University Hospitals of Leicester NHS
NHS Trust

Patient Group Directions Policy
(for supply of medicines to patients)

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CONTENTS

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

January 2023 (v7 to v8):

- Trust lead updated.
- PHE changed to UKHSA
- Removal of three year re-assesment period for competency in working under a PGD

KEY WORDS

Patient Group Directions; PGDs

1 INTRODUCTION AND OVERVIEW

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trust Policy for the supply and/or administration of medicines under a Patient Group Direction (PGD).

1.2 The policy follows the advice given in the Crown Report (1998), Health Service Circular Patient Group Directions (Department of Health August 2000) and a Practical guide and framework of competencies for all professionals using patient group directions (National Prescribing Centre, 2009). This document replaces all other Standing Order/ Group Protocol/ Patient Group Directions Policies.

1.3 Supply and administration under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

1.4 The aims of this policy are to:

- Ensure PGDs are written to a high standard to provide consistent style, high quality, and good practice in supplying or administering medicines to patients under a PGD.
- Ensure patient safety by preventing medication errors and promoting best safe practice.
- Ensure staff are fully aware of the professional and legal responsibilities associated with the use of PGDs.
- Ensure that all groups and individuals that fall within the scope of this policy are trained and competent to undertake this extended professional activity.
- Ensure PGD use is audited for appropriateness; to ensure PGDs are only introduced or reapproved where there is demonstrable ongoing need in line with the other aims above.

2 POLICY SCOPE

2.1 This policy applies to all PGDs used across the University Hospitals of Leicester (UHL) NHS Trust, i.e. core PGDs which are applicable across the whole of UHL, and non-core (local) PGDs which are applicable at a more restricted level, e.g. Clinical Management Group (CMG) or Alliance-specific.

2.2 This policy applies to all professional groups which are defined under legislation to be able to supply and administer medicines under a PGD – see Appendix 1.

2.3 This policy defines the training and competencies required for individual practitioners within an authorised professional group to be able use PGDs.

3 DEFINITIONS AND ABBREVIATIONS

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

3.2 **Core PGD:** a PGD authorised for use across all clinical areas within UHL for use in appropriate adult patients. PGDs for use in children are outside the remit of a core PGD. A definitve list of Core PGDs approved for use is maintained on INSite: http://insite.xuhl-tr.nhs.uk/homepage/clinical/medicines-information/pgds .

3.3 **Local PGD:** a PGD authorised for use in one or more specified clinical area. A definite list of Local PGDs approved for use in each area is maintained on INSite, with each CMG or corporate area having its own sub-page within the main PGD page on INSite as given in 3.2 above.

3.4 **Unlicensed medicine:** one which has not received a Marketing Authorisation (Product Licence) from the regulatory authority for any indication.

3.5 **Off-label medicine:** one which has received a Marketing Authorisation (Product Licence) from the regulatory authority but not for the indication for which the medicine is intended to be used.

3.6 **Administer:** To give a medicine by either introduction into the body, whether by direct contact with the body or not, (e.g. orally or by injection) or by external application (e.g. application of an impregnated dressing).

3.7 **Supply:** To provide a medicine to a patient/carer for administration.

3.8 **Controlled drug:** Narcotic drugs or other drugs liable to misuse which are subject to special controls under the Misuse of Drugs Act 1971.

3.9 **POM:** Prescription Only Medicine. Can only be supplied or administered via a prescription from an appropriate medical or non medical prescriber, or by specific PGD

3.10 **P:** Pharmacy medicine. Can only be sold or supplied through a registered pharmacy or under the supervision of a pharmacist

3.11 **GSL:** General Sales List medicine. A medicine that can be sold or supplied without a prescription

4 ROLES

4.1 The Executive Director with overall responsibility for this policy is the Medical Director.

4.2 The Medical Director is responsible for signing off all UHL core PGDs with the Chief Nurse and Chief Pharmacist (or delegated deputy).

4.3 The **Medicines Optimisation Committee (MedOC)** is designated the PGD authorisation group.

- All new PGDs will be authorised by MedOC. Urgent requests for new PGDs may be approved outside of MedOC at the discretion of the Chief Pharmacist (or delegate deputy), with subsequent retrospective ratification by MedOC.
- All existing PGDs will be re-authorised by MedOC if there are significant changes to clinical criteria.
- Existing PGDs with minor or no changes to clinical criteria will be re-authorised by pharmacy with notification to MedOC.
- MedOC will authorise the development of all new core PGDs

4.4 The **Chief Pharmacist** is responsible for:

- delegating responsibilities as listed to an appointed PGD pharmacy Lead
- ensuring the use of Core PGDs is audited.

4.5 The **PGD pharmacy lead** is responsible for:

- Ensuring core PGDs, and a list of CMG / Alliance PGDs, are maintained in current form on the Trust's intranet and that any new national legal or practice issues affecting PGDs are brought to the attention of PGD writers, managers and practitioners.
- Authorising a nominated practitioner responsible for writing or revising a PGD

- Checking the clinical content, legal compliance, and compliance with the PGD writing guidelines
- Sign off of all CMG level PGDs with the CMG clinical director and head of nursing, or other senior medic and/or nurse.
- Ensuring that a database is maintained in Pharmacy of all authorised PGDs.
- Highlighting to the lead author / CMG those PGDs that are within 6 months of expiry that a review is required.

4.6 Clinical Management Group (CMG) / Alliance

- Clinical Directors, Heads of Nursing and CMG Lead Pharmacists are responsible for approving the production of local PGDs.
- It is the responsibility of the CMG / Alliance to maintain an up to date record of all practitioners authorised to supply or administer medicines via each PGD.
- Audit against CMG / Alliance-specific PGDs is the **CMG / Alliance** responsibility; evidence of audit is a requirement for PGD re-authorisation
- It is the responsibility of **line managers** to authorise practitioners to supply and administer specified medicines under a PGD through assessment of competence, training and need.
- Practitioners nominated and authorised by the **PGD Pharmacy Lead** to write or revise a PGD must ensure they follow the guidance within this policy**.**

4.7 Authorised practitioner

- Professionals supplying and administering under a PGD must be registered members of their profession, act within their appropriate code of professional conduct and must be at least 6 months post registration before undertaking current PGD administration. A list of registered professionals who can supply or administer medicines using PGDs is included in Appendix 1.
- It is the responsibility of the **authorised practitioner** to act within their professional guidelines, the Trust policy and legal framework for PGDs, to undertake the e-learning PGD training and competency assessment module and to present evidence of this to their line manager before use of PGDs can commence.

5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS

5.1 Guidance for administering or supplying under a PGD

5.1.1 Documentation

Any medication which is supplied should be recorded in the appropriate electronic form. For eMeds it should be selected from the relevant PGD list.

For areas using paper drug charts any medication should be written in the once only box on the patients drug chart in red signed by the practitioner followed by their professional group e.g. RN, RM. No further doses may be given unless indicated on the individual PGD. A doctor must then prescribe the medication for subsequent doses if indicated.

If other arrangements for recording exist (for example in settings where there is no drug chart), these must be stated on the individual PGD.

Electronic signed copies of all currently approved PGDs are available on the PGD pages of INSite. Paper or other electronic copies of PGDs must **not** be kept in clinical areas. Practitioners must refer to INSite to ensure they are working in line with the current approved version of the relevant PGD.

5.1.2 **Supply and storage**

The medications will be dispensed from the stock of medication kept normally in the area unless details are otherwise specified in the individual PGD.

5.1.3 **Exclusion criteria**

Refer to individual PGDs to check exclusion criteria for the individual medications.

5.1.4 **Refusal of administration under PGD**

If patients do not wish to receive medication under a PGD then a referral should be made to a member of the patient's medical team where appropriate, or, if out of hours, to the on-call clinician for that area. This will allow a review of the patient and to assess the need for, and where appropriate prescribing of, medication.

5.2 Authorisation for a new PGD

5.2.1 Approval for submission for authorisation to write a new CMG / departmental PGD must be obtained from the medical, nursing and pharmacy lead for that CMG (or equivalent senior practitioners when appropriate, e.g. radiography). When considering the need for a new PGD, reference must be made to the flowchart 'To PGD or Not PGD' found in appendix 3.

5.2.2 Local (CMG / Alliance-specific) PGDs are only required for prescription only medicines (POMs). Other medicines (P or GSL) previously covered by PGDs should be reviewed at local level in conjunction with Lead Pharmacists and authorised as category C guidelines.

5.2.3 The production of a new PGD for a Department / CMG will only be started once authorisation has been given by the Trust PGD Pharmacy Lead or Chief Pharmacist. A request for PGD authorisation will be submitted by the person taking responsibility for writing the PGD, normally a senior CMG nurse or pharmacist (see Appendix 4 for authorisation submission form). Writing will not commence until authorisation is received.

5.2.4 If a PGD is already in existence for another Department / CMG and is identical or close to the requirements for the proposed new PGD, authorisation will be delayed to determine if the existing PGD can be modified to meet the needs of both departments/CMGs. If this is deemed to be possible, the existing PGD will only require signing by the appropriate doctor, nurse and pharmacist associated with the new submission. The numbering of the original PGD will be retained.

5.2.5 If there are deemed to be sufficient differences in requirements between the existing and proposed new PGD, authorisation will be granted to progress with the new PGD. Every effort will be made to reduce duplication of PGDs across the Trust.

5.2.6 If more than three departments / CMGs require a similar PGD, consideration will be given by the PGD Pharmacy Lead to converting the existing PGDs to a core UHL PGD.

5.3 Writing a new PGD

5.3.1 Once authorised, the first draft of a new PGD will normally be written by the registered senior practitioner and/or pharmacist for the submitting department / CMG. The PGD will be produced using the PGD template current at the time of writing (available from the intranet or on request from the CMG / Alliance Lead Pharmacist) (Appendix 6).

5.3.2 The PGD Writing Guide (Appendix 7) will be used unless an alternative approach is approved by the UHL PGD Pharmacy Lead. Drafts of new PGDs which have not followed the writing guidelines or are submitted on an out-of date template will be returned to the author(s) for correction.

5.3.3 Local adoption of nationally approved PGDs may be appropriate as an alternative to use of the local template; this can reduce duplication of effort, give greater assurance about PGD content, and reduce the time to PGD introduction. Examples include PGDs produced by United Kingdom Health Security Agency (UKHSA) or NHS England Specialist Pharmacy Service (SPS), but those from other national organisations may also be considered. Whenever these are used, they are allocated a UHL PGD reference number and UHL specific details including signatories are added in line with the usual UHL PGD approval processes. See appendix 8 for examples.

5.4 Revising an existing PGD

5.4.1 The revision process for an existing PGD must be started six months before the expiry date to ensure the PGD is signed-off at Trust and department / CMG levels before it expires. The revision process must follow the writing guide (Appendix 7) to ensure consistency of content and presentation. The following process must be followed for updating an existing PGD:

- Check that the PGD is still required in practice.
- Check the text to ensure that it is accurate and reflects current practice.
- Check the Summary of Product Characteristics (SPC), usually from the eMC website, to ensure changes are incorporated into the revision.
- Check that the signatories are still valid.
- Check that the PGD template has not changed – if it has transfer the information to the new template.
- Make all changes required on the electronic copy of the previous ‘final’ version, using track changes. Rename the file by changing the version number and type, e.g. PGD-01-v2-0(final) becomes PGD-01-v3-0(draft1).
- Undertake an internal consultation if required to ensure clinical acceptability.
- Ensure practice against the PGD has been audited to demonstrate compliance with all elements of the PGD, including documentation requirements and line manager authorisation of practitioners (expected minimum 10 patients). This should be submitted with the PGD for re-authorisation. An example audit template is included at Appendix 9. Alternative audit formats may be used, for example where the audit is being completed to meet other requirements too.
- Submit to the CMG / Alliance Lead Pharmacist for clinical checking and sign-off.

5.5 Checking and sign-off

5.5.1 All drafts of new and revised PGDs will be submitted to the CMG / Alliance Lead Pharmacist for clinical and consistency checking. The CMG / Alliance Lead Pharmacist will complete a Quality Assurance form for review of a PGD (Appendix 5) and submit to the Chief Pharmacist (or delegated PGD Pharmacy Lead). The submitting author will be contacted within four weeks if there are any content / accuracy issues that need resolution before the PGD can be authorised.

5.5.2 All new PGDs will authorised by MedOC. Urgent requests for new PGDs may be approved outside of MedOC at the discretion of the Chief Pharmacist (or delegated deputy), with subsequent retrospective ratification by MedOC. All existing PGDs will be re-authorised by MedOC if there are significant changes to clinical criteria. Existing PGDs with minor or no changes to clinical criteria will be re-authorised by pharmacy with notification to MedOC. PGDs will be authorised within four weeks of submission of a completed Quality Assurance form (if authorisation by MedOC is not required) or within 8 weeks (if authorisation required through MedOC).

5.5.3 Once the PGD has been authorised an electronic copy of the PGD will be sent to the author or other designated person for signing within the department/CMG by the appropriate medical, nursing and pharmacy leads or other authorised signatories. These signatures should be electronic. Once signed, the electronic copy of the PGD must be returned to pharmacy. The electronic copy of the PGD will then be signed by or on behalf of the Chief Pharmacist and the PGD will be uploaded to INSite as a PDF, and the author(s) notified. The PGD must not be used until the signed PDF version is available on INSite.

5.5.4 A copy of the fully signed PGD will be retained electronically by pharmacy. There is no longer a requirement for a signed paper master copy to be held at Department / CMG or pharmacy level.

5.5.5 UHL Core PGDs will be approved by the Trust's Medical Director, Chief Nurse and Chief Pharmacist (or delegated deputy). These will be available on INSite as signed PDF documents.

5.6 PGD Expiry and review

5.6.1 PGDs will have a maximum expiry / revision date 2 years from the publication date specified on the PGD. This may exceptionally be increased to 3 years with the agreement of the Chief Pharmacist.

5.6.2 PGDs will cease to be valid three months after the published expiry date. Use of PGDs after this date may carry patient risk which will be the responsibility of the Department /CMG.

5.6.3 The UHL PGD Pharmacy Lead or CMG/Alliance Lead Pharmacist must be informed of any PGDs which become redundant and which are not to be revised.

This policy is supported by the following processes / procedures / standards found in the associated documents as detailed below, which must be used in conjunction with this policy:

Procedure / Process / Standard	Appendix
Line Manager Authorisation for PGD Administration	2
Authorisation Request for New PGD	4
Quality Assurance form for review of a new / updated PGD	5
PGD Template	6
PGD Writing Guide	7

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 Staff must undergo the UHL PGD e-learning module and competency assessment. The registered professional must complete the Line Manager Authorisation for PGD Administration Form' (Appendix 2) with their line manager. A copy of this form should be stored locally by the line manager.

6.2 The practitioner will be responsible for ensuring that their practice is up to date and the line manager will be responsible for providing the opportunity for update training.

6.3 Additional CMG-based training and competence assessment may be required in addition to that provided by the core package. This will be at the discretion of CMG leads.

6.4 Members of staff who move between CMGs / departments within UHL should complete the authorisation form with their new line manager, to confirm which PGDs are appropriate for that area. Members of staff who are new to UHL should complete the e-learning package and authorisation form, even if they have previously administered drugs under a PGD in a previous role.

6.5 If new PGDs are introduced into clinical areas then appropriate training and authorisation must be given to all staff that are to administer under this PGD. This should be stipulated in the 'Continued training requirements' section of the individual PGD.

7 PROCESS FOR MONITORING COMPLIANCE

7.1 See Policy Monitoring Table on page 12.

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

- HSC 2000/026: Patient group directions [England only], NHS Executive, August 2000
- Patient Group Directions - a practical guide and framework of competencies for all professionals using patient group directions, December 2009: National Prescribing Centre.
- Patient Group Directions in the NHS. Guidance on the development, implementation and review of Patient Group Directions in the NHS. Medicines Healthcare products Regulatory Agency (MHRA). MHRA website. Update October 2010
- Human Medicines Regulations 2012 (SI 2012/1916). Available from http://www.legislation.gov.uk/uksi/2012/1916/contents/made
- NICE Good Practice Guidnace on Patient Group Directions https://www.nice.org.uk/guidance/mpg2

- Health and Social Care Act 2008 (Regulated Activities) Regulations 2009
- NHSE, HSC 1998/051. A Report on the Supply and Administration of Medicines under Group Protocols.
- NICE Competency Frameworks for Healthcare Professionals developing/reviewing authorising and using Patient group Directions. Jan 2014

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 This Policy will be reviewed every three years or sooner in response to clinical, risk or legislative issues.

10.2 The updated version of the Policy will then be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system

POLICY MONITORING TABLE

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements Who or what committee will the completed report go to.
% of PGDs in date and available on INSite	Pharmacy PGD Lead	Report to MedOC	6-weekly	Medicines Optimisation Committee
% of reauthorised PGDs with evidence of audit	Pharmacy PGD Lead	MedOC KPIs	6-weekly	Medicines Optimisation Committee

This Appendix identifies all professional groups which are defined under legislation to be able to supply and administer medicines under a PGD.

This list may change during the tenure of this policy if legislation changes.

- Pharmacists
- Registered Chiropodists andPodiatrists
- Registered Dental Hygienists
- Registered Dental Therapists
- Registered Dieticians
- Registered Midwives
- Registered Nurses
- Registered Occupational Therapists
- Registered Optometrists
- Registered Orthoptists
- Registered Orthotists and Prosthetists
- Registered Paramedics
- Registered Physiotherapists
- Registered Radiographers
- Registered Speech and Language Therapists

Line manager authorisation for PGD administration	University Hospitals of Leicester NHS NHS Trust **Appendix 2**

See next page

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

Line Manager Authorisation for PGD Administration

Name of staff member……..……..Ward……..……Date.....……

	Yes	No	N/A
I confirm I have seen evidence of the completion of the PGD e-learning			
I confirm that this member of staff has completed a medicine administration assessment, if appropriate, within the last 3 years (nursing and midwifery staff only)			
I confirm that the member of staff is 6 month post registration			
I confirm that I have discussed with the member of staff which PGDs are appropriate to their role			

The following **core** PGDs can be administered by the above member of staff within this clinical area:

PGD No	Core PGD	Yes	No
UHA-01	*Emulsifying Ointment BP topically*		
UHA-02	*Glycerin suppositories rectally*		
UHA-03	*Glyceryl Trinitrate sublingual/spray*		
UHA-04	*Ispaghula Husk (Fybogel)*		
UHA-05	*Lactulose solution orally*		
UHA-06	*Co-magaldrox (Maalox/ Mucogel)*		
UHA-07	*Microlette micro-enema rectally*		
UHA-08	*Oxygen*		
UHA-09	*Paracetamol orally/ rectally*		
UHA-10	*Phosphate enema rectally*		

PGD No	Core PGD	Yes	No
UHA-11	*Senna orally*		
UHA-13	*Sodium Chloride 0.9% Injection Intravenous Flush*		
UHA-14	*Sodium Chloride 0.9% Injection Nebuliser Solution*		
UHA-15	*Chlorphenamine tablets*		
UHA-16	*Glucagon*		
UHA-17	*Oxygen/nitrous oxide (Entenox®)*		
UHB-01	*Stellisept® Med skin wash*		
UHB-02	Mupirocin (Bactroban®) nasal ointment		
UHB-03	Naseptin nasal ointment		

In addition to this, the following **local** PGDs can also be administered by the above member of staff in this clinical area.

PGD no	PGD Name

PGD no	PGD Name

Line manager's signature…… Date……

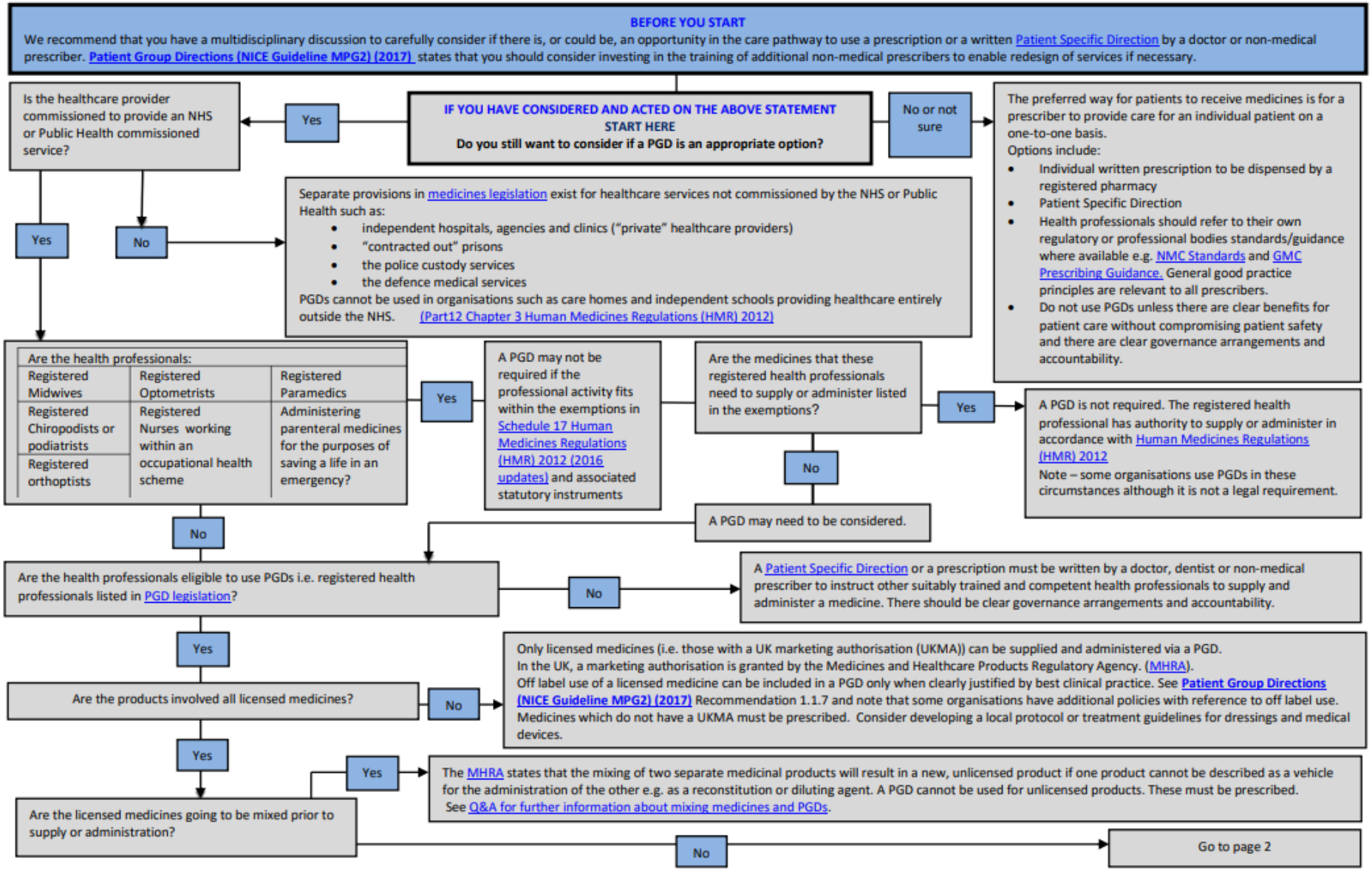
Member of staff signature…… Date……

A copy of this form should be stored locally by the line manager (e.g. in staff personnel file). Each CMG is responsible for maintaining records of staff authorised to work under PGDs (e.g. through addition to HELM, as a skill on HealthRoster, or by other locally agreed means).

See next page

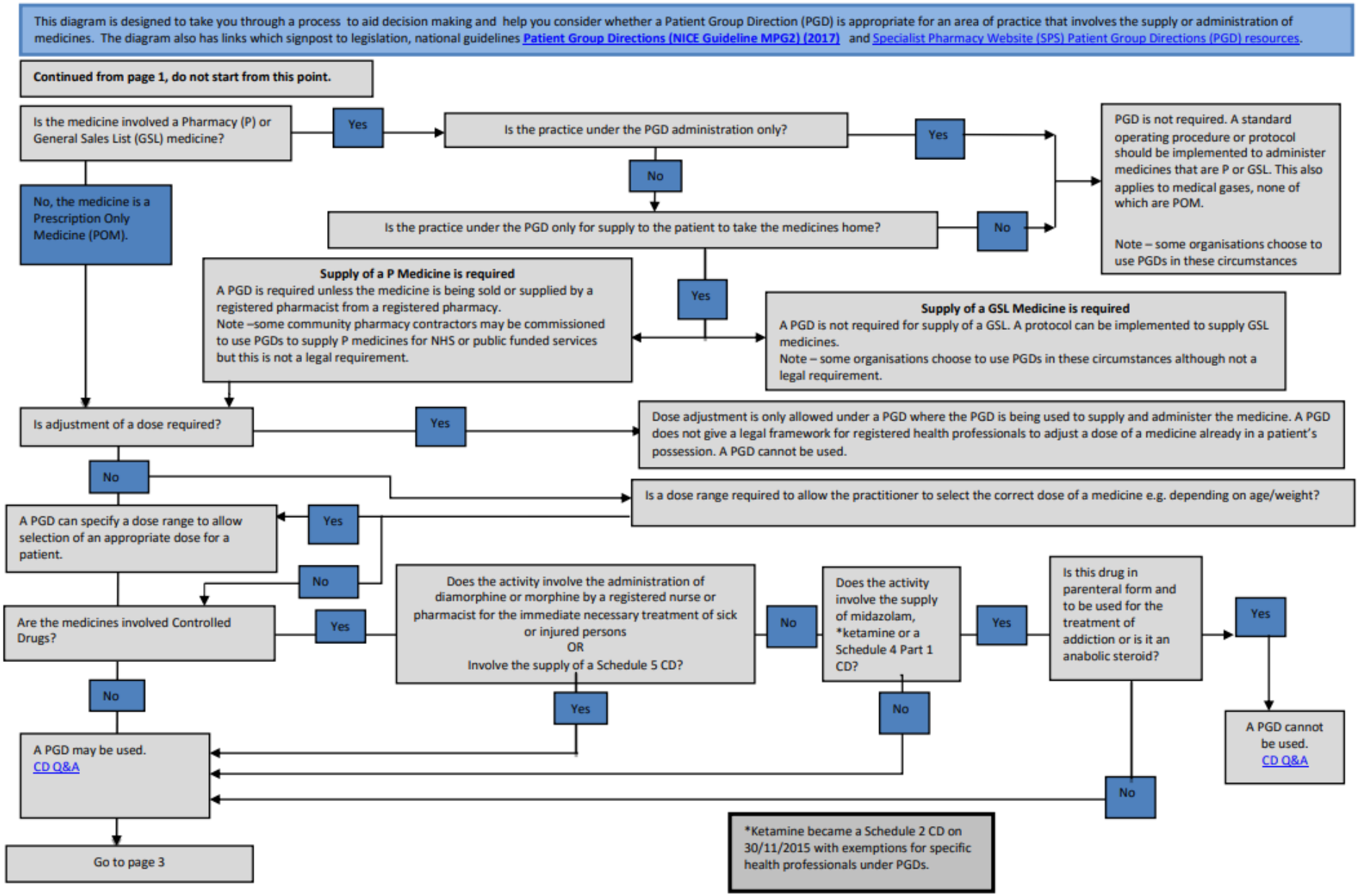
TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations

This diagram is designed to take you through a process to aid decision making and help you consider whether a Patient Group Direction (PGD) is appropriate for an area of practice that involves the supply or administration of medicines. The diagram also has links which signpost to legislation, national guidelines **Patient Group Directions (NICE Guideline MPG2) (2017)** and Specialist Pharmacy Website (SPS) Patient Group Directions (PGD) resources.



To PGD or not to PGD Version 9.5. Update of links. Published by SPS PGDs (England) January 2018. **THIS VERSION IS FOR ENGLAND ONLY. Review due June 2018 (or earlier subject to legislation or other guidelines changes). If you are referring to a hard copy of this document – please check the SPS website (England) www.sps.nhs.uk to make sure that you are using the most recent version.**

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



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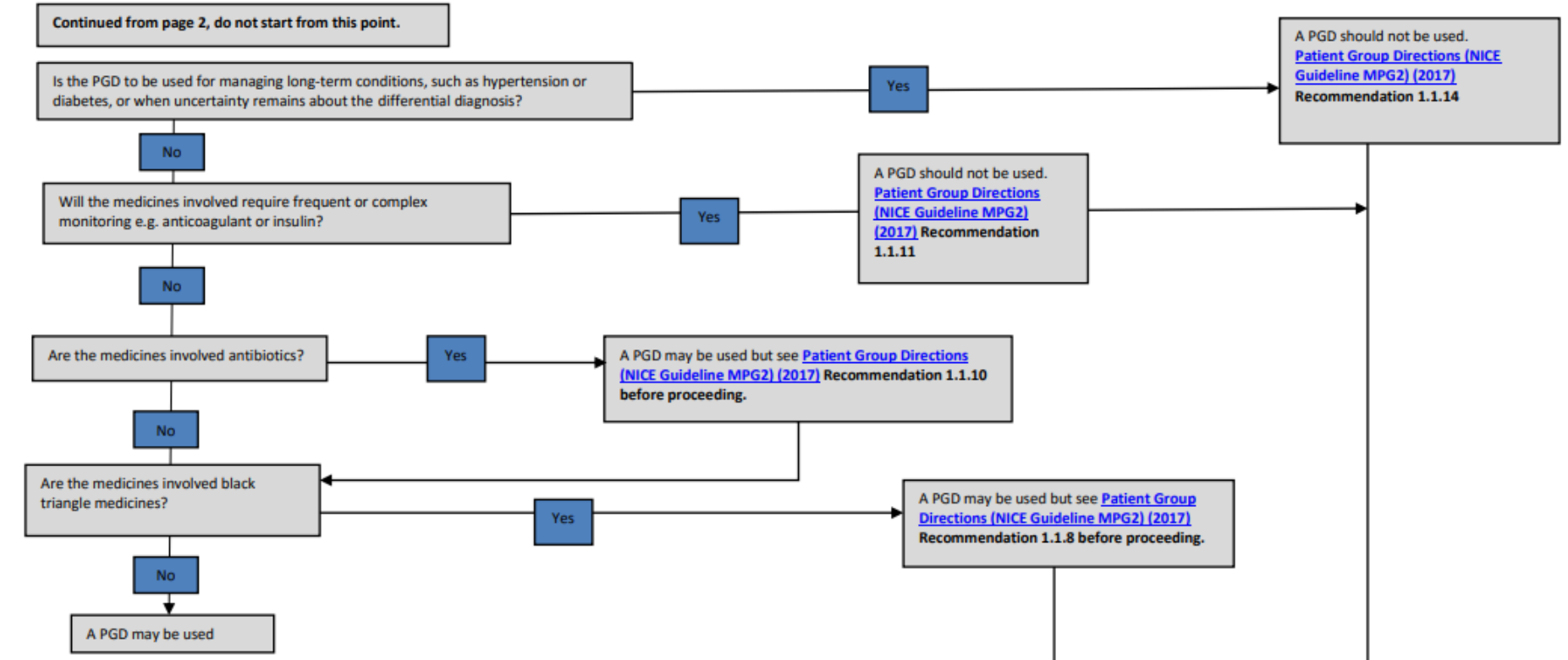


This chart may not cover all situations proposed for using PGDs. The proposed activity should meet the principles stated in Patient Group Directions (NICE Guideline MPG2) (2017)

Supply or administration of medicines under PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

If having considered all of the above, you decide that a PGD may be an appropriate route to provide this clinical activity, also ensure that you consider other medicines legislation and clinical governance issues at each stage of the process. We recommend that you also refer to the following:

PGD Q&A – abortifacients
PGD Q&A - labelling of POMs supplied under PGD
PGD Q&A - delegation
PGD Q&A – trainee supervision
Quality PGDs -7 Steps to success and other resources such as PGD Q&As on the SPS website
Patient Group Directions (NICE Guideline MPG2) (2013) Pathway and Tools and Resources
PGD multi-disciplinary e learning package
Your local Medicines and PGD Policies

To PGD or not to PGD Version 9.5. Update of links. Published by SPS PGDs (England) January 2018. **THIS VERSION IS FOR ENGLAND ONLY. Review due June 2018 (or earlier subject to legislation or other guidelines changes). If you are referring to a hard copy of this document – please check the SPS website (England) www.sps.nhs.uk to make sure that you are using the most recent version.**

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
PHARMACY SERVICE

Authorisation Request for New PGD

A request for authorisation to write a new PGD must be made whenever a new PGD is under consideration at department, CMG or divisional levels. Any PGD written and submitted for approval without prior authorisation will not be considered until a request for authorisation is submitted and agreed.

When completed, email this form to CMG Lead Pharmacist or specialist pharmacist who will review before liasing with pharmacy PGD lead.

Drug(s) proposed for PGD	
Indications	
Department and/or CMG	
Name, job title, and email of lead author *Note: Must be an authorised health professional who can practice under a PGD*	
Have you consulted the CMG Lead Nurse and medical and pharmacist leads *(if designated)* on this PGD?	**YES / NO**
If so, name of lead pharmacist	
Give details of any similar PGDs in use in other departments/CMGs	
Give reasons for requiring this new proposed PGD	
Name/job titles(s) of those who have approved this request to be made	

Signature		Date	

Date recd		Outcome		Notified	

Quality Assurance Form for Review of a New / Updated PGD

University Hospitals of Leicester NHS
NHS Trust

Appendix 5

All PGDs are authorised by the Chief Pharmacist or nominated deputy. To facilitate this process the following form must be completed.

Please sign to confirm that the following checks have been completed. This should be completed by a Band 8a pharmacist or above working in the clinical area. The form then needs to be submitted with an electronic copy of the PGD. If completing electronically the name of the person completing the form and the date should be typed into the box and the form submitted from the person's email account.

PGD reference no.	
PGD name	
Confirmation with clinical area that PGD is still required in practice	
Evidence of audit of PGD use received from clinical team	
Text checked to ensure it is accurate and still reflects current clinical practice	
Checked against antimicrobial guidelines and/or checked by antimicrobial pharmacist (Antimicrobial PGDs only)	
Checked against most recent version of SPC to ensure any changes are incorporated into the revision	
All references updated to reflect most recent version e.g. SPC	
PGD written as per most recent template, and complies with PGD policy v7.0 including the PGD Writing Guide (Appendix 7)	
PGD has correct version number, e.g. PGD-01 v2 becomes PGD-01 v3	
PGD has correct dates; usual UHL practice is to give PGD a review date of 2 years unless otherwise determined (e.g. when adopting a national PGD)	
Approval for current version has been received from all signatories (i.e. electronic	

signatures are not just included from previous version)	

PGD Template	University Hospitals of Leicester NHS NHS Trust **Appendix 6**

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST PHARMACY SERVICE	**Issue Date:**	**Mon YYYY**
	Review Date:	**Mon YYYY**
	Protocol No:	**ABC-01**
PATIENT GROUP DIRECTION	**Version:**	**1.0**

Supply and administration of:

Master copy held by:	Available on INSite
Department/Directorate(s):	

- This PGD is to be read by all health professional staff it applies to. Staff must always refer to the current live version of the PGD available on INSite. Other electronic or paper copies should not be kept.
- All staff supplying or administering medicines under this PGD must have this documented on their 'Line Manager Authorisation for PGD Administration' form.

1. Clinical Condition

Define situation / condition	
Criteria for inclusion	
Criteria for exclusion	
Action if excluded	
Action if patient declines	

2. Characteristics of staff

Qualifications required	
Additional requirements	
Continued training requirements	

3. Description of treatment

Name of medicine and pharmaceutical form	
POM / P / GSL	
Dose(s)	
Route	

Frequency	
Total dose / number	
Precautions	
Adverse effects	
Action to be taken if adverse effects reported	
Follow up treatment	
Written / verbal advice for patient / carer before / after treatment	
Supply and storage	
Documentation	

References:

1. HSC 2000/026: Patient Group Directions, Department of Health, August 2000
2. British National Formulary, Number nn, Date (month/year)
3. Summary of Product Characteristics (SPC) – [Product], [Manufacturer], accessed via www.medicines.org.uk, last updated DD Mon YYYY
4. UHL Policy for the Supply and Administration of Medicines under Patient Group Directions (PGDs). Version 7.0. October 2019.
5. Local guidelines/policies 1
6. Local guidelines/policies 2

Authorising Personnel

To include signatures of:

- UHL Medical Director or Head of Service/CMG Medical Lead
- UHL Director of Nursing or Senior CMG Nurse
- Chief Pharmacist - Chair of the Medicines Management Group (or designated representative) who approves the PGD on behalf of the Trust

and optionally:

- CMG Lead Pharmacist
- Consultant(s) whose patients will receive treatment under this PGD
- CMG Clinical Governance Manager
- Other authorised senior CMG/Department representative(s) with a PGD responsibility

Signature	Name and position
	Insert name **Clinical Director, Name of CMG**
	Insert name **Head of Nursing, Name of CMG**
	Insert name **Chief Pharmacist / Deputy Chief Pharmacist**

Refer to Appendix 6 – current PGD template – for format of a PGD.

PGD field	Content guide
Issue Date:	Month and year PGD is singed off. *Managed by PGD co-ordinator.*
Review Date:	Month and year by which next version needs to be in place - normally 2 years from Issue Date. *Managed by PGD co-ordinator*.
Protocol No:	Assigned by PGD co-ordinator to reflect clinical area with responsibility for PGD. *Managed by PGD co-ordinator*.
Version:	2-yearly new version (full revision) will be assigned next sequential number, e.g. 3.0. Minor revision within 2-year cycle will be assigned a sub-version number, e.g. 3.1, 3.2 etc. *Managed by PGD co-ordinator*.
Supply and administration of:	Name of medicine (uppercase, bold) with formulation (e.g. Injection) and strength if necessary. Avoid use of proprietary/trade names where possible. Use BNF style e.g., AMOXICILLIN Capsules 250mg.
Master copy held by:	Available on INSite (physical master copies no longer held)
Department / CMG(s):	Full department (where appropriate) and CMG name(s).

1. Clinical Condition	
Define situation / condition	Indications for use of medicine(s), e.g. 'Management of an acute exacerbation of asthma, COPD or allergic seasonal rhinitis'.
Criteria for inclusion	Specify criteria which guide patient selection. • Who is eligible to receive the medicine e.g. age/sex. • Do you include pregnant women? • Do you include breast feeding women? **Clinical criteria** Must reflect local and/or national clinical guidelines or policies where available. Examples may be: • Acute asthma attack in known adult asthmatic patients. • Acute exacerbation in known patients with chronic obstructive pulmonary disease (COPD). • Grade 3 anaphylaxis management. • Severe allergic seasonal rhinitis. • Children over 16 years old. Use bullet points when there are multiple lines. Use BNF/BNFC/SPC. Take into account any Clinical guidelines or policies that are available locally or nationally e.g. Trust guidelines/NICE.
Criteria for exclusion	Use bullet points to list exclusions. Who is not eligible to receive the medicine? Must reflect local and/or national clinical guidelines or policies where available. Reasons for exclusion may include:

	• Age. • Concurrent conditions. • Concurrent treatment - such as patients taking medicines which may give rise to toxicity or need for increased dose e.g. salbutamol PGD – exclusion - patients taking beta blockers. • Previous local or general reactions to the medicine. • Hypersensitivity to the medicine or any of its ingredients. • Pregnancy and breast feeding. • Anything else stated in the SPC that may give reason for exclusion of specific patients. State cut off points for exclusion / limitations for service i.e. to age or patient groups e.g. "children under 2 years old" not just "children". If possible, reasons for exclusion to be provided e.g. Patients taking x increases toxicity of y). Contra-indications and specific issues which would preclude use of a PGD. Note: It may be possible for the drug to be prescribed by doctor/non-medical prescriber if use under PGD is excluded. E.g. • Hypersensitivity to any ingredient. • Ocular Herpes simplex. • Patient unable to swallow. • Severe renal impairment. • Children under 16 years old. • Pregnancy and breastfeeding. Use BNF and SPC to help identify relevant exclusions/contra-indications. Use bullet points when there are multiple lines.
Action if excluded	What immediate action will be taken if any of the exclusion criteria apply? This may be as simple as 'Refer to clinician'. Detail any records to be kept.
Action if patient declines	What action will be taken if patient declines to be treated under a PGD? This could be 'Refer to clinical to prescribe drug' or there may be agreed alternative processes already in place which will be specified here. Details any records to be kept.

2. Characteristics of staff	
Qualifications required`	Include professional title/grade/band. Specify current employment.
Additional requirements	Successful completion of specified courses, (insert). Any other relevant training or qualifications (including e.g. working at Band X in xxxx area for xxx [specify period].
Continued training and competency requirements	Specify competencies with evidence of annual updates as required. Specify mandatory training such as CPR/life support/anaphylaxis competencies with evidence of annual updates as required. Specify experience or competencies for working under the PGD. Actively partaking in CPD and annual appraisal (COMPULSORY).

3. Description of treatment	
Name of medicine and Pharmaceutical form	Name of medicine, strength and form. • Use generic whenever possible. • If brand specific state generic then brand in brackets. • Use BNF format e.g. Atenolol 50 mg tablets. • If more than one medicine included in the PGD repeat information for all drugs. If the information is different for each drug, either split the appropriate columns in the

	Section 3 table OR repeat the Section 3 table for each drug. *Contact the PGD co-ordinator for advice when inclusion of more than one drug is being considered.*
	• If more than one medicine, explain how they will be used e.g.
	  ○ x will be administered 30 minutes before Y or
	  ○ x will be supplied only if the patient is excluded from having Y or
	  ○ patient will be supplied all medicines unless they are excluded from doing so

POM / P / GSL	Use one of the following in full: POM (Prescription-only Medicine) P (Pharmacy Medicine) GSL (General Sales List) Relate legal category to pack size supplied.
Dose(s)	Are dosages licensed – add reference / note to support use in unlicensed / off-label circumstances. State practical information such as “after food” or “dissolved in water”. Liaise with clinical pharmacist on practical issues relating to dosage and quantity to supply. Decide on format to express dosage especially in children – for example, if on a mg/kg basis – will doses be rounded up or down to the nearest spoonful? *Liaise with clinical pharmacist to agree.* For POMs to be taken away, express dosage format to match that of the pharmacy label e.g. one tablet to be taken three times a day. For GSL and P medicines to be taken away, refer to pack that is to be supplied and ensure dose on pack reflects dose to be taken as required by the PGD. Clinical pharmacist can advise on the relevant duration of treatment to ensure that appropriately labelled packs are available if required.
Route	To avoid errors, state in full and do not use Latin or abbreviations e.g. oral not p.o.; eyedrops not guttae.
Frequency	State frequency in full. Do not use Latin or abbreviations e.g. stat or tds.
Total dose/number	State total number of doses to be supplied and relate to pack size e.g. 28 tablets; 28 tablets from pack of 30; 15g tube; 100 mL
Precautions	Use bullet points to list cautions and the action to be taken. Must reflect local and/or national clinical guidelines or policies where available. List Interactions – include where clinically significant and relevant to this PGD. Enter specific details of action to be taken e.g. advice to be given to patient e.g. warfarin interaction: patients taking warfarin may need closer monitoring at start of treatment. Anything else stated in the SPC that may give reason for caution for specific patients but does not exclude them. Always explain reasons and action to be taken Note – if you are considering action under cautions which leads to the patient being excluded, this should be stated in Section 1 under ‘Criteria for exclusion’. *See also optional statement below*
Adverse effects	Use bullet points to clearly list the most common side effects and any potential serious symptoms the practitioner or the patient needs to look out for. Only include side effects which are most likely to occur with the single dose or short duration of treatment under a PGD. Exclude side effects which will only occur after long-term treatment. Add in order of frequency e.g. Common (more than 1 in 100 people). This list may not represent all reported side effects of this medicine. The following optional statement can be added when considered appropriate for both precautions and adverse effects: *Consult SPCs for complete list of Adverse effects. SPCs available through Medicines Information (6491) or on e-MC website (http://www.medicines.org.uk)*

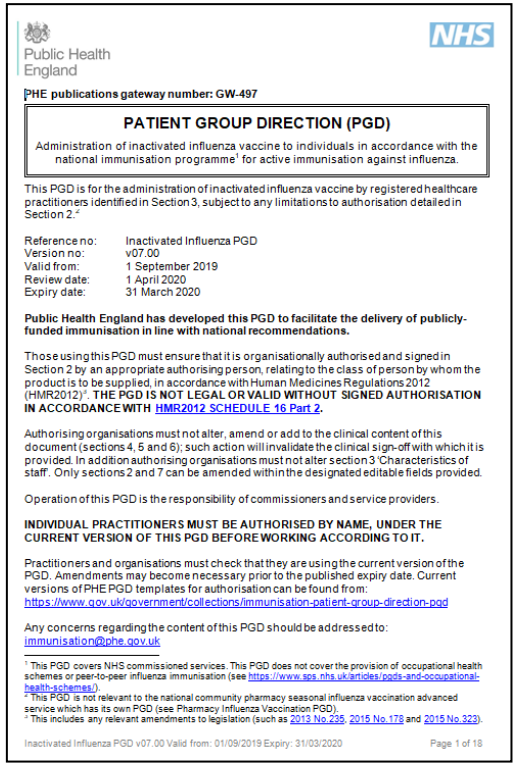
	For black triangle medicines: If the medicine carries the black triangle symbol, this means that this medicine is monitored intensively by the MHRA and ALL suspected adverse reactions should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme. Any suspected adverse drug reaction, whether to a drug supplied or administered to the patient by the practitioner or to a drug already taken by the patient must be reported to a doctor immediately or as appropriate. Suspected adverse reactions to any therapeutic agent should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme. *Contact the clinical pharmacist to ensure any retrospective reports are carried out.* The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so. Prepaid Yellow Cards may be offered to each patient receiving medicines under this PGD. These can be obtained from the Pharmacy Department as well as pharmacies and GP surgeries. Yellow cards can also be obtained via Freephone 0808 100 3352 or online at www.yellowcard.gov.uk .
Action to be taken if adverse effects reported	Specify the actions that will be taken that are specific to each drug and detailed in local or Trust guidelines policy. This may include stopping further doses, referring patient to doctor for assessment and alternative treatment, contact GP if patient taking medicine home. Black triangle medicines: If the medicine carries the black triangle symbol, this means that this medicine is monitored intensively by the MHRA and ALL suspected adverse reactions should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme. Any suspected adverse drug reaction, whether to a drug supplied or administered to the patient by the practitioner or to a drug already taken by the patient must be reported to a doctor immediately or as appropriate. Suspected adverse reactions to any therapeutic agent should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme. *Contact the clinical pharmacist to ensure any retrospective reports are carried out.* The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so. Prepaid Yellow Cards may be offered to each patient receiving medicines under this PGD. These can be obtained from the Pharmacy Department as well as pharmacies and GP surgeries. Yellow cards can also be obtained via Freephone 0808 100 3352 or online at www.yellowcard.gov.uk .
Follow up treatment	Enter requirements e.g. clinical observations after administration, letter to GP, further appointments
Written/Verbal advice for patient/carer before/after treatment	Provide Manufacturer's Patient Information Leaflet. Provide approved Trust Information Leaflet (name). Any further instructions to aid compliance (state). Counselling points e.g. do not drive for two hours after having these eyedrops. Storage or expiry information e.g. store in a fridge. Practical advice on self-care if appropriate. Advice on recognising side effects and what to do (see Side effects). Advice on where to seek help if treatment fails or condition worsens Consider any other information that would be helpful to the patient at this point of their care e.g. signposting to local self help groups/ issue of an information prescription. Referral details for any other support the patient may require
Supply and storage	State supply and specific storage requirements. Supply will normally be 'Supplied from Pharmacy' or supplied from ward stock. There may be some specific supply arrangement in some clinical areas. Storage could include advice, when appropriate such as

	• Store at room temperature. • Store away from light. • Store in a refrigerator.
Documentation	The following must be recorded: • Name of the health professional providing treatment. • Patient identifiers. • Details of the medicine provided. • Date the medicine is supplied or administered. • Patient consent or refusal. • Patient inclusion or exclusion from PGD. • Information given to the patient. • Batch number and expiry date must also be recorded for immunisations, vaccinations and blood derived products such as immunoglobulins clotting factors. • State any other agreed records to be kept for audit purposes. • Add statement specifying how and where all patient assessments and treatments will be recorded and where those records will be kept.

References:	Always include: • HSC 2000/026: Patient Group Directions, Department of Health, August 2000 • UHL Policy for the Supply and Administration of Medicines under Patient Group Directions (PGDs). Version 7.0. October 2019. • British National Formulary, Number nn, Date (month/year) *Omit if not listed in BNF.* • Summary of Product Characteristics (SPC) – [Product], [Manufacturer], accessed via www.medicines.org.uk, last updated DD Mon YYYY • Local and/or national guidelines/policies *if referred to in the PGD, or if to give information on a local procedure or variation from normal practice, including SPC.* Include, where available, internet link (URL) to where published.

Authorising Personnel	To include signatures of: • UHL Medical Director or Head of Service/CMG Medical Lead • UHL Director of Nursing or Senior CMG Nurse • Chief Pharmacist - Chair of the Medicines Management Group (or designated representative) who approves the PGD on behalf of the Trust and optionally: • CMG Lead Pharmacist • Consultant(s) whose patients will receive treatment under this PGD • CMG Clinical Governance Manager • Other authorised senior CMG/Department representative(s) with a PGD responsibility

Local adoption of nationally approved PGDs may be appropriate to reduce duplication of effort, give greater assurance about PGD content, and to reduce the time to PGD introduction. Examples include PGDs produced by Public Health England (PHE) or NHS England Specialist Pharmacy Service (SPS), but those from other national organisations may also be considered. Whenever these are used, they are allocated a UHL PGD reference number and UHL specific details including signatories are added, but the format and apperance of these may be unfamiliar to staff. The below example front sheets are therefore included to demonstrate the appearance of such PGDs (although others may vary) and provide reassurance that they are appropriate for use within UHL. As with all PGDs, staff must only use the current live UHL-approved versions as available on the PGD pages of INSite.



Public Health England

NHS

PHE publications gateway number: GW-497

PATIENT GROUP DIRECTION (PGD)

Administration of inactivated influenza vaccine to individuals in accordance with the national immunisation programme[1] for active immunisation against influenza.

This PGD is for the administration of inactivated influenza vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.[2]

Reference no: Inactivated Influenza PGD
Version no: v07.00
Valid from: 1 September 2019
Review date: 1 April 2020
Expiry date: 31 March 2020

Public Health England has developed this PGD to facilitate the delivery of publicly-funded immunisation in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[3]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

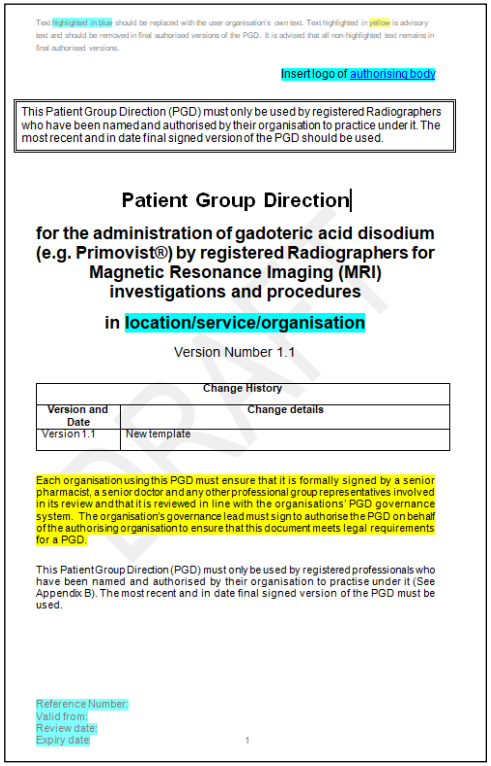
Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

[1] This PGD covers NHS commissioned services. This PGD does not cover the provision of occupational health schemes or peer-to-peer influenza immunisation (see https://www.sps.nhs.uk/articles/pgds-and-occupational-health-schemes/).
[2] This PGD is not relevant to the national community pharmacy seasonal influenza vaccination advanced service which has its own PGD (see Pharmacy Influenza Vaccination PGD).
[3] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178 and 2015 No.323).

Inactivated Influenza PGD v07.00 Valid from: 01/09/2019 Expiry: 31/03/2020 Page 1 of 18

Fig 1: Example PHE PGD



Text highlighted in blue should be replaced with the user organisation's own text. Text highlighted in yellow is advisory text and should be removed in final authorised versions of the PGD. It is advised that all non-highlighted text remains in final authorised versions.

insert logo of authorising body

This Patient Group Direction (PGD) must only be used by registered Radiographers who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the administration of gadoteric acid disodium (e.g. Primovist®) by registered Radiographers for Magnetic Resonance Imaging (MRI) investigations and procedures

in location/service/organisation

Version Number 1.1

Change History	
Version and Date	**Change details**
Version 1.1	New template

Each organisation using this PGD must ensure that it is formally signed by a senior pharmacist, a senior doctor and any other professional group representatives involved in its review and that it is reviewed in line with the organisations' PGD governance system. The organisation's governance lead must sign to authorise the PGD on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix B). The most recent and in date final signed version of the PGD must be used.

Reference Number:
Valid from:
Review date:
Expiry date:

1

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Fig 2: Example SPS PGD

PGD Audit Template	University Hospitals of Leicester NHS NHS Trust **Appendix 9**

All PGDs should be audited ahead of review and reapproval. The below template is intended as a guide to support this. Alternative audit formats may be used, for example where the audit is being done to meet other requirements too. Evidence of audit should be submitted together with the updated PGD and Quality Assurance Form (Appendix 5) to the pharmacy PGD lead.

PGD reference no.		**PGD name**	
Next review due		**Date audit completed**	
Audit completed by (name & designation)			

Clinical condition	
Number of patients audited (minimum of 10; if < 10 patients treated, consider ongoing need for PGD)	
All patients treated for stated indications	**Yes / No** Details where 'no':
All patients meet inclusion criteria	**Yes / No** Details where 'no':
No patients meet exclusion criteria	**Yes / No** Details where 'no':

Characteristics of staff	
All staff operating under this PGD have appropriate qualifications as defined in PGD	**Yes / No** Details where 'no':
All staff operating under this PGD meet any additional requirements as defined in PGD	**Yes / No** Details where 'no':
All staff operating under this PGD meet any continued training requirements as defined in PGD	**Yes / No** Details where 'no':
All staff operating under this PGD have Line Manager Authorisation in place, including for this specific PGD	**Yes / No** Details where 'no':

Treatment	
All patients received correct treatment including: • Correct product • Correct dose • Correct route • Correct frequency • Not exceeding maximum no. of doses	**Yes / No** Details where 'no':
All patients given any follow up treatment and written / verbal advice as defined in PGD	**Yes / No** Details where 'no':

Medicine has been appropriately stored & supplied from correct source as defined in PGD	**Yes / No** Details where 'no':
All patients have supply / administration documented in medicial notes / prescription chart / in other documentation as defined in PGD	**Yes / No** Details where 'no':

Resulting Actions	
Any required changes identified as result of audit considered for inclusion in updated PGD	**Yes / No / N/A** Please give details of changes considered, stating whether incorporated into updated PGD or not (and rationale) or other action taken (e.g. re-training of staff):
Action Plan produced to address any deficiencies	**Yes / No / N/A** Please include summary or attach plan as appropriate.