NHS Grampian | NHS Highland | NHS Orkney | NHS Shetland | NHS Tayside | NHS Eileanan Siar Western Isles

Policy For North Of Scotland Patient Group Direction (PGD) Working For Healthcare Professionals In NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

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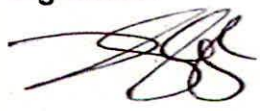
Signature: 		**Signature:** 

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NoS/Policy/PGD_Policy/ 1585	December 2027	December 2024

Policy Statement:

It is the responsibility of all staff to ensure that they are working to the most up to date and relevant guideline, policies, protocols and procedures.

Version 2

Executive Sign-Off

This document has been endorsed by the Interim Chief Executive, NHS Grampian

Signature: 

Replaces: NoS/Policy/PGD_Policy/1132, Version 1.1

Document application: NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles.

Revision History:

Revision Date for this policy	Summary of changes	Section Heading
October 2024	Qualified healthcare professionals updated to include pharmacy technicians.	Legal Requirements for a PGD.
October 2024	Flow charts updated.	Appendices.
October 2024	Practice manager and GPs removed. Lead nurses added.	Summary of Responsibilities Relating To Patient Group Directions.
October 2024	Medic statement amended.	Roles and responsibilities.

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Note: See Appendix 1 for definitions of terms referenced within this policy.

1. Introduction

The preferred way for patients to receive the medicines they need is for a prescriber to provide care for an individual patient on a one-to-one basis. Historically, a doctor (or dentist) would prescribe a medicine(s) for an individual patient. A pharmacist (or dispensing doctor) would then dispense the medicine against the prescription and supply the medicine(s) to the patient. This traditional 'medical model' changed in the years after publication of the final Crown report - Review of prescribing, supply and administration of medicines in 1999. Legal frameworks were developed that have allowed services to be redesigned and healthcare professionals to work more flexibly for the benefit of patients. As a result of these changes, there are now several legal options for supplying and/or administering medicines, including Patient Group Directions (PGDs).

The extended role of healthcare professionals must take into account the need to protect patient safety, ensure continuity of care and safeguard patient choice and convenience. It also has to be cost effective and bring demonstrable benefits to patient care.

PGDs provide a legal framework that allows some registered healthcare professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber. However, supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care, without compromising patient safety.

Legislation establishing PGDs was introduced in 2000 and HDL 2001(7) provided additional guidance. The current legislation for PGDs is included in The Human Medicines Regulations 2012.

PGDs are written instructions to help specified healthcare professionals supply or administer medicines to patients, usually in planned circumstances. They take a significant amount of time and resource to develop and implement.

This policy relates specifically to PGD's developed internally for use across NOS. This does not apply to those PGDs that are developed nationally and then adopted by NOS, e.g. Public Health Scotland, NHS 24 and Specialist Pharmacy Services PGDs where there are defined governance processes.

1.1 Objectives

This policy outlines the recommendations for all staff employed by NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, collectively known as the North of Scotland (NoS) Boards who use or have involvement in developing, reviewing or approving NoS PGDs, with the aim of ensuring patients receive safe and appropriate care and timely access to medicines.

This policy will ensure adherence to legislation governing the provision of medicines by PGD as included in the Scottish Government HDL 2001(7) and The Human Medicines Regulations 2012.

The policy will provide guidance on the process for the identification, development, review, dissemination, implementation, monitoring and audit of PGDs within NHS NoS Boards, and assist compliance with best practice.

1.2 Purpose of policy

The purpose of the PGD Policy is to:

- Ensure effective patient care that is appropriate in a pre-defined clinical situation is delivered, without compromising patient safety.
- Offer a significant advantage to patient care by improving access to appropriate medicines.
- Provide equity in the availability and quality of services when other options for supplying and/or administering medicines are not available.
- Provide a safe legal framework to protect patients and relevant staff.
- Reduce delays in treatment.
- Maximize the use of the skills of a range of health professionals.
- Set out the mechanism for developing and using NoS PGDs within NHS NoS Boards.

Additionally, the purpose of this document is to ensure adherence to legislation governing the provision of medicines by Patient Group Directions as included in The Human Medicines Regulations 2012 and Patient group directions: who can use them - GOV.UK

1.3 Options for supplying and administering medicines to patients

The majority of clinical care should be provided on an individual, patient-specific basis. If the current care pathway can include the issue of a prescription or a written Patient Specific Direction (PSD) by a doctor or non-medical prescriber, so that the patient receives the medicine in a timely manner, then a PGD should not be required.

There are now several legal options for prescribing, supplying and/or administering medicines including the use of PSDs, independent and supplementary prescribing, PGDs and medicines exemptions.

Exemptions from medicines legislation

A PGD is not required for anyone (whether they are a healthcare professional or not) to administer any of the medicines listed in The Human Medicines Regulations (2012) legislation Schedule 19 for the purpose of saving a life in an emergency.

Additionally there are a number of healthcare professions which have specific exemptions in medicines legislation to supply or administer specific licensed medicines. Currently exemptions are available for the following registered healthcare professionals:

- Nurses (for occupational health schemes only)
- Midwives
- Optometrists*
- Orthoptists
- Chiropodists/podiatrists*
- Paramedics.

*Optometrists and chiropodists/podiatrists can train to use a wider range of medicines under a list of additional exemptions. More information about working under exemptions can be found via the professional bodies' websites and The Human Medicines Regulations (2012) Legislation Schedule 17 and Human Medicines (Amendment) Regulations 2016.

Note: These exemptions are distinct from prescribing and the arrangements for PGDs. A full list of all the medicine exemptions is included in The Human Medicines Regulations (2012) legislation in Schedule 17 and Schedule 19.

1.4 Identification of need for a PGD

PGDs are written instructions which 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.

Prior to development of a PGD the need for the PGD must be assessed. The majority of clinical care should still be provided on an individual, patient specific basis. The supply or administration of medicines under PGDs should be reserved for situations where it offers an advantage for patient care, without compromising patient safety and where it is consistent with appropriate professional relationships and accountability. Managers who wish to set up new systems for supply or administration of medicines have a range of methods to choose from and should select the most appropriate route in each case.

Any service considering the use of a PGD must assess the following:

- Is there a genuine service need?
- Is the patient group appropriate for supply or administration under a PGD (offers an advantage to patient care without compromising patient safety)?
- Is this the most effective way of providing the medicine(s) to a patient?
- Are the healthcare professionals identified as potential users of the PGD included in the groups legally entitled to use PGDs (e.g. health care assistants are not included in the legislation) and is this medicine(s) appropriate to the scope of practice of this professional group?
- How will the supply of the medicine(s) be obtained and stored before use and will it comply with labelling legislation for the supply of medicines under a PGD?

Pharmacy Only (P) and General Sales List (GSL) Medicines

Medicines legislation states that a PGD is not required to administer a P or GSL medicine. The use of a simple protocol is advisable for best practice and from a governance perspective. All medicines administered must be recorded in the patient's medical record. Where a GSL medicine is to be supplied it must be taken from lockable premises and supplied in a pre-pack which is fully labelled and meets the GSL requirements.

However, a PGD may be required at times for the supply/administration of GSL and/or P medicines by anyone other than a registered pharmacist, nurse or midwife. Further advice should be sought from the NoS PGD Group secretary if such a PGD is considered necessary. Further information is also available from the MHRA.

Controlled Drugs

PGDs can be developed for certain controlled drugs. The legislation supports the use of PGDs for Schedule 4 controlled drugs (provided that it is not in a parenteral form for the treatment of addiction or an anabolic steroid) and Schedule 5 controlled drugs. The legislation states that midazolam can be supplied and administered under a PGD and is the only Schedule 3 controlled drug allowed under PGD legislation.

Legislation has been enacted enabling diamorphine and morphine to be supplied or administered by nurses and pharmacists under a PGD for the immediate and necessary treatment of sick or injured persons in any setting.

Legislation in the future may allow the use of other controlled drugs under PGD (e.g. ketamine), so it is essential that regulations are checked if a controlled drug is being considered for use by means of a PGD.

Patient Group Directions are not appropriate in the following situations:

- The patient has been seen by a doctor or dentist as part of their episode of care and a prescription or written direction can feasibly be written.
- A prescription can be written by a doctor or dentist in advance where it is known that the individual patient will require a particular medicine.
- The medicines in question can be prescribed by a qualified independent prescriber.
- The medicines in question can be prescribed by an appropriately qualified supplementary prescriber provided that the medicine(s) are included in the individual patient's documented Clinical Management Plan (CMP).
- Adjustment of a prescribed dose(s) is required as opposed to supply or administration of a medicine that has not previously been prescribed for the patient. This may be addressed more appropriately through supplementary prescribing. The use of a simple protocol is advisable for best practice and from a governance perspective.
- The medicines in question are specified under exemptions in the Human Medicines Regulations 2012.
- The medicine needs frequent dosage adjustments or frequent or complex monitoring (for example, anticoagulants or insulin).
- In the management of long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.

2. Legal Requirements For A PGD

All NHS NoS Boards have a legal responsibility to ensure that the development and implementation of PGDs complies with current PGD legislation The Human Medicines Regulations 2012 and Patient group directions: who can use them - GOV.UK

PGDs must only include medicines with a UK marketing authorisation, in line with legislation. Ensure that off-label use of a licensed medicine is included in a PGD only when clearly justified by best clinical practice. Clearly state that the medicine is being used outside the terms of the marketing authorisation in the PGD and inform the patient or their carer that the use is off-label.

A medicine with black triangle status should only be included in a PGD when clearly justified by best clinical practice. Clearly indicate the black triangle status in the PGD.

Ensure that an antimicrobial is included in a PGD only when:

- Clinically essential and clearly justified by best clinical practice.
- A local specialist in microbiology has agreed that a PGD is needed and this is clearly documented.
- Use of the PGD is monitored and reviewed regularly.

Legislation requires that the following must not be included in a PGD:

- Unlicensed medicines, including:
  - the mixing of 2 licensed medicines to form 1 new (unlicensed) product, unless 1 is a vehicle for administration, such as water for injection
  - special manufactured medicines
- Dressings, appliances and devices
- Radiopharmaceuticals
- Abortifacients, such as mifepristone.

Only the following qualified healthcare professionals may supply or administer medicines under a Patient Group Direction. It is important to note that these professionals may only supply or administer medicines under a PGD as named individuals:

- Chiropodists and podiatrists
- Dental hygienists
- Dental therapists
- Dieticians
- Midwives
- Nurses
- Occupational therapists
- Optometrists
- Orthoptists
- Orthotists and Prosthetists
- Paramedics
- Pharmacists
- Pharmacy Technicians
- Physiotherapists
- Radiographers
- Speech and language therapists.

PGD legislation may be updated in the future and other groups of healthcare professionals could be added to the list of those authorised to use a PGD. A link to the legislation can be found at the Medicines and Healthcare products Regulatory Agency.

A record of the named individuals operating under each PGD must be maintained by the senior management of each service. Additionally, the healthcare professional operating under the PGD must be the person who administers the medicine or supplies the medicine to the patient or carer for the patient or carer to take themselves. This cannot be delegated to another person

According to the legal requirements, a PGD must include:

- The name of the business who owns the direction, e.g. NHS Grampian, Highland or Tayside.
- The start and end date of the PGD.

- A description of the medicine(s).
- The class of the healthcare professional who can supply or administer the medicine.
- A signature of a doctor or dentist (as appropriate) and a pharmacist.
- A signature by an appropriate organisation (e.g. clinical commissioning groups, NHS trusts, special healthcare authorities, the NHS Board).
- The clinical condition or situation to which the direction applies (e.g. the specified condition/conditions that can be treated).
- A description of patients excluded from treatment under the direction.
- A description of when more advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral.
- Details of appropriate dosage, maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period to administer the medicine.
- Relevant warnings, including potential adverse reactions.
- Details of any necessary follow-up actions.
- A statement of the records to be kept for audit purposes.

Labelling of Medicines Supplied Under a PGD

Legislation for the labelling of medicines applies to all supplies of medicines, including those supplied under PGD. In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.

Authorising a PGD

Legislation requires that a PGD must be signed by a doctor (or dentist) and a pharmacist - and is good practice for a senior representation of the healthcare profession that will be utilising the PGD to also sign.

Additionally, the PGD must be approved and authorised by the relevant appropriate body as set out in the legislation. In Scotland this is a role for NHS Health Boards. Under the current arrangements as detailed in the Memorandum of Understanding for NoS PGD working, NHS Grampian's Chief Executive has the vested authority to authorise and executively sign PGDs, each individual Boards Area Drugs and Therapeutics Committee (ADTC) or equivalent group must then endorse the NoS PGDs for use within their individual Boards.

Note: Until a PGD has been authorised by the NoS PGD Group it has no legal status and must not be used. Furthermore, it is not acceptable or legal for an individual practitioner to decide to use a PGD that has expired.

3. Development And Review Of A PGD

A flowchart outlining the process for a new PGD is included in Appendix 2.
A flowchart outlining the process of review of a PGD is included in Appendix 3.
Individual and group responsibilities in this process are outlined in Appendix 4 and 5.

Once the requirement for a new PGD has been identified a New PGD Application (Appendix 6) must be completed and submitted to the NoS PGD Group for approval. The NoS PGD Group must approve, in principle, the need for the PGD and the development of the PGD should not be initiated until approval to proceed has been received. Following approval the NoS PGD Group Secretary will provide the lead author with all relevant NoS PGD documentation. The legislation specifies that each PGD must contain specific information, therefore the NoS PGD template must be used when developing a PGD to ensure that all legal criteria are included. The best available evidence, such as NICE, SIGN or the Green Book, as well as other sources of high-quality information must be used when developing PGDs including the Summary of Product Characteristics.

The development group for a PGD should include as a minimum 4 healthcare professionals. To comply with current PGD legislation the group must include a doctor (or dentist), a pharmacist and it is best practice to also include a representative of the healthcare professional group to which the PGD will apply. It is good practice to appoint a lead author who must ensure all required information is entered onto the current NoS PGD template. The lead author must also ensure that the draft PGD is circulated widely to all interested parties for comment, and any revision comments are collated, agreed and written into the PGD before a final version is submitted to the NoS PGD Group for approval.

The lead author must ensure that every healthcare professional involved in the development/review of a PGD, completes a PGD Consultation Reply Form (Appendix 7) which must be returned to the lead author. These forms ensure governance arrangements for the development of a PGD have been met, and must be kept by the lead author. These should be available upon request to be submitted with the PGD to the NoS PGD Group for approval. Additionally, the lead author is also responsible for the completion of the PGD Submission Cover Form (Appendix 8) which must be submitted with the PGD for approval.

Acknowledgement of approval, non-approval, or requirements for amendment of a submitted PGD, will be provided by the NoS PGD Group to the nominated PGD lead author following the meeting at which the PGD has been discussed (see Appendix 3 for more detailed information on this process).

For completed approved PGDs, arrangements will be made by the NoS PGD Group Administrator for the PGD to be assigned a record number or identifier, it will then be sent for signing to the identified PGD signatories before being signed by NHS Grampian's Chief Executive. Completed, signed PGDs will then be distributed to each of the NoS Boards as per their NoS PGD working local protocol or specification. Each

individual Board is then responsible for the dissemination of the approved PGD to the staff who will use the PGD. (See Appendix 9 - PGD Post Approval Process for further information).

PGD Expiry Dates and Extensions

PGDs should be reviewed at least every three years or sooner if current treatment recommendations change. All PGDs have a set expiry date of a maximum of 3 years.

Note: It is the responsibility of the nominated lead author to assess if the PGD is still required prior to any review being undertaken. For PGDs that are identified as no longer being required, the lead author must contact the NoS PGD Group via email to inform them and to request that the PGD be withdrawn. Likewise, should an individual Board no longer wish to continue using a PGD they should contact the NoS PGD Group to inform them that this is the case.

There may be an occasion where a PGD will require an extension without review. Extension of expiry dates without review of a PGD is not without risk (Summary of Product Characteristics (SmPC) for the medicine may have changed/national guidance may have changed), however the NoS PGD Group may deem this necessary where it is in the interests of patient safety; for example there may be a risk where withdrawing the PGD could result in significant service disruption and potential patient safety issues due to lack of access to medicines.

PGD extensions will only be granted in very exceptional circumstances. The period of extension will be decided by the NoS PGD Group Chair and an extension cover letter must be attached to the current PGD providing the date to which the PGD can continue to be used. Healthcare professionals who do not wish to practice under a PGD that has had an extended expiry should discuss concerns with their manager in the first instance.

4. Implementation Of A PGD

All NoS Boards should follow their local processes for dissemination, implementation, monitoring and any training requirements in relation to NoS PGDs.

5. Audit

Records must be kept by the practice, ward, or department to allow the process to be audited both internally and externally. The NoS PGD audit tool (Appendix 10) is required to be completed annually by all NoS member Boards. The purpose of undertaking the audit is to demonstrate compliance with the PGD(s) and to ensure that the requirements of the service are met.

6. Retention Of PGDs

PGDs must be retained for the same periods as advised for patient records, as specified in Records Management: NHS Code of Practice Version 2.1 January 2012.

Annex B (Page 47) Stipulates;

Record Type	Minimum NHS Retention Period
Adult	6 years after date of last entry or 3 years after death if earlier.
All types of records relating to Children and young people (including children's and young person's Mental Health records)	Retain until the patient's 25th birthday or 26th if young person was 17 at conclusion of treatment, or 3 years after death. If the illness or death could have potential relevance to adult conditions or have genetic implications, the advice of clinicians should be sought as to whether to retain for a longer period.

In practice, it is difficult to stipulate the exact retention period for an individual PGD as it may in theory have been used to administer medication to a patient whose record is still in use 50 years or more later. The signed master copy of NoS PGDs must therefore be retained for an indefinite period. It is acceptable for this to be in electronic format.

Individual Board Level

It is advised that a PDF of the signed master copy of each NoS PGD be retained by every Board either electronically or in print. Further to this it is up to each individual Board to specify responsibility for the retention of the signed Appendices pages of each PGD.

7. References

1. Patient Group Directions. Scottish Executive Health Department Letter: NHS HDL (2001)7. January 2001. (http://www.show.scot.nhs.uk/sehd/mels/HDL2001_07.htm)

2. NICE: Patient Group Directions Medicines practice guideline (2017): Accessed 17/10/24 https://www.nice.org.uk/guidance/mpg2/resources/patient-group-directions-1779401941189

3. MHRA - Patient Group Directions: who can use them: Accessed 17/10/24https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them

4. Human Medicines Regulations 2012 Schedule 17 http://www.legislation.gov.uk/uksi/2012/1916/schedule/17/made

5. Human Medicines Regulations 2012 Schedule 19
http://www.legislation.gov.uk/uksi/2012/1916/schedule/19/made

6. Scottish Government Records Management: NHS Code of Practice (Scotland) Version 2.1 January 2012
http://www.scotland.gov.uk/Publications/2012/01/10143104/0

Responsibilities for implementation:

Organisational:	Chief Executive and Management Teams
Corporate:	Senior Managers
Departmental:	Heads of Service/Clinical Leads
Area:	Line Managers
Hospital/Interface services:	Deputy General Managers and Clinical Leads
Operational Management Unit:	Unit Operational Managers
Policy statement:	It is the responsibility of all staff to ensure that they are working to the most up to date and relevant policies, protocols procedures.
Review:	This policy will be reviewed in three years or sooner if current treatment recommendations change.

Appendix 1 - Definitions

Definitions

Patient Group Direction (PGD):
A written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

Note: This definition should not be interpreted as indicating that the patient should not be identified. Patients may or may not be known to the service. PGDs provide a legal framework that allows the supply and/or administration of a specified medicine(s), by named, authorised, registered healthcare 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. Using a PGD is not a form of prescribing.

Patient Specific Direction (PSD):
A written instruction, signed by a doctor, dentist or non-medical prescriber for a medicine to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.

General Sales List (GSL) medicine
A medicine that may be sold in registered pharmacies and other lockable retail outlets, such as supermarkets.

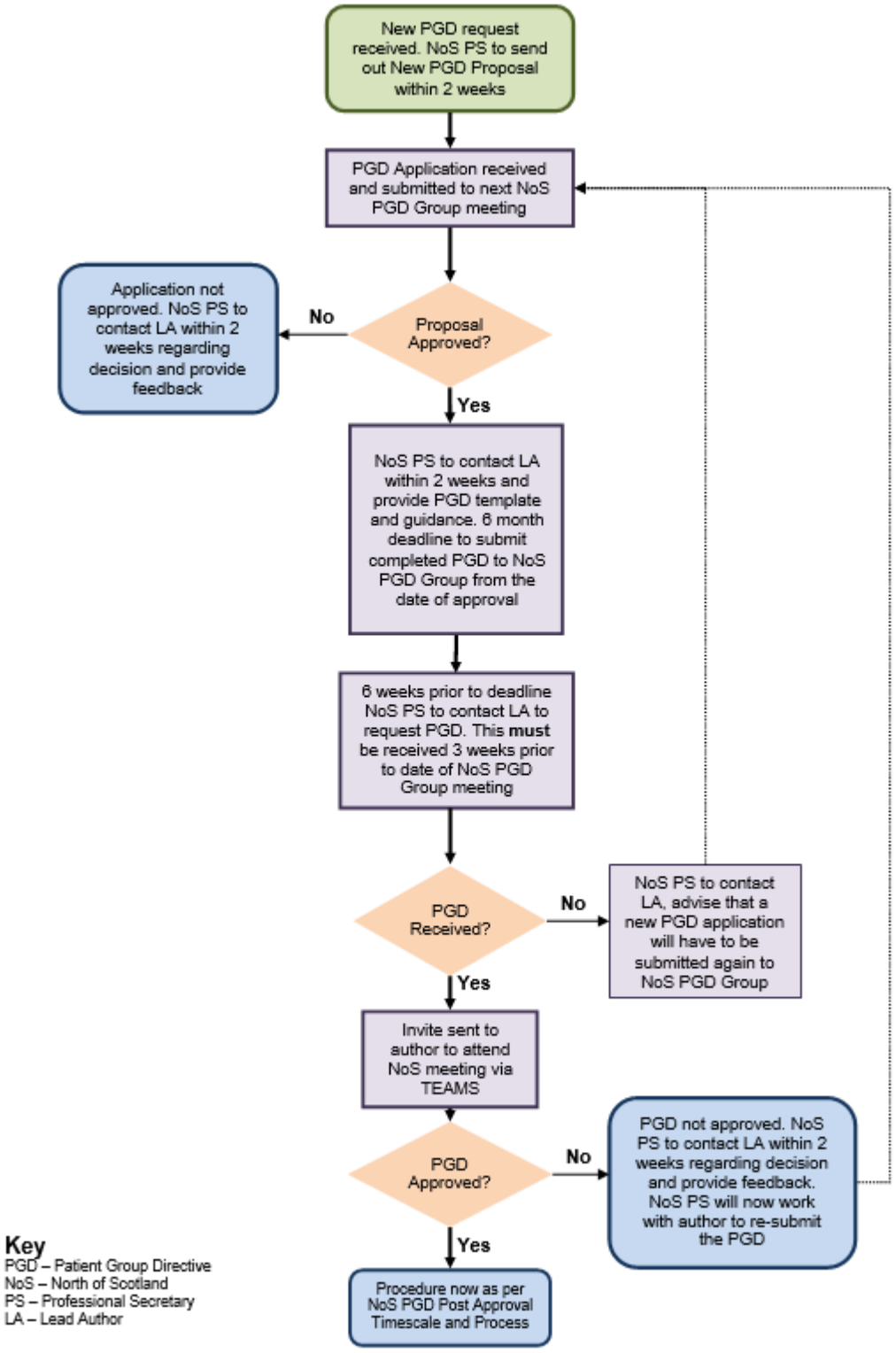
Pharmacy (P) medicine
A medicine that may be sold in registered pharmacies by a pharmacist or a person acting under the supervision of a pharmacist.

Prescription-only medicine (PoM)
A PoM is generally subject to the restriction of requiring a prescription written by an appropriate practitioner before it can be sold or supplied. There are exemptions to requiring a prescription in some circumstances, such as using a PGD.

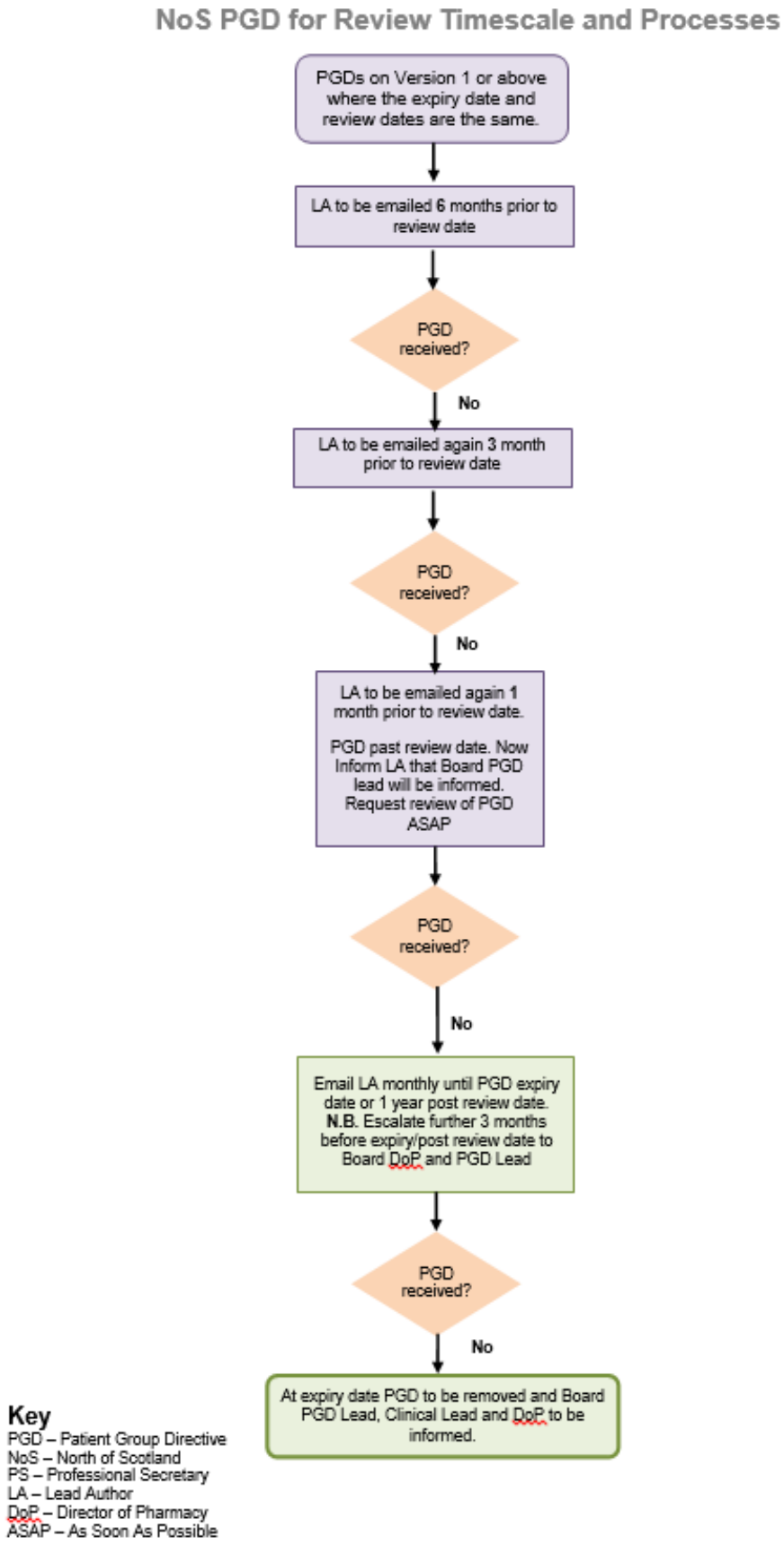
Unlicensed medicine
A medicine that does not have a UK marketing authorisation.

Medicines with Black Triangle ▼Status
New medicines and vaccines that are under additional monitoring have an inverted black triangle symbol (▼) displayed in their package leaflet and summary of product characteristic, together with a short sentence explaining what the triangle means – it does not mean the medicine is unsafe. All suspected Adverse Drug Reactions (ADRs) should be reported for these products.

Appendix 2 - New PGD Process



Appendix 3 – Process for NoS PGD Review



Appendix 4 - Summary Of Responsibilities Relating To Patient Group Directions

Summary of Responsibilities Relating To Patient Group Directions

Lead Nurses/Team Leader/ Ward or Department Manager is responsible for:

- Disseminating PGDs to staff in the clinical area where the PGD is to be used.
- Identifying and approving staff for training in the use of a specific PGD.
- Ensuring appropriate and adequate training in the use of the PGD is provided.
- Providing written evidence that individual staff are authorised to provide care under specific PGDs by signing the authorisation to administer/supply medicines under PGD form.
- Ensuring the use of the most up-to-date version of a PGD (and ensuring that superseded PGDs are removed from the clinical area and destroyed).
- Compiling and updating a list of all competent, qualified and trained professionals authorised to administer/supply medicines under each individual PGD.
- Annual review of lists of authorised staff.
- Audit of practice.

Staff authorised to work under a particular PGD are responsible for:

- Working within the terms of the PGD.
- Reporting adverse effects/incidents/pharmacovigilance.
- Working within their competency, training and experience.
- Working within their Code of Professional Conduct.
- Ensuring that they have had relevant training.
- Participating in regular audit of practice.

NoS PGD Group Secretary is responsible for:

- Issuing the agreed NoS PGD template.
- Providing advice/involvement in drafting the PGD.
- Arranging for the PGD to be signed off by the appropriate signatories and by NHS Grampian's Chief Executive.
- Providing a signed PDF copy of the PGD to the designated contacts or PGD Leads for each individual Board for dissemination.
- Maintaining a database and record of all NoS PGDs currently in use, in development or archived.

NoS PGD Group is responsible for:

- Agreeing, in principle, the need for a PGD to be developed.
- Directing the development of the PGD.
- Approving the final draft of a PGD.
- Ensuring compliance with medicines legislation and the recommendations outlined in Scottish Executive Health Department Letter (HDL 2001(7)).

Appendix 5 - Roles And Responsibilities Of The Reviewer's And Lead Authors Of Patient Group Directions (PGDs)

Roles and Responsibilities of the Reviewer's and Lead Author's of Patient Group Directions (PGDs)

The purpose of this document which has been adapted from the Specialist Pharmacy Service (2020) is to provide an overview of the roles and responsibilities of the people who must be involved in the review and/or signing of a PGD as set out in the legislation.

Roles and responsibilities of PGD reviewers/signatories are listed in this document as follows:
Section 1: Role and responsibilities of the PGD lead author
Section 2: Role and responsibilities of the medical professional (or dentist) reviewer/signatory
Section 3: Role and responsibilities of the pharmacist reviewer/signatory
Section 4: Role and responsibilities of the reviewer/signatory who is a representative of the professional group expected to supply/administer medicines under the PGD

Section 1: Role and Responsibilities of the PGD Lead Author

The lead author may be a doctor (or dentist), pharmacist or representative of any other professional group who will practice under the PGD, or another person such as the service lead. The lead author of a PGD is responsible for updating and coordinating the timely review of the PGD, and ensuring that both a medical professional (or dentist) and pharmacist are involved in the process.

Related Duties to Meet Role and Responsibilities of the PGD Lead Author

- Ensures that they have the appropriate skills and knowledge to update and review the PGD.
- When reviewing a PGD – establishes the case for a PGD, identifies the benefits to patient care and ensures the views of all stakeholders have been considered. This would include establishing that;
  - Individual prescribing is not a suitable mechanism following a review of current prescribing systems and the care pathway being considered e.g. may delay timely access to treatment and that a PGD is appropriate and legal.
  - There are no relevant exemptions in legislation which allow supply and/or administration of the medicine without the need for a PGD

- Uses the NoS standard PGD template to ensure the format for PGDs is consistent across the organisation.
- Ensure all legally required information is included in the PGD.
- Undertake an appropriate literature search to identify new evidence. This then needs to be evaluated to assess its relevance and validity.
- Ensures that they are satisfied that the PGD is fit for purpose for the health professional (e.g. nurses) delivering care to patients in that particular service and locality.
- Ensure PGDs are 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 national guidance, the Green Book and other sources of high-quality information when reviewing the PGD. Include key references within the PGD.
- Identifies suitable and appropriate healthcare professionals to comprise the consultation group for the PGD review, ensuring that the group has a minimum of 5 members, one of which must be a medical professional (or dentist), a pharmacist (an additional medical professional or pharmacist is required if lead author is a medical professional or pharmacist) and senior representation from the user group.
- Includes the PGD consultation reply forms when sending the draft PGD out for comment, and are responsible for ensuring the return of the completed signed forms.
- Seek views on draft PGD, and agree final draft PGD with all members of the consultation group, including the medical professional (or dentist) and pharmacist reviewers.
- Works within any locally agreed timeframes to ensure timely review and approval of the PGD.
- Submits the PDG post consultation to North of Scotland PGD Group (NoS) along with the completed consultation rely forms and the PGD Submission Covering Form.
- Act on NoS feedback and suggested amendments within the allocated time frame.
- Final checking and signing of the PGD once executively signed.
- Ensure that an updated PGD is communicated and disseminated effectively to all relevant clinical areas and professionals who will work under the PGD.
- Are responsible for the unscheduled review and updating of a PGD, when the need for this has been identified. This should include responding to:
    - changes in legislation
    - important new evidence or guidance that changes the PGD, such as new NICE/SIGN guidance
    - new information on drug safety
    - changes in the summary of product characteristics
    - changes to the NoS boards formulary.
- Ascertains that where a medicine is to be supplied to a patient to take away, appropriately labeled packs can be procured in a legal and timely manner across the boards.

Section 2: Role And Responsibilities Of The Medical Professional (Or Dentist) Reviewer/Signatory

The doctor (or dentist) signatory is responsible for ensuring that the PGD will provide safe and appropriate treatment to a pre-defined group of patients requiring prophylaxis or treatment for a specific condition, within agreed parameters described in the PGD. They are responsible for ensuring the clinical content of the PGD is accurate and up to date, at the time of review and sign off. This responsibility is discharged by reviewing the PGD against appropriate data sources, including the up to date manufacturer's data sheet, and for vaccines the "Green book" chapter for the vaccination under consideration, along with any Scottish Vaccination guidance and highlighting any clinical concerns or discrepancies.

Patient group directions (NICE guideline MPG2, 2017) states: when reviewing/signing the PGD, the doctor (or dentist) and pharmacist take joint responsibility and accountability for the accuracy of both the clinical and pharmaceutical content of the PGD. This role should be undertaken by senior professionals with full consideration of the clinical service in which the PGD is to be used.

The doctor (or dentist) is responsible for ensuring the clinical content of the PGD is accurate and up to date.

Note: If the lead author of a PGD is a medical professional (or dentist) they cannot also act in the capacity of the medical/dentist reviewer for the PGD, a second medical professional (or dentist) must act as the reviewer/signatory for the PGD.

Related Duties to Meet Role and Responsibilities of a Medical Professional (or Dentist) Clinical Reviewer/Signatory

- Ensures that they have the appropriate skills and knowledge to review the PGD for the specific role in which they are required to sign the PGD.
- When reviewing a PGD – establishes the case for a PGD, identifies the benefits to patient care and ensures the views of all stakeholders have been considered. This would include establishing that;
  - Individual prescribing is not a suitable mechanism following a review of current prescribing systems, and the care pathway being considered, e.g. may delay timely access to treatment and that a PGD is appropriate and legal.
  - There are no relevant exemptions in legislation which allow supply and/or administration of the medicine without the need for a PGD.
- Ensures that appropriate advice is given on actions to be taken e.g. medical referral for excluded patients or a potential drug interaction which might be managed by contact with the doctor (or dentist) first then relevant advice to the patient by the practitioner. This could then allow continuing practice under the PGD, depending on the type of the interaction.
- Ensures that relevant references to specific supporting guidelines, etc are made within the PGD.
- Ensures that appropriate follow up advice to the patient is safe, e.g. see GP after 48 hours if no change in condition.
- Ensures the specified action for excluded patients is clinically appropriate and indicates appropriate referral where required.
- Ensures that they are satisfied that the PGD is fit for purpose for the medical and/or dental care being delivered to patients in that particular service.
- Works within any agreed timeframes to ensure timely review and approval of the PGD.

Section 3: Role And Responsibilities Of The Pharmacist Reviewer/Signatory

The pharmacist is responsible for ensuring that the PGD will provide safe and appropriate treatment to a pre-defined group of patients needing prophylaxis or treatment for a specific condition, within agreed parameters described in the PGD .

Patient group directions (NICE guideline MPG2, 2017) states: when reviewing/signing the PGD, the medical professional (or dentist) and pharmacist take joint responsibility and accountability for the accuracy of both the clinical and pharmaceutical content of the PGD. This role should be undertaken by senior professionals with full consideration of the clinical service in which the PGD is to be used.

The Pharmacist is responsible for provision of pharmaceutical advice and support during the PGD review, including advice on the feasibility of the PGD with reference to licensed status of the medicine, local formulary and other guidelines relating to the medicine. The Pharmacist is responsible for ongoing provision of pharmaceutical advice and support when the PGD is in practice and during review.

Note: If the lead author of a PGD is a pharmacist they cannot also act in the capacity of the pharmacist reviewer for the PGD, a second pharmacist must act as the reviewer/signatory for the PGD.

Related Duties to Meet Role and Responsibilities of a Pharmacist Reviewer/Signatory

- Ensures that they have the appropriate skills and knowledge to review the PGD for the specific role in which they are required to sign the PGD.
- When reviewing a PGD – establishes the case for a PGD, identifies the benefits to patient care and ensures the views of all stakeholders have been considered. This would include establishing that;
  - Individual prescribing is not a suitable mechanism following a review of current prescribing systems, and the care pathway being considered, e.g. may delay timely access to treatment and that a PGD is appropriate and legal.
  - There are no relevant exemptions in legislation which allow supply and/or administration of the medicine without the need for a PGD
- Establishes that the clinical and pharmaceutical content in the PGD is accurate by checking all relevant resources such as the Summary of Product Characteristics for the medicine(s), the current British National Formulary (BNF), the BNF for Children and the Department of Health Green Book if a vaccine is involved. Additionally ensures that the PGD is supported by the best available evidence and has considered local and national guidelines.

- Ensures that the medicines content of the PGD is legal and accurate including;
  - Formulary and license status of medicine.
  - Advice on appropriate actions to be taken, e.g. a potential interaction may exclude a patient from a PGD or could be managed by advice to the patient, depending on the type of interaction.
- Ensures that they are satisfied that the PGD is fit for purpose for the medical and/or dental care being delivered to patients in that particular service and locality.
- Ensures that local formularies and procedures are complied with when considering inclusion of a medicine in a PGD e.g. off label use may require local organisational approval.
- Works within any locally agreed timeframes to ensure timely review and approval of the PGD.

Section 4: Role And Responsibilities Of The Reviewer/Signatory Who Is A Representative Of The Professional Group Expected To Supply/Administer Medicines Under The PGD

The representative of the professional group expected to supply/administer medicines under the PGD is responsible for the provision of specialist professional advice and support including provision of information on service delivery within their clinical area. It is not a legal requirement to have the representative of the professional group as a signatory but is seen as good practice.

Patient group directions (NICE guideline MPG2, 2017) states: that they are also responsible for ongoing professional advice and support for practitioners when the PGD is in practice.

Related Duties to Meet Role and Responsibilities of the Reviewer/Signatory Who is a Representative of the Professional Group Expected to Supply/Administer Medicines Under the PGD

- Ensures that they have the appropriate skills and knowledge to review the PGD for the specific role in which they are required to sign the PGD.
- Ensures that they are satisfied that the PGD is fit for purpose for the health professional (e.g. nurses) delivering care to patients in that particular service and locality.
- When reviewing a PGD – establishes the case for a PGD, identifies the benefits to patient care and ensures the views of all stakeholders have been considered. This would include establishing that;
  - Individual prescribing is not a suitable mechanism following a review of current prescribing systems, and the care pathway being considered, e.g. may delay timely access to treatment and that a PGD is appropriate and legal.
  - There are no relevant exemptions in legislation which allow supply and/or administration of the medicine without the need for a PGD
- Works within any locally agreed timeframes to ensure timely review and approval of the PGD.

Section 5: Role And Responsibilities Of The Nos PGD Group

A Memorandum of Understanding (MoU) between all the aforementioned Boards exists by which the NoS PGD Group has been delegated the responsibility by each Board in regard to the development of NoS PGDs, as well as the ratification and approval of PGDs which are considered for use by approved healthcare professionals as authorised within current legislation, within NoS.

The NoS PGD Group will ensure that the requirements of the MoU between all the aforementioned Boards are delivered and further to the responsibilities laid out above, it will also provide a forum to discuss, escalate and resolve issues which may arise in relation to PGDs for use within the NoS Health Boards. This group allows for harmonisation of PGD ratification and approval across NoS Health Boards.

- Ratify and approve all PGDs for use in the NoS (delegated responsibility from the stakeholder Boards GADTC/ADTC and their chief executives).
- When reviewing a PGD for approval the group must establish that a PGD is fit for purpose, i.e.:
  - The PGD has been developed according to the correct NHS organisational procedures and processes
  - There are robust governance arrangements in place, which have been followed
  - All legal requirements have been met
  - Those involved in the development of the direction are competent to do so.
- Ensuring that decision-making is robust and transparent with final decisions on PGDs formally recorded and communicated to appropriate stakeholders.
- Reviewing and prioritising proposals for NoS PGD development, ensuring PGDs are not developed without approval in principal in the first instance by the relevant PGD approval groups within each Board.
- Ensuring approved and authorised PGDs are disseminated to the Boards who intend to use them.
- To develop, review, approve and authorise for use a NoS PGD template including relevant timely review of such template.

Section 5: Role And Responsibility Of Authorising Health Board

Current UK PGD legislation states that PGDs must be authorised for use only by an appropriate authorising body in-line with the Human Medicines Regulations 2012. In Scotland this is a role for NHS Health Boards. It is therefore possible for several Health Boards to collaborate in regard to PGDs and for one Health Board to be appointed as the authorising body to executively sign and authorise the use of PGDs across all Boards.

In order for NHS Grampian to have the vested authority to authorise and executively sign PGDs, each individual Boards ADTC or equivalent group, along with the Chief Executive and Director of Pharmacy for each Board must grant authorisation for NHS Grampian to act in this capacity on their behalf.

NHSG will function as the nominated authorising body to executively sign and authorise NoS PGDs for use across all 6 NoS Boards.

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 6 - New Patient Group Direction Application

New Patient Group Direction Application

1. **Title of PGD**

2. **Development Group for Proposed PGD**

Medical Practitioner	
Senior Member of Relevant Profession **Name:** **Job Title:**	
Pharmacist	

3. **Contact Details for Lead Author/Co-ordinator**

Name	
Clinical Area	
Address	
Postcode	
Telephone	
E-mail	

4. Details of clinical area(s) where the PGD will be used

5. Description of clinical condition to be treated, considering patient inclusion and exclusion

6. Current method of provision of this/these medicine(s)

7. Why can't a prescriber do this?

8. Perceived benefits to patient care

9. Potential risks to patient safety

10. Details of medicine to be supplied/administered

11. Health professionals who will use the PGD / competency and training needs and how they will be addressed

12. Current and/or future service provisions for supplying and/or administering the medicine

13. Evidence base to support the medicine/treatment/indication (e.g. SIGN, NICE)

14. Resources needed to deliver the service, e.g. pre-packs, storage facility

Form completed by	
Job Title	
Date	

Please forward this completed form via email to: gram.nospgd@nhs.scot

Date proposal received: _____

Appendix 7 - Patient Group Direction Consultation Reply

Patient Group Direction Consultation Reply

Patient Group Direction For The Supply/Administration Of Insert Medicine By Insert Staff Group Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles Version #

In order to document the consultation process complete and return this page via email to: gram.nospgd@nhs.scot

Please tick the appropriate box below. I have read the above PGD and;

I have no comments/additions/amendments to add ☐

I have attached the PGD with my annotated comments/additions/amendments ☐

I have the following comments to make on the PGD outlined below ☐

Print Name _____

Title _____

Signed _____ Date _____

Appendix 8 - Patient Group Direction (PGD) Submission Form

Details of PGD	
Title of PGD	
Lead author details **Name:** **Title:**	
Reason for PGD	
Clinical areas in which the PGD will be used	
Have national guidelines/relevant organisational guidelines been utilised and/or incorporated?	
Consultation Process	
List all groups/persons involved in the consultation process:	
Have all comments and/or suggestions been duly considered?	☐ **Yes** ☐ **No**

Declaration: By signing this submission form you are taking responsibility for the content of the submitted PGD and providing assurances regarding its development/review.

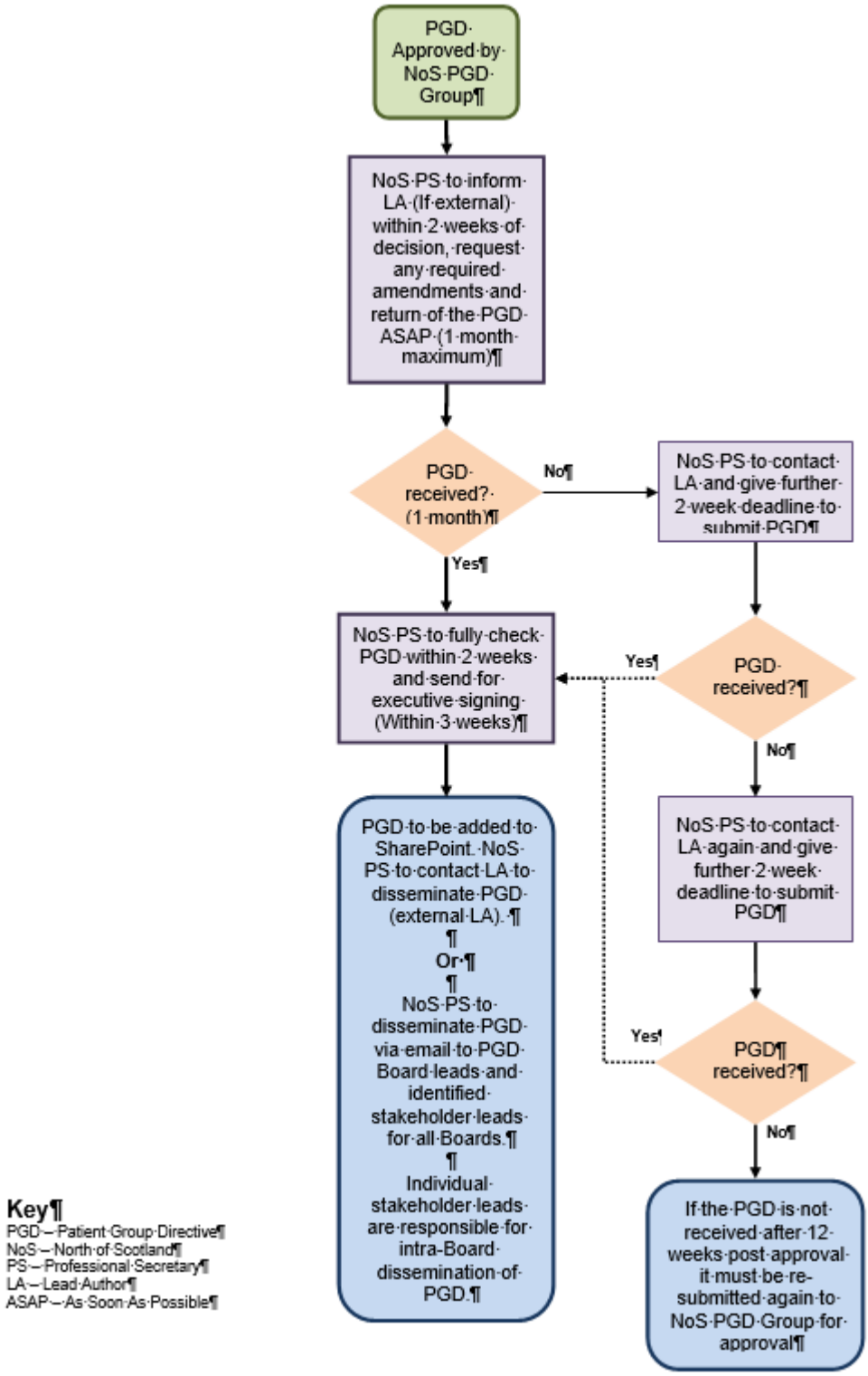
Print Name _____

Title _____

Signed _____ **Date:** _____

Please complete and return this page either via email to: gram.nospgd@nhs.scot

Appendix 9 - PGD Post Approval Process



NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 10 - NoS PGD Audit Tool

North of Scotland (NoS) Patient Group Direction (PGD) Audit Tool	
The NoS PGD audit tool is recommended to be completed annually by all NoS member Boards. The purpose of undertaking the audit is to demonstrate compliance with the PGD(s) and to ensure that the requirements of the service are met. The healthcare professional responsible for authorising staff to work under the PGD is responsible for ensuring that the audit is undertaken. When completing the audit do not leave any blanks. A minimum of five PGDs and 5 patient records should be audited. Records should be selected at random for sampling. Where a PGD is in use in multiple clinical sites, audit should be undertaken on each site. The audit data should be submitted to the NoS PGD Group for assurance. Once completed, return via e-mail to the NoS PGD Administrator gram.nospgd@nhs.scot	
Name of Healthcare Professional Undertaking the Audit:	
Job Title:	
Date of Audit:	

Audit of Completion of Staff Records for PGDs						
Enter yes or no as appropriate, if 'no' state action required and date for completion.						
PGD	Do the managers as detailed in Appendix 2 of the PGD hold a current list of authorised staff? (Y/N)	Has Appendix 2 been signed by both the staff authorised to use the PGD and the manager? (Y/N)	Are all the staff authorised to work under the PGD members of one of the healthcare professions listed in the PGD? (Y/N)	Does the staff working under the PGD have a copy available for reference at the time of consultation? (Y/N)	Are all medicines supplied or administered under the PGD stored according to the PGD where this is specified? (Y/N)	Comments/Action to be taken
1						
2						
3						
4						
5						

Audit of Completion of Patient Records for PGDs						
Enter YES or NO as appropriate, if 'NO' state action required						
PGD	Was the date of supply or administration recorded? (Y/N)	Does it state "given under PGD" in the notes? (Y/N)	Was the signature and name in capital letters of the healthcare professional who supplied the medicine recorded (Y/N)	Was injection site, route, batch and expiry recorded, or strength and quantity if non-injectable (Y/N)	Was the medicine given in accordance with the inclusion criteria? (Y/N)	Comments/Action to be taken
1						
2						
3						
4						
5						

Date Impact Assessed ******