Lothian NHS Board

NHS Lothian Headquarters
Waverley Court
4 East Market Street
Edinburgh
EH8 8BG
www.nhslothian.scot

Date 10 July 2026
Your Ref
Our Ref 11608

Enquiries to Richard Mutch
Extension 35687
Direct Line 0131 465 5687
loth.freedomofinformation@nhs.scot
richard.mutch@nhs.scot

Dear

FREEDOM OF INFORMATION – PATIENT GROUPS

I write in response to your request for information in relation to Patient Groups.

Question:
1. Does your ICB hold central oversight or coordination of PGD governance across your system? Please indicate: Yes — managed centrally / Partial — oversight held centrally but operational management devolved / No — fully devolved to member organisations / Unknown.

Answer:
There is not an ICB structure in NHS Scotland.

NHS Lothian is responsible for approving PGDs for use in secondary care, primary care and community pharmacies (for NHS commissioned services) across the Health Board area.
PGDs for use in a GP practice also require an additional signature of approval by one of the GP partners.

Question:
2. If PGD governance is fully or partially devolved, please identify which organisations within your system are responsible, where known.

For example: GP federations, Primary Care Networks, acute trusts, community trusts, NHS 111/urgent treatment centres, community pharmacy contractors. Please name these organisations where possible.

Answer:
Community Pharmacy contractors would be responsible for the approval of any private PGDs that they use.

Question:
3. Does your ICB have any system-wide PGD policy, framework, template, or register that applies across member organisations?
If yes, please briefly describe its scope and format.

Answer:

Procedures available on Policy Online include:

- Procedure for registered healthcare practitioners working under Patient Group Directions
- Retention of NHS Lothian Patient Group Direction documentation
- Patient Group Directions procedure
- Procedure for Lead Registered Healthcare Practitioners and Service Managers using Patient Group Directions within their service
- Medicinal products that do not require a prescription or Patient Group Direction or Patient Specific Direction for administration or supply.

Templates that are used are:
PGD template – attached
PGD authorisation for GP practice – attached
PGD audit tool – attached
PGD checklist – attached
New PGD request form – attached
Existing PGD request form - attached

This information is exempt under Section 25 of the Freedom of Information (Scotland) Act 2002 - Information otherwise accessible

(1) Information which the applicant can reasonably obtain other than by requesting it under section 1(1) is exempt information.

Question:

4. Who is the most appropriate contact within your ICB for medicines governance or PGD matters?
   Please provide name, job title, and email address.

Answer:

Loth.patientgroupdirections@nhsl.scot
Contact via this email account, for a member of staff with responsibility for PGD governance

Question:

5. Where PGD governance is devolved, please provide the name, job title, and email address of the most appropriate contact at each member organisation, or indicate who would be best placed to redirect this request.

Answer:

Not applicable

Question:

6. If this request is being redirected or forwarded to another organisation, please confirm the name and contact details of that organisation.

Answer:

Not applicable

I hope the information provided helps with your request.

If you are unhappy with our response to your request, \you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at www.itspublicknowledge.info/Appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the FOI Reviewer at the email address at the head of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: https://org.nhslothian.scot/FOI/Pages/default.aspx

Yours sincerely

ALISON MACDONALD
Executive Director, Nursing
Cc: Chief Executive
Enc.

APPLICATION FOR A SERVICE TO USE AN EXISTING NHS LOTHIAN PATIENT GROUP DIRECTION (PGD)

1. **Before completing this application, please ensure that the senior Doctor, Pharmacist and Clinical Service Lead (known as the Local Clinical Development Team) have reviewed the resources available on the Specialist Pharmacy Services (SPS) website** Introduction to PGDs – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice. This will ensure they understand when it is appropriate to use a PGD within a service.

Senior Doctor:	.....	(Print Name)	.....	(Signature)
Pharmacist	.....	(Print Name)	.....	(Signature)
Senior Member of Relevant Profession:	.....	(Print Name)	.....	(Signature)
Date form submitted:	.....			

2. **Is the Professional Group wishing to work under this PGD included within legislation?**
   Patient group directions: who can use them - GOV.UK
   Pharmacy technicians working under Patient Group Directions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
   YES / NO

3. **Name of existing PGD including number (if known)**

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 are current prescribers unable to continuing prescribing this medicine?**

8. **What are the perceived benefits to patient care?**

9. **What are the potential risks to patient safety?**

10. **What professional group will use the PGD? (Include evaluation of competency and training needs and how they will be addressed).**

11. **What are the current and/or future service provisions for supplying and/or administering the medicine(s)?**

12. **Are the resources needed to deliver the service in place, e.g. over labelled packs, storage facility?**

Please check that you have completed this form correctly. Incomplete forms will be returned to the service.

Forward the completed form to: loth.patientgroupdirections@nhs.scot

For Office Use:	
PGD Review Group: Approval to Proceed: **YES / NO**	
If **YES:** Email signed form to loth.patientgroupdirections@nhs.scot and advise Local Clinical Development Team that they can proceed with PGD development.	**Tick**
If **NO:** Advise Local Clinical Development Team of reasons why approval not granted. List reasons below:	**Tick**

PGD Committee Chairperson(s)					
	(Print Name)		(Signature)		(Date)
	(Print Name)		(Signature)		(Date)

APPLICATION FOR PGD COMMITTEE TO PROCEED WITH DEVELOPMENT OF A NEW PATIENT GROUP DIRECTION (PGD)

1. **Before completing this application, please ensure that the senior Doctor, Pharmacist and Clinical Service Lead (known as the Local Clinical Development Team) have reviewed the resources available on the Specialist Pharmacy Services (SPS) website** Introduction to PGDs – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice. This will ensure they have the appropriate knowledge to write the PGD. Please also consider the following before applying to develop a PGD:

2. Is the medicine unlicensed**? If YES a PGD cannot be used**

3. Is the item a device/dressing**? If YES a PGD cannot be used**

4. **Contact details of Local Clinical Development Team**

Name of GP Practice/Ward or Clinic:	**Address:**
Tel No.:	
Work Email address(s):	

Senior Doctor: ..... (Print Name) ..... (Signature)

Pharmacist ..... (Print Name) ..... (Signature)

Senior Member of Relevant Profession: ..... (Print Name) ..... (Signature)

Date form submitted: .....

5. **Is the Professional Group wishing to work under this PGD included within legislation?**
Patient group directions: who can use them - GOV.UK
Pharmacy technicians working under Patient Group Directions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
YES / NO

6. **Is the medicine unlicensed? YES / NO (If YES then a PGD cannot be used)**

7. **Is the medicine a device? YES/NO (If YES then a PGD cannot be used)**

8. **Which medicine is required on this PGD?**

..... Tick if ERF ❑

.....

9. **If the medication is NOT included in the ERF please provide the reason**

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

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

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

13. **Why are current prescribers unable to continuing prescribing this medicine?**

14. **What are the perceived benefits to patient care?**

15. **What are the potential risks to patient safety?**

16. **What Professional Group will use the PGD? (Include evaluation of competency and training needs and how they will be addressed).**

17. **What are the current and/or future service provisions for supplying and/or administering the medicine(s)?**

18. **What is the evidence base to support the medicine/treatment/indication? (e.g. SIGN, NICE). (N.B. for off label use of a licensed medicine to be administered/supplied under a PGD evidence that this is clearly justified by best clinical practice must be provided).**

19. **Are the resources needed to deliver the service in place, e.g. over labelled packs, storage facility?**

20. **If an authorised PGD is available or is currently under development, give reasons why this does not meet local needs and can therefore not be adopted.**

Please check that you have completed this form correctly. Incomplete forms will be returned to the Local Clinical Development Team.

Forward the completed form to: loth.patientgroupdirections@nhs.scot

For Office Use:	
PGD Review Group: Approval to Proceed: **YES / NO**	
If **YES:** Email signed form to loth.patientgroupdirections@nhs.scot and advise Local Clinical Development Team that they can proceed with PGD development.	**Tick**
If **NO:** Advise Local Clinical Development Team of reasons why approval not granted. List reasons below:	**Tick**

PGD Committee Chairperson(s)					
	(Print Name)		(Signature)		(Date)
	(Print Name)		(Signature)		(Date)

NHS Lothian Patient Group Direction (PGD) Audit Tool

Title:	NHS Lothian Patient Group Directions Audit Tool		
Date effective from:	July 2025	**Review date:**	July 2027
Approved by:	Patient Group Direction Committee		
Approval date:	July 2025		
Author/s:	Patient Group Direction Procedures SLWG		
Document owner/s:	Patient Group Direction Committee		
Target audience:	Services using NHS Lothian PGDs		
Supersedes:	NA		
Keywords (min. 5):	Patient group direction, PGD, audit, governance		

Version Control

Date	Author	Version/page	Reason for change

1.0 Purpose

NICE PGD guidance states that there should be a planned programme of monitoring and evaluation of PGD use within a service. [1]

Within NHS Lothian there is a requirement that PGD use should be audited as part of the review process for existing PGDs. Submission of audit data helps provide assurance to NHS Lothian PGD Committee that PGD use within a service is appropriate and does not compromise patient safety or healthcare practitioner professional governance. The results of the audit can inform whether a PGD remains the most suitable mechanism to supply/administer a medication and whether the PGD is still required within a particular service to offer an advantage to patient care.

NHS Lothian has developed an audit tool to support services to undertake audit of PGDs and this tool is included in this document.

2.0 Responsibilities

The lead healthcare practitioner / manager who is responsible for authorising staff to work under a PGD is responsible for ensuring that the audit is undertaken. This may or may not be a person who was part of the PGD development team.

3.0 Completion of the audit

- The audit must be completed in full and there should not be any blanks
- A minimum of 5 patient records must be audited per annum. Services should consider how many patients they have been treating under the PGD and make an informed decision on the number of records to audit.
- Records must be selected at random for sampling
- Where a PGD is in use in multiple sites, audit must be undertaken for each site
- The audit can be undertaken by non-registered staff under appropriate supervision
- The final copy of the audit must be signed (wet signature or electronic) by the lead healthcare practitioner/manager of the service
- A copy of the audit must be sent to the PGD committee when requested as part of the PGD review and reauthorisation process
- Any DATIX reports submitted associated with the use of the PGD must be detailed at the end of the document

Reference

1. NICE. Overview | Patient group directions | Guidance | NICE [Internet]. Nice.org.uk. NICE; 2017. Available from: https://www.nice.org.uk/Guidance/MPG2

Name of Healthcare Practitioner undertaking audit	
Job title	
Date of audit	
Audit of completion of Healthcare Practitioner (HCP) records and medication storage requirements for:	
PGD name	
PGD number	
PGD version number	

Enter Yes/No/NA as appropriate, if 'No' state action required and date for completion.

Is there a current list of HCP authorised to work under the PGD in a dedicated PGD folder?	**Have all authorised HCP and authorising HCP/ manager signed off the authorised practitioner list within the PGD?**	**Are all the HCP authorised to work under the PGD members of one of the healthcare professions listed in the PGD*?**	**Do the HCP working under the PGD have a copy available for reference at the time of consultation?**	**Are all medicines supplied or administered under the PGD stored according to the PGD where this is specified?**	**Comments/action to be taken**
(Y/N/NA)	(Y/N/NA)	(Y/N/NA)	(Y/N/NA)	(Y/N/NA)	(Y/N/NA)

*Staff working under the PGD must also be a registered member of list of healthcare practitioners permitted to work under a PGD The Human Medicines Regulations 2012

Name of HCP undertaking audit						
Job title						
Date of audit						
Audit of completion of patient records for:						
PGD name						
PGD number						
PGD version number						
Enter Yes/No/NA as appropriate, if 'No' state action required and date for completion.						
Sample size =	**Was the date of supply or administration recorded? (Y/N)**	**Does the record include the statement "given under PGD …"? (Y/N)**	**Was the signature and name (in capitals) of the HCP recorded (if applicable)? (Y/N/NA)**	**Was injection site, route, batch and expiry date recorded OR name of medicine and quantity if non injectable? (Y/N)**	**Was the medicine supplied/administered in accordance with the inclusion criteria? (Y/N)**	**Comments/action to be taken**
1						
2						
3						
4						
5						

Name of HCP undertaking audit	
Job title	
Date of audit	
Details of any DATIX reports or significant event analyses associated with the use of:	
PGD name	
PGD number	
PGD version number	

	Date of event	**Patient harm (Y/N/not known)**	**Details of DATIX report**	**Service learning and response to DATIX report**
1				
2				
3				
4				

Name of lead HCP/Service Manager responsible for audit	
Job title of lead HCP/Service Manager responsible for audit	
Date	

PGD Title					
PGD Number		**PGD Version Number**		**Review Date**	
Summary of Changes					
Completion Instructions	• Sections 1 -5 – Service Lead Healthcare Practitioner/Manager • Section 6 and 7 – Pharmacist • Section 8 – Doctor/Dentist				

1. Registered Healthcare Practitioners identified in the PGD			**Comments (please detail any procedures and processes used to provide assurance)**
Are the healthcare practitioners identified in the PGD included in the classes of individuals who may supply/administer as per current PGD legislation? (2)	Y/N	PGDs can only be used by the registered healthcare practitioners listed in Schedule 16 Part 4 of the Human Medicines Regulations. Rules for the sale, supply and administration of medicines for specific healthcare professionals - GOV.UK	
Are the healthcare practitioners allowed to supply/administer the medicine according to the exemptions in Schedule 17 The Human Medicines Regulations 2012. (3)	Y/N	If the answer is yes a PGD is not required. The Human Medicines Regulations 2012	
Have the staff using the PGD undergone the appropriate training as detailed in the PGD?	Y/N/comments		
2. Requirement for PGD and Patient Safety			**Comments (please detail any procedures and processes used to provide assurance)**
Is there an ongoing need for the PGD in terms of benefit for patient care? (Please provide details.)	Y/N/comments	PGDs should only be used where there are clear benefits for patient care without compromising patient safety and there are clear governance arrangements and accountability. (1) https://www.sps.nhs.uk/articles/when-pgds-can-be-used/	

Has the service considered investing in the training of additional non-medical prescribers to enable redesign of the service?	Y/N /comments	Patient Group Directions (NICE Guideline MPG2) (2017) states that you should consider investing in the training of additional non-medical prescribers to enable redesign of services if necessary. (1)	
How is patient safety assured?	Y/N/comments	Consider the training requirements for staff, any risk assessments in place, how does the service deal with errors/near misses, what audit arrangements are in place?	
Does the service have a PGD folder including a list of names and signatures of staff using the PGD?	Y/N	Service should ensure that the staff list of PGD users is up to date and is fully signed.	
Is there evidence of appropriate use of patient leaflets as detailed in the PGD?	Y/N/comments		
Is there evidence of appropriate patient counselling as detailed in the PGD?	Y/N/comments		
Have the staff using the PGD undergone the appropriate training as detailed in the PGD?	Y/N/comments		
3. Storage			**Comments (please detail any procedures and processes used to provide assurance)**
Can the service meet the storage requirements of the medication detailed in the PGD?	Y/N/comments	This may include temperature sensitive medicines and/or safe storage of Prescription Only Medicine (POM) medicines within the clinical setting.	
4. Record Keeping			**Comments (please detail any procedures and processes used to provide assurance)**
Is there evidence that staff are recording the information required as per the PGD?	Y/N/comments		

5. Audit			Comments (please detail any procedures and processes used to provide assurance)
Has the service using the PGD undertaken an appropriate audit of practice?	Y/N/comments	PGDs should be audited as part of any organisation's medicines audit programme and results of audits should be considered when PGDs are reviewed. This allows assessment of whether a PGD remains the most suitable mechanism of supply/administration of the medicine. **Please provide details of audit.**	
6. Medication to be supplied under the PGD (2)			**Comments (please detail any procedures and processes used to provide assurance)**
Ensure that Sections 2 and 3 of the PGD form have been completed correctly and double check all clinical content. The Specialist Pharmacy website can give guidance on medication to be used in a Patient Group Directions (4)			
Is the clinical and pharmaceutical content in the PGD accurate and supported by the best available evidence?	Y/N	Is the PGD supported by local/national guidelines and formulary use?	
Is the PGD being used in pregnancy/breastfeeding?	Y/N	Are there clear directions in the PGD regarding use in pregnancy/breastfeeding with associated cautions or whether pregnancy/breastfeeding is excluded?	
7. Medicine to be supplied under the PGD - additional considerations			**Comments (please detail any procedures and processes used to provide assurance)**
Is the medicine licensed? (5) Check Home - electronic medicines compendium (emc) and MHRA Products | Home.	Y/N	Only licensed medicines (i.e. those with a UK marketing authorisation UK Metric Association (UKMA) can be supplied and administered via a PGD.	
Is the medicine going to be mixed prior to supply/administration? (5)	Y/N	The Medicines & Healthcare products Regulatory Agency (MHRA) states that the mixing of two separate medicinal products will result in a new, unlicensed product if one product cannot be described as a	

		vehicle for the administration of the other e.g. as a reconstitution or diluting agent.	
Is the medicines a Pharmacy (P) medicine or General Sales list (GSL) medicine? (6)	Y/N	A PGD is not required for the administration of medicines that are P or GSL medicine. A PGD is not required for supply of a GSL.	
Is adjustment of a dose required? (7)	Y/N	Dose adjustment is only allowed under a PGD where the PGD is being used to supply and administer the medicine. A PGD does not give a legal framework for registered healthcare practitioners to adjust a dose of a medicine already in a patient's possession.	
Is a dose range required to allow the practitioner to select the correct dose of a medicine e.g. depending on age/weight and is this included in the PGD? (8)	Y/N	A PGD can specify a dose range to allow selection of an appropriate dose for a patient.	
Is the medicine a Controlled Drug (CD)? (9)	Y/N	See specific advice on Specialist Pharmacy service (SPS) website for restrictions on CD use in PGDs	
Is the medicine an antimicrobial? (10)	Y/N	A PGD may be used but see Patient Group Directions (NICE Guideline MPG2) (2017) Recommendation 1.1.10 before proceeding. Recommendations | Patient group directions | Guidance | NICE	
Is the medication being used off-label? (11)	Y/N	Ensure that off-label use of a licensed medicine is included in a PGD only when clearly justified by best clinical practice.	
Is the PGD to be used for managing long-term conditions? (12)	Y/N	A PGD should not be used.	
Will the medicine require frequent or complex monitoring? (10)	Y/N	A PGD should not be used.	

Does the medicine have Risk Minimisation Measures (RMM) in place? (13)	Y/N	A medicine with RMM for close monitoring and supervision of patients may not be suitable for inclusion in a PGD. If a decision is taken to include a medicine with RMM in a PGD, the requirements of the RMM must be included in the PGD.	
Is the medicine a black triangle medicine? (1)	Y/N	A PGD may be used but see Patient Group Directions (NICE Guideline MPG2) (2017) Recommendation 1.1.8 before proceeding. Recommendations | Patient group directions | Guidance | NICE	
Are there adequate legal supplies of medicines available in the clinical areas?	Y/N/comments	Issuing a supply of the medicine may involve obtaining an appropriately labelled pre-pack noting medicines cannot be supplied under a PGD from spilt packs (see NICE MPG2 Patient Group Directions 2017). (10) Ensure time for obtaining the appropriately labelled supply from an appropriately licensed unit been factored into your service delivery targets. Ensure it is financially viable to obtain such packs to the required specification(s) in the quantities required.	
Are the storage requirements detailed in the PGD appropriate?	Y/N	Consider any storage requirements detailed in the Summary of Product Characteristics (SPC), appropriate local security requirements and the legal status of medication e.g. controlled drugs.	
8. Safety and clinical appropriateness of the PGD			Comments (please detail any procedures and processes used to provide assurance)
Is the PGD clinical content appropriate?	Y/N	Use the best available evidence, such as NICE guidance and other sources of high-quality information, to review the PGD.	

Is the relevant supporting guidance appropriately referenced?	Y/N	Ensure that key references reacting to evidence are included as an appendix to the PGD.	
Is there appropriate follow-up/safety netting advice for the patient? (14)	Y/N	Confirm that the safety netting advice included in the PGD is appropriate to ensure that the patient can identify the need to seek further medical help if their condition fails to improve, changes, or if they have concerns about their health?	
Is the availability of medical /dental advice for excluded patients timely and appropriate?	Y/N		
Is the PGD appropriate for the clinical care being delivered in the service/locality?	Y/N	Will the PGD provide safe and appropriate clinical treatment to the pre-defined group of individuals within agreed parameters described in the PGD?	

Service Lead Healthcare Practitioner Name		**Pharmacist Name**		**Doctor/Dentist Name**	
Service Lead Healthcare Practitioner Signature		**Pharmacist Signature**		**Doctor/Dentist Signature**	
Date		**Date**		**Date**	

References

1. Patient group directions (nice.org.uk)
2. Patient group directions: who can use them - GOV.UK (www.gov.uk)
3. The Human Medicines Regulations 2012 (legislation.gov.uk)
4. What medicines are suitable to be used in a PGD? The Specialist Pharmacy Service (SPS) website gives guidance
   When PGDs can be used – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
   When not to use a PGD – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
5. Unlicensed medicines and use of PGDs – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
6. P and GSL medicines with PGDs – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
7. Using a Patient Group Direction to adjust doses of medicines – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
8. Inclusion of dose ranges in a single Patient Group Direction – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
9. Supply and/or administration of Controlled Drugs under a PGD – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
10. Recommendations | Patient group directions | Guidance | NICE
11. Off label medicine use under a Patient Group Direction – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
12. Using PGDs to manage long term conditions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
13. Including medicines with Risk Minimisation Measures (RMM) in PGDs – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
14. Safety-netting in the consultation | The BMJ

PATIENT GROUP DIRECTION FOR THE ADMINISTRATION /SUPPLY [delete as appropriate] OF .....[NAME OF MEDICINE]..... IN .....[SETTING]..... BY .....[REGISTERED HEALTHCARE PRACTITIONER]

	Name	Signature	Date
Developed by LOCAL DEVELOPMENT TEAM			
Doctor	[Type name here]	[Sign here]	[DD/MM/YYYY]
Practitioner	[Type name here]	[Sign here]	[DD/MM/YYYY]
Pharmacist	[Type name here]	[Sign here]	[DD/MM/YYYY]

Approved by PGD SUB-GROUP OF THE MEDICINES POLICY COMMITTEE			
Chairperson			
Chairperson			

Approved by AUTHORISED NHS LOTHIAN DRUGS AND THERAPEUTICS COMMITTEE			
Chairperson/Deputy of Committee			
Chairperson/Deputy of Committee			

AUTHORISED BY			
Medical Director			

LOCAL MANAGEMENT TEAM FOR SERVICE USING THE PGD			
Practice/Ward/Department/Directorate	[Type practice/ ward/ department/ directorate here]		
Clinical Lead	[Type name here]	[Sign here]	[DD/MM/YYYY]
Practitioner Manager (if applicable)	[Type name here]	[Sign here]	[DD/MM/YYYY]
Pharmacist (if applicable)	[Type name here]	[Sign here]	[DD/MM/YYYY]
Name of Designated PGD Holder (Responsible for ensuring names of healthcare practitioners issuing under this PGD are kept up to date	[Type name here]	[Sign here]	[DD/MM/YYYY]

DATE AUTHORISED FOR USE	REVIEW DATE	EXPIRY DATE
[DD/MM/YYYY]	[DD/MM/YYYY]	[DD/MM/YYYY]

PGD Version Number X.X

Change History		
Version	**Date**	**Change details**
	DD/MM/YYYY	
	DD/MM/YYYY	
	DD/MM/YYYY	
	DD/MM/YYYY	
	DD/MM/YYYY	
	DD/MM/YYYY	

PGD for supply / administration (delete as appropriate) of [medicine name] in [setting] by [registered healthcare practitioner] version [version number]

(Valid from DD/MM/YYYY to DD/MM/YYYY)

AUTHORISATION

Responsibilities of registered healthcare practitioners working under the PGD

- This PGD does not remove the individual's professional obligations and accountability.
- It is the responsibility of each practitioner to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct.
- The practitioner must ensure familiarity with the marketing authorisation holder's Summary of Product Characteristics for medicines administered / supplied in accordance with this PGD.
- The decision to supply/ administer any medication rests with the individual practitioner who must abide by the PGD and any associated NHS Lothian policies.
- The PGD is not legally valid if it is out of date or does not have the necessary authorisation signatures on page one.

Declaration or registered practitioner working under the PGD

- I have read the statement above and I agree to administer/ supply [medicine name] only in accordance with this PGD.
- I have checked that the PGD is in date and that the necessary authorisation signatures are present on page 1of the document.
- I have read and understood the PGD and agree to use it and acknowledge that it is my responsibility to maintain my knowledge, skills and competencies through continuous professional development (CPD).

Name	Signature	Professional Group	Date

Name	Signature	Professional Group	Date

AUTHORISING LEAD HEALTHCARE PRACTITIONER / SERVICE MANAGER

I confirm that the registered healthcare practitioners named above are suitably trained and competent to work under this PGD. I give authorisation on behalf of NHS Lothian for the above named health care practitioners who have signed the PGD to work under it.

Authorised practitioners will be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

This authorisation sheet will be retained to serve as a record of those practitioners authorised to work under this PGD as per NHS Lothian governance requirements.

Lead healthcare practitioner/manager for the service area:

Name……

Signature ……

Date DD/MM/YYYY

1. CHARACTERISTICS OF STAFF	
Define Practitioner Group	This section must reflect the registered profession within the PGD legislation e.g. NMC registered nurse employed by NHS Lothian. ▪ [Insert name of registered profession(s)]
Qualifications Required (initial training)	▪ Undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD. ▪ Undertaken appropriate training for working under PGDs for the supply and administration of medicines, including completion of PGD module on TURAS. ▪ Able to assess the person's capacity to understand the nature and purpose of the medication in order to give or refuse consent. Refer to NHS Lothian guidance Consent; Guidance. ▪ Where the PGD refers to administration of medicines the practitioner must be competent to administer the medicine(s) and follow NHS Lothian guidance Administration of medicines in hospital and NHS Lothian Healthcare Premises Procedure.pdf. ▪ [Insert further training requirements]
Competency Assessment	▪ Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. ▪ Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health practitioners using patient group directions Tools and resources | Patient group directions | Guidance | NICE. ▪ [Insert further required competencies]
Continued training requirements	▪ Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. ▪ All mandatory training as required by NHS Lothian must be up to date. ▪ Completion of the TURAS PGD module every 2 years. ▪ [Insert further training requirements]
The decision to supply/ administer any medication rests with the individual registered health practitioners who must abide by the PGD and any associated organisation policies.	

2. DESCRIPTION OF TREATMENT	
Names of Medicines included	[Insert generic name of medicine (brand only if relevant), strength and formulation]
Marketing Authorisation (previously UK Product Licence)	YES
Out with terms of the Summary of Product Characteristics (SPC)	YES / NO [delete as appropriate] If YES add reference/ note to support use in off label circumstances.
2nd Pharmacist Check	**Include name of second pharmacist (mandatory)** **……**
Controlled Drugs **If YES, consultation with Controlled Drugs Governance Team (CDGT) to check legal compliance**	YES / NO [delete as appropriate] **If YES include name of specialist (mandatory)** **……**
Antimicrobial **If YES, consultation with Microbiologist/Antimicrobial Management Team**	YES / NO [delete as appropriate] **If YES include name of specialist (mandatory)** **……..**
Children under 13 years of age to be treated **If YES, consultation with Paediatric Specialist**	YES / NO [delete as appropriate] **If YES include name of specialist (mandatory)** **……**
Record / Audit trail	Use NHS Lothian approved records or approved prescribing document/ systems. Record: ▪ That valid informed consent was given. ▪ Name of individual, address, date of birth and GP with whom the individual is registered (if relevant). ▪ Name of registered health practitioner. ▪ Name of medication supplied/ administered. ▪ Date of supply/ administration. ▪ Dose, form and route of supply/ administration ▪ Quantity supplied/administered. ▪ Batch number and expiry date (if applicable). ▪ Advice given, including advice given if excluded or declines treatment. ▪ Details of any adverse drug reactions and actions taken.

	▪ Supplied via Patient Group Direction (PGD) number [insert PGD number here]……. ▪ Records should be signed and dated (or a password controlled e-record). ▪ When a medicine is being used off-label, record advice given to the patient informing them that the use is off label. ▪ All records should be clear, legible and contemporaneous. ▪ Records must be maintained according to NHS Lothian policy. ▪ A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. ▪ [Insert further recording requirements]

3. MEDICINES AND CLINICAL CONDITION	
Clinical condition or situation to which this PGD applies	[Define situation/ condition/ indication]
Criteria for inclusion (including patient group)	▪ Informed consent gained – if under 16 years consider requirements for consent. ▪ [Additional inclusion criteria to be inserted here, clinical criteria, define age range, are pregnant/ breastfeeding individuals included?]
Criteria for exclusion	▪ Informed consent not gained. ▪ [Additional exclusion criteria to be inserted here, consider upper and lower age limits, concurrent conditions, concurrent treatments, pregnancy and breastfeeding, any contraindications in the SPC]
Action if excluded	▪ Record reasons for exclusion in an individual's clinical record. ▪ Refer to another clinician or prescriber as appropriate. ▪ [Additional action(s) to be inserted here]
Action if patient declines	▪ Document advice given. ▪ Refer to another clinician or prescriber as appropriate. ▪ [Additional action(s) to be inserted here]
Arrangements for referral for medical advice	▪ Refer to the appropriate clinician or prescriber in the care pathway. ▪ [Additional action(s) to be inserted here using bullet points]
Name of medicine (include pharmaceutical form and strength)	[Insert name of medicine, include pharmaceutical form and strength]

POM / P / GSL / ▼	[Insert legal category e.g. prescription only medicine POM]
Dose/s	[State dose in full. Do not use any Latin or abbreviations. Include any practical information such as "after food".] Any dose calculations require a check by a second registrant.
Duration of treatment	[Insert duration of treatment]
Route/Method	[Inset route of administration]
Frequency (To include maximum/ minimum timescales)	[Insert frequency of administration and include the maximum duration of treatment]
Total dose/ number	[Insert the total dose/ number of dose units that can be supplied/ administered under the PGD]
Quantity to be supplied	[For supply only – include the total quantity to be supplied under the PGD]
Storage	▪ Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk. ▪ [Insert further storage requirements if required]
Drug interactions and action to be taken	All concurrent medications must be checked for interactions. The following interactions have been identified as clinically significant: ▪ [Include all clinical significant drug interactions] A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF website www.bnf.org.
Cautions (including action to be taken if caution applies)	▪ [Include all cautions that apply when using the PGD and the action to be taken in the event of a caution. Refer to the SPC]
Identification and management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF website www.bnf.org.

	The following possible adverse effects are commonly reported with [insert name of medicine] (but may not reflect all reported adverse effects): ▪ [List all very common / common side effects] If an adverse reaction is suspected or occurs, the patient must be referred to a doctor.
Management of and reporting procedures for adverse reactions **(▼ - include yellow card details)**	▪ Record all adverse drug reactions (ADRs) in the individual's clinical record. ▪ Advise patient to contact nurse/ doctor if side effects occur. ▪ If a serious adverse reaction is suspected please report to the Commission on Human Medicines (CHM) via the Yellow Card Scheme http://yellowcard.mhra.gov.uk/. ▪ ▼ Medicines. Any adverse events that may be attributable to [name of medicine] should be reported to the Commission on Human Medicines (CHM) via the Yellow Card Scheme via http://yellowcard.mhra.gov.uk/. ▪ [Additional action(s) to be inserted here]
Written information to be given to individual or carer	▪ Give marketing authorisation holder's product information leaflet (PIL) provided with the product. ▪ [Additional information to be inserted here]
Additional advice and information	▪ Inform the individual/ carer of possible side effects and their management. ▪ The individual carer should be advised to seek medical advice in the event of an adverse reaction. ▪ Where the medication is being used off label, practitioners must inform the patient or their carer that the medication is being used off label. ▪ Advise to contact nurse/ GP if condition worsens or symptoms persist. ▪ [Additional information to be inserted here]
Referral, patient monitoring and follow-up	▪ Refer to the appropriate clinician or prescriber in the care pathway. ▪ [Add details of any other actions to be, and include monitoring or follow up]

4. REFERENCES

1. Summary of Product Characteristics accessed on …….. via http://www.medicines.org.uk. (Version updated on ……..)
2. BNF [version] last accessed via https://www.medicinescomplete.com on ……..
3. NHS Lothian Protocol and Procedure for the Administration of Adrenaline in Life Threatening Anaphylaxis http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/ClinicalGuidance/General/Adrenaline%20administration%20in%20Life%20Threatening%20Anaphylaxis.pdf
4. NICE Medicines practice guideline "Patient Group Directions" Overview | Patient group directions | Guidance | NICE
5. [Additional reference(s) to be inserted here]

PGD for supply / administration (delete as appropriate) of (medicine name) in (medical practice name) by (registered healthcare practitioner) version number

(valid from ……. to …….):

AUTHORISATION

Responsibilities of registered practitioner working under the PGD

- This PGD does not remove the individual's professional obligations and accountability.
- It is the responsibility of each healthcare practitioner to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct
- The healthcare practitioner must ensure familiarity with the marketing authorisation holder's Summary of Product Characteristics for medicines administered / supplied in accordance with this PGD.
- The decision to supply/administer any medication rests with the individual healthcare practitioner who must abide by the PGD and any associated NHS Lothian policies.
- The PGD is not legally valid if it is out of date or does not have the necessary authorisation signatures.

Declaration or registered practitioner working under the PGD

- I have read the statement above and I agree to administer / supply (medicine name) only in accordance with this PGD.
- I have checked that the PGD is in date and that the necessary authorisation signatures are present within the document.
- I have read and understood the Patient Group Direction and agree to use it and acknowledge that it is my responsibility to maintain my knowledge, skills and competencies through CPD.

Name	Signature	Professional Group	Date

Name	**Signature**	**Professional Group**	**Date**

CLINICAL SERVICE LEAD / LEAD GENERAL PRACTITIONER

I confirm that the healthcare practitioner(s) named above are suitably trained and competent to work under this NHS Lothian PGD.
I give authorisation for the above-named healthcare practitioner(s) who have signed the PGD to work under it within ……..medical practice.

Authorised healthcare practitioner(s) staff will be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

This authorisation sheet will be retained to serve as a record of those practitioners authorised to work under this PGD as per NHS Lothian governance requirements.

Lead clinician /Lead GP for the practice:

Name……

Signature ……..

Date XXXXXX