FRAMEWORK FOR THE DEVELOPMENT, APPROVAL AND IMPLEMENTATION OF PATIENT GROUP DIRECTIONS (PGDs)

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The latest approved version of this document is online.
If the review date has passed please contact the Author for advice.

Version Control

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue to replace MMP014v2	July 2022

Item No.	Contents	Page
1	Policy Statement / Introduction	6
2	Objective	6
3	Definitions	6
4	Responsibilities	7
5	Patient Group Direction Application, Consideration, Development, Approval, Authorisation, Implementation and Review/ Renewal Process	10
6	Monitoring Compliance, Audit, and Review	19
7	References	20
App. No.	**Appendices**	**Page**
A	Patient group direction sub-group terms of reference	21
B	Patient Group Direction Template	23
C	Quality checklist	44
D	Proposal for new, or updated PGD	52
E	Practitioners using PGDs: Training and competency	59
F	Flowchart of PGD development process	61
G	email that is sent to the service lead when PGD is completed/ reviewed	62
H	PGD Department audit tool	63
I	Governance audit tool	72

ENGAGEMENT & CONSULTATION

Key Individuals/Groups Involved in Developing this Document

Role / Designation
Lead PGD pharmacist
Head of Community Services Medicines Management
Chief Pharmacist

Circulated to the following for Consultation

Date	Role / Designation
17/5/22	PGD subgroup
7/7/22	Approved by the APG
19/7/22	Medical Director

Evidence Base
Please list any National Guidelines, Legislation or Health and Care Standards relating to this subject area 1.Medicines Act 1968 and Human Medicines regulations 2. WHC (2000) 116 http://www.wales.nhs.uk/documents/WHC%282000%29116.pdf 3. The Human Medicines Regulations 2012 No. 1916 http://www.legislation.gov.uk/uksi/2012/1916/contents/made 4. National Institute for Health and Care Excellence (NICE), Medicines Practice Guidelines (MPG2) Patient Group Directions (2014, minor update 2017) https://www.nice.org.uk/Guidance/MPG2 5. Specialist Pharmacy Service Patient Group Directions – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

IMPACT ASSESSMENTS

Equality Impact Assessment Summary					
	No impact	**Adverse**	**Differential**	**Positive**	**Statement** ***Please provide supporting narrative for any adverse, differential or positive impacts that may arise from the implementation of this policy***
Age				x	
Disability	x				
Gender reassignment	x				
Pregnancy and Maternity	x				
Race	x				
Religion or Belief	x				
Sex	x				
Sexual Orientation	x				
Marriage and Civil Partnership	x				
Welsh Language	x				

Risk Assessment Summary

Have you identified any risks arising from the implementation of this policy / procedure / written control document?

No risks identified

Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document?

Requires a database of PGD users to be developed. Will be accessible only by MM PGD lead and Internal Audit. IG to confirm this is appropriate.

Have you identified any training and / or resource implications as a result of implementing this?

Training for staff involved in each step of the process will be required as personnel change. Ongoing awareness training for PGD users will be required, as is already the case. Completion of the following e-learning programme, developed by SPS in partnership with HEE and UKHSA. Patient Group Directions - elearning for healthcare (e-lfh.org.uk)

Training requirements for individual PGDs will be identified in the PGD itself.

1 Policy Statement / Introduction

Patient Group Directions (PGDs) provide a legal framework to allow the supply and/or administration of a specified licensed medicine(s) by named, authorised, registered healthcare professionals, to a pre-defined group of patients needing prophylaxis or treatment for a condition described within the PGD without the need for a prescription or instruction from a prescriber.

Powys Teaching Health Board (PTHB) recognises the benefits in specific, appropriate and safe circumstances (where the patient consents), of being able to supply and/or administer medicines to the patient, without them having to see a prescriber, where there are appropriate professional relationships and clear governance arrangements and accountability. Use of the PGD must enable the highest standard of practice for each clinical situation to be achieved. Medicines recommended should be cost effective and evidence based. Before developing a PGD, other options for treating the condition should be explored as listed in section 5.2.

Where the PGD is to be used outside of the provider PTHB structure (for example, by GP practices or Community Pharmacies), the Health Board and the user organisation have a joint responsibility to ensure that this is within the legal framework and governance arrangements are in place and remain so for each PGD.

2 Objective (Mandatory Heading)

This document sets out the process for the application, consideration, development, approval, implementation and review of a Patient Group Direction (PGD), to the legal and NICE guidance standards, under which designated registered health professionals (working for PTHB or approved primary care contractor organisations) may be empowered to supply and/or administer medicines to NHS patients.

Policy implementation will support compliance with legislation, improve access to clinical care and ensure up to date guidelines are followed.

3 Definitions (Mandatory Heading)

- AWMSG All Wales Medicines Strategy Group
- CSM Community services manager
- HCPs Healthcare professionals
- NICE National Institute for Clinical Excellence
- PADR Personal Appraisal Development Review
- PGD Patient Group Direction
- PHE Public Health England

- PHW Public Health Wales
- PTHB Powys Teaching Health Board
- SPC Summary of Product Characteristics
- SPS Specialist Pharmacy Service
- UCP Unscheduled Care Practitioner
- UKHSA UK Health Security Agency

4 Responsibilities(Mandatory Heading)

4.1 PGD subgroup

Responsibilities of the PGD subgroup, as detailed in appendix A:

- To critically review applications for development of new or renewal of existing patient group directions. Ensuring that a PGD is the most appropriate way to deliver care in that area
- To manage the process of developing, reviewing and quality assuring PGDs on behalf of PTHB
- To agree the scope of the PGD request
- To agree who needs to be involved in the development of the PGD
- To determine the priority of the PGD request in view of the PGD subgroup workplan
- To agree the timeline for development of the PGD
- Advise on the development of PGDs and assure the content, prior to obtaining Health board approval of the final PGD
- Ensure that all legislative, policy and patient safety/medicines optimisation requirements regarding the use of PGDs are addressed
- Ensure appropriate initial and ongoing training and competence assessments are developed and available to support the safe use of PGDs
- Develop and maintain a network across Health Board Healthcare Professionals and Services to ensure that appropriate advice concerning PGD use is readily available to respond to patient or service needs
- Maintain a database of approved PGDs
- Ensure that PGDs are used appropriately and planned audits of practice are carried out
- Declare any conflicts of interest

4.2 PGD Requestor

Requests for new PGDs: All requests for PGDs must be submitted using the template in Appendix D. The template must be fully completed before being submitted to the PGD subgroup via: info.medicinesmanagement.powys@wales.nhs.uk.

	Requests for renewal of existing PGDs: The requestor will need to complete questions 2 and 3 from the PGD audit tool (Appendix H) and complete the template (Appendix D) to demonstrate that a PGD is the most appropriate way to deliver the service. Both should be submitted to the PGD subgroup via: info.medicinesmanagement.powys@wales.nhs.uk
	4.3 Community Services Manager (or equivalent service lead) • Identifies service need for PGD use and works with PGD subgroup to explore other ways of delivering services e.g training independent prescribers. • If requesting a new PGD, completion of the 'proposal for new or updated PGD' form (appendix D) and submission to the PGD subgroup. • Ensures appropriate education and training for staff using the PGD is undertaken. • Ensures a register of staff names competent to use the PGD is kept in the relevant clinical area. Each approved practitioner must have access to a copy of the document. • Ensures the 'proposal for new or updated PGD' form (appendix D) is completed no less than 6 months before the PGD expiry date, to consider whether its use remains appropriate. • Ensures the results of the PGD review and any proposed changes are submitted to the PGD subgroup. • Ensure that staff have access to the most up to date versions of the PGDs. • Ensure that processes are in place to support audit of PGD use. • Ensure that robust processes are in place to inform staff of new, updated and withdrawn PGDs
	4.4 Doctor/Dentist A lead doctor or dentist will work in conjunction with the medicines management team to develop the PGD and establish that the clinical and pharmaceutical content of the PGD is accurate and supported by the best available evidence.
	4.5 PGD Authorised Signatories Signatories for the PGD, after approval through the PGD subgroup, who confirm the Patient Group Direction can be implemented. The Medical director may also, exceptionally, approve extension of the expiry date of a PGD (NB. Under no circumstances should any extension exceed 3 years from the date that the PGD was originally authorised)

	4.6 Medicines Management Team PGD Lead • Review and recommend updates to PGD development procedures in line with current legislation and good practice, to the PGD subgroup • Lead pharmaceutical review of PGD content • Ensures other ways of delivering treatment have been explored • Sets agenda for PGD subgroup • Acts as a resource for clinical or legislative enquiries regarding PGDs • Ensures appropriate PGD training is in place for developers, authorisers and users of PGDs • Conducts audit of PGD implementation using the PGD audit tool (Appendix H) • Ensure that service leads are informed when PGDs are withdrawn from practice and where new PGDs are published. •
	4.7 Medicines Management Team Admin • Maintain a database of current PGDs, review dates and expiry dates, that can be published on the Powys Health Board Internet • Archive withdrawn/expired PGDs, ensuring compliance with Records Management requirements. Inform the service lead via email when an expired PGD is removed from the website, requesting that they contact medicines management if this is likely to have a significant impact on their service. • Ensures document trail for PGD development and approval • Develop and maintain a register of users of PGDs • Email the agenda of the PGD subgroup meetings to members and take minutes of the meetings • Informs the head of the professional group to whom the PGD applies when a new/updated PGD is approved
	4.8 Practitioners intending to use PGDs PGDs must be used only by named and authorised registered health professionals who can legally supply and/or administer medicines using a PGD, including: • chiropodists and podiatrists • dental hygienists • dental therapists • dieticians • midwives • nurses • occupational therapists • optometrists

	• orthoptists • orthotists and prosthetists • paramedics • pharmacists • physiotherapists • radiographers • speech and language therapists Registrants can only work to PGDs if they are signed off as being competent and approved to work to a defined PGD by their line manager. Individuals working to PGDs are required to: • Gain and maintain appropriate competencies to use the PGD as outlined in the PGD • Complete the agreed e-learning package on how to use PGDs • Sign relevant documentation to permit use of the PGD • Act in accordance with their professional code of practice • Ensure the most recent, in date, signed version of the PGD is used (i.e. accessed from the health board's internet site) • Highlight to their line manager if amendments to the PGD are required • Use the PGD according to the legal framework, Summary of Product Characteristics, relevant AWMSG/NICE guidance and any other guidance referenced in the PGD • Confirm that all stipulated training requirements are up to date (on an annual basis) by signing in the relevant box on their PADR (Performance Appraisal Pay Progression Form). See Appendix E • Make appropriate records
5 PGD Application, Consideration, Development, Approval, Authorisation, Implementation and Review/ Renewal Process See flowchart appendix F	
	5.1 Submit outline proposal to create a PGD The service lead should complete all sections of the 'Proposal for new, or updated PGD' form in Appendix D and submit this to the PGD subgroup via: info.medicinesmanagement.powys@wales.nhs.uk. This must provide evidence that other options have been considered and that the use of a PGD for administration and/or supply by approved practitioners will lead to improved patient care or organisational advantages without any reduction in patient safety or quality of care.

PGDs to support the national Immunisation program that already have a UKHSA template will not require an application form to be completed.

5.2 Determine whether a PGD is appropriate

PGDs must only be used where there is no other suitable mechanism for the administration or supply of the medicine within the legislation. Careful consideration should be given to opportunities within the care pathway to use a prescription or a written Patient Specific Direction and also consider the use of exemptions.

The preferred way for patients to receive the medicines they need is for a prescriber to provide care for an individual patient on a one-to-one basis. PGDs are NOT intended as a substitute for individual prescribing where there is an opportunity in the care pathway for a medicine or medicines to be prescribed i.e. where an episode of care is planned.

Upon receipt of a completed 'Proposal for new, or updated PGD' form, the PGD subgroup will consider whether a PGD is/remains the best method for medicines supply or administration in the given circumstances and consider any risk issues. They will use the SPS guide "To PGD or not to PGD – That is the question" to help with the decision-making process. When to use a PGD – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Other legal options for prescribing, supplying and/ or administering medicines	
Prescribing by medical or non-medical prescribers	Prescriber takes responsibility for clinical assessment of patient, establishing a diagnosis, the clinical management needed and prescribing
Supplementary prescribing	A voluntary partnership between a doctor or dentist and a supplementary prescriber, to prescribe within an agreed patient-specific clinical management plan with the patient's agreement
Medicines Act Exemptions (further information can be accessed via: https://www.sps.nhs.uk/wp-	There are some exemptions from medicines legislation, which are distinct from prescribing and arrangements for PGDs. A range of exemptions enable registered

content/uploads/2019/03/SPS-When-PGDs-should-not-be-used-V1.3-March-21.pdf)	chiropodists and podiatrists, midwives, orthoptists, paramedics and optometrists, and occupational health schemes to supply and/or administer particular medicines. There are parenteral medicines that can be administered in an emergency without the directions of a prescriber e.g. adrenaline (epinephrine).
Administration of P or GSL medicines or supply of a GSL medicine	A PGD is not necessary and should not be used where the medicine to be **administered** is a General Sales List (GSL) or Pharmacy (P) medicine or where the medicine to be **supplied** is a General Sales List (GSL) medicine. A locally approved protocol can be used in these situations. This may also apply to medical gases, as these are not commonly Prescription Only Medicines (POMs).
Supply of a P medicine / Self care	Consider referral to a registered pharmacy
Emergency supplies from a registered pharmacy	In an emergency and under certain conditions, a pharmacist can supply previously prescribed medicines, including Prescription Only Medicines (POM) to a patient without a prescription, if requested by a prescriber or the patient.

PGDs must only include medicines with a UK marketing authorisation or a temporary marketing authorisation under Regulation 174 of the HMR 2112 granted by the MHRA. Unlicensed medicines cannot be administered under a PGD, this also includes licensed medicines which are combined to make an unlicensed product. Medical devices and dressings do not have UK medicines authorisation and therefore cannot be supplied or administered under a PGD - a local protocol could be considered if appropriate.

	Medicines used outside the terms of their marketing authorisation (off label use) may be included in PGDs provided such use is clearly justified by current evidence/best clinical practice. Each PGD should clearly state when the product is being used outside the terms of the marketing authorisation and the documentation should include the reasons why such use is necessary. Black triangle medicines are those recently licensed and subject to special reporting arrangements for adverse reactions. They may be included in PGDs provided such use is clearly justified by current best clinical practice. The PGD must clearly indicate the black triangle status of the product. Black triangle vaccines used in immunisation programmes may be included in PGDs, provided they are used in accordance with the schedules recommended by the Joint Committee on Vaccination and Immunisation (JCVI). Ensure that a controlled drug is included in a PGD only when legally permitted and clearly justified by best clinical practice. See SPS website for further information. Antimicrobial resistance is a major public health concern and great care should be taken to ensure that the inclusion of antibiotics in a PGD is absolutely necessary and will not jeopardise strategies to combat increasing resistance. A local microbiologists should be one of the authors of PGDs that include antimicrobials. Do not include a medicine needing frequent dosage adjustments or frequent or complex monitoring in a PGD (e.g. anticoagulants or insulin). Do not use PGDs for managing long term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis. The risks and benefits of including more than one medicine in a PGD should be carefully considered on a case-by-case basis. The PGD subgroup will require assurance that there are arrangements in place for the security, storage and labelling of all medicines, along with a secure system for recording and monitoring how medicines are used including stock control. There will also need to be a system in place to record names of the health-care professionals supplying / administering the treatment, patient identifiers and the medicines provided. This information will be required for audit purposes. The PGD subgroup will consider the priority for development of the PGD against all PGDs in the current work program. They will also consider who needs to be involved in the development of the PGD.

	The requestor will be informed of the result within 5 working days of the PGD subgroup meeting date. If required, the requestor may be asked to submit further information. If the PGD subgroup does not grant approval to develop a PGD, the reason why, and where appropriate, alternative options will be suggested. If the proposer wishes to request an appeal of the decision, this must be submitted before the next PGD subgroup meeting, along with any additional supplementary information.
	5.3 Creation of PGD document When support for the proposal is given, a working group will be convened to develop a safe and evidence based document, using the PGD template (appendix B). A multidisciplinary group will develop the PGD, including a pharmacist, a doctor (or, if appropriate, a dentist), a member of the profession who will be using the PGD, and other healthcare professionals where appropriate. If necessary, the PGD subgroup may identify the most appropriate local clinical specialist with the relevant expertise to check the clinical accuracy and appropriateness of the PGD for the condition being treated. The PGD should be consistent with relevant SPCs. All PGDs for antibiotics must be developed in association with a Consultant Microbiologist. The lead author will check whether there is a national template that can be adapted for local use. Authors must be familiar with NICE PGDs MPG2 https://www.nice.org.uk/Guidance/MPG2 and consider their training and competency needs using the NICE Resource Toolkit: "Competency framework for people developing and/or reviewing and updating patient group directions" Tools and resources | Patient group directions | Guidance | NICE. Authors should complete the following e-learning programme, developed by SPS in partnership with HEE and UKHSA. Patient Group Directions - elearning for healthcare (e-lfh.org.uk) The PGD will have an expiry date no longer than 3 years from the authorisation date, and a review date no longer than 2 years 6 months from the development date.

	5.4 Approval of PGD content The PGD will be checked by Medicines Management Lead for PGDs, then emailed to the medicines management admin officer with a note that the PGD is ready for electronic organisational signatures (along with the quality checklist in Appendix C to ensure that all steps have been completed). All clinical signatories are required to check the content of the PGD before signing.

	5.5 Authorisation of PGD
	
	Legislation requires that a PGD must be signed by a doctor (or dentist) and a pharmacist and guidance states that they should be involved in the development of the PGD.
	
	Patient group directions (NICE guideline MPG2, 2017) recommends that, although not required by legislation, it is good practice for PGDs to be signed by representative/s of the registered health professional group (s) intended to supply and/or administer the medicine/s under the PGD. Where the representative of the registered health professional group/s is a pharmacist, it would be good practice to involve an additional pharmacist with expertise in the specific clinical area of practice who would use the PGD.
	
	Additionally the PGD must be authorised by a representative of the relevant authorising body.
	
	Electronic signatures on PGDs:
	The MHRA have confirmed that electronic systems can be used to authorise a PGD. Compliance with the following guidance, agreed with the MHRA and Department of Health and Social Care (DHSC), is required:
	
	• An electronic signature must be linked uniquely to an individual and under their sole control.
	• The standards laid down for electronic prescribing should be observed:
	  ○ uniquely linked to the signatory.
	  ○ capable of identifying the signatory.
	  ○ created using means that the signatory can maintain under his sole control.
	  ○ linked to the data to which it relates in such a manner that any subsequent change of data is detectable.

- The final document must be securely protected and the signature cannot be lifted out e.g. must be in a protected pdf format rather than a word processed document.
- The use of a JPEG or similar picture of a signature inserted into a file is unacceptable unless the document is securely protected to prevent the signature being removed or changed as described previously.
- The authorising organisation takes responsibility for the system in place and to ensure that lines of accountability and governance within the organisation or any partner organisation are documented.

-for organisational use

The PGD will be sent electronically to named signatories for approval. This includes:

- A doctor (or dentist if appropriate)
- A pharmacist
- A senior representative of the professional group that will be using the PGD (e.g. the Director of Nursing (or designated deputy) for PGDs to be used by nursing staff within PTHB)
- A governance lead to sign the PGD off on behalf of the organisation.

The medicines management admin officer will then cascade to the relevant lead users and publish the PGD on the PTHB internet page, with the review and expiry dates clearly stated.

- for practitioner use

Following organisational approval, the medicines management admin officer will email the head of the professional group to whom the PGD applies (contact details are found on the review and update form that is submitted along with the PGD), including a link to the new/updated PGD (see Appendix G: sample email). They will request that the authorising manager:

- Cascades the new or revised PGD to all relevant professionals intending to use the PGD, to be read, agreed, and signed to confirm that they will comply with any conditions imposed by the PGD document
- Scores through unused rows in the list of authorised practitioners to prevent practitioner additions post managerial authorisation
- Keeps a register of staff names competent to use the PGD in the clinical area
- Provides a signed copy of staff names competent to use the PGD to the Medicines Management PGD Admin at info.medicinesmanagement.powys@wales.nhs.uk.

- Ensures that the most up to date PGD is accessed via the internet when used in clinical practice
- Removes any superseded/ expired versions of the PGD from departments (working to PGDs that have been printed off is strongly discouraged due to the increased risk of accessing PGDs that have been superseded)

It is the responsibility of the individual working under the PGD and also the head of the professional group to whom the PGD applies to ensure that **all** training (including appropriate use of the PGD, awareness of pharmacological issues and professional accountability) has been undertaken before the PGD is used.

5.6 Implementation

Use of a PGD by an authorised practitioner

Before using a PGD, it is the responsibility of each practitioner to ensure they are authorised to work to the most up to date version of the PGD. They must also be competent to deal with each patient under the terms of the PGD and have completed any training outlined in the PGD. If the practitioner is in any doubt as to their competency they should not supply or administer in accordance with the PGD but should seek advice. A practitioner is only authorised to act under a PGD in the setting in which it applies. Supply and/or administration of a medicine must not be assigned or delegated to any other person under a PGD – the practitioner needs to complete the whole process from deciding to supply/administer to supplying/administering to the patient, regardless of their professional group or level of training.

When practicing under a PGD, a healthcare professional should:

- Ensure that they can determine that the patient meets the PGD inclusion criteria
- Ensure that they can determine no exclusion criteria apply
- Discuss alternative treatment options when appropriate
- Assess each patient's circumstances and preferences
- Recognise when signposting or referral to another HCP or service is needed, as specified in the PGD
- Understand relevant information about the medicines in the PGD such as administration techniques, action of the medicine in the body, dosage calculations, how to recognise and manage potential adverse effects, drug interactions, contraindications and cautions, storage requirements (especially cold chain management), follow up arrangements
- Counsel the patient or carer about the medicine.

5.7 Review

Clinical Audit of PGD use
Audit will be arranged by the service lead and performed annually, using the PGD department audit tool (Appendix H). The results will be reviewed by the service lead, who will provide recommendations for any areas of concern. The audit results will also form the basis of an ongoing training and development programme.

Medicines management will complete the governance audit tool (Appendix I) annually.

Patient safety incident
Any patient safety incidents relating to PGD use will be reported, collated and reviewed via the once for Wales Incident Reporting System.

5.8 Renewal

When a PGD reaches its review date, or requires updating for safety or service reasons, the service lead should submit a 'Proposal for new, or updated PGD' form (appendix D) to the PGD subgroup, who will consider if the PGD remains appropriate, and inform the requestor of the decision made, within 5 working days of the meeting date. When a PGD is within 6 months of its expiry date, the PGD administrator will send the service manager an electronic copy of the review form for completion.

After the expiry date a PGD is no longer valid unless it has been reapproved by the PGD subgroup following review by the authors. It must not legally be used as a framework for providing the medication – an alternative authorisation could be a prescription.

Unscheduled review and updating of a PGD will be started in response to:

- Legislative change
- Important new evidence or guidance which changes the PGD
- New information on safety of the medicine
- Changes to the SPC
- Local formulary changes
- Other relevant changes highlighted by users, service managers, or Medicines Management

Review should include:

- Re-assessment of the PGD as the best way to provide medicines access
- Review of clinical content, as for a new PGD, and review of usage
- Submission of the updated document and review findings to the PGD subgroup
- The PGD must be re-authorised in line with legislation

If a PGD needs amending before the designated review date, the Lead Author must discuss the proposed changes with the PGD subgroup. Minor changes may be agreed following discussion with the Chair of the PGD subgroup. More extensive changes may require discussion at a PGD subgroup meeting.

PGDs for National programmes will be automatically updated, they will not require a 'Proposal for new, or updated PGD' form to be submitted.

When a PGD has been approved for renewal, a working group will be convened to develop a safe and evidence-based document, using the PGD template (appendix B). The named lead author will conduct an appropriate literature search to identify new evidence. They will ensure this evidence is evaluated to assess its relevance and validity as detailed in the NICE Medicines Practice Guideline [MPG2] Patient Group Directions. They will add information to the 'change history' textbox on the PGD and complete a quality checklist (appendix C) to ensure that all steps have been completed.

When the PGD has been updated, authorised and signed off, the updated PGD will be published on the PTHB internet and the head of the professional group to whom the PGD applies will be informed via email that a new version of the PGD is available (see appendix G). The service lead will be required to ensure that all relevant documentation is updated, and the new version of the PGD is cascaded to all HCPs authorised to practice under the PGD to read, agree and sign. One signed copy should be retained by the authorising manager, and one copy sent to medicines management. Old copies must be archived after review and service leaders are responsible for ensuring only current copies are in use.

It is the responsibility of the individual working under the PGD and also the head of the professional group to whom the PGD applies to ensure that **all** training (including appropriate use of the PGD, awareness of pharmacological issues and professional accountability) has been undertaken before the PGD is used.

6 Monitoring Compliance, Audit & Review *(Description of how monitoring compliance with your policy will be undertaken)*

The procedure will be monitored through the receipt of PGD proposals and PGD documents by the PGD subgroup. The procedure, supporting processes and guidance will be reviewed and revised every three years, or earlier should audit results or changes to legislation / practice within PTHB indicate otherwise.

7 References / Bibliography *(If you include a PTHB document please ensure you have the document code and correct title)*

Acknowledgement: Elements of this document are based on work done in West Sussex and the Borders.

National Institute for Health and Care Excellence (2013 - updated 2017). Patient Group Directions. Medicines Practice Guideline [MPG2]. http://www.nice.org.uk/guidance/MPG2/chapter/1-Introduction

Human Medicines Regulations 2012. No 1916, Schedule 16, Part 4 http://www.legislation.gov.uk/uksi/2012/1916/schedule/16/part/4/made

"Patient group directions: who can use them" Updated 4 December 2017 Patient group directions: who can use them - GOV.UK (www.gov.uk)

Appendix A

PATIENT GROUP DIRECTION SUB-GROUP
TERMS OF REFERENCE

COMMITTEE	PATIENT GROUP DIRECTION SUB GROUP
PURPOSE	• To manage the process of developing, reviewing and quality assuring PGD/PSDs on behalf of the Health Board within agreed work plan timescales. • Ensure that all legislative, policy and patient safety/efficiency requirements regarding the use of PGD/PSDs within the Health Board are addressed. • Make recommendations to the Medicines Safety and Governance Group regarding the organisational requirements/approval of PGD/PSDs.
MEMBERSHIP	• Chief Pharmacist • Senior Pharmacist (PGD Lead) • Head of Community Services Pharmacy • Senior Nurse Medicines Management • Immunisation and Vaccination Coordinator. • Assistant Director Women and Childrens services. • Senior nurse MIU. • Medicines Management Administration support Additional members will be co-opted to support PGD development in their service (for example, radiography, dental, Bowel Screening Team) – relevant to PGDs being reviewed • Occupational Health Nurse or deputy • Assistant Director for Safeguarding • Head of Therapies or deputy • Head of Midwifery or deputy • Consultant microbiologist Secretarial support will be provided from within the Medicines Management team.
DUTIES	• Develop the rationale for PGDs, advise on the development of PGDs and assure the content of PGDs, prior to the approval of the final PGD by MSGG. • Ensure appropriate initial and ongoing training and competence assessments are developed and available to support the safe use of PGD/PSDs in the Health Board.

	• Develop and maintain a network across Health Board Healthcare Professionals and Services to ensure that appropriate advice concerning PGD/PSDs use is readily available to respond to patient or service needs. • Maintain a database of approved PGD/PSDs.
MEETINGS	Frequency: Meetings shall be held monthly. The meeting will be quorate when at least 3 members are present.
COMMUNICATION	Area prescribing Group
REPORTING	Area prescribing Group

All members on this group should assess their competency against the NICE PGD guidance toolkit resources here
Tools and resources | Patient group directions | Guidance | NICE

Appendix B: PGD template

Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This patient group direction (PGD) must only be used by registered health professionals 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. Health professionals should always access the PGD via the PTHB intranet to ensure that they are always working to the most up to date version

Patient Group Direction

for the supply and/or administration of

name of medicine

by registered health professionals

for

condition/situation/patient group

in Powys Teaching Health Board / Powys GP practice or community setting

Version number: number

Valid from:

Review date: (max 2 years 6 months from issue)

Expiry date:

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys
Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Change history

Version number	Change details	Date

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior Doctor Dr Kate Wright	Lead Doctor for PTHB		
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB		
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement		
Senior Representative of Professional Group using the PGD Claire Roche	Executive Director of Nursing and Midwifery for PTHB		

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

PGD adoption by the provider (signatures to be determined locally if PGD is to be used by an independent clinic that has a contract with PTHB)

Name	Job title and organisation	Signature	Date

Training and competency of registered health professionals	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • Paramedics and physiotherapists registered with Health & Care Professions Council (HCPC) • Pharmacists registered with the General Pharmaceutical Council (GPhC) All registered health professionals should: Have a current contract of employment with Powys Teaching Health Board OR Be working in premises specified in a Service Level Agreement (SLA) between the contractor and Powys Teaching Health Board The practitioners must also fulfil the training and additional requirements detailed below. Check Appendix A: Staff accredited to use the Patient Group Direction
Initial training	• The administration/supply of drug name and knowledge of its uses, contraindications and adverse effects. • The management and reporting of adverse drug reactions. Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions)

	• must have completed Patient Group Directions training available via ESR • must be familiar with the product(s) and alert to changes in the BNF/ Summary of Product Characteristics/ Immunisation Against Infectious Disease (the Green Book)/ national and local immunisation programmes as appropriate • must have undertaken training appropriate to this PGD as required by local policy and, if applicable, in line with the National Minimum Standards and Core Curriculum for Immunisation Training and online training available at: http://www.wales.nhs.uk/sitesplus/888/page/70069- please contact PTHB immunisation co-ordinator for further information • if applicable, must be competent to undertake immunisation and to discuss issues relating to immunisation • if applicable, must be competent in the handling and storage of vaccines, and management of the 'cold chain' • if applicable, must be familiar with the All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the recognition and management of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Life Support skills (Basic Life Support Skills are PTHB standard; Intermediate Life Support Skills for MIU). • must have access to the Patient Group Direction and associated online resources • Should fulfil any additional requirements defined by local policy • Must have undertaken and completed at least level 3 Safeguarding of Children, Young people and Vulnerable adults – Training and Competency passport, as applicable to the role (include in injury / potential abuse PGDs) **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**

Competency assessment	Evidence of ongoing PGD training to be submitted to Line Manager annually. Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. Practitioners must make a self-declaration of competency on PADR.
Ongoing training and competency	Updating at least every 2 years on the use of PGD's and medicine. Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, Life Support Skills, with evidence of appropriate Continued Professional Development (CPD). Compliance with all mandatory NHS training. Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and / or Public Health Wales and / or NHS Wales and other sources of medicines information. For vaccines, the most current national recommendations should be followed but a Patient Specific Direction may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**

Clinical condition or situation to which this PGD applies	
Clinical condition or situation to which this PGD applies	**It is the responsibility of the administering healthcare professional to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.**

Inclusion criteria	• Medical and drug history taken, no reason for exclusion • Include clinical criteria • Do you include pregnant/ breastfeeding women? • Define age range • Informed consent • NB Refer to PTHB Consent to Treatment and Examination Policy • In case of any doubt, contact medical team or emergency services Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below).
Exclusion criteria (Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Conditions outside of the clinical situations criteria • Patient or representative refuses treatment. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received (for further information on consent see Chapter 2 of the The Green Book). Refer to sections "action to be taken if the patient is excluded" and "action to be taken if the patient or carer declines treatment". • Known hypersensitivity to the active ingredient or to any component of the product • Consider specifying severity of renal/ hepatic impairment • Consider Pregnancy / breastfeeding • Age limits • Concurrent treatment / conditions
Cautions /reasons for seeking further advice from a prescriber	• Patients with complex multiple pathologies, polypharmacy or multiple allergies. • Must reflect local and / or national clinical guidelines • Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or

	homeopathic products. List clinically significant medicines interactions which do not exclude patients but where there may be action to be taken, eg. Closer monitoring (Refer to BNF/SPC for full list) • Enter specific details of action to be taken (eg. Advise diabetic patients that they may need to monitor blood glucose levels more frequently at the start of treatment) • Include anything else stated in the SPC that may give reason for caution for specific patients but does not exclude them (eg. Advice on breastfeeding) Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the Minor Injury Unit guidelines followed, along with PTHB safeguarding policies. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • To generic email address: PowysTHB.Safeguarding@wales.nhs.uk And • Central Safeguarding number: 01686 252806 • Out of hours: 08457 573818 Advice can also be sought from local Safeguarding leads: • CNS for Safeguarding North Powys Office: 01874 442082; mobile: 07964 132698 Or • CNS for Safeguarding South Powys Office: 01874 442098; mobile 07973 686520
Arrangements for referral for medical advice	Contact GP, paediatrician, or consultant in communicable disease control for advice, or refer to DGH if applicable. Document advice given.

Action to be taken if patient excluded	Record reason for exclusion and any action taken. Explain reason to patient / carer. If appropriate refer to GP / DGH /OOH, offer alternative management if appropriate. If relating to a vaccine: • Seek appropriate advice from the local screening team and Immunisation co-ordinator, local Health Protection Team, PTHB Infection Control Team or the individual's clinician when a vaccine is indicated outside the remit of this PGD rather than delay immunisation as a PSD may be indicated • The risk to the individual of not being immunised must be taken into account • If vaccination is deferred, advise patient/ parent or guardian, and arrange recall for later vaccination
Action to be taken if patient declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for administration and recorded appropriately. The patient information leaflet should be available to inform consent. Where a person lacks capacity, in accordance with the Mental Capacity Act 2005, a decision to treat may be made in the patients best interests. For further information on consent see Chapter 2 of The Green Book. Explain consequences of refusing treatment. Make patient or their representative aware of alternative sources of treatment (DGH or GP as appropriate). Offer alternative management if appropriate. Document refusal and any advice given. Complete a Discharge Against Advice Form if appropriate. Inform or refer to GP/follow local procedures as appropriate. Follow local policy for deferred consent. Inform child health if appropriate – if any vaccination is declined for a child under 18, child health must be informed and appropriate form completed.

	Where appropriate, complete the letter on the WPAS system and send to the GP.

Details of the medicine	
Name, form and strength of medicine ***Include ▼for black triangle medicines***	
Legal category	
Indicate any off-label use (if relevant)	• Add reference to support off-label use, if appropriate For vaccines: • Vaccine should be stored according to the conditions detailed in the storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines and any relevant local policies / guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. Where the medication/ vaccine is recommended off-label consider, as part of the consent process, informing the individual/ patient/ carer that it is being offered in accordance with national guidance/ justified by best clinical practice but that this is outside the product license.

Route/method of administration	For vaccines: • When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. • For individuals with a bleeding disorder, vaccines normally given by an IM route should be given in accordance with the recommendations in the Green Book Chapter 4. Check expiry date and correct product has been chosen.
Dose and frequency	• State in full, do not use abbreviations • Can specify a single dose or a dose range up to a maximum (the clinical criteria for selecting a dose within the range would need to be specified) • If supplying medication to patients, the dose should be expressed in the same way as on the label of medicine • State practical information, such as "dissolve in water" or "after food"
Quantity to be administered and/or supplied	

Supplies	For vaccines: Centrally purchased vaccines for the National Immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for the school programmes are ordered as per local policy and arrangement. Contact PTHB Medicines Management Department for details. Vaccines for the national childhood immunisation programme are provided free of charge. Vaccines for private prescriptions, occupational health use or travel are excluded from this PGD. Vaccine is not provided free of charge and should be ordered from the manufacturers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines**.**
Maximum or minimum treatment period	This may be specific, for example, five days for an antibiotic or no more than x number of days for an analgesic. Consider practical issues relating to dose and quantity, such as rounding up or down to nearest appropriate pack size if required and making sure appropriately labelled packs are available for the duration of treatment.

Storage	For vaccines: Store at +2°C to +8°C in a dedicated vaccines refrigerator. For transportation a validated cool box with minimum/ maximum thermometers or data-loggers should be used. Store in original packaging to protect from light. Do not freeze. If the vaccine has been frozen, it should be discarded and a report completed on Immform. Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage (see All Wales Advisory document on Ordering Storage and Handling of Vaccines and green Book chapter 3.). In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to "Vaccine Incident guidance: responding to vaccine errors" Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk), and via the Once for Wales Reporting System.
Disposal	For vaccines: Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the Technical Memorandum 07 01: Safe management of healthcare waste (Department of Health, 2021) and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.

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

Identification and management of adverse reactions	• Use bullet points to clearly list the most common side-effects and any potential serious symptoms the practitioner or patient needs to look out for.
	• Refer to SPC/*BNF* and any Medicines and Healthcare products Regulatory Agency (MHRA) advice.
	• Add in order of frequency, eg, common (more than 1 in 100 people).
	
	This list is not exhaustive. Refer to BNF or SPC via medicines.org.uk for complete list.
	Report any suspected adverse reactions to a doctor.
	
	You can add additional action to be taken in the event of unexpected adverse reactions, eg:
	• if necessary seek appropriate emergency advice and assistance
	
	In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use:
	Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a telephone must be available for immediate use.
	In case of anaphylaxis:-
	• Refer to adrenaline (epinephrine) PGD and anaphylaxis policy
	  • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E
	  • Ensure reaction is fully documented in patient notes
	  • Ensure all patient records are marked **ALLERGIC TO medicine**.
	  • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers
	Report via Datix system

Reporting of adverse reactions	Healthcare professionals and individuals/ parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme at: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication/ vaccine should be reported. If a black triangle medicine/ vaccine, report all suspected reactions. Guidance on the yellow card system is available at the back of the BNF, or using the above link. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. • All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System
Special considerations / additional information	Ensure there is immediate access to resuscitation equipment including adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.

Records to be kept	Record consultation details as required by local procedures. In addition, record: • Name, address and DOB of patient • Name and address of GP • Medical and drug history taken, including any allergies and previous adverse events. Measure and record weight of child where appropriate. • Any reasons for exclusion or referral, including actions taken. • Any advice received from medical cover and advice given to patient/ carer. • If the patient has refused treatment, and any advice given in this circumstance. • That valid informed patient consent to treatment was obtained, or a decision to treat made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent if appropriate. • That the drug is being supplied/ administered in accordance with a PGD- record PGD title, number and version. • Record any advice given to the individual For administration, record: • Date and time of administration. • Name, form, strength and dose of drug administered. • Route of administration • If a vaccine is administered, record volume administered and anatomical site of injection • If a vaccine, record product name, manufacturer and batch number • The local Child Health Records Department must be notified using the appropriate documentation/ pathway as required by any local or contractual agreement. If a vaccine is administered to a child up to 18 years of age, forward a notification of vaccination given to Child Health Department (based in Brecon hospital for under 5 years and Llandrindod hospital for school age)

	• Where a vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. • Expiry date(s) • Details of any adverse reactions and actions taken. For <u>supply</u>, record • Date and time of supply • Name, form, strength, dose, route, frequency and quantity of medication supplied • Expiry date of medicine supplied The record must include the printed name and signature of the healthcare professional responsible for administration/supply. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should be kept for audit purposes in accordance with local policy.

Patient information

Written/verbal information to be given to patient or carer	• Provide patient information leaflet. Draw patient's or representative's attention to the label and patient information leaflet. Give appropriate advice if medication is used off-label. • Further information for printing and website links suitable for patients can be found on the Public Health Wales intranet site: Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS direct Wales and Health Information Resources
Follow-up advice to be given to patient or carer	Inform individual of possible side effects and their management. Advise them to seek medical advice immediately if they have any unexpected reaction or other cause for concern. Contact GP via surgery or emergency on call service. When applicable, advise the patient / carer when the subsequent dose is due. When administration is postponed advise the individual / carer when to return for vaccination.

Key references

1.

Appendix A Staff accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP Practice for the named healthcare professionals below who have signed the PGD to work under it.

Practitioner: *By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct*.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Name of health professional	**Signature**	**Senior representative authorising health professional**	**Date**

The authorising manager should retain a copy of the list and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU for audit purposes.

The healthcare professional should retain a copy of the document after signing.

Appendix C: Quality checklist

Powys Teaching Health Board: PGD Review and Update Form

PGD Title	
PGD Ref No	
PGD Issue date	
PGD Planned Review Date	
Name of Lead Author for Review and Update	
Date Review and Update Commenced	
Who this PGD should be sent to when completed	

Multidisciplinary PGD working group		
Name	Role	Date Contacted and Comments

Does the PGD remain the most appropriate option to deliver the service?

(Consider local monitoring and evaluations, frequency of use of the PGD, views of health professionals working under the PGD and views of relevant stakeholders, such as patients or their carers)

Ref NICE Guideline-patient Group Directions 2013

"The Health Service Circular (HSC 2000/026) states that 'the majority of clinical care should be provided on an individual, patient-specific basis'. The GDG (Guidance Development Group) agreed that prescribing or a PSD remains the preferred option for the majority of care. Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care without compromising patient safety, and there are clear governance arrangements and accountability.

The GDG agreed that the purpose of using a PGD was to:

- *deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety*
- *offer a significant advantage to patient care by improving access to appropriate medicines*

- *provide equity in the availability and quality of services when other options for supplying and/or administering medicines are not available*
- *provide a safe legal framework to protect patients*
- *reduce delays in treatment*
- *maximise the use of the skills of a range of health professionals*."

Review and update

Literature Search
(Conduct an appropriate literature search to identify new evidence. Ensure that this evidence is evaluated to assess its relevance and validity)

Reference Source	Amendments identified? Y/N	Date Checked	Signature
Public Health Wales templates http://www.immunisation.wales.nhs.uk/pgds-psds (list resources used)			
BNF *(state date accessed online)* • British National Formulary (BNF); accessed online • British National Formulary for Children (cBNF) – accessed			
NICE Clinical guidance (state details)			
• Summary of Product Characteristics (SPC)-(for various brands if applicable) available at www.emc.medicines.org.uk • Patient information leaflet (PIL): available at www.emc.medicines.org.uk; last updated			
Google search of relevant PGD (state details) NB- Use for ideas not as a reference source			

Literature Search (2)
(Conduct an appropriate literature search to identify new evidence. Ensure that this evidence is evaluated to assess its relevance and validity)

Reference Source	Amendments identified? Y/N	Date Checked	Signature
Immunisation Against Infectious Disease (The Green Book) HMSO https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book (list chapters consulted and date of last update)			
Powys Teaching Health Board, Infection Control Guidelines (state date of document)			
Powys LHB Anaphylaxis Policy (state date of document)			
UK Guidance on Best Practice in Vaccine Administration (state date of document)			
National Minimum Standards and core curriculum for Immunisation Training for registered health care professionals (state date of document) https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners			
Search of Chief Medical Officers letters http://gov.wales/topics/health/cmo/publications/?lang=en			

Literature Search (3)
(Conduct an appropriate literature search to identify new evidence. Ensure that this evidence is evaluated to assess its relevance and validity)

Reference Source	Amendments identified? Y/N	Date Checked	Signature
AWMSG recommendations http://www.awmsg.org/awmsgonline			
Chief Medical Officer Updates http://gov.wales/topics/health/cmo/updates/?lang=en			
PGD proposal form completed by user/s			
	Comments		
Expiry date of PGD (*Determine the expiry date for an individual PGD on a case-by-case basis, with patient safety paramount. Ensure that this date does not exceed 3 years from the date the PGD was authorised)*			

Please note The Health Service Circular (HSC 2000/026) states that 'generally, a direction should be reviewed every two years'.	
Identify personnel responsible for sign-off, for example **Lead Doctor** **Lead Pharmacist** **Director of Nursing** **Clinical Governance Lead (on behalf of the organisation)** **Lead GP Partner (if used in the GP setting)**	Senior doctor Dr Kate Wright Chief Pharmacist Jacqui Seaton Senior representative of professional group using the PGD Claire Roche Clinical Governance Lead Amanda Edwards

Revised PGD	Date Checked	Signature
Ensure page 2 of **PGD Review and Update Form** has been FULLY completed		
Updates made to original PGD clearly identifying changes- Tracked changes document		
Final check that no changes have been made to SPC used immediately prior to passing to the medicines management admin officer for sign-off		
Ensure the PGD contains all information required by legislation:- 1. The period during which the direction is to have effect. 2. The description or class of medicinal product to which the direction relates. 3. The clinical situations which medicinal products of that description or class may be used to treat or manage in any form. 4. Whether there are any restrictions on the quantity of medicinal product that may be sold or supplied on any one occasion and, if so, what restrictions. 5. The clinical criteria under which a person is to be eligible for treatment. 6. Whether any class of person is excluded from treatment under the direction and, if so, what class of person 7. Whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances. 8. The pharmaceutical form or forms in which medicinal products of that description or class are to be administered. 9. The strength, or maximum strength, at which medicinal products of that description or class are to be administered 10. The applicable dosage or maximum dosage. 11. The route of administration.		

12. The frequency of administration. 13. Any minimum or maximum period of administration applicable to medicinal products of that description or class. 14. Whether there are any relevant warnings to note and, if so, what warnings. 15. Whether there is any follow up action to be taken in any circumstances and, if so, what action and in what circumstances. 16. Arrangements for referral for medical advice. 17. Details of the records to be kept of the supply, or the administration, of products under the direction.		
Check:- • A manufacturer's patient information leaflet must be provided to patients who have a medicine supplied under a PGD. This is not required by legislation when a medicine is administered. • PGDs must only include medicines with a UK marketing authorisation, in line with legislation. • Ensure that off-label use of a licensed medicine is included in a PGD only when clearly justified by best clinical practice. Clearly state that the medicine is being used outside the terms of the marketing authorisation on the PGD. Consider informing the patient or their carer that the use is off-label, in line with General Medical Council guidance. • Ensure that a black triangle medicine is included in a PGD only when clearly justified by best clinical practice. Clearly indicate the black triangle status on the PGD. • Ensure that a controlled drug is included in a PGD only when legally permitted and clearly justified by best clinical practice		

Revised PGD	Date Checked	Signature
Check • Do not jeopardise local and national strategies to combat antimicrobial resistance and healthcare-associated infections. Ensure that an antimicrobial is included in a PGD only when: ▪ clinically essential and clearly justified by best clinical practice, such as Public Health England guidance[4] ▪ a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented ▪ use of the PGD is monitored and reviewed regularly • Do not include a medicine needing frequent dosage adjustments or frequent or complex monitoring in a PGD (for example, anticoagulants or insulin). • Do not make dose adjustments to a medicine supplied under a PGD when the medicine is already in the patient's possession. • Carefully consider the risks and benefits of including more than 1 medicine in a PGD on a case-by-case basis. Ensure all legal requirements are met for each medicine. • Do not use PGDs for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.		

Appendix D

Patient Group Direction Proposal Template version 1 July 2020	GIG CYMRU NHS WALES Bwrdd Iechyd Addysgu Powys Powys Teaching Health Board

Proposal for new, or updated PGD

This form should be submitted to the PGD Approval Group through the Medicines Management team by e-mailing it to info.medicinesmanagement.powys@wales.nhs.uk

Before submitting the proposal, the rationale and service implications must be discussed with the relevant professional manager or service lead. The "To PGD or not to PGD" tool[i] should be used support decision making on whether a PGD is appropriate. The aim of this tool is to ensure that patients receive safe and appropriate care and timely access to medicines, in line with legislation.

The proposal must provide evidence that the provision for the administration and/or supply of a medicine by approved practitioners under a PGD will lead to improved patient care or organisational advantages without any reduction in patient safety or quality of care. The PGD Approval Group will consider whether a PGD is the best method for medicines supply or administration in the given circumstances and consider any risk issues or provisos.

Submissions will be discussed and reviewed at the next available PGD Approval Group meeting. A decision on the outcome will be communicated to the proposer within 5 working days of this meeting.

Please note that approval for PGD development will not be granted where exemptions in legislation allow for medicines to be supplied and/or administered without the need for a PGD[ii].

If approval is given to the development of the proposed PGD a PGD Working Group will be established and a nominated pharmacy professional will lead the PGD development, in collaboration with the professional group that will be working to the PGD.

Proposal Form template (on next page) **ALL sections of this form must be completed before submission (forms with blank sections will be returned for completion)**:

Proposed content of PGD

What medicine(s) do you wish to administer and / or supply?

List the name, form and strength of each medicine, including dosage, route, frequency, duration of treatment and quantity. PGDs are not permitted for unlicensed medicines, however off-label use of licensed medicines is permissible providing good evidence for unlicensed use is referenced.

What indication / condition will the medicines be given for?

Does the medicine have a licence for the proposed indication / age group (if to be given to children)?
If the medicine is not licensed for the proposed indication / age group, state why no licensed alternative can be used and provide evidence source for the off-label use.

How will patients be identified?

List clinical criteria

Are there any patients' characteristics that should exclude them from medication provision under this PGD?

Will patients be given a supply to take home?

If a supply will be given, please state duration of treatment / pack size. When completing this section please consider the self-care agenda and whether it would be appropriate to ask the patient to purchase the medicine rather than making a supply under a PGD.

Potential risks to patient safety?

How will supply be obtained?

Where from? Cold chain required?

How will supply and / or administration be recorded?

What records will be kept?

Is supply and / or administration possible through patient specific process

The majority of clinical care involving supplying and/or administering medicines should be done on an individual patient-specific basis (i.e. using a prescription or Patient Specific Direction (PSD)).

PGDs should only be developed after careful consideration of the legal classification of the medication and all the potential methods of supply and/or administration of medicines, including prescribing by doctors, dentists or independent or supplementary prescribers and consideration of the legal exemptions that may be applicable.

Is provision of the medicine possible through a protocol

Medicines that are classified as Pharmacy (P) or General Sales List (GSL) medicines can be **administered** without the need for a PGD or PSD, and pre-packed GSL medicines can be **supplied** without a PGD. The supply of a P medicine requires a PGD or PSD unless an exemption applies.

Have all other options been considered e.g non-therapeutic options, or self-care.

For requests for a PGD renewal, please provide audit or usage data around the current PGD version for the last 3 months

Medicines storage and security

What facilities are / will be available for the storage of the medicines?

Special consideration will need to be given to refrigerated items or controlled drugs.

If medicines are to be supplied to patients to take away, how will supply be monitored?

Medicines must be pre-labelled for issue to patients and staff are required to follow standard pre-pack issue procedures.

Staff and training

In which department(s) or site(s) will the PGD(s) be used?

Could the PGD be relevant to other services within the Health Board? If so, has there been collaboration with these other areas?

Which staff groups will work under the PGD?

Is the service currently utilising PGDs? If so, are all staff trained in PGD use?

What additional training and / or competencies will be needed specific to this PGD?

Who will provide this training and assess competency?

Will practitioners have access to the PTHB intranet/internet to ensure that they are working to the most up to date PGD document(s)?

Service provision

How is this service provided now?

Describe the current process for medicines administration and / or supply.

Why is a PGD the most appropriate means of providing the service?

Explain why the PGD is needed and why other methods, such as obtaining individual prescriptions from doctors or non-medical prescribers, are not appropriate. What are the expected benefits of a PGD?

Has this service development been included in the IMTP for your area, what are future plans for delivery of this service?

E.g development of Non-Medical Prescribers

Authorship and approval

Have you identified who needs to be involved in the development of this PGD?

An expert prescriber may be needed and should be consulted early on in the production process.

Who will authorise individuals within the service to work under the PGD?

Do you have approval from your Head of Service, Department Lead (or equivalent) to submit a request to support the development of a PGD?

Changes in the provision of clinical services require the approval of the Head of service/Department Lead (or equivalent). Other responsibilities are outlined in the PtHB PGD Procedure.
Please provide a name and job title and their signature?

Audit and review

How will the PGD be audited?

How will the use of the PGD be documented to support audit? Regular data on the frequency of use of the PGD will be requested?

Proposed by:			
Name	**Job title**	**Signature**	**Date**
Sponsored by			

Latest version should be accessible from :
http://nww.powysthb.wales.nhs.uk/medicines-management-pgds-psds-and-ptls

[i] TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations. SPS PGDs (England) January 2018.
[ii] When Patient Group Directions (PGDs) are not required: Guidance on when PGDs should not be used and advice on alternative mechanisms for supply and administration of medicines. Specialist Pharmacy Service. February 2020

Appendix E

Practitioners using PGDs: Training and competency

Practitioners should complete the following e-learning programme, developed by SPS in partnership with HEE and UKHSA. Patient Group Directions - elearning for healthcare (e-lfh.org.uk)

Before using a PGD, it is the responsibility of each practitioner to ensure they have undertaken the necessary initial training and CPD and are competent to deal with each patient under the terms of the PGD. They must have read and understood the context and content of the PGD. They must have been assessed as competent, signed the appropriate documentation and been authorised to practice by the provider organisation. If the practitioner is in any doubt as to their competency they should not supply or administer in accordance with the PGD but should seek advice. A practitioner is not authorised to act under a PGD in an area of practice to which it does not apply.

Health professionals must ensure they can determine that the patient meets the inclusion criteria, and that no exclusion criteria apply. Health professionals must assess each individual patient's circumstances and preferences and be able to discuss alternative options for treating the patient's condition, where appropriate. Supply and/or administration of a medicine must not be assigned or delegated to any other person under a PGD, regardless of their professional group or level of training.

The practitioners working under the PGDs must have access to the approved PGDs and any related guidance within their clinical areas. The CSM, service manager or equivalent, is responsible for ensuring that the most up-to-date PGDs are used and that a register of staff names competent to use the PGD is kept in the clinical area.

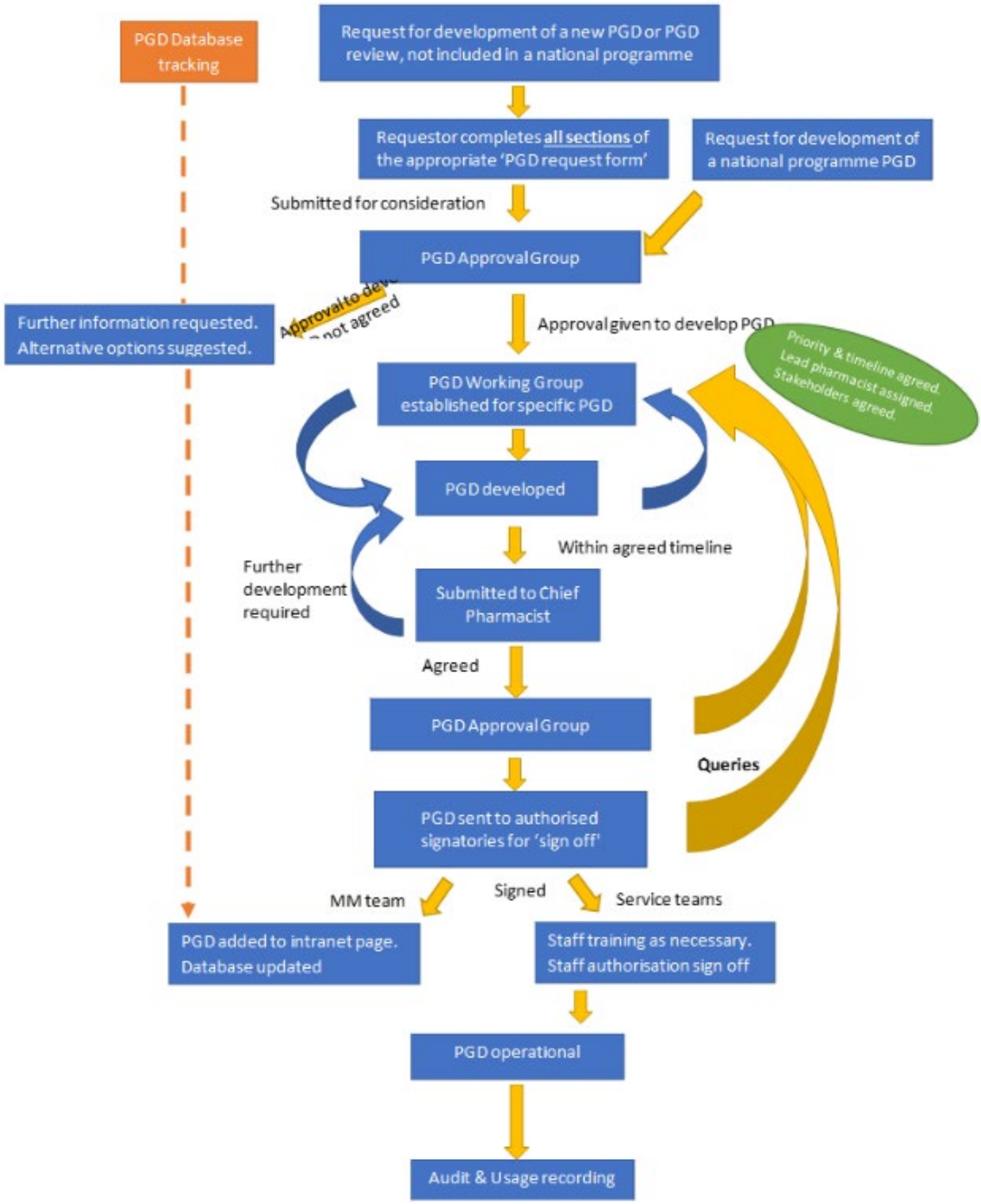
It is important that the use of any medicine is consistent with the Summary of Product Characteristics (SPC) for the relevant product and any relevant guidance from NICE.

A record of the supply or administration of medicines under a PGD must be made for every patient. Authors may decide where this record should be made. These records must include relevant details such as the following, that will be defined within the PGD:
Name, address and date of birth, consent to treatment, known medicine allergies, current medicines taken, any relevant contraindications or exclusion criteria, name of any doctor or

pharmacist consulted, any advice given by Doctor or pharmacist, approved name of the medicine to be administered and/or supplied, details of the dose, frequency of the supply (if appropriate), quantity, route and site (if by injection) of administration (always record the expiry, and, if recommended by relevant national guidance e.g. vaccines, batch number), date and time of administration and/or supply, name and signature of the practitioner, a statement that supply or administration is by using a PGD- record version number of PGD.

Any medicines supplied under a PGD must be supplied as pre-packs (including a patient information leaflet), using a secure system for recording and monitoring medicines use, from which it should be possible to reconcile incoming stock and outgoings on a patient by patient basis.

Appendix F: Flowchart



Appendix G: email that is sent to the service lead when PGD is completed/ reviewed

Dear _____

PGD_____

Please use the following link to access the PGD for _____which has now been approved for local use. I would be grateful if you could cascade this link to all relevant staff.

Insert Link to the PGD

Although the PGD may need to printed off for the purpose of signing, when used in clinical practice the PGD should always be accessed via the intranet to ensure that the most up to date version is used. Staff members are responsible for ensuring that they are authorised to work to the most up to date version.

Please note:
It is the responsibility of the head of the professional group to whom the PGD applies to ensure that **all** training (including appropriate use of the PGD, awareness of pharmacological issues and professional accountability) has been undertaken before the PGD is used.

The authorising manager **MUST** ensure that **each new or revised** PGD is read, agreed and signed by all Health Care Professionals it applies to. The authorising manager must score through unused rows in the list of authorised practitioners to prevent practitioner additions post managerial authorisation. Superseded/ expired versions of the PGD must be removed from departments (NB: working to PGDs that have been printed off is strongly discouraged due to the increased risk of accessing PGDs that have been superseded).

The authorising manager should retain a copy of the list and a copy must be sent to the Medicines Management Team at the address below, for audit purposes.

Thank you
Medicines Management Admin Officer

Appendix H:
PGD department audit tool (adapted from SPS)

Please answer all 5 questions to facilitate prompt review and renewal of PGDs.

Department: **Completed by (name and position):**

Date completed:

1. Please list all the PGDs that have been used in your clinical area in the last 12 months (list PGD reference number and name). Please continue on a separate sheet if necessary.	
Reference number:	Name:

2. For each PGD listed in question 1, please provide the following information:

	Write the PGD reference number(s) in the row below, then answer the questions for each PGD					
PGD reference no.						
Number of times the PGD has been used in the last 12 months						
Do staff always have access to a copy of the latest version of the PGD they are working under available for reference at the time of the consultation?						
How is the PGD accessed? (write **P** for paper copy, **E** for electronic copy saved to computer, **W** for via the Health Boards' website, or please specify if accessed in another way)						
Have all staff working under the PGD signed the latest version of that PGD?						
Are all staff working under the PGD competent to work under that PGD? (Either signed off by their senior clinician/manager or self-certified)?						
Are all staff authorised to work under the PGD employed as one of the registered health professions listed in the PGD?						
Is there an up-to-date list held within the service, of all staff authorised to work under each PGD in use?						
Have all staff completed the necessary training and						

continuing professional development specified in the PGDs they are authorised to work under?						
Is there an up-to-date record within the service of all staff who have attended any required specific PGD training?						

3. Please answer the following questions for **each PGD**, based on your review of a sample of 5 clinical records for patients where the PGD has been used (if the PGD has been used less than 5 times, then please review the clinical records for all patients)

PGD reference number:	Clinical record 1	Clinical record 2	Clinical record 3	Clinical record 4	Clinical record 5
Is the clinical indication (listed in the PGDs inclusion criteria) stated in the patient's record?					
Is there a record of all the following: patients full name, date of birth, registered GP (where applicable)? **If not**, please indicate which **have** been recorded					
Is there a statement in the patient's record that supply and/or administration of the medicine was made using a PGD?					
Is there a record of any written or verbal information/advice that was given to the patient when supplying/administering any medicine under any given PGD?					
Is there a record of the patient consent?					
If the patient was excluded, is the reason recorded?					
If the patient was excluded, is there a record of the action taken?					
If the patient refused treatment, is there a record					

of advice provided on alternatives/ risk of no treatment?					
Is there a register or other record of stock received and issued to patients under this PGD?					
Does the patient record contain details of the medicine supplied or administered (name, strength, dose, quantity, route)?					
For vaccines, was both the batch number and expiry date recorded?					
Was the date of supply or administration recorded?					

PGD reference number:	Clinical record 1	Clinical record 2	Clinical record 3	Clinical record 4	Clinical record 5
Is the clinical indication (listed in the PGDs inclusion criteria) stated in the patient's record?					
Is there a record of all the following: patients full name, date of birth, registered GP (where applicable)? **If not**, please indicate which **have** been recorded					
Is there a statement in the patient's record that supply and/or administration of the medicine was made using a PGD?					
Is there a record of any written or verbal information/advice that was given to the patient when supplying/administering any medicine under any given PGD?					
Is there a record of the patient consent?					
If the patient was excluded, is the reason recorded?					

If the patient was excluded, is there a record of the action taken?					
If the patient refused treatment, is there a record of advice provided on alternatives/ risk of no treatment?					
Is there a register or other record of stock received and issued to patients under this PGD?					
Does the patient record contain details of the medicine supplied or administered (name, strength, dose, quantity, route)?					
For vaccines, was both the batch number and expiry date recorded?					
Was the date of supply or administration recorded?					

PGD reference number:	Clinical record 1	Clinical record 2	Clinical record 3	Clinical record 4	Clinical record 5
Is the clinical indication (listed in the PGDs inclusion criteria) stated in the patient's record?					
Is there a record of all the following: patients full name, date of birth, registered GP (where applicable)? **If not**, please indicate which **have** been recorded					
Is there a statement in the patient's record that supply and/or administration of the medicine was made using a PGD?					
Is there a record of any written or verbal information/advice that was given to the patient when supplying/administering					

any medicine under any given PGD?					
Is there a record of the patient consent?					
If the patient was excluded, is the reason recorded?					
If the patient was excluded, is there a record of the action taken?					
If the patient refused treatment, is there a record of advice provided on alternatives/ risk of no treatment?					
Is there a register or other record of stock received and issued to patients under this PGD?					
Does the patient record contain details of the medicine supplied or administered (name, strength, dose, quantity, route)?					
For vaccines, was both the batch number and expiry date recorded?					
Was the date of supply or administration recorded?					

PGD reference number:	Clinical record 1	Clinical record 2	Clinical record 3	Clinical record 4	Clinical record 5
Is the clinical indication (listed in the PGDs inclusion criteria) stated in the patient's record?					
Is there a record of all the following: patients full name, date of birth, registered GP (where applicable)? **If not**, please indicate which **have** been recorded					
Is there a statement in the patient's record that supply and/or administration of the medicine was made using a PGD?					

Is there a record of any written or verbal information/advice that was given to the patient when supplying/administering any medicine under any given PGD?					
Is there a record of the patient consent?					
If the patient was excluded, is the reason recorded?					
If the patient was excluded, is there a record of the action taken?					
If the patient refused treatment, is there a record of advice provided on alternatives/ risk of no treatment?					
Is there a register or other record of stock received and issued to patients under this PGD?					
Does the patient record contain details of the medicine supplied or administered (name, strength, dose, quantity, route)?					
For vaccines, was both the batch number and expiry date recorded?					
Was the date of supply or administration recorded?					

PGD reference number:	Clinical record 1	Clinical record 2	Clinical record 3	Clinical record 4	Clinical record 5
Is the clinical indication (listed in the PGDs inclusion criteria) stated in the patient's record?					
Is there a record of all the following: patients full name, date of birth, registered GP (where applicable)? **If not**, please indicate which **have** been recorded					

Is there a statement in the patient's record that supply and/or administration of the medicine was made using a PGD?					
Is there a record of any written or verbal information/advice that was given to the patient when supplying/administering any medicine under any given PGD?					
Is there a record of the patient consent?					
If the patient was excluded, is the reason recorded?					
If the patient was excluded, is there a record of the action taken?					
If the patient refused treatment, is there a record of advice provided on alternatives/ risk of no treatment?					
Is there a register or other record of stock received and issued to patients under this PGD?					
Does the patient record contain details of the medicine supplied or administered (name, strength, dose, quantity, route)?					
For vaccines, was both the batch number and expiry date recorded?					
Was the date of supply or administration recorded?					

PGD reference number:	Clinical record 1	Clinical record 2	Clinical record 3	Clinical record 4	Clinical record 5
Is the clinical indication (listed in the PGDs inclusion criteria) stated in the patient's record?					
Is there a record of all the following: patients full					

name, date of birth, registered GP (where applicable)? **If not**, please indicate which **have** been recorded					
Is there a statement in the patient's record that supply and/or administration of the medicine was made using a PGD?					
Is there a record of any written or verbal information/advice that was given to the patient when supplying/administering any medicine under any given PGD?					
Is there a record of the patient consent?					
If the patient was excluded, is the reason recorded?					
If the patient was excluded, is there a record of the action taken?					
If the patient refused treatment, is there a record of advice provided on alternatives/ risk of no treatment?					
Is there a register or other record of stock received and issued to patients under this PGD?					
Does the patient record contain details of the medicine supplied or administered (name, strength, dose, quantity, route)?					
For vaccines, was both the batch number and expiry date recorded?					
Was the date of supply or administration recorded?					

4. Are you aware of the use of any PGDs that have been developed outside of PTHB (for example, by a visiting practitioner, working under an SLA)

Yes / No

If yes, please give details:

5. Could you please state the number of non-medical prescribers working in your clinical area:

6. Could you please record the number of non-medical prescribers currently being trained in your clinical area:

Thank you for completing this audit- please email the completed form back to medicines management via:
info.medicinesmanagement.powys@wales.nhs.uk

Appendix I:

Governance audit tool: to be completed by Medicines Management (adapted from SPS)

Questions		Yes / No
1	Does the organisation have a PGD oversight group or similar?	
2	Are there records of terms of reference and minutes or notes by the group?	
3	Does the PGD oversight group or similar report into the organisation's clinical governance framework?	
4	Is there a current PGD policy?	
5	Does the current PGD policy include:	
5.1	• Considering the need for a PGD and obtaining agreement to develop a PGD	
5.2	• Developing and submitting a PGD including review of need for a PGD/ alternative mechanisms for administration/ supply	
5.3	• Authorising a PGD	
5.4	• Authorising named, registered health professionals to use a PGD	
5.5	• Training and competency	
5.6	• Audit, review and updating a PGD (including in life amendments and review of continued need for PGD)	
6	Is there a current and up-to-date list of all the PGDs in use within the organisation, including their review/expiry dates?	
7	Are all master authorised copies of all current PGDs held by the organisation (and where applicable the authorising commissioning organisation)?	
8	Are master copies of all expired versions of the PGDs held by the organisation (and where applicable the authorising commissioning organisation)?	
9	Is there an audit timetable for PGD audits (Appendix H) within each service?	
10	Are there any PGD related risks on the risk register?	
11	Number of PGDs currently in use within the organisation	
12	Do all medicines administered/supplied under a PGD have a UK Marketing Authorisation?	
13	Have all medicines which have a current "black triangle" status been clearly indicated on the relevant PGD?	
14	Is any off-label use clearly indicated on the relevant PGD?	
15	Is there evidence that all antimicrobial PGDs have had an input from the local microbiology specialist?	
16	Are there any PGDs in the trust that have been developed and used for the management of long-term conditions?	
17	Are any of the medications included in PGDs for **administration** of a GSL, P or medicines exempt under schedule 17 or 19 the HMR 2012?	

18	Are any of the medications included in PGDs for **supply** of a GSL, (P if only from a registered pharmacy) or medicines exempt under schedule 17 the HMR 2012?	
19	Are all medicine packs supplied in their original pack (or a licensed pre pack) when supplied under a PGD? (i.e. packs not split)	
20	Do all medicines supplied under any PGD have appropriate instruction labels on the pack including the Trust's name, address and contact details?	