Title	**Patient Group Direction (PGD) Development Policy For NHS Borders**
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KEY POINT FOR ALL USERS:

Before commencing a new PGD development always check if one already exists on the NHS Borders Patient Group Directions Intranet Micro-site.

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1. Introduction

This 'PGD Pack' contains a documentation set or 'tool kit', to provide healthcare professionals with practical information and advice for the development, review, authorisation and use of PGDs.

The aims of this pack are to ensure that:

1. Practice complies with the legal requirements for PGDs
2. A standard approach is applied to the development and review of PGDs across NHS Borders.
3. Practitioners using PGDs are assessed as being competent in their use and are identified on the hard copy of each PGD kept in the clinical area in the PGD folder.

2. General Information

2.1 What is a Patient Group Direction?

A Patient Group Direction (PGD) is a specific written instruction for the supply and/or administration of medicines to groups of patients (subject to specified exclusions) who cannot be individually identified before presentation for treatment. A PGD can be used instead of a prescription when treatment is provided by a NHS trust, health board, GP, dental practice, or NHS funded family planning clinic. A PGD must be signed by a senior doctor (or, if appropriate, dentist), nurse and pharmacist, all of whom have been involved in developing the PGD. The majority of clinical care however should be provided on an individual, patient specific basis and not via a PGD.

2.2 Who can use them?

The law states that nurses, midwives, health visitors, podiatrists/chiropodists, pharmacists, ambulance paramedics, optometrists, radiographers, orthoptists and physiotherapists are able to supply and administer specified medicines using a PGD.

It is important to note that the above professionals may only supply or administer medicines under a PGD as named individuals. A record of named individuals eligible to use each PGD must be recorded on the PGD master copy, which is held by the responsible person for that location.
In Primary Care, before individual practitioners sign the master copy of the PGD, they must ensure the Practice Authorisation section has been signed by a local GP with relevant interest and involvement in the PGD development (see appendix 2: Blank PGD Template)

2.3 What can they be used for?

PGDs should be used in situations where patients can receive additional benefit; this includes -

- timely access to treatment
- reduction in patient waiting times
- avoidance of hospital admissions

- maximise the use of resources
- fully utilise professional skills

In most cases care will be provided on an individual patient basis by a specific prescriber to a specific individual patient. Medicines may be supplied or administered under PGDs in limited situations where this offers an advantage for patient care without compromising safety, and where it is consistent with appropriate professional relationships and accountability.

2.4 What can't they be used for?

The use of any medicine should be consistent with the product license i.e. Summary of Product Characteristics (SPC) for the relevant products and any relevant guidance.

PGDs can be used to supply specific Controlled Drugs. (Please see appendix 8 for the list of controlled drugs that can be provided under PGD)

PGDs should only be used in **exceptional circumstances** for:

- Black triangle drugs
- 'Off Label' use of Medicines
- Antimicrobials (refer to frequently asked questions)

2.5 What are the alternatives to PGDs?

Other ways of providing medicines should also be considered:

- Individual Patient Prescription, including Non Medical Prescribing
- Patient Specific Directions
- Exemptions to the Medicines Act
- Individualised Care Pathways (ICPs) or clinical protocols
- Symptomatic Relief Policy

3. Framework for Development of a Patient Group Direction

3.1 How do I begin a PGD?

The clinical team who will use the PGD should be involved in its development. This will be a multi-disciplinary approach and should be driven by an identified service/patient need and aligned to Health Board non-medical prescribing strategy. The professionals involved comprise the Local Clinical Team and line management support. A clinical pharmacist may be used to provide pharmacy expertise, but should not author the document as they will be required to engage in the review process.

How should I go about it?

- As author of the PGD you are responsible its review and control
- The PGD must be reviewed biennially, this is a legal requirement, you will be informed automatically by the web team when the PGD is due for review and will be expected to review the PGD within the required

timescale. It is essential that you inform Area Drugs and Therapeutics Committee (ADTC) of any issues which may delay review and formally request a temporary extension to ADTC, detailing the mitigating circumstances

- Your line manager will be informed at the point of expiry of the PGD and that it is no longer valid
- The PGD will be removed from the microsite and will not be legally valid for staff to operate under if it has not been received in pharmacy by the expiry date
- A short audit (appendix 3) of the PGD's use in practice is required following the first 6 months of a new PGD and then as part of the review process biennially. The PGD will not be approved without this audit
- Once the PGD has been received in pharmacy the expiry date will be extended for a maximum of 8 weeks to enable review, approval and sign off
- The front cover for the PGD (appendix 4) was changed in May 2014, this version must accompany all PGDs submitted for review

As the PGD owner you will be expected to identify and to ensure PGD Sign Off by the following individuals:

1. Author of the PGD
2. Person responsible for Audit & Training: This should be defined for each clinical area as the most appropriate person by the author. More than one person may require to be identified.
3. Author of PGD: Discussion and agreement of PGD within local clinical team.
4. Specialist Clinician: Defined by the author as the most appropriate local Clinical Specialist with the relevant expertise (must not be the author and should be a prescriber).

The PGD will reflect best practice and published evidence. The training needs of the practitioners using the PGD will be identified and any gaps in skills and knowledge addressed. Arrangements to obtain the medicines required should be made together with any additional supporting equipment. In order to facilitate an audit trail, you will also need to consider treatment records (refer to section 8 and appendix 6 and 7) and agree referral pathways.

A senior representative of each profession should be responsible for ensuring that only fully competent, qualified and trained persons are authorised to use PGDs. All professionals involved in the development, review and operation of the PGD must act within the legal requirements as well as the appropriate code of professional practice and conduct. Any professional signing the PGD must be satisfied that this matter has been addressed appropriately. Use the PGD template (appendix 4) to ensure that the PGD contains the legally required information. An electronic version of the PGD template is available on the NHS Borders PGDs intranet page.

3.3 What are each group or individual practitioner responsible/legally liable for?

Professionals using PGDs assume a duty of care to the patient. If a professional using a PGD acts in any way outside of its terms, for instance in supplying the wrong medication, they are accountable for that decision. If the requirements of the PGD are fulfilled but the patient comes to harm as a result of the supply (e.g. if they experience an adverse drug reaction) then the organisation that has agreed the use of the PGD is accountable.

The persons responsible for assessing the competence of individuals supplying or administering under a PGD may be held partly liable if it were decided that the assessment was not appropriate.

Individuals operating under a PGD are responsible for determining their own competence. All individuals must ensure that the activities they undertake are covered by adequate indemnity arrangements.

3.4 What next?

The current list of PGDs that have been approved for use within NHS Borders can be viewed on the Patient Group Directions intranet site. If a PGD is needed, the appropriate Local Clinical Team is responsible for writing the PGD. Until the approved PGD has been authorised by NHS Borders, (Signed by the ADTC Chair, Director of Pharmacy and Professional Lead) the PGD has no legal status and cannot be used.

3.5 Who is responsible at a local level, for maintaining the PGD folder (PGD pack, master copies of PGDs and up-to-date list of authorised PGDs)?

The NHS Borders Pharmacy Department is responsible for maintaining the organisations list of active PGDs. A list of all the approved PGDs are published and maintained on the PGD Intranet Micro-site.

Local Clinical Teams will be reminded to review their PGDs 3 months prior to their expiry, if the PGD is not reviewed in this time it will be removed from the intranet and will no longer be authorised for use.

The Local Clinical Team, who developed the PGD, should retain a master copy and the lead for each clinical area will maintain the PGD folder for that area which will contain the signed master copies of all of the relevant PGDs.

Contact Details:

PGD Administrator
NHS Borders
BGH

Operational Lead – Non Medical Prescribing and Medicines Governance

3.6 How often should PGDs be reviewed?

National guidance recommends that PGDs are reviewed every two years and this is the standard that NHS Borders will strive to maintain.
PGDs must also be reviewed following any changes to the relevant Summary of Product Characteristics of any medicine listed within a PGD.

4. Process of Development to Authorisation of Patient Group Directions NHS Borders (see appendix 2)

- 1st review is by the local clinical team
- 2nd review is by an appropriate clinical specialist with relevant expertise (organised by, but must not be the author)
- For subsequent resubmissions an audit (appendix 3) is required as part of the submission to ADTC
- 3rd review is by the Clinical Pharmacist covering clinical area
- 4th review is by the NMP lead where the PGD will be assessed against a PGD risk matrix (appendix 9). All drugs considered to be high risk or with indentified concerns will be discussed at a local multidisciplinary working group with medical and pharmacy representation
- 5th review is by the ADTC (electronic voting is used and a quorate decision based upon minimum review by x1 Primary care physician, x1 Secondary care physician and x2 pharmacists
- Final review is the sign off process by appropriate clinical leads and chair of ADTC (as defined in the signatory section of the PGD)
- The 3rd and 5th review is not required for Nationally developed PGDs

Please refer to the information contained in appendices 1 & 2.

5. Training, Competency Assessment and Responsibilities of Practitioners Operating within PGDs

Line managers of professionals working under PGDs are responsible for ensuring that only fully competent, qualified and trained persons are authorised to operate under the PGD.

Professionals signing the PGD must be satisfied that this matter has been addressed appropriately, and that the staff training specified will enable safe operation of the PGD.

It is therefore important that the Local Clinical Team assess the training needs of local practitioners who will be expected to operate within a particular PGD, **before they produce a PGD for approval** or adapt/adopt an authorised PGD locally.

5.1 Advice to Practitioners Operating within a PGD

Practitioners operating within a PGD must:

1. Ensure that they have up-to-date knowledge relating to the clinical situation covered by the PGD, the medicine and its use for the indications specified
2. Ensure that they have undertaken any training required for operation of the PGD including the NHS Borders PGD e-learning.
3. Be satisfied that the PGD is legally valid and that it has been authorised by NHS Borders
4. Ensure that when medicines are supplied or administered the agreed protocol is followed and the information specified in the PGD is recorded. These records must include the identity and signature of the practitioner assuming responsibility for each supply or administration.
5. Act within the legal requirements of the PGD as well as the appropriate code of professional practice and conduct.
6. Each individual operating under a PGD is responsible for determining their level of competence.

6. Labelling and Patient Information Leaflets

All medicines supplied under a PGD must be labelled in accordance with the EC Labelling and Leaflet Directive 92/97. All medicines supplied under a PGD must be labelled as dispensed medicinal products. A manufacturer's patient information leaflet must be supplied to the patient when a medicine is supplied or administered.

6.1 Labels

The container of a dispensed medicinal product must be labelled to show the following particulars

1. name of the person to whom the medicine is to be administered
2. name and address of the person who supplies the medicinal product
3. date of dispensing
4. the words "Keep out of reach of children"
5. name of the product
6. pharmaceutical form of the product
7. quantity of the product
8. directions for use, including the method and if necessary, the route of administration of the product
9. precautions relating to the use of the product
10. the phrase "For external use only" within a rectangle if the product is not on a general sales list and is an embrocation, liniment, lotion, liquid antiseptic or other liquid preparation or gel and is for external use only
11. any special storage precautions for the product

Medicines may only be supplied under a PGD if these labelling requirements are met.

6.2 Patient Information Leaflets

Patient information leaflets will be supplied each time a medicine is supplied.

The principal reason for supply of a leaflet is to ensure that all information required for safe and effective use of the medicine is conveyed to the patient. Where possible, availability of leaflets in different languages/Braille should be considered.

7. Security of Transport and Storage

It is essential that due consideration is given to the arrangements for the supply, security, storage and stock rotation of all medicines.
NHS guidance has indicated that all medicines should be supplied in pre-packs made up by a pharmacist. Refer to the NHS Borders Code of Practice for the Control of Medicines (2013) for additional information.

8. Record of Supply/Administration of Medicines under a Patient Group Direction

8.1 Record Keeping

Proper audit trails must be in place in order to demonstrate whether the PGD has been followed, i.e. to show that the healthcare professional has made an appropriate supply to the patient. This requires a robust system for the recording of medicines used under the PGD on an individual patient-by-patient basis. Stock balances must be reconcilable with receipts, administration, records and disposals i.e. any non-administration leading to wastage of medication must be documented. From this it should be possible to identify what patient has had what medicine. The names of the health professionals providing treatment must be recorded. The record acts both as a record of the transaction and a prompt for the healthcare professional supplying/administering the medicine.

8.2 What should be recorded?

Details of supply and administration of a medicine under a PGD must be recorded as for all medicines supplied/administered to patients. The medicine chart would need to be completed in the hospital.

It is recommended that a stock record must also be completed each time stock is received for the purposes of supply or administration against a PGD. This will allow reconciliation of receipts and supplies of medicines on an individual patient by patient basis. (see appendix 6 which could be a record book rather than separate forms). For some medications and PGDs, the suggested records in appendices 6 and 7 may be merged with existing records.

Records must include

- the GP practice, clinic, hospital, and ward or department
- the patient name and CHI number
- the medicine name, dose, route, time of dose(s), and where appropriate, start date, number of doses and or period of time, for which the medicine is to be supplied or administered
- drug batch number and expiry
- the signature and printed name of the approved healthcare

professional who supplied or administered the medicine
- the patient group direction title and/or number
- quantity supplied / received and current stock balance (appendix 7)

8.3 Patients Medical Notes

To ensure all members of the multidisciplinary team are aware that the patient has had a medicine supplied or administered under a PGD, details of this must be recorded in the patient's paper notes and on the computer records (if available).

This must include whether the patient met the inclusion criteria and whether the exclusion criteria were assessed.

The supply of manufacturer's patient information leaflet, action taken and any counselling given to the patient must be recorded.

Details and quantity of drug supplied/administered must be recorded as well as any failed attempt to administer medication under a PGD.

9. Audit of Patient Group Directions

Records must be kept by the clinical area to allow the process to be audited internally (by Local Clinical Team) and externally. An audit process (appendix 3) is required after 6 months of a new PGD and at each biennial review.

The following are suggestions of methods that you could employ to check the quality of the supply of medicines under PGDs.

- **Record Keeping**

A simple audit would be to look at the records and ascertain whether they have been completed properly. Incomplete record keeping could lead to NHS Borders removing the approval for an individual healthcare professional to supply / administer against PGDs.

- **Inclusion/exclusion criteria**

A check on whether healthcare professionals are following the inclusion/exclusion criteria in all cases. A simple review of the records will demonstrate whether this is being followed.

- **Counselling**

If the PGD does not specify the content and quantity of counselling that should be given, then each healthcare professional must decide how much counselling they think is appropriate for each patient. It is good practice to make a formal decision about how much counselling and what areas the healthcare professional would wish to cover with each supply/administration. It would be useful to produce a counselling checklist.

In order to audit counselling the healthcare professional could review the actual counselling noted in the records against their decision about how much counselling was required. The healthcare professional may then want to reflect on whether they are actually delivering all the counselling that they thought necessary and decide whether to change their practice.

- **Significant Events**

An important form of auditing practice is to note any significant events that have happened during supply/administration of a medicine under a PGD. A significant event could be a supply/administration which was particularly difficult or went particularly well.

After a supply/administration that you did not handle particularly well, try to reflect on why you had a problem. What could you do differently next time? How could you have dealt with the client better? Could your peers give you some insight into how to improve your techniques?

Similarly, after a supply/administration that you were particularly happy about – what did you do particularly well? Is there something you could incorporate into future supplies/administrations?

Significant events are important in highlighting learning experiences. If possible, share your experiences, either good or bad, with colleagues and staff so that they can also learn. If appropriate, complete a DATIX incident report for Medication Events (including "Near-Misses").

- **Formal Audit Reporting**

In order to ensure safe and effective mechanisms a formal audit of the PGD will be required during the first year of a PGD and again as part of the 2 year review process.

This audit (*appendix 3*) will be the responsibility of the responsible clinician defined in the PGD. If not completed within a 6 week period the PGD will be withdrawn and staff will not be covered to work under it

10. Frequently Asked Questions

Can you have a PGD for more than one drug?

PGDs will cover individual drugs, with certain exceptions, e.g. midwifery. Due to the level of information legally required within a PGD, PGDs for more than one drug may be confusing, unless for a combination product.
It is unlikely that a different PGD would be required for different brands of the same drug. If there is any doubt please seek advice from Pharmacy.

Is it acceptable to have a dose range specified in the PGD rather than a specific dose?

This is acceptable. The legislation requires that the applicable dose or maximum dose is specified. The PGD may therefore specify a single dose or a range up to a specified maximum. Healthcare professionals signing the PGD must be satisfied that the dose range is clinically appropriate and within the terms of the medicine's marketing authorisation. The clinical criteria for selecting a dose within the range must be specified. The healthcare professional supplying/administering under the PGD must be assessed as competent to make the dosage decision.

Is it allowable to have a PGD for Antimicrobials?

Yes, but particular caution should be exercised in any decision to draw up a PGD relating to antimicrobials. Microbial resistance is a public health matter of major importance and great care should be taken to ensure that their inclusion in a PGD is absolutely necessary and will not jeopardise strategies to combat increasing resistance. A local microbiologist/antimicrobial pharmacist should be involved in development of the PGD. Any such PGDs will be consistent with local policies and subject to external audit which will be considered during the PGD's development.

Can a medicine be supplied under a PGD from a GP practice if a nurse named in the PGD is not available?

No. Only named individuals, named on the PGD can supply or administer under PGDs. It is therefore essential that when a named nurse is not available, nursing staff are able to refer patients for treatment if required.

Who is responsible for ensuring the competence of the professionals supplying or administering under PGDs?

Line managers/clinical leads of professionals involved in supplying or administering medicines under a particular PGD are responsible for ensuring that personnel are adequately trained and competent to undertake such a role. Practitioners involved in supply or administration under a PGD are also responsible for ensuring that they have received appropriate training and are competent. (Refer to Section 5). All practitioners supplying or administering under PGDs will have completed the NHS Borders PGD e-learning.

I am a nurse authorised to supply a medicine under a PGD in a different NHS Health Board/Trust. Can I supply under the PGD in NHS Borders?

No. Each PGD is organisation specific. An individual supplying or administering under a PGD must be named in the PGD (Signed the health professional's authorisation form). If a nurse is not named in a particular PGD they cannot supply or administer it regardless of whether they are authorised elsewhere for other PGDs.

Does a medicine supplied under PGD have to be given to the patient in person?

No. A medicine could be supplied to a carer or representative if the patient is unable to present to the practice in person. However, the healthcare

professional has a professional responsibility to ensure that the medicine is suitable and that the patient has all the information necessary for safe and effective use of the medicine. If the healthcare professional cannot be satisfied that the supply is appropriate or that all the necessary information will be accurately conveyed, the patient should be referred in line with the referral guidance detailed in the PGD. Ideally the patient should be assessed on a face to face basis against the criteria of the PGD.

What is the position if a medicine is being used outside the terms of its Summary of Product Characteristics (SPC)? ('off label')

A medicine with a valid marketing authorisation gives guarantees of safety, quality and efficacy for its licensed indications. Once a product is used outside the terms of its SPC, no such guarantees exist. NHS Scotland guidance states that a medicine being used outside the terms of its SPC, can be included in a PGD in exceptional circumstances and where its use is justified by current best clinical practice. The status of the product must be clearly indicated in the PGD.

Those healthcare professionals involved in drawing up PGDs, and those supplying or administering under PGDs as authorised individuals, must use their professional expertise to ensure that the use of a product outside the terms of its SPC is appropriate given that there are no guarantees of safety, quality and efficacy. Healthcare professionals must ensure that the benefits to patients will outweigh the risks. Practitioners must ensure that patients are informed that the product is being used out-with its license ('off label').

A PGD cannot be used to supply or administer unlicensed medicines. To understand the difference between 'off-label' and 'unlicensed' use of medicines, please see the appropriate section of the NHS Borders Medicines Code (2013) and the Unlicensed/Off Label Use of Medicines Policy. Please seek advice from the Pharmacy Department if required.

11. Glossary

ADTC	NHS Borders Area Drug & Therapeutics Committee.
Approval of PGD	PGD meets the required specification and is suitable for authorisation by NHS Borders
Authorisation	PGD meets legal and ethical requirements such that the organisation authorising the pgd can accept vicarious liability.
CMP	Clinical Management Plan
Crown Report	Report of the Review of Prescribing, Supply and Administration of Medicines. The review team was led by Dr J Crown. The report makes recommendations to the Department of Health on a proposed new framework for the prescribing, supply and administration of medicines.

Exemptions	Exemptions to the medicines act allowing the sale, supply and administration of medicines to patients by certain professionals without requiring a prescription.
MSAC	Medication Safety Action Committee
NHS HDL (2001) 7	Scottish Executive Health Department Letter which gives details of **legal requirements** and guidance for PGDs
Local Clinical Team	Local senior doctor (or, if appropriate, a dentist), nurse and a pharmacist involved with the development of the PGD, and a senior representative of the professional group expected to supply or administer medicines under the PGD.
NMP	Non Medical Prescribing
NMAHP/P	Nursing Midwifery and Allied Health Professional Prescribing
PGD	Patient Group Direction
PGD List	The PGD List is an electronic list, maintained by Pharmacy and is available on the NHS Borders Patient Group Directions Intranet page. It is used to aid document control and dissemination of PGDs.
PGD Folder	Contains controlled documentation (PGD Pack and authorised PGDs) and up-to-date list of authorised PGDs.
PGD Policy Pack	Documentation set or 'tool kit' to provide health professionals with practical information and advice for the development, operation, review approval and authorisation of PGDs.
PSD	Patient Specific Direction
Review	PGD is clinically appropriate, meets the required specification, **of PGD** complies with legal requirements and is suitable for approval by ADTC.
RPSGB	Royal Pharmaceutical Society of Great Britain
SPC	Summary of Product Characteristics

12. Reference Documents

1. NHS Borders Code for the Control of Medicines (2013)
2. NHS Borders Unlicensed and Off-Label use of Medicines Policy (2010)
3. Scottish Executive Health Department. Patient Group Directions. NHS HDL (2001) 7. January 2001.

4. Home Office Circular 027/2007 - Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007

5. NICE Patient Group Directions – Good Practice Guidance (2013)

6. To PGD or Not to PGD (Scottish Version) (2008) – NHS Education for Scotland, Adapted from Department of Health Guidance.

7. First Report of the UK review of Prescribing, Supply and Administration of Medicines. A Report on the Supply and Administration of Medicines under Group Protocols. Crown J (Chair). Department of Health (April 1998).

8. Review of Prescribing, Supply and Administration of Medicines: Final Report. Crown J (Chair). Department of Health (March 1999).

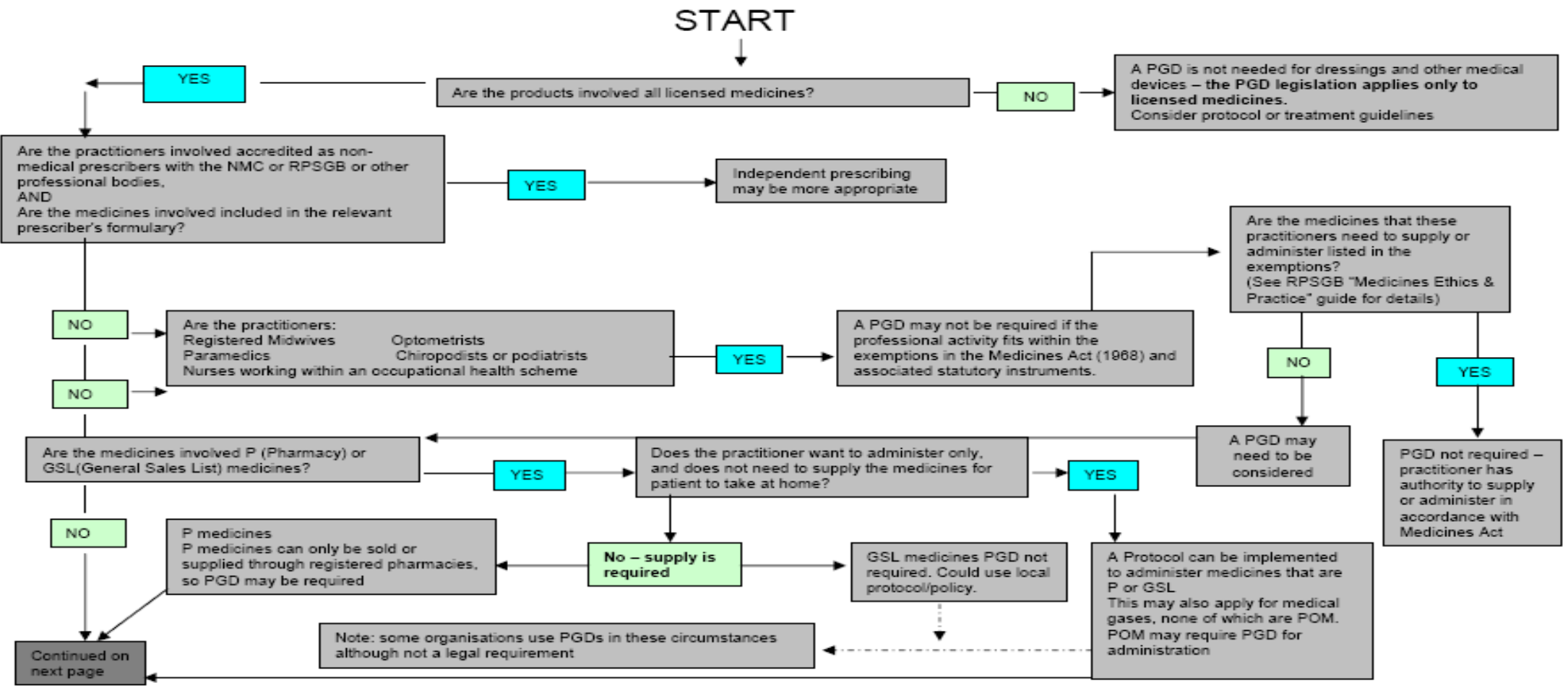
9. Royal Pharmaceutical Society of Great Britain. Professional Standard Directorate Patient Group Directions: A resource pack for pharmacists.

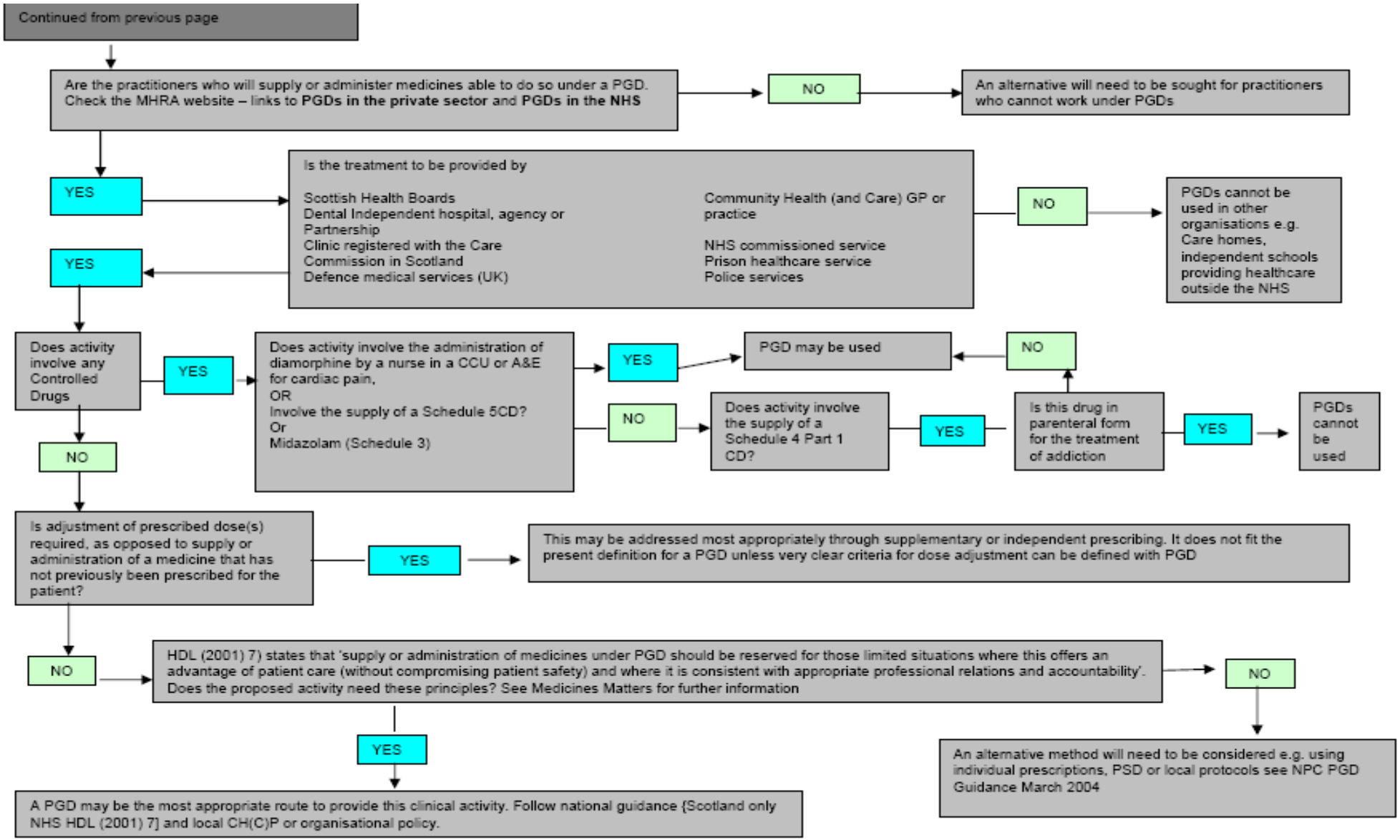
10. Tayside Prescriber. ADTC Supplement No.14. Patient Group Directions: New Responsibilities. July 2001.

Appendix 1

TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations

You need to consider whether a Patient Group Direction (PGD) would be appropriate for an area of practice that involves the supply or administration of medicines. Medicines Matters published by Department of Health is a useful reference source which describes the mechanisms available for the prescribing, supply and administration of medicines. This diagram takes the practitioner through a logical process that aims to assist decision-making. **SCOTTISH VERSION ONLY.**
NOTE: The majority of clinical care should still be provided on an individual, patient-specific basis.

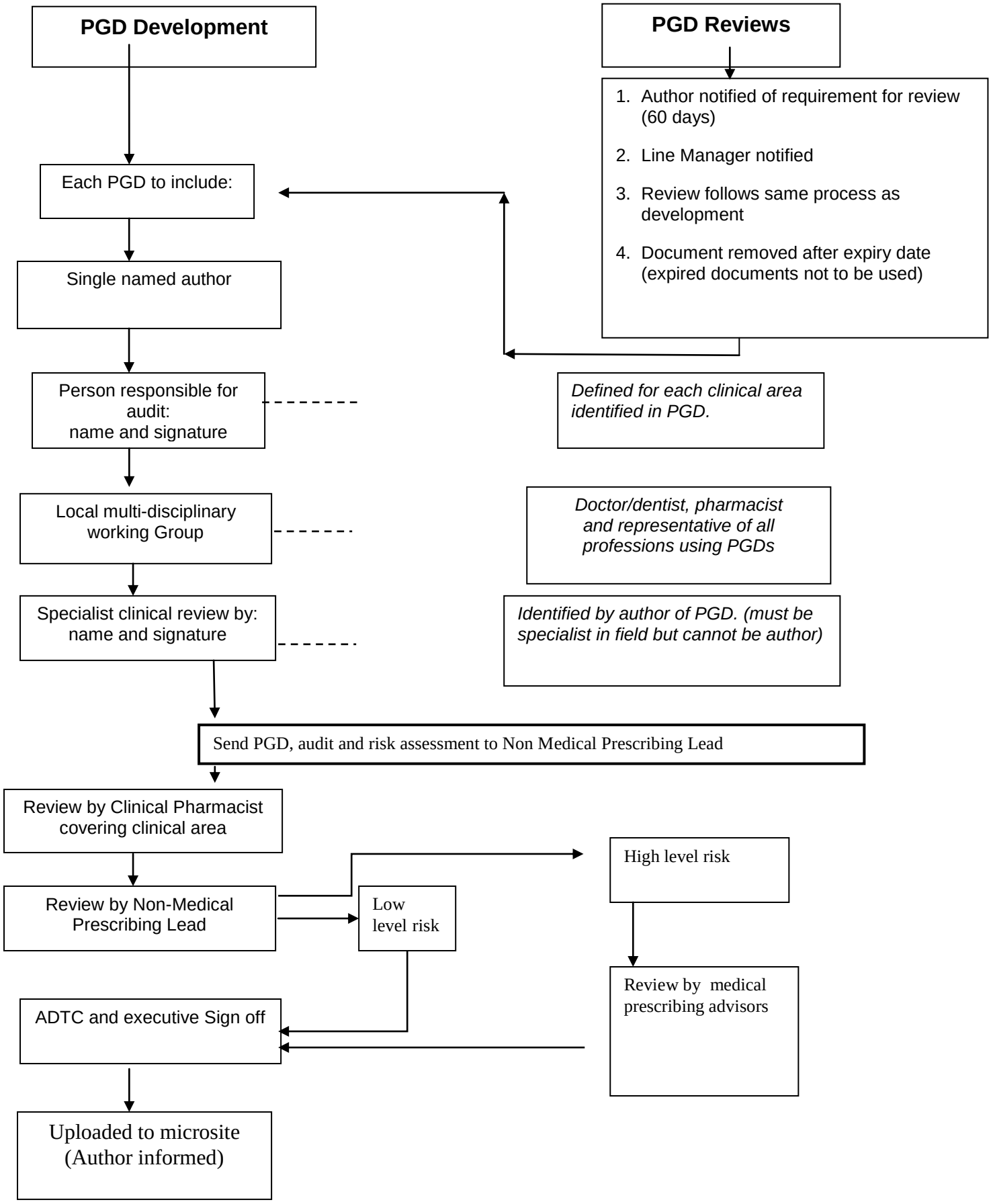




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Appendix 2

Patient Group Direction (PGD)



NHS Borders

Audit Tool for Patient Group Directions (PGDs)

Audit Tool for Self Inspection of Compliance with Policy for Patient Group Directions (PGDs)

Please record details in table below. The completed Audit Tool should be returned – Pharmacy Admin Office.
(Please retain a copy for your files).

Date (s) of Audit	**Auditor(s)**	**Job Title(s)**
Comments		
Definitions: ***PGD Group – Local Group who have written the PGD.** ***Audit – See PGD Policy. Scope of audit defined by PGD Group.**		

NHS Borders
Audit Tool for Patient Group Directions (PGDs)
Scope – examination of Patient Group Directions

Aims of a Patient Group Direction Service

To provide a safe and efficient service which satisfies patient requirements.
To provide patients with the correct medicinal products in accordance with patient group directions.
To ensure all products held in stock are stored under the correct conditions required to assure quality for patients.

Aims of the Audit

To specify standards, in the form of acceptance criteria, as agreed with local and national policy and guidelines.
To provide a means of monitoring performance against these standards.
To identify and initiate action to rectify deficiencies surrounding the administration of medicines under PGDs.
To aid in the continuous improvement of the Service.
To report results of audits to Clinical Governance Committee and PGD Sub Group.

Acceptance Criteria

As listed in this audit tool
The criteria encompass critical components of the service i.e. factors which will impact upon the quality of the medicinal product.
The agreed criteria will be reviewed and revised by the RQAS on an annual basis and/or whenever considered necessary, e.g., as a result of legislative or local/national policy changes.

Methods of Monitoring

Inspecting records for evidence of completion and within limits or note of action taken.
Examining by inspection of the procedures and documentation.
Observing tasks being undertaken
Discussing with relevant personnel.

Scoring System **Y = Complete Compliance with acceptance criteria**
N = Does NOT Comply
N/A = Not Applicable
For each section within the audit schedule, deficiencies are categorised based on the level of non-compliance with the acceptance criteria and the risk to patient safety/product quality.
Critical = high risk requiring an immediate corrective action plan to rectify non-compliance(s)
Major = medium risk requiring a short-medium term corrective action plan to rectify non-compliance(s)
Other = corrective action plan required to rectify non-compliance(s)
Satisfactory = complies with standards.

References
The following guidelines and local in-house documents may be referred to in the course of the audit:
National Guidelines
1. Patient Group Directions – Best Practice Statement 2006.
Local in-House Documentation (which may include):
1. The PGD
2. Patient Group Direction Policy
3. Standard Operating Procedures (SOP)
4. Patient records/notes.

Separate audits to be carried out for each PGD in the department.

NHS Borders
Audit Tool for Patient Group Directions (PGDs)

Section No: 1 **Management** **Category: Critical/Major/Other/Satisfactory**

No	Acceptance Criteria	Audit Result	Comments
1.1	**General statements**		
1.1.1.	The Patient Group Direction (PGD) under inspection is still clinically relevant	Y N NIA	
1.1.2	The PGD reflects content of current Summary of Product Characteristics (SPC)	Y N NIA	
1.1.3	The PGD is within its expiry date	Y N NIA	
1.1.4	The PGD has not been suspended	Y N NIA	
1.1.5	Practitioners operating under PGD are as stated in the PGD	Y N NIA	
1.1.6	There is evidence of approval of the PGD for use within the particular department	Y N NIA	
1.2	**Review of PGDs**		
1.2.1	There is evidence that any changes required (e.g. alterations in product licence) have been put in place via the PGD group.	Y N NIA	

Section No: 2 **Training** **Category: Critical/Major/Other/Satisfactory**

No	Acceptance Criteria	Audit Result	Comments
2.1	**Training for working under the direction of a PGD**		
2.1.1	Training programmes have been developed and implemented	Y N NIA	
2.1.2	There is evidence that all practitioners utilising the PGD have been appropriately trained – training records.	Y N NIA	
2.1.3	Competency should be re-assessed at regular intervals – a re-assessment programme should be available and evidenced	Y N NIA	
2.2	**Additional training requirements e.g. IV administration, cannulation, vaccine administration**		
2.2.1	Any additional training requirements for operating under the PGD have been met through appropriate training programmes	Y N NIA	
2.2.2	Competency requirements have been assessed and evidenced	Y N NIA	
2.2.3	There is evidence of re-assessment and continuing competency	Y N NIA	

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Section No: 3 **Medication Administration** **Category: Critical/Major/Other/Satisfactory**

No	Acceptance Criteria	Audit Result	Comments
3.1	**Inclusion/Exclusion – Patients must meet the inclusion criteria for administration of medicines under the PGD.**		
	Inclusion criteria		
3.1.1	From PGD records analysed during audit, no patients have received treatment where PGD inclusion criteria have not been met.	Y N NIA	
3.1.2	If any patients have received treatment where the PGD criteria have not been met, then the reasons have been documented.	Y N NIA	
3.1.3	The PGD Group has been contacted to raise awareness of need to review inclusion criteria	Y N NIA	
	Exclusion criteria		
3.1.4	Patients are referred to medical practitioners if they are excluded from treatment under PGD	Y N NIA	
3.1.5	Reasons for referral are documented along with reasons for exclusion	Y N NIA	
3.1.6	Where a patient declines the treatment, the reasons are noted in the patient case notes and referral to medical practitioner documented	Y N NIA	

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Section No: 3 **Medication Administration** **Category: Critical/Major/Other/Satisfactory**

No	Acceptance Criteria	Audit Result	Comments
3.2	**Recording – the following details are recorded on the Patient Record Sheet by practitioners when administering a medicine under the PGD**		
3.2.1	Name of the practitioner supplying/administering medication under PGD	Y N NIA	
3.2.2	Signature of practitioner	Y N NIA	
3.2.3	Patients/carers are informed of fact that administration of medicine is within PGD protocol and consent is documented	Y N NIA	
3.2.4	Patient information supplied	Y N NIA	
3.2.5	Medication, route and strength is on record	Y N NIA	
3.2.6	Confirmation of patient meeting inclusing criteria	Y N NIA	
3.2.7	Details of exclusion criteria	Y N NIA	
3.2.8	Any adverse events noted	Y N NIA	
3.2.9	Evidence of completion of clinical incident form following an adverse event	Y N NIA	
3.2.10	A copy of the patient record sheet is held by the PGD practitioner and a second copy is placed in the patient notes	Y N NIA	

Section No: 3 **Medication Administration (contd)** **Category: Critical/Major/Other/Satisfactory**

No	Acceptance Criteria	Audit Result	Comments
	Recording – the following details are recorded on the Patient Record Sheet by practitioners when administering a medicine under the PGD		
3.2.11	Date of supply/administration	Y N NIA	
3.2.12	Patient Name	Y N NIA	
3.2.13	CHI number	Y N NIA	
3.2.14	Quantity supplied/administered	Y N NIA	
3.2.15	Batch No	Y N NIA	
3.2.16	Expiry date of product	Y N NIA	
3.2.17	Treatment period	Y N NIA	

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Section No: 4 **Risk Management** **Category: Critical/Major/Other/Satisfactory**

No	Acceptance Criteria	Audit Result	Comments
4.1	**Incident Reporting**		
4.1.1	Incidents and near misses are recorded via DATIX	Y N NIA	
4.1.2	Remedial actions are reviewed to ensure effectiveness	Y N NIA	
4.1.3	Any known suspected/unexpected adverse drug reactions involving the medicine administered under a PGD are recorded via a local policy/guidance on the patient record sheet	Y N NIA	
4.1.4	Any suspected/unexpected adverse drug reactions involving the medicine administered under a PGD are recorded via national yellow card system and also on the patient record sheet	Y N NIA	
4.1.5	Reports for suspected/unexpected drug reactions are available for review	Y N NIA	

Section No: 5 **Storage** **Category: Critical/Major/Other/Satisfactory**

No	Acceptance Criteria	Audit Result	Comments
5.1	**Storage of PGD medicines**		
5.1.1	Medicines for administration under PGDs are stored according to NHS Borders Code of Practice for the Control of Medicines	Y N NIA	
5.1.2	Medicines are locked in appropriate drug cupboards (if applicable)	Y N NIA	
5.1.3	Medicines to be stored between 2 degrees C and 8 degrees C are stored in pharmaceutical refrigerators	Y N NIA	
5.1.4	Domestic refrigerators are not used	Y N NIA	
5.1.5	Temperatures are monitored in refrigerators using appropriately calibrated thermometers	Y N NIA	
5.1.6	Readings are recorded	Y N NIA	
5.1.7	Any results found to be out of specification are actioned	Y N NIA	
5.1.8	Pharmacy is contacted to assess the suitability of medicines for use following storage under incorrect conditions	Y N NIA	
5.1.9	There is evidence of correct stock rotation	Y N NIA	
5.1.10	Stock is correctly reconciled after each supply/administration	Y N NIA	

Section No: 6 **Documentation** **Category: Critical/Major/Other/Satisfactory**

No	Acceptance Criteria	Audit Result	Comments
6.1	**General**		
6.1.1.	All PGD documentation is subject to central document control	Y N NIA	
6.1.2	All PGD documentation is signed and dated before use	Y N NIA	
6.1.3	All PGD documentation is completed and signatures obtained prior to supply/administration of medicines	Y N NIA	
6.2	**Archiving**		
6.2.1	All record sheets are retained in agreement with local and national policies for retention of documentation.	Y N NIA	
6.2.2.	A tested system is in place to allow retrieval of archived documentation if required	Y N NIA	

Section No: 7 **Auditing PGD practice** **Category: Critical/Major/Other/Satisfactory**

No	Acceptance Criteria	Audit Result	Comments
7.1	**Self-Inspection**		
7.1.1	There is an approved procedure for carrying out regular self inspections/audits which includes how to follow up on actions reported during an inspection	Y N NIA	
7.1.2	The self-inspection schedule covers all aspects of the service	Y N NIA	
7.1.3	There is documented evidence that self-inspections are carried out – 6 months after introduction of PGD and prior to each review (PGDs must be reviewed every 2 years)	Y N NIA	
7.1.4	There is evidence that corrective actions are dealt with appropriately and timeously	Y N NIA	
7.1.5	There is evidence that findings from audit have been communicated to all relevant members of staff.	Y N NIA	

Appendix 4

Patient Group Direction for the supply and/or administration of *(insert drug name here)* **to** *(insert patient group here)* **receiving treatment from NHS Borders.**

This document authorises the supply and/or administration of *(insert drug name here)* **by** *(Professional group e.g. registered nurses/midwives/podiatrists/pharmacists)* **to** *(insert patient group here)* **who meet the criteria for inclusion under the terms of the document**

The *(Professional group e.g. registered nurses/midwives/podiatrists/ pharmacists)* **seeking to supply and/or administer** *(insert drug name here)* **must ensure that all patients have been screened and meet the criteria before supply takes place**

The purpose of this Patient Group Direction is to allow management of *(insert condition to be treated here)* **in NHS Borders by** *(Professional group e.g. registered nurses/midwives/podiatrists/pharmacists)***.**

PGD previously approved: *(date originally approved/ for pgd reviews)*

This direction was authorised on: *(date authorised by ADTC)*

The direction will be reviewed by: *(review date must be a maximum of two years from authorisation date)*

Author of PGD:

Clinician(S) responsible for Training and Audit: *(Job Title of person responsible e.g. Team Manager, H@N team or Clinical Lead, BECS)*

Specialist clinical review by: *(must not be the author):*

Patient Group Direction for the supply and/or administration of *(insert drug name here)* **without a prescription for a named individual by** *(Professional group e.g. registered nurses/midwives/podiatrists /pharmacists)* **employed by NHS Borders.**

1. This Patient Group Direction relates to the following specific preparation:

Name of medicine, strength, formulation	*(insert drug name here)*
Legal status	*(e.g. POM Prescription Only Medicine/ P Pharmacy Medicine)*
Storage	*(as per manufacturers instructions)*
Dose	
Route/method	
Frequency	
Total dose Quantity (Maximum/Minimum)	
Advice to Patients	
Relevant Warnings	*(side effects/reactions)*
Follow up Arrangements	

2. Clinical condition:

Clinical Condition to be treated	
Criteria for inclusion	
Criteria for exclusion	
Action if excluded	*(Refer for specialist/medical review)* *(Use of alternative treatment, refer to appropriate action/pgd)*
Action if declines	

Interactions with other medicaments and other forms of interaction	

3. Documentation/Record keeping.

a) The following records should be kept (either paper or computer based)-

The GP practice, clinic, hospital, and ward or department
The patient name and CHI number
The medicine name, dose, route, time of dose(s), and where appropriate, start date, number of doses and or period of time, for which the medicine is to be supplied or administered
Drug batch number and expiry
The signature and printed name of the healthcare professional who supplied or administered the medicine
The patient group direction title and/or number
Whether patient met the inclusion criteria and whether the exclusion criteria were assessed

(add in any specific recording required in the clinical area/specific to the medication etc)

b) Preparation, audit trail, data collection and reconciliation-

Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient by patient basis.

c) Storage-

(as per manufacturers instructions)

4. Professional Responsibility.

- All Health Professionals will ensure he/she has the relevant training and is competent in all aspects of medication, including contra-indications and the recognition and treatment of adverse effects.
- He/she will attend training updates as appropriate.
- For those involved in immunization, regular anaphylaxis updates are mandatory.
- *(identify the professional code of the regulatory body for the professionals identified within the PGD e.g.* Nurses will have due regard for the NMC Code of Professional Conduct, standards for conduct, performance and ethics 'The Code' (2008) and NMC Standards for Medicines Management (2008)
- *(any specific qualifications required e.g. family planning certificate/clinical decision making module etc.)*

5. Sources of Evidence used for the PGD creation should be stated.

(e.g. BNF/NICE/SIGN/Cochrane Reviews/PGDs or guidance from other Boards etc)

Patient Group Direction for the supply and/or administration of *(insert drug name here)* **by health professionals employed by NHS Borders/GP Practice**

This Patient Group Direction is approved for use by the under-signed :			
Job Title	**Name**	**Signed**	**Date**
Senior Doctor/Dentist for relevant clinical area	Sheena MacDonald		
NHS Borders Director of Pharmacy	Alison Wilson		
NHS Borders Senior Health Professional for Clinical Area	Evelyn Rodger		
PGD AUTHORISED ON ……. /……. /…….. **Signed by ADTC CHAIRPERSON: …….** **Name: …Karen McNicoll……**			

The Health Professionals named below, being employees of NHS Borders based at *(*Clinic OR GP Employer Name*)***are authorised to provide and/or administer this medication under this Patient Group Direction and agree to provide and/or administer this medication in accordance with this Patient Group Direction**

Name of Health Professional	**Job Title**	**Signed**	**Date**

Appendix 5

Patient Group Direction Review
Table of Changes/Version Log

PGD Title: _____

Review Date: _____

PGD Section/Page No	Changes made from Previous Version	Changes made by:	

Appendix 6: Sample RECORDING FORM FOR ADMINISTRATION OF…….. UNDER Patient Group Direction

Surname: …… **Forename(s): ……..** **CHI Number: ……** **Date of Birth: ……..** **Address: ……..** **……** **Post Code: ……**	**Administered at: (State GP Name and address/Clinic/Hospital/Ward/Dept.)** …… …… ……

1) Inclusion criteria (Please tick appropriate box[s])
Patients should meet the following inclusion criteria (adapted to suit PGD)

•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know

2) Exclusion Criteria
Patients should be excluded if: (adapted to suit PGD)

•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know

3) Referral Criteria
Patients should be referred to GP if: (adapted for each PGD)

•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know
•	☐ Yes	☐ No	☐ Don't Know

4) Counselling
Please note the counselling given to the patient:

Dose	☐ Yes	☐ No
Administration	☐ Yes	☐ No
Adverse Reactions	☐ Yes	☐ No
Advice about seeing GP when necessary	☐ Yes	☐ No

5) Action Taken: (*delete where appropriate)

Supply:	**Dose:**	**Route:** e.g. *Oral / Intravenous etc	**Time of Administration:**	**Record issue in Receipt & Supply Book:** * Yes / No
Batch Number / Expiry Date of Medication supplied:				
Referral:				

The above information is correct to the best of my knowledge. I have been counselled on the use of ……. and understand the advice given to me by the health professional.

Patient's signature: …… Date: ……..

The action specified was based on the information given to me by the patient, which, to the best of my knowledge is correct.

Health Professional Signature: …… Date: ……...

Appendix 7:

Sample STOCK RECORD FOR MEDICATION ORDERED & SUPPLIED UNDER A PGD

STOCK RECORD FOR MEDICATION ORDERED & SUPPLIED UNDER A PGD			
DATE	**QUANTITY & MEDICATION ORDERED**	**MEDICATION ISSUED**	**RUNNING BALANCE**
--\--\--	e.g. Received 100 x influenza vaccine	-	**100**
--\--\--	-	60 x doses for 'flu clinic	**40**
--\--\--	-	1 x influenza dose for home visit	**39**

This could be a form or a specific record book.

Appendix 8

Controlled drugs

The use of controlled drugs continues to be regulated under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001. Currently, the following controlled drugs can be included in PGDs:

Schedule 2: Morphine and Diamorphine (Only registered nurses and pharmacists for the immediate necessary treatment of a sick or injured person (except for treating addiction)).

Schedule 3: Midazolam

Schedule 4: All drugs except anabolic steriods and injectables used for treating addiction.

Schedule 5: All drugs.

(Taken from the MHRA website accessed at: http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingsellingandsupplyingofmedicines/ExemptionsfromMedicinesActrestrictions/PatientGroupDirectionsintheNHS/index.htm on 30/10/2013)

Appendix 9

PGD Risk Assessment Review Form	Comments	Impact graded by risk matrix	Likelihood of happening graded by risk matrix	Risk as calculated using risk score and score tool			**If High, can the risk be reduced or managed? Yes or No**
This form will be used to identify non-routine PGDs that require further discussion as per the PGD review flow chart. The specific risk will be							
Risk to patients				**Low**	**Medium**	**High**	
Injectables		Extreme	Unlikely			**High**	Yes
High side effect profile		Major	Possible			**High**	Yes
High risk drugs	Frail elderly >75: Positive inotropic medication, Diuretics, Beta blockers, Hypertension and Heart failure, Anticoagulants and Protamine, Hypnotics and Anxiolytics, Antipsychotics, Antidepressants, Opioid analgesics, Medication used in rheumatic diseases	Major	Possible			**High**	Yes
Variable dosing schedules		Major	Possible			**High**	Yes
Public Health Risk							
Antimicrobials	NMP lead to discuss with microbiologist	Major	Possible			**High**	Yes
Risk to NHS Borders							
Off label use	Clear indications and evidence base required	Major	Possible			**High**	Yes
Unlicenced	Clear indications and evidence base required	Major	Possible			**High**	Yes