NHS Grampian

Policy For Patient Group Directions (PGDs) For Staff Working Within NHS Grampian

Co-ordinator:		Approver:
Medicines Management Specialist Nurse		Grampian Area Drug and Therapeutics Committee

Signature:		Signature:
		

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Executive Sign-Off

This document has been endorsed by the Medical Director, NHS Grampian

Signature: 

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Document application:	NHS Grampian
Purpose/description:	The purpose of this policy is to ensure that Patient Group Directions developed and implemented within NHS Grampian comply with the legal requirements and the recommendations and guidance set out in the circular, HDL 2001(7); MHRA guidance, NICE guidance.

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.

This document is also available in large print and other formats and languages, upon request. Please call NHS Grampian Corporate Communications on (01224) 551116 or (01224) 552245.

Note: This policy was impact assessed15/02/2024

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June 2023	3 yearly update.	
June 2023	Amended appendixes numbers.	
June 2023	Review timescale changed from 2 yearly review to three yearly.	PGD Expiry Dates and Extensions
June 2023	Statement and hyperlink added about the PGD TURAS training requirements.	Training Requirements
June 2023	PGD extension statement amended to state PGDs will only be extended in very exceptional circumstances.	PGD Expiry Dates and Extensions

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Note: See Policy Definitions for definitions of all 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.

1.1 Objectives

This policy outlines the recommendations for all staff employed by NHS Grampian who use or have involvement in developing, reviewing or approving 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 Grampian, 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.
- Maximise the use of the skills of a range of health professionals.
- Set out the mechanism for developing and using PGDs within NHS Grampian.

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 NHS Quality Improvement Scotland Best Practice Statement ~ March 2006 - Patient Group Directions

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. The NHS Grampian Medicines Management Team can be contacted to assist with this decision making and assessment of need.

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 necessary 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 NHS Grampian Medicines Management Team. 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 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

NHS Grampian has a legal responsibility to ensure that the development and implementation of PGDs complies with current PGD legislation and the NHS Quality Improvement Scotland Best Practice Statement ~ March 2006 - Patient Group Directions.

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
- Physiotherapists
- Radiographers
- Speech and language therapists.

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.
- 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. Within NHS Grampian the process of approval has been assigned to the Medicine Guidelines and Policies group part of the Grampian Area Drug and Therapeutics Committee (GADTC) structure. All approved PGDs for use within NHS Grampian must then be authorised by the Chief Executive.

There may be occasions were PGDs developed by NHS Grampian will be adopted for use within NHS Highland, NHS Orkney, NHS Shetland, NHS Tayside and NHS Western Isles. For these PGDs the process described within this guidance in relation to the development and implementation of PGDs still applies. NHS Grampian will also ensure it is compliant with current legislation governing the authorisation of multi-Board PGDs.

Note: Until a PGD has been authorised by NHS Grampian or North of Scotland PGD Group (NoS), 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 Appendix5

Once the requirement for a new PGD has been identified a New PGD Application (Appendix 6) must be completed and submitted to the NHS Grampian Medicines Guidelines and Policies Group (MGPG) for approval. Then MGPG 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 from MGPG. Following approval the NHS Grampian Medicines Management Team will provide the lead author with all relevant NHSG PGD documentation. The legislation specifies that each PGD must contain specific information. The NHS Grampian PGD template must be used when developing

a PGD to ensure that all legal criteria are included NHSG PGD Template. 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 best practice to have 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 NHS Grampian 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 MGPG 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 MGPG for approval. Additionally, the lead author is also responsible for the completion of the PGD Submission Cover Form (Appendix 9) which must be submitted with the PGD to MGPG for approval.

Acknowledgement of approval, non-approval, or requirements for amendment of a submitted PGD, will be provided by the MGPG 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 MGPG Administrator for the PGD to be assigned a record number or identifier then signed by the appropriate individuals on behalf of NHS Grampian. Completed, signed PGDs will be linked to SharePoint and then published on the NHS Grampian intranet with public access if applicable (see Appendix 10 - PGD Post Approval Process).

Amendment of a PGD

All clinical amendments made to a PGD, including minor ones require a PGD to be reauthorised. Reauthorising requires the agreement of, and resigning by, the development signatories (i.e. the doctor/dentist, pharmacist and member of professional group using the PGD) and the signatories responsible for approving and authorising PGDs on behalf of NHSG. Each signatory needs to agree the amendment and complete a Patient Group Direction Amendment Consultation Reply form (Appendix 8).

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 maximum 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 MGPG via email to inform them and to request that the PGD be withdrawn.

PGD extensions will only be granted in very exceptional circumstances. The period of extension will be decided by the MGPG 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

(See Guidance for the use of Patient Group Directions in Primary and Secondary Care by Qualified Healthcare Professionals Working within NHS Grampian for more detailed information on this process).

Dissemination

The lead author and/or NHS Grampian MGPG Team will advise when a PGD has been approved and is ready use. An email will be sent to the appropriate healthcare professional leads, e.g. nurse managers, managers or general practitioners in the appropriate areas where a PGD is to be used. They will also provide a signed electronic copy of the PGD via email, along with any relevant link for the PGD as it will feature on the NHS Grampian Medicines Management website.

Managers, nurse managers and other appropriate healthcare managers and/or general practitioners have the responsibility for disseminating PGDs they receive. They must also ensure that when a PGD has been reviewed and updated that the outdated PGD is replaced and only the current PGD is subsequently used. PGDs should only be disseminated to appropriate clinical areas. Any old versions must be deleted from electronic storage devices and paper copies destroyed.

Implementation

Nurses and other healthcare professionals (including bank staff) who will be administering/supplying medicines under PGD must be employed by NHS Grampian, general practitioners, or contracted to provide NHS services in partnership with NHS Grampian. All individuals who are to operate under a PGD must complete and retain a copy of the Healthcare Professional Agreement to Supply/Administer Medicine(s) Under Patient Group Direction within each PGD they are to use.

Individuals authorised to operate under PGDs should be identified by name and approved by nurse managers, other appropriate healthcare managers and/or general practitioners. All managers and healthcare professionals who are to work under a PGD must complete the Healthcare Professionals Authorisation to Supply/Administer Medicine(s) Under Patient Group Direction in every PGD they are to use. It is the responsibility of these managers to ensure that staff administering/supplying medicines under PGD have received appropriate and adequate training to enable them to administer/supply medicines safely in accordance with the PGD.

Staff administering/supplying medicines under PGD should be provided with written evidence that they are authorised to provide care under specific PGDs. Each nurse or other healthcare professional administering/supplying medicines under a PGD must agree not to act beyond their professional competence nor out with the recommendations in the PGD. They must sign to confirm that they have understood the contents of the PGD, and have received the appropriate training. The signed forms should be retained by the appropriate senior nurse manager, other appropriate healthcare manager and/or general practitioner. In community pharmacy the individual pharmacist who signs the Healthcare Professional Agreement to Supply/Administer Medicine(s) Under Patient Group Direction is responsible for sending a copy of this to the NHSG Pharmaceutical Care Services Team.

A senior person in each profession should be designated with the responsibility of ensuring that only competent, qualified and trained professionals operate under the PGDs and that a list of those professionals is maintained and kept up to date for each individual PGD. Copies of these lists of authorised staff must be retained by the appropriate manager of each area where PGDs are being used and can be subject to audit.

When a new/reviewed PGD is disseminated, staff may be required to undertake further training if this is considered necessary in order to maintain their own professional level of competence and knowledge according to their Code of Professional Conduct. The authorisation certificate, the list of authorised personnel and the agreement to be professionally accountable will need to be completed again for any amended or new version of the PGD.

Nurse Managers, healthcare professional managers and/or general practitioners should ensure that facilities and equipment where staff are administering/supplying medicines under PGD meet the required standards. This includes having a copy of the PGD available in the setting in which the care is provided. A named person must be identified at each location that will be responsible for keeping the PGDs and ensuring they are accessible to staff and are up to date.

Training Requirements

Specialist qualifications, training, experience and competence considered necessary and relevant to the clinical condition to be treated, and the medicines used in the PGD should be identified. All individuals should receive appropriate training and have undertaken NoS PGD module training on TURAS Learn (search for - Patient Group Directions (PGDs)). It is the responsibility of the line manager of staff working under each PGD to arrange the necessary training for individuals to be authorised under the PGD and to ensure that it is delivered as appropriate.

Monitoring

Nurse Managers, healthcare professional managers and/or general practitioners must make arrangements for monitoring pharmacovigilance and all communications (e.g. drug recalls) in relation to PGDs. This should include a mechanism for identification of problems or errors resulting from use of a PGD.

Audit

Records must be kept by the practice, ward, or department to allow the process to be audited both internally and externally. A regular annual local audit should be undertaken to determine the numbers of qualified staff authorised to administer under specific PGDs.

5 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 14/06/23 https://www.nice.org.uk/guidance/mpg2/resources/patient-group-directions-1779401941189

3. MHRA - Patient Group Directions: who can use them: Accessed 09/10/19 https://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. NHS Quality Improvement Scotland Best Practice Statement ~ March 2006 - Patient Group Directions http://www.healthcareimprovementscotland.org/previous_resources/best_practice_statement/patient_group_directions.aspx

Appendix 1 - Policy Definitions

NHS Grampian

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.

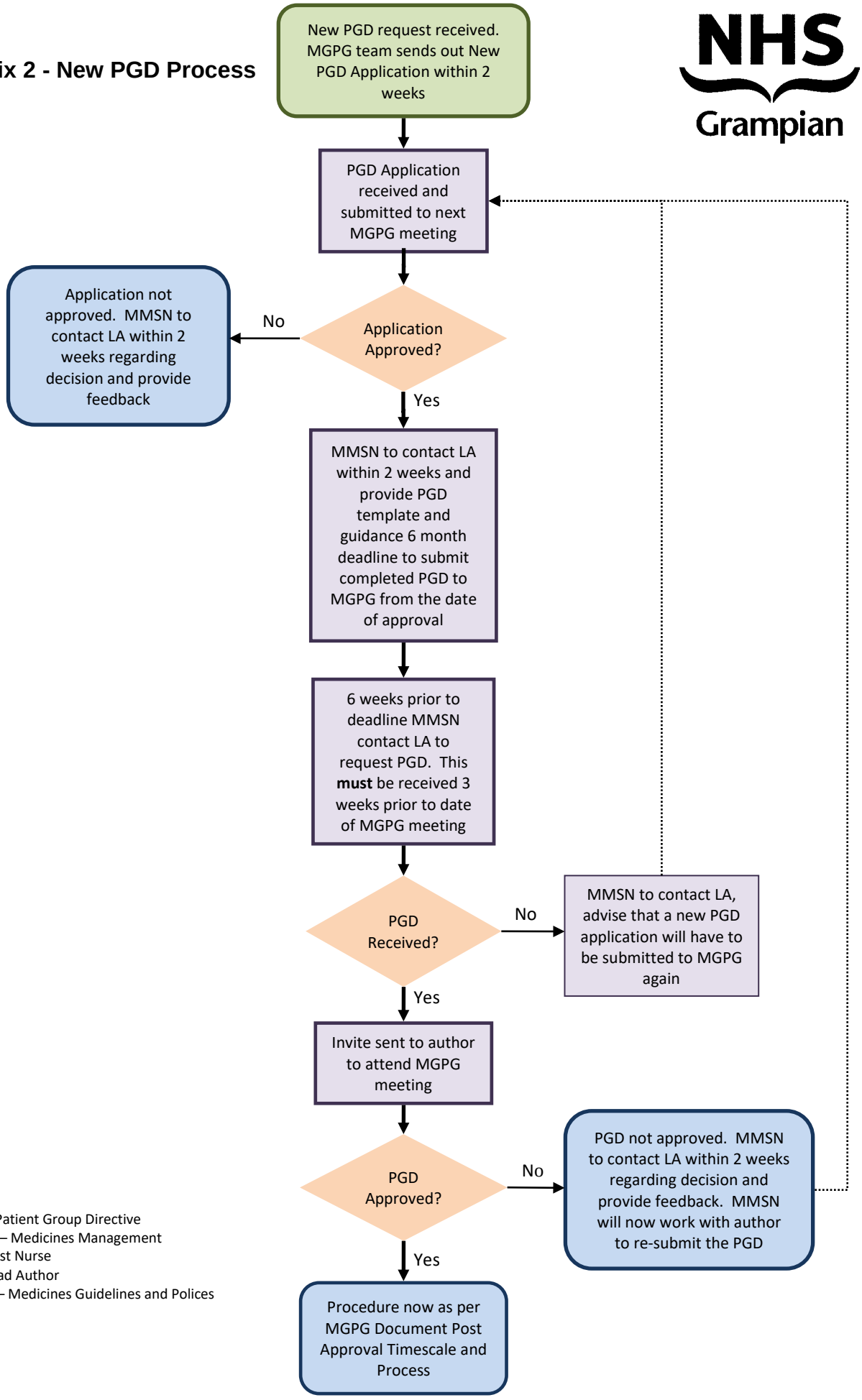
Pharmacy (P) medicine
A medicine that may be sold in registered pharmacies by a pharmacist or a person acting under the supervision of a pharmacist.

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.

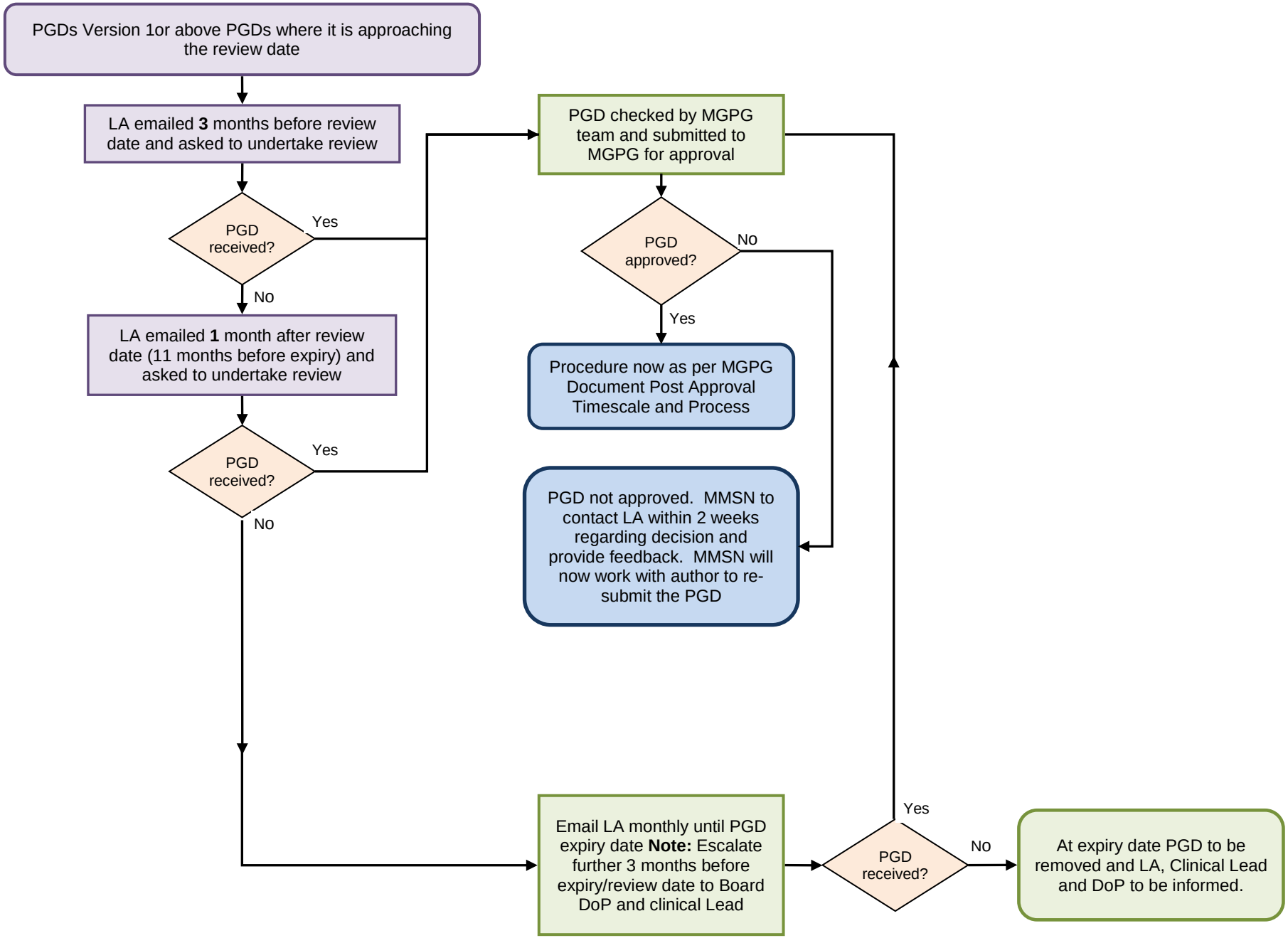
Appendix 2 - New PGD Process



Key

PGD – Patient Group Directive
MMSN – Medicines Management Specialist Nurse
LA – Lead Author
MGPG – Medicines Guidelines and Polices Group

Appendix 3 - Process for PGD Review



Appendix 4 - Summary of Responsibilities Relating To Patient Group Directions

Summary of Responsibilities Relating To Patient Group Directions

Practice Manager/General Practitioner/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.

NHS Grampian MGPG Team is responsible for:

- Issuing the agreed NHS Grampian PGD template.
- Providing advice/involvement in drafting the PGD.
- Ensuring that up-to-date, approved PGDs and other relevant information is available for downloading from the NHS Grampian Intranet/Internet.
- Arranging for the PGD to be signed off by the appropriate signatories for NHS Grampian.
- Providing a signed PDF copy of the PGD to the lead author for dissemination.
- Maintaining a database and record of all PGDs currently in use, in development or archived in NHS Grampian.

Medicines Guidelines and Policies 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

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

The purpose of this document which has been adapted from the Specialist Pharmacy Service (2017) 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 this 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 practise 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 (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 NHSG 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) and a pharmacist (an additional medical professional or pharmacist is required if lead author is a medical professional or pharmacist).
- 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 NHSG Medicines Guidelines and Policies Group (MGPG), along with the completed consultation rely forms and the PGD Submission Covering Form.
- Act on MGPG 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 local formulary.

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

The medical professional (or dentist) reviewer/signatory 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 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
- Ascertains that where a medicine is to be supplied to a patient to take away, appropriately labelled packs can be procured in a legal and timely manner.
- 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.

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.

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, and whether it is in the Grampian Formulary

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 to:

Medicines Guidelines and Policies Administrator
Pharmacy and Medicines Directorate
Westholme
Woodend Hospital
Aberdeen
AB15 6LS
E-mail: gram.mgpg@nhs.scot

Date proposal received: _____

Patient Group Direction Consultation Reply

Patient Group Direction For The Supply/Administration Of Insert Drug By Insert Staff Group Working Within NHS Grampian Version

In order to document the consultation process complete and return this page either via email to: ADDRESS@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 _____

Patient Group Direction Amendment Consultation Reply

Patient Group Direction For The Supply/Administration Of Insert Drug By Insert Staff Group Working Within NHS Grampian
Version

In order to document the amendment consultation process please complete and return this form via email to: ADDRESS@nhs.scot

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

I approve the amendments and have no comments/additions to add ☐

I do not approve the amendments and 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: _____

Professional Registration PIN/Number: _____

Signed _____ Date _____

Appendix 9 - 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 _____

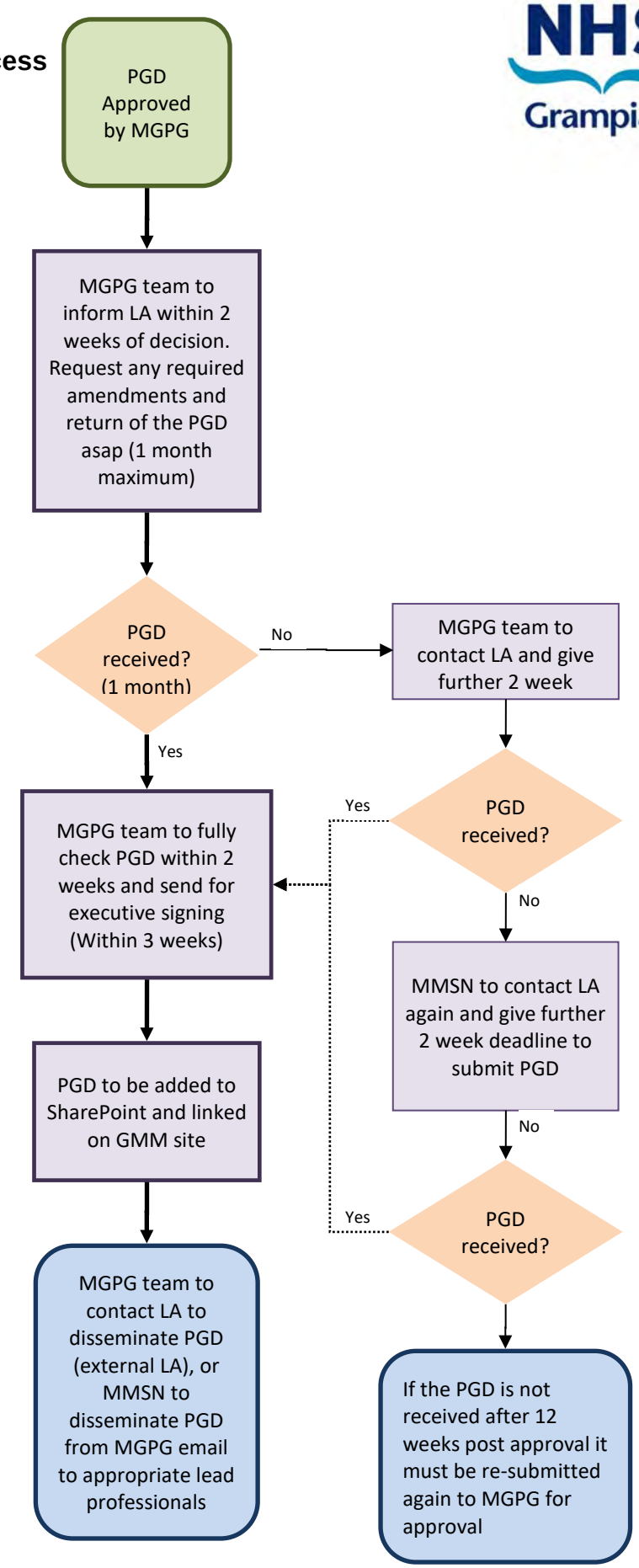
Title _____

Signed _____ **Date:** _____

Please complete and return this page either via email or post to:

Medicines Guidelines and Policies Group, Pharmacy Medicines Unit, Westholme, Woodend, Queens Road, Aberdeen, AB15 6LS. Email: gram.mgpg@nhs.scot

Appendix 10 - PGD Post Approval Process



Key

PGD – Patient Group Directive
MMSN – Medicines Management Specialist Nurse
LA – Lead Author
MGPG – Medicines Guidelines and Polices Group
GMM – Grampian Medicines Management

Appendix 1

Healthcare Professional Agreement to Supply/Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply/administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction for the Supply/Administration of Insert Medicine by Insert Staff Group Working Within NHS Grampian

I have completed the appropriate training to my professional standards enabling me to supply/administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2

Healthcare Professionals Authorisation to Supply/Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply/administer the medicine(s) under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply/administer the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply/administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction for the Supply/Administration of Insert Medicine by Insert Staff Group Working Within NHS Grampian
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date