for administration or supply](#). Out with these circumstances medicines may be supplied or administered under Patient Group Directions (PGDs).

PGDs can be used in limited situations when doing so offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability.

Supplying and /or administering medicines under a PGD is not a form of prescribing. A 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.'

PGDs are written instructions which provide a legal framework that allows the supply and/or administration of a specified medicine(s), by specific named, authorised, registered healthcare practitioners, to a pre-defined group of patients who require prophylaxis or treatment for the condition described in the PGD, without the need for a prescription or an instruction from a prescriber.

Only certain registered healthcare practitioners can legally work under a PGD and this is listed in the Human Medicines Regulations [The Human Medicines Regulations 2012](#).

This procedure outlines the responsibilities of staff working under PGDs within NHS Lothian.

## The Procedure

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### **1.0 Approval process for new PGDs**

- 1.1 The NHS Lothian PGD Committee is a multidisciplinary collaboration of doctors, pharmacists, nurses and allied healthcare practitioners and reports directly to the NHS Lothian Area Drug and Therapeutics Committee. The PGD Committee is responsible for the overarching governance and oversight of the use of PGDs within NHS Lothian. The PGD Committee provides assurance that PGDs within NHS Lothian are developed, authorised, implemented and reviewed in line with legal requirements and clinical governance standards to provide safe and effective patient care without compromising patient safety.

- 1.2 Prior to the development of a PGD by a service the need for a PGD must be assessed. Most of the clinical care should still be provided on an individual, patient specific basis and PGDs must only be used where there is no other suitable mechanism for the administration or supply of the medicine. There should be consideration of investment in the training of additional non-medical prescribers to enable the redesign of services if necessary.
- 1.3 Where a service wants to develop a PGD there must be consultation with all appropriate stakeholders to confirm that the proposed direction is appropriate and necessary within the service, does not compromise patient safety, and is consistent with professional relationships and accountability.
- 1.4 Any service that wants to develop a PGD must first seek approval from the NHS Lothian PGD Committee using the approved application form for development of a PGD ([PGD intranet page](#)). The Committee will then consider the PGD application to determine whether a PGD is the most appropriate mechanism for medicine supply/ administration without compromising patient safety and advise the service whether they can develop a PGD. If development of a PDG is approved, the Committee will provide the service with the NHS Lothian PGD Template. (no link as this document will be controlled).
- 1.5 The PGD content must be agreed locally by the multidisciplinary team including a doctor /dentist, pharmacist, and lead registered healthcare practitioner for the healthcare practitioners providing care under the direction. This multidisciplinary team are known as the PGD local development team.
- 1.6 The local development team is responsible for developing the clinical content of the PGD, ensuring that the PGD is legally appropriate and for signing off an associated assurance checklist. In addition, the development group is responsible for ensuring the provision of ongoing advice and support for the duration of the use of the PGD in service.
- 1.7 Within the local development group, the doctor/dentist signatory is responsible for ensuring the PGD will provide safe and appropriate clinical treatment to the pre-defined group of individuals within agreed parameters described in the PGD. The pharmacist is responsible for ensuring the PGD will provide safe and appropriate pharmaceutical treatment, and the lead registered healthcare practitioner is responsible for proving assurance that the PGD can be safely and effectively implemented within the service.
- 1.8 Legislation requires that once approved a PGD must be signed by a doctor (or dentist), and a pharmacist. NHS Lothian requires that a lead registered healthcare practitioner for the service must also sign the PGD. Additionally, the PGD must be approved and authorised by the relevant appropriate body as set out in the legislation. To meet this obligation all NHS Lothian approved PGDs will be signed by the Chairperson(s) of the PGD Committee, and further approval and signatures will be obtained from the Chairperson(s) of the Area Drug and Therapeutics Committee and the Medical Director.
- 1.9 Until a PGD has been authorised by the NHS Lothian PGD Committee and fully signed it has no legal status and cannot be used by registered health care practitioners in services.
- 1.10 There are an increasing number of nationally developed and approved PGDs, e.g., for vaccinations, which may be available for use. These PGDs still require review by the local development team and approval for use via the NHS Lothian PGD Committee.

1.11 The NHS Lothian approval process, application form to develop a PGD and template for PGDs are available here [Patient Group Directions \(scot.nhs.uk\)](https://www.scot.nhs.uk/patient-group-directions/).

## **2.0 Review Process for PGDs**

- 2.1 A PGD can remain in use for up to 3 years from the date it was authorised. However, the expiry date will be determined on a case-by-case basis by the PGD Committee, considering patient safety, clinical relevance, and any changes in legislation or guidance.
- 2.2 Within NHS Lothian PGDs have a review date which is usually 2 years after the approval date. At the point of the review date the PGD requires reauthorisation by the PGD Committee. If the PGD is still required, the local development team must review the need for the PGD and if required send an updated version and associated checklist to [loth.patientgroupdirections@nhs.scot](mailto:loth.patientgroupdirections@nhs.scot) for approval following the review process detailed on the [PGD intranet page](#).
- 2.3 The PGD Committee will send a reminder to services when a PGD is due for review, however responsibility for reviewing and resubmitting the PGD for reauthorisation lies with the service who submitted the PGD. If there is no resubmission, the PGD will be removed from the authorised list once the PGD reaches the expiry date.
- 2.4 There is a requirement for services to audit the use of PGDs in use and evidence of audit should be submitted to the PGD Committee when the PGD is resubmitted. There is an exemplar audit available for services to use to support this process ([PGD intranet page](#)).
- 2.5 The service must have a process in place for communication to healthcare practitioners that the PGD has been reviewed, and a new version is available which will require practitioners to sign the authorisation section of the new version of the PGD before they can practice under it.
- 2.6 Lead registered healthcare practitioners/service managers are responsible for document retention regarding archived versions of PGDs and associated authorisation sheets. Guidance regarding the retention of documentation is available on the [PGD intranet page](#).
- 2.7 PGDs are controlled documents and should not be printed off by individual staff members. Services must ensure that staff have access to clinical content of the current PGD that is in use within their service and be able to verify that the PGD is appropriately signed and in date. Lead registered healthcare practitioners / service managers may print a copy of the PGD to allow staff to sign the authorisation sheet. This printed PGD should be stored in a dedicated PGD folder for the service as evidence of appropriate staff sign off and to allow access to clinical content. An easy to refer to electronic copy of the up-to-date PGD could be stored within a dedicated shared drive for that service.
- 2.8 PGDs are only authorised for use in the service named within the document. If any other clinical area requires to use a PGD they must contact [loth.patientgroupdirections@nhs.scot](mailto:loth.patientgroupdirections@nhs.scot). The request will then be considered by the PGD Committee and where permission is granted a signed copy will be sent via email to the service lead.

### **3.0 Responsibilities when using a PGD within a Service**

- 3.1 Lead registered healthcare practitioners / service managers within services have responsibilities to ensure the safe and appropriate implementation of PGDs within a service ([Procedure for Lead Registered Healthcare Practitioners and Service Managers using Patient Group Directions within their service](#)).
- 3.2 Individual registered healthcare practitioners have responsibilities when working under a PGD and may only supply/administer drugs under a PGD that is approved by NHS Lothian and fully signed ([Procedure for registered healthcare practitioners working under Patient Group Directions](#)).
- 3.3 Healthcare professionals working under a PGD must have undertaken the appropriate training as detailed within the PGD and be competent to work under the PGD.
- 3.4 Healthcare practitioners must sign the PGD authorisation section before they can legally work under the PGD.
- 3.5 It is not acceptable or legal for healthcare practitioners to supply/administer medicine under a PGD that is unsigned or has expired.

### **4.0 Additional legislation and governance**

- 4.1 Legal restrictions are in place regarding which healthcare practitioners can administer and supply medicines via a PGD. Refer to 'The Human Medicines Regulations 2012' for a comprehensive list. [The Human Medicines Regulations 2012](#)
- 4.2 Health care professionals should refer to the relevant NHS Lothian medicines policy procedures [Practitioners authorised to administer medicines \(nhslothian.scot\)](#) and must follow their own regulatory body guidance.
- 4.3 There are legal restrictions relating to the administration of controlled drugs under PGDs. ([The Misuse of Drugs Regulations 2001](#), [The Misuse of Drugs Regulations 2001](#))

### **5.0 Restrictions on the use of PGDs**

- 5.1 There are further restrictions on the use of PGDs, including for the management of long-term conditions or the long-term, repeat supply of medicines to individuals to manage a long-term condition, where there is delegation of responsibility to supply/administer the medicine, where there are dose adjustments of a medicine already in a patient's possession e.g. insulin, unlicensed medicines (including mixing of medicine which render them unlicensed) and dressings/medical devices. Further information can be found here ([When not to use a PGD – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#))

Associated materials/references:

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[NHS Lothian Safe Use of Medicines Policy](#)

[Safe Use of Medicines – Policy Online](#)

NICE. "Overview | Patient Group Directions | Guidance | NICE." *Nice.org.uk*, NICE, 2 Aug. 2017, [www.nice.org.uk/Guidance/MPG2](http://www.nice.org.uk/Guidance/MPG2)

Specialist Pharmacy Service. "Patient Group Directions." *SPS - Specialist Pharmacy Service*, SPS, 2025, [www.sps.nhs.uk/category/guidance/patient-group-directions-guidance/](http://www.sps.nhs.uk/category/guidance/patient-group-directions-guidance/)

[Administration of medicines in hospital and NHS Lothian Healthcare Premises Procedure.pdf](#)

[Practitioners authorised to administer medicines](#)

NHS Education for Scotland (2025). *NHS Lothian TURAS Module Patient Group Directions* [online] Available at: [Search Results | Turas | Learn](#)

NHS Education for Scotland (2025). *NHS Grampian TURAS Module Patient Group Directions* [online] Available at: [Patient group directions \(PGDs\) | Turas | Learn](#)

NICE (2017) *Overview | Patient group directions | Guidance | NICE*. [online] *Nice.org.uk*. Available at: <https://www.nice.org.uk/Guidance/MPG2>.

GOV.UK (2016) [Patient group directions: who can use them - GOV.UK](#)

[Procedure for Lead Registered Healthcare Practitioners and Service Managers using Patient Group Directions within their service](#)

[Procedure for registered healthcare practitioners working under Patient Group Directions](#)

[Retention of NHS Lothian Patient Group Direction documentation](#)