NHS
North East and North Cumbria

Corporate	ICBP032 Policy for the Development and Authorisation of Patient Group Directions (PGDs)

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3	July 2025	July 2027

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Approved By:	Executive Committee

EQUALITY IMPACT ASSESSMENT

Date	Issues
November 2023	None noted

POLICY VALIDITY STATEMENT

Policy users should ensure that they are consulting the currently valid version of the documentation. The policy will remain valid, including during its period of review. However, the policy must be reviewed at least once in every 3-year period.

ACCESSIBLE INFORMATION STANDARDS

If you require this document in an alternative format, such as easy read, large text, braille or an alternative language please contact nencicb-sun.icbcorporateoffice@nhs.net

Version Control

Version	Release Date	Author	Update comments
1	July 2022	Senior Manager of Clinical Services, NECS	Not applicable. First Issue
2	January 2023	Hira Singh (Senior Medicines Optimisation Pharmacist, NHS NECS)	The policy has been updated to: • Include the governance review checklist process, which will support the ICB governance responsibilities, when authorising PGDs • Included process for signing of PGDs used by ICB nursing staff • Adjusted the sections to clarify the PGD policy content
3	July 2025	Hira Singh (Acting Head of Medicines and Pharmacy, SubICBL Co. Durham, NENC ICB MO Team) Marie Thompkins (Senior Medicines Optimisation Pharmacist)	The policy has been updated to: • Include the governance review and authorisation flow chart to summarise the process • Include a "how to submit a PGD" summary guidance • Add additional audit questions to the governance review checklist to further enhance the governance review of submitted PGDs • To include internet address details of where the ICB PGDs are available on-line • Include ICB Medical Directors to act as additional authorised signatories • Include the role of the ICB Medicines Safety Group within the ICB PGD governance process.

Approval

Role	Name	Date
Approver	ICB Board	July 2022
Approver	Executive Committee	January 2023

Approver	Quality and Safety Committee	September 2025

Contents

1. Introduction

The policy and supporting procedures and processes have been developed to meet the requirements for the Integrated Care Board (ICB) to meet their statutory responsibilities as an authorising body to consider and approve the development and use of Patient Group Directions (PGDs).

This policy applies to PGDs that have been authorised by the ICB for the treatment of NHS patients by authorised healthcare professionals, whether working in the ICB provider organisations or are directly employed healthcare professionals supporting the delivery of NHS commissioned services.

A summary flow chart of the ICB development and approval process can be found in **Appendix C**.

The supply and administration of medicines is controlled by The Medicines Act 1968 and controlled drugs (CDs) are regulated by The Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001.

The legislation enabling registered practitioners to operate under a PGD was outlined in the Health Service Circular (HSC 2000/26) and consolidated in 2012 within The Human Medicines Regulations 2012 (SI 2012 /1916). This details the provision for PGDs and sets out the legal requirements to develop and operate under a PGD. Failure to comply with these criteria falls outside of the law and could result in criminal prosecution under the Medicines Act (Department of Health, 1968).

A PGD is not an authorisation to prescribe and the preferred way for patients to receive medicines is for an appropriately qualified health care professional to prescribe for an individual on a patient-specific basis. As such, a PGD should not be used when it is reasonable to expect that a prescription (FP10) or a PSD (patient specific direction) could be obtained.

Therefore, the use of PGDs should be limited to specific situations where they offer an advantage to patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.

1.1 Where can a PGD be used

This ICB policy aligns with national guidance and regulation. PGDs may be used in all areas in which NHS healthcare is directly provided and where services in the private, voluntary or charitable sector are NHS funded. PGDs do not however, extend to independent and public sector care homes or independent sector schools that provide healthcare entirely outside the NHS and out of scope of this policy.

2. Purpose and scope

Patient group directions allow authorised healthcare professionals to supply and administer specified medicines to pre-defined groups of patients, without a prescription. This policy aims to ensure that patient group directions are used in line with legislation and appropriate governance.

The purpose of this Policy is to

- To set out the process for the identification, development, adoption, dissemination, implementation, monitoring, audit, and review of Patient Group Directions (PGDs).
- To provide the framework for service, clinical and professional leads to assist in the identification of and outline the process for the development of PGDs.
- To outline the role the ICB has in the authorisation of PGDs used to support NHS health care services commissioned by the ICB.
- To provide a robust approach across the whole organisation and incorporates the recommendations made in the Patient Group Directions NICE Guideline (MGG2) NICE August 2013 (updated March 2017)

The policy applies to all ICB staff and to authorised healthcare professionals providing NENC ICB directly commissioned NHS services.

Private Practice - The development of PGDs for privately funded services will not be supported by the ICB, e.g., Hepatitis B vaccine given on a private basis for travel purposes, or NHS practices using private PGDs. This is out of scope of this policy.

3. Definitions

A Patient Group Direction (PGD) can be defined as:
" a written instruction for the sale, supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment." HSC2000/026 'Patient Group Directions [England Only]
A PGD is NOT an authorisation to prescribe. PGDs allow health care professionals specified within the legislation to supply and/or administer a medicine directly to a patient with an identified clinical condition without the need for a prescription or an instruction from a prescriber. The health care professional working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD

A Patient Specific Direction (PSD) can be defined as:
“a written instruction from an independent prescriber (doctor, dentist or independent nurse/pharmacist prescriber) to another healthcare professional, to supply or administer a medicine directly to a named patient, or to several named patients.”

4. Development and management of PGDs

Specialist Pharmacy Service (SPS) provide useful guidance for commissioning and provider organisations, potential authors and signatories of PGDs as a prompt, to think about and follow necessary procedures before and during the stages of developing and authorising PGDs.

ICB commissioned service providers (except for those providers that are also authorising bodies, such as acute trusts) are unable by law to authorise **and** implement PGDs. A PGD must be developed by the ***commissioned service provider*** and submitted to the ICB (see below) for review and approval if deemed to meet the necessary criteria.

The commissioned service provider is responsible for implementation of the PGD.

A PGD must be developed, approved and used in accordance with legislation and national guidance as listed below.

- HSC 2000/026 – Health Service Circular – Patient Group Directions (England Only) www.dh.gov.uk Health Service Circular (HSC 2000/026.
- Human Medicines Regulations 2012 (SI 2012 No 1916).
- Good Practice Guidance (No. 02) - Patient Group Directions (NICE 02/08/13, updated 2017.
- The Misuse of Drugs Regulations 2001.
- Standards for the Medicines Management (NMC 2009)
- The Code. Standards of conduct, performance and ethics (NMC 2008)
- British National Formulary (current online edition).
- Immunisation against Infectious Disease ("The Green Book") online edition available at https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book .
- Patient Group Directions – NHS Specialist Pharmacy Services PGD resources, accessed at https://www.sps.nhs.uk/home/guidance/patient-group-directions/ .
- Legislation relating to prescription charges and exemptions.

4.1 Identifying the need for a Patient Group Direction

The need for a PGD should be established.

The SPS Guidance 'When to use a PGD' should be used to establish if a PGD is legal and/or appropriate.

4.2 Limitations on PGD usage /When is use of a PGD inappropriate?

A PGD is not required:

- If an exemption exists under the Medicines Act
- If the medicine involved is on the General Sales List (classified as GSL)
- For medical gases: these are not usually classified as Prescription Only Medicines (POMs)
- For dressings, appliances, medical devices, or chemical agents: these are not legally classed as medicines
- For medicines e.g., adrenaline for anaphylaxis where exemptions in legislation allow their supply and/or administration without the need for a PGD

Not all medicines are suitable to be included in a PGD

A PGD cannot be used for the following:

- unlicensed medicines including:
    - The mixing of two licensed medicines to form a new (unlicensed) product, unless one is a vehicle for administration, such as water for injection
    - Special manufactured medicines
- Anabolic steroids, and any injectable preparation used for treating addiction
- For management of long-term conditions, such as hypertension or diabetes
- Where uncertainty remains about the differential diagnosis, particularly when further investigations or diagnostic tests are needed, for example erectile dysfunction
- Where the medicine needs frequent dosage adjustments, or frequent or complex monitoring, for example anticoagulants or insulin (NICE guidance (MPG2))
- For unlicensed medicines
- Radiopharmaceuticals
- Abortifacients, such as mifepristone.

PGDs should not be used to circumvent the repeat prescribing systems used in general practice, therefore a PGD will not be permitted when a prescription (FP10), or a Patient Specific Direction (PSD) could be written in advance.

4.3 Drugs requiring special consideration

Certain medicines require special consideration before inclusion in a PGD and some are restricted by legislation.

Controlled drugs, black triangle medicines and off-label use of a licensed medicine should only be included in a PGD when clearly justified by best clinical practice and legally permitted.

4.3.1 Use outside the terms of Summary of Product Characteristics (SPC)

In exceptional circumstances, and justified by best practice, licensed medication can be used outside the terms of its product license (so-called 'off label' use) and as such may be included in a PGD (the status of the product must be clearly described).

In taking a decision whether or not to support inclusion in a PGD, the relevant PGD Approval Group(s) will consider whether there is acceptable evidence for the use of that product for the intended indication, e.g. follows nationally agreed guidelines, such as the Joint Committee on Vaccination and Immunisation (JVCI).

4.3.2 Drugs subject to special reporting arrangements (Black Triangle Drugs ▼)

Black triangle drugs (licensed in the previous 12 months) will only be considered in exceptional circumstances by the ICB.

Treatment guidelines must be followed and the PGD must clearly state the status of the product.

4.3.3 Antimicrobial drugs

A PGD should only be used for antibiotics if:

- clinically essential and clearly justified by best practice guidance.
- a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented
- the use of the PGD is monitored and reviewed regularly

4.3.4 Controlled Drugs

Only certain controlled drugs can be included in a PGD according to The Misuse of Drugs Regulations (2001). The SPS provides useful information on the Supply and/or administration of Controlled Drugs under a PGD

- Schedule 2: Morphine and diamorphine may be used by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person. Not for treating addiction)
- Schedule 2: Ketamine
- Schedule 3: Midazolam
- Schedule 4: All drugs except anabolic steroids and injectable medications used for treating addiction.
- Schedule 5: All drugs

Not all professions listed in the PGD legislation can administer controlled drugs under a PGD. The following regulated professions groups cannot administer or supply any CDs in any of the five schedules under a PGD:

- Dieticians
- Speech and language therapists
- Dental therapists
- Dental hygienists

4.3.5 Risk Minimisation Measures (RMM)

There are regulatory requirements for some medicines and are a critical part of the product licence (marketing authorisation) to help maintain a favourable benefit-risk profile. Medicines with a requirement for RMM may not be suitable for inclusion in a Patient Group Direction (PGD)

If a decision is taken to include a medicine with RMM in a PGD, the requirements of the RMM must be included in the PGD

4.4 Obtaining agreement to develop a patient group direction

Once the need for a PGD is established by the provider organisation, an application for permission to develop a PGD should be completed by that provider organisation in accordance with the relevant SOP. This would also apply to the ICB in circumstances that require it to produce PGDs for a service (**See Appendix A**). This form will then be submitted to the ICB for consideration and approval by the Medicines Committee or appointed subgroup. The currently appointed subgroup is the ICB Medicines Safety Group

(Please also refer to section 4.2)

4.5 Who should be involved?

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The Health Service Circular (HSC 2000/026) states that PGDs 'should be drawn up by a multidisciplinary group involving a doctor, a pharmacist and a representative of any other professional group expected to supply medicines under the PGD'. The NICE MPG2 calls this the 'PGD Working Group'.

The responsibility for the membership of the PGD Working Group will usually lie with the provider organisation developing the PGD. It is expected that the PGD Working Group is set up in line with NICE MPG2 Recommendations 2.3 'Developing Patient Group Directions'.

For commissioned services – The responsibility for the membership of the PGD Working Group will lie with the provider organisation and it should be set up in line with NICE MPG2 recommendations.

For PGDs developed by the ICB – The responsibility for the membership of the PGD Working Group will be agreed with the ICB Director of Medicines and /or Medicines Committee or delegated subgroup, such as the Medicines Safety Group. External organisations may be involved where appropriate.

Review and renewal of PGDs should be done by the PGD Working Group.

4.6 Who Is Permitted to Use Patient Group Directions

PGDs must only be used by those qualified registered health care professionals listed in the current legislation

Staff authorised can only use PGDs as named individuals.

4.7 Developing PGDs

The development of the PGD should follow the principles set out in the SPS Guidance "How to develop a Patient Group Direction".

If the request for PGD development is supported by ICB Medicines Committee and approved by the ICB Director of Medicines, approval should be communicated in writing and should include:

- Confirmation of the doctor, pharmacist and other members of the working group proposed or, if not identified in the request, identification of the persons to develop the PGD.

- Stipulation of any specific requirements or limitations to the PGD including:
  - Minimum qualification/training requirements for those using the PGD
  - Maximum doses or length of treatment
  - Criteria for patients to be excluded from the PGD
  - Criteria for exclusions or restrictions on the use of the PGD regarding service provision.

PGDs must comply with legal requirements and best practice, so must include specific information (See PGD example Template: Appendix B). This template is an example of a best practice PGD and must not be amended or used as an approved PGD.

Information about how the PGD will be audited should be included within the individual PGD. The commissioning organisation may, or may not be, the organisation that develops the PGD.

- **For ICB developed PGDs:**
  - the PGD lead author will ensure that the draft PGD is put into the current ICB PGD template (**See Appendix B**). The current PGD template has been developed to comply with legal and best practice requirements as set out in HSC 2000/26 and the Human Medicines Regulations 2012 and NICE Guidance and should not be altered in any way.

- **For PGDs developed by a commissioned independent provider:**
    - The lead author will ensure that their own PGD template complies with all legal and best practice requirements as set out previously, including HSC 2000/26, the Human Medicines Regulations 2012 and NICE Guidance.
    - Once complete these PGDs will need to be submitted to the ICB Medicines Optimisation Team and will require to be governance assessed using the PGD governance authorisation check list (**See Appendix F part 2).** A minimum 30-day time period is required to complete the governance review by the ICB

- **For PGDs adopted by the ICB or a commissioned independent provider:** These are PGDs such as the national immunisation templates produced by the UKHSA The lead author will ensure that their draft PGD is either put into the current ICB PGD template (**See Appendix B**), or that their adopted PGD template complies with all legal and best practice requirements as set out previously.
    - Once complete these PGDs will need to be submitted to the ICB Medicines Team and will require to be governance assessed using the PGD governance review checklist (part 2 of the ICB Governance Authorisation Form (**See Appendix F**).

A clinical protocol must be developed and implemented in conjunction with the PGD.

Specific training needs for individuals working under a PGD must be identified within the individual PGD.

The PGD will be informed by legislation, local and national frameworks, polices, guidelines, local formularies, and other bodies with medicines expertise.

References – all relevant guidelines and pertinent reference sources must be consulted as part of the development / review. All reference sources must be noted in the PGD documentation.

A PGD should include processes to ensure NHS prescription charges are collected where necessary.

4.8 Approving and Ratifying a PGD

For NHS commissioned services only Integrated Care Boards (ICBs), local authorities, NHS Trusts, NHS Foundation Trusts, Special Health Authorities and NHS England can authorise PGDs.

National PGD templates from the Specialist Pharmacy Service (SPS) will be adopted by the ICB if appropriate. The standard approval process would still need to be followed.

The authorised signatories for the ICB are: Director of Medicines and Pharmacy or Deputy Director of Medicines and Pharmacy; The Medical Director and Assistant Medical Directors.

4.8.1 For newly developed PGDs

The PGD is to be presented to ICB Medicines Committee, or delegated subgroup once it had been approved by a doctor, pharmacist and practitioner involved in the PGD development.

When the PGD authors have signed and submitted the proposed PGD, the ICB Medicines Optimisation Team will complete an assessment and then recommend ICB authorisation to the ICB Signatory
The assessment will include a completion of a governance review checklist by a MO senior pharmacist (see appendix F). If the PGD is to be used by ICB nursing staff then a governance review checklist will need to be completed by a senior pharmacist and by an ICB Director of Nursing.

A copy of each PGD with the required supporting documentation (including the details of the providers PGD policy) will be submitted to the Medicines Safety Group to provide assurance to the ICB that the PGD has been developed with appropriate governance in place.

For each PGD, the provider organisation should:

a) Identify a senior, responsible medical/dental representative from within the service to authorise named, registered health professionals to practice under the PGD
b) Ensure that authorised health professionals have signed the appropriate documentation.
c) Have internally approved their PGD
d) Follow all other NICE recommended actions required for provider organisations

Arrangement for authorisation of the PGD by the ICB signatory may diverge from the usual related processes during extraordinary circumstances (e.g. during a pandemic) or due to urgency, to ensure that PGDs remain within legislation and that patient safety is protected.

4.8.2 For national PGDs adopted by the ICB

This will be similar to section 4.8.1, except that the governance review checklist, once completed can be submitted and approved by the Director of Medicine and Pharmacy where they are satisfied that all governance review criteria are met. (This is provided by the completion of the checklist). The PGD can then be presented to the Medicines Committee for formal recording of approval.

4.8.3 For PGDs adopted by the ICB for ICB healthcare staff

There are staff, such as career start nurses, within the ICB that provide support to NHS commissioned immunisation services. These staff members are managed by nurse managers at sub ICB region and will be responsible for working with the ICB Medicines Director/Director of Medicines and Pharmacy to approve adopted PGDs for their use. See above processes.

4.9 Implementing a PGD

Once ratified the PGD will be shared with the proposers for implementation.

Providers will then disseminate to relevant staff. They will ensure that those who are going to be operating under the PGD have access to the document, have signed to operate under it and that any training needs have been identified and addressed.

Professionals using a PGD must hold a current registration as identified within the PGD and act within their appropriate codes of conduct.

Providers will retain a copy of the signed authorisation sheet for each PGD and keep a record of staff who have signed up to the PGD. These records may be inspected by relevant bodies e.g., ICB, CQC or MO team.

In the clinical setting where the PGD is being used the following must be in place:

- Copy of supporting protocols, SOPs, or guidelines
- Copy of current PGD
- List of staff authorised to work under the PGD

4.10 PGD Review and Revalidation

PGDs must have an expiry date, and must not be used beyond their expiry date, because any supply and/or administration of a medicine(s) would be without legal authorisation.

The expiry date for a PGD should be considered and determined on a case-by-case basis with patient safety paramount. NICE recommend that this should be a maximum of 3 years from the date the PGD was authorised (or re-authorised following review).

The commissioned service provider is responsible for ensuring that PGDs are reviewed in good time to ensure continuity of care. It is also responsible for identifying / ensuring that appropriate persons form the PGD Working Group. PGDs should be reviewed and revised following the same processes as for new PGDs and involve consultation with all stakeholders.

The expiry date of a PGD can only be extended if there is a justifiable delay in renewing a PGD. For PGDs where a review is not completed within 1 year of the expiry date will be withdrawn from use.

PGDs updated before their review will need to be re-ratified.

Each new or revised PGD should be re-signed by all appropriate staff to ensure competence is up to date.

PGD staff authorisation records must be kept for 8 years (10 years for implants for adults and 25 years if they relate to children.

The Clinical Lead or manager of the provider service should establish a robust and transparent process for the unscheduled review and updating of a PGD, when the need for this has been identified. This should include responding to:

- changes in legislation
- important new evidence or guidance that changes the PGD, such as new NICE guidance
- new information on drug safety
- changes in the summary of product characteristics
- changes to the local formulary

Any senior medical representative of a commissioned service or lead of a provider organisation can request an unscheduled review and updating of a PGD, when the need for this has been identified.

Any proposed changes, including minor amendments, will require the PGD to go through the review process and be re-authorised.

Each version of the PGD must be kept by the MO team for 10 years for adults and 25 years if they relate to children.

4.11 PGD Version Control

The ICB Director of Medicines (and their team) will ensure PGD version control

a) During the development process, strict version control must be followed, and draft versions must be watermarked on each page as “draft”.
b) A new PGD in development will begin as 0.1
c) Subsequent amended versions will become 0.2, 0.3, 0.4 etc.
d) The first ratified PGD will be version 1.0
e) When a PGD is under review the version changes to 1.1. As different groups are consulted and changes are made, the version changes 1.2, 1.3 etc.
f) The next final reviewed and ratified guideline becomes 2.0, and so on.

5. Duties and Responsibilities

Each PGD signatory has responsibilities appropriate to their role in PGD development, authorisation and implementation.

The doctor (or dentist) and pharmacist signatories must establish that the clinical and pharmaceutical content are accurate and supported by the best available evidence. The doctor should have relevant expert clinical knowledge. The representative of the professional group expected to supply medicines under the PGD must ensure that

they are satisfied that the PGD is fit for purpose for the health professional (e.g., nurses) delivering care to patients in that particular service and locality.

Organisations have a responsibility to ensure that a PGD is authorised within the legal framework and local governance arrangements (see section 3.4 of NICE MPG2 PGD guidance).

Those signatories who have designated responsibility for signing PGDs on behalf of the ICB for a ICB commissioned service must establish that:

- Processes and governance arrangements have been followed
- All legal requirements have been met
- There is effective implementation of the policy
- There has been full consideration of the service in which the PGD is to be used for governance purposes, the clinical governance signatory should not be involved in developing the PGD and will not practice under the PGD.

The clinical governance signatory on behalf of the authorising organisation should not be required to check clinical content of the PGD in detail but should be provided with sufficient evidence to be assured that the doctor (or dentist) and pharmacist signatories (and anyone else involved in the development of the PGD) have the competency, skills and experience to carry out their role and responsibilities.
A satisfactory governance review checklist must have been completed by the ICB MO team as part of the evidence to support ICB sign off. Staff employed by external organisations such as an NHS Commissioning Support Unit (CSU) may be involved in this.

Note: Electronic signatures may be used in line with MHRA guidance. However, attaching a scanned picture of a signature is not acceptable.

All staff, including temporary and agency staff, are responsible for:

- Compliance with relevant process documents. Failure to comply may result in disciplinary action being taken.
- Co-operating with the development and implementation of policies and procedures and as part of their normal duties and responsibilities.
- Identifying the need for a change in policy or procedure because of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager accordingly.
- Identifying training needs in respect of policies and procedures and bringing them to the attention of their line manager.
- Attending training / awareness sessions when provided.

6. Implementation

A PGD may need to be 'adopted' by the provider organisation(s) if they have not been involved in developing and authorising it. For example, when a PGD is developed and authorised by an ICB for use across multiple GP practices or a PCN, a process would need to be in place for each GP practice to adopt the PGD for use in their practice. An MOU, SLA or similar should be in place between the practices detailing the arrangements that have been agreed.
This should include that staff are authorised as competent to operate under the locally approved PGD. This authorisation must be undertaken by the employing practice. The employing practice will be responsible for any educational and training requirements and for ensuring that appropriate indemnity insurance is in place.
and state that a registered HCP, authorised and legally able to operate under a PGD within one practice within the PCN, can also operate under that same PGD when managing patients registered with other practices within the PCN for the purpose set out in the MOU/SLA or similar.
Additionally, it should include details of:

- how records will be maintained
- any incidents recorded
- how stock will be requisitioned/funded, stored and if required, monitored and disposed of
- any additional financial aspects
- staff indemnity cover

Organisations are advised to follow the ICB Process of Adopting a PGD SOP. Where organisations require ICB PGD authorisation, they must follow the ICB approval process.

7. Training

PGD development:

- This policy will be available to all staff who use/develop Patient Group Directives within the ICB.
- All directors and managers are responsible for ensuring that relevant staff within their own directorates and departments have read and understood this document and are competent to carry out their duties in accordance with the procedures described.

PGD Use:

- Specific training needs for individuals working under a PGD must be identified within the individual PGD.
- The senior medical representatives within the commissioned service are responsible for ensuring that all staff using a PGD are competent to assess all relevant aspects of the patient's clinical condition, take responsibility for supply and/or administration of the medicine and make related decisions.
- All staff supplying and/or administering medicines under PGDs must have written evidence of competence, training, knowledge, experience,

and continuing education relevant to the clinical condition/situation to which the PGDs apply.

- The practitioner operating under the PGD must take personal responsibility for ensuring they maintain their competence and knowledge and attend additional training when appropriate.
- In the service provider organisation (e.g. GP Practice) it is the responsibility of the senior partner or designated senior doctor/dentists/clinical lead to ensure the competency, and to counter sign the documents for any nurse, or other authorised healthcare professional working under PGDs within the service.
- The provider organisation will keep these signed authorisations as both evidence of individuals' competency and as a record of staff authorised to use the PGD.
- Adequate educational materials should be available to enable individual people and organisations to deliver safe and effective services in which PGDs are used.
- Training and re-training of health professionals using PGDs should incorporate a post-training assessment of competency.

8. Monitoring, Review and Archiving etc

8.1 Monitoring

The ICB Board will agree a method for monitoring the dissemination and implementation of this policy. Monitoring information will be recorded in the policy database No deviation from this policy will be allowed. Any PGD that has been developed independently of this policy will not be authorised for use by ICB.

8.2 Audit

As stated in HSC 2000/026, care provided under a patient group direction must be audited.

It is a legal requirement as per HSC 2000/026 to keep records of administration and/or supply under PGD for audit purposes.

It is the responsibility of the service lead and/or provider to monitor and audit the use of PGDs within their setting to ensure compliance with procedures

Information about how the PGD will be audited should be included within the individual PGD.

There must be a list of professionals who are able to work under the PGD available at any given time.

Monitoring and evaluation of PGDs within the ICB may be undertaken in conjunction with CQC or ICB Medicines Optimisation team. The results of the audit should be shared within the service and reported to the ICB Medicines Committee on request..

The records of administration or supply against each PGD must be audited as frequently as determined by the commissioner by each provider so that the appropriateness of the supply or administration (or of not supplying or administering a medicine) can be reviewed.

It is the responsibility of the signatory senior medical representative or delegated other member of the provider to ensure that the audits are completed and that practitioners are working in accordance with the PGD.

It is recommended that an audit of PGDs is undertaken annually. For new staff, practice should be audited six months after commencing the post.

The results should highlight areas of best practice as well as areas of concern and identify any areas of training and development need.

PGDs will not normally be accepted for revision unless an audit report has been provided.

8.3 Record Keeping

When a health care professional is working to a PGD the following information must be recorded:

- Patient's details: name, condition presented, medical history.
- Patient assessment and diagnosis.
- Contra-indications to any medicines.
- Medicines which have caused allergic reactions or side effects.
- Allergies to the drug and/or excipients.
- Current and recent prescription medicine, including over the counter (OTC) medicines and herbal preparations.
- Reasons for exclusion and referral.
- Medicine supplied and/or administered: name; form; strength; quantity; batch number; expiry date; information and advice given.
- Name and/or signature of the health care professional providing treatment and supplying the medicine.

All records must be signed, dated, and kept for 10 years after last attendance, or up to the patient's 25th birthday if longer than 10 years away. Records should be kept in the patient's notes and either sent to the patient's GP, or as detailed in the individual PGD.

Details of administration of vaccines to children must be sent to the appropriate Child Health Information System.
Where available, an entry on the computer record under the healthcare professional's individual identification and password is an acceptable alternative.

8.4 Organisational Governance

For each PGD, the commissioning and provider organisation(s) should collaborate to firmly establish local governance arrangements with clear lines of responsibility and accountability and arrangements are in place to ensure compliance with the Organisational Governance recommendations in the NICE MPG 2.

8.5 Incident reporting

Compliance with this policy will be monitored using an analysis of incidents and complaints where there has been a failure to follow procedure. It is the contractual responsibility of the service provider to notify the ICB of errors/incidents.

Quarterly medication medicines error/incident reports will be reviewed by the ICB Medicines Committee and as appropriate reported to the Quality and Safety Committee. Action plans to manage improvement in compliance will be developed where necessary.

8.6 Compliance

No deviation from this policy will be allowed. Any patient group direction that has been developed independently of this policy will not be authorised for use.
Key findings of both audit and monitoring of compliance will be reported to the Quality and Safety Committee.

8.7 Administration and Dissemination of new PGDs

Notification of newly published PGDs (new or updated) will be sent to designated individual(s) to co-ordinate distribution to appropriately trained staff.

It is the responsibility of the designated individual (usually the Service Lead / Manager) to ensure new staff are authorised to use relevant PGDs. This means that they are responsible for all paperwork being correct (i.e., current version on intranet) and all professionals using that PGD being signed up to it in advance.

Copies of this paperwork must be kept in a safe place e.g. in a folder specifically for that purpose and may be required for inspection.

8.8 Policy Review

The ICB Board will ensure that this policy document is reviewed in accordance with the timescale specified at the time of approval. No policy or procedure will remain operational for a period exceeding three years without a review taking place.

Staff who become aware of any change which may affect a policy should advise their line manager as soon as possible. The Executive Director or nominated deputy will then consider the need to review the policy or procedure outside of the agreed timescale for revision.

For ease of reference for reviewers or approval bodies, changes should be noted in the 'document history' table on the front page of this document.

NB: If the review consists of a change to an appendix or procedure document, approval may be given by the Executive Director in the ICB and a revised document may be issued. Review to the main body of the policy must always follow the original approval process.

8.9 Archiving

The ICB Board will ensure that archived copies of superseded policy documents are retained in accordance with Records Management: NHS Code of Practice 2021.

9. Indemnity insurance

Those signing PGDs must ensure that adequate indemnity arrangements are in place.

Individual health care professionals should have their own Professional Indemnity Insurance and ensure that the insurance provider is aware that they are operating under PGDs.

Those employed (as opposed to being self-employed), may be covered for these purposes but individuals should check with their employer. Most employers provide vicarious liability insurance to cover the acts or omissions of their employees, but health care professionals must check that they are covered.

The service lead/manager authorising staff to operate under PGDs within their service should also ensure that their professional indemnity insurance covers their authorising PGDs for use within their service.

Health care professionals, who are members of a professional organisation, or trades union, may also be covered additionally by this body.

10. Related Documents

10.1 Other related policy documents

- Appendix A - Request for the Development of a Patient Group Direction
- Appendix B – Template Patient Group Direction (PGD) Example
- Appendix C - ICB PGD Development and Approval Process Flow chart
- Appendix D - Management & Monitoring of Patient Group Direction
- Appendix E - PGD Service Specification
- Appendix F – NENC ICB Governance Authorisation Form
- Appendix G - Patient Group Direction Audit Tool Example

10.2 Legislation and statutory requirements

- HSC 2000/026: Patient Group Directions (England only); Department of Health, Health Service Circular 9th August 2000

10.3 Best practice recommendations

- NICE. Patient Group Directions. Medicines Practice Guideline (MPG2). (August 2013, updated March 2017). Available at: https://www.nice.org.uk/guidance/mpg2
- MHRA Guidance. Patient Group Directions: who can use them. (December 2017). Accessed December 2021. Available at: https://www.gov.uk/government/publications/patient-group-directions-pgds/patient- group-directions-who-can-use-them
- NHS Patient Group Directions (PGD) website. Available at: https://www.sps.nhs.uk/home/guidance/patient-group-directions/ MHRA. Accessed December 2021
- Specialist Pharmacy Services (SPS). Retaining PGD documentation. (August 2018). Accessed December 2021. Available at: https://www.sps.nhs.uk/articles/retaining-pgd-documentation/

Appendix A

Request for the Development of a Patient Group Direction

Request for the Development of a Patient Group Direction - Template

The following document should be completed prior to the development of a full PGD.

Request to Develop a Patient Group Direction

Title of PGD (i.e. Drug and Clinical Indication)	
New PGD or Review of Existing PGD	
Ref No or version (revision only)	
Expiry date (revision only)	
Timescale for development/revision	
Proposer details:	
Name:	Job Title:
Organisation:	Email Address:
Telephone No.:	
Head of Service details:	
Name:	Email Address:
Telephone Number:	
Organisational details:	
Commissioning Organisation:	
Provider Organisation;	
Organisation delivering service where PGD used	
Setting(s) where the PGD will be used	
Health professional group(s) working under the PGD	
Persons who will be writing the PGD (PGD Signatories):	
Lead Author:	Organisation:
Profession:	Email Address:
Doctor / Dentist (delete as appropriate)	
Organisation:	Email:
Pharmacist:	
Organisation	Email

Professional Group Representative (working to the PGD)	

Organisation:	
Email Address:	
Service Manager/Lead:	
Organisation:	Email:
Clinical Lead (This may be doctor or dentist):	
Organisation:	Email:
Email:	

PGD Purpose and Benefit to Patient Care:
Provide details to the criteria below and include supporting evidence:

Circumstances in which the PGD is to be used						
Condition or health need to be met & benefit to patient care						
Medicine(s) to be included in PGD (include dosage, quantity, formulation and strength, route and frequency of administration, duration of treatment, license status (licensed, unlicensed and or off-label use), class e.g. POM, CD, Black Triangle and whether it is included in the local formulary)						
Please tick below to indicate how the medicine will be provided:						
Supply		Administration		Both		
Professional group(s) to be included in PGD						
Specific qualifications or training & competency requirements.						
Benefits and advantages of using a PGD over other methods of supply or administration e.g. prescribing, patient specific direction.						

Is the PGD required to support a new service development? Yes / No **If yes please provide details including indication as to whether service development has been approved and funded.**
Potential risks to patient safety
Resources needed to deliver the service (details of how medicine will be funded, purchased, stored, staff resources required, including development and implementation)
Current and/or future service provisions for supplying and/or administering the medicine(s), including its position within the care
Current and/or future service provisions for supplying and/or administering the medicine(s), including its position within the care
Other available options to provide the service – risks and benefits
Stakeholder View

Please send completed form to [nominated ICB Medicines Safety Group email address TBC**]**

Appendix A - continued

Part 2
The request to develop a Patient Group Direction for use within NHS NENC ICB has / has not been (delete as appropriate) approved for development.

	Signature	Date
ICB PGD Approval group (chair)		

Approval has been granted on the condition that the following requirements or restrictions are included in the Patient Group Direction.

Qualifications, training and competency
Other requirements / restrictions

Other comments/reasons for not granting:

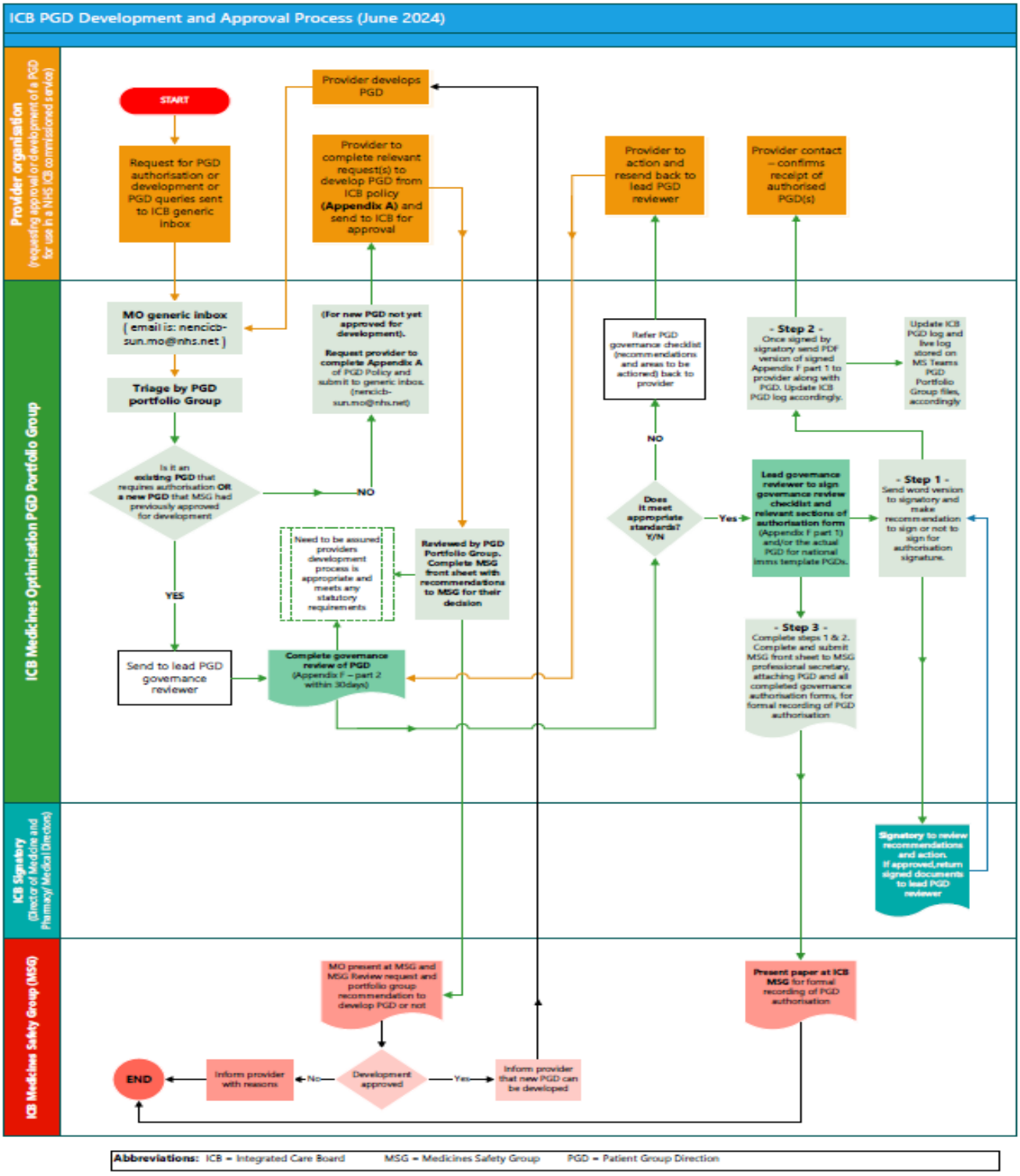
Appendix B

Template Patient Group Direction (PGD) Example

ICB PGD Template.pdf

ICB PGD Template.doc

Appendix C
ICB PGD Development and Approval Process Flow chart



Appendix D
Management & Monitoring of Patient Group Direction

PGD Number *Name of Medication*

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD.

The following healthcare professionals are authorised to administer

Name of Medication under the Patient Group Direction (*PGD number*)

PGD Valid from date: PGD Expiry Date:

Healthcare Professional			Authorised by:		
Name	Signature	Date	Name	Signature	Date

PGD Valid from:	Review Date:	Expiry Date:

APPENDIX E

PGD - Title
Service Specification

Service Specification No.	
Service	
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1.	**Population Needs**
1.1	**National/local context and evidence base**
2.	**Outcomes**
2.1	**NHS Outcomes Framework Domains & Indicators**
3.	**Scope**
3.1	**Purpose**
3.2	**Aims and Intended Service Outcomes**
3.3	**This service should benefit patients when:**
3.4	**Scope of Service**
3.5	**Pharmacy & Pharmacist Accreditation**
3.6	**Population covered**
3.7	**Any acceptance and exclusion criteria and thresholds**
3.8	**Interdependence with other services/providers**
4.	**Applicable Service Standards**
4.1	**Applicable national standards (e.g. NICE)**
4.2	**Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)**
4.3	**Additional reading / further learning options**
4.4	**Other Local Policies to Note**
5.	**Applicable quality requirements**

5.1 Applicable Quality Requirements **5.2 Clinical Incident Reporting** **5.3 Complaints Procedure**
6. Location of Provider Premises
The Provider's Premises are located at:

Quality Requirements

Quality Requirement	**Threshold**	**Method of Measurement**	**Consequence of Breach**	**Timing of application of consequence**

Appendix F:

Governance Authorisation Form (includes Part 1 - ICB Commissioner Authorisation and Part 2 – Governance Review Checklist)

Notes on use:

- Part 1 of the NENC ICB Commissioner Authorisation section is not required for national immunisation PGD templates, as an authorising body sign off section is already included within the national immunisation templates.
- For adoption of National Immunisation Template PGDs that will be used by ICB employed nursing staff, a governance review checklist must be completed and signed off by a senior pharmacist and the appointed ICB Director of Nursing
- If the PGD does not meet the governance approval checklist, the nominated senior pharmacist (assessor) will work with the PGD authors to clarify/update any areas required for amendment.
- When the senior pharmacist completing the governance review is satisfied that the PGD meets all PGD statutory and best practice requirements they will sign the PGD Governance Review Checklist (Part 2) and the ICB Authorisation Form (part 1) as an additional signatory.
- For each PGD the completed Commissioner Authorisation (part 1) and governance review checklist (Part 2) of the form is sent together with the PGD(s) to The Director of Medicines and Pharmacy and where satisfied the Director will authorise the PGD.
- These documents will then be submitted to the Medicines Committee for formal recording of approval.
- Once the ICB has authorised the submitted PGD (i.e. the ICB signatory and additional signatory have signed the Commissioner Authorisation section (Part 1)), the ICB will send to the provider the pdf version of the signed NENC ICB Commissioner Authorisation section (Part 1/front page only) of the ICB PGD Governance Authorisation Form + the providers final submitted PGD

NHS North East and North Cumbria (NENC) Integrated Care Board (ICB)
Patient Group Direction (PGD) Governance Authorisation Form

Part 1 - NENC ICB Commissioner Authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation by the appropriate Authorising Body.
The submitting NHS commissioned provider is responsible for ensuring that any submitted PGD complies with all relevant statutory, governance and best practice requirements.
It is the responsibility of the organisation that has legal authority to authorise the PGD to ensure that all legal and governance requirements are met.
The authorising body **NHS NENC ICB** is signing that **[insert name of provider organisation]** has followed the required processes and required governance arrangements for this PGD

Patient Group Direction	
PGD Title	Click or tap here to enter text.
Version	Click or tap here to enter text.
Reference no.	Click or tap here to enter text.
Provider	Click or tap here to enter text.

NHS NENC ICB authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
[insert name of provider] providing services within NHS NENC ICB
Limitations to authorisation
Authorisation is limited to registered practitioners listed in the PGD who are employed by [**add name of provider**] and commissioned by NHS North East and North Cumbria ICB to deliver NHS services located within the North East and North Cumbria NHS ICB region

NHS NENC ICB Commissioner organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director of Medicines and Pharmacy (and Chair of Medicines Committee) NHS NENC ICB	**Ewan Maule**		Click or tap here to enter text.

Additional signatories required for the NENC ICB governance assurance review			
Role	**Name**	**Sign**	**Date**
Senior Medicines Optimisation Pharmacist, (NHS NECS)	**Hira Singh**		Click or tap here to enter text.

Part 2

Patient Group Direction (PGD) Governance Review Checklist

This PGD review checklist forms part of the governance assurance and approval process required by the North Cumbria and North East (NENC) Integrated Care Board (ICB), to support their responsibilities in authorising or adopting PGDs used in the delivery of NHS commissioned services, including PGDs previously commissioned by legacy CCGs within NENC ICB region.

To be completed on behalf of NENC-ICB by the nominated senior pharmacist. (This must also be completed by the nominated senior nurse for PGDs to be used by ICB staff).

(This completed signed form along with the reviewed PGD must be submitted to the nominated NENC ICB responsible person/signatory (e.g., Medical Director, Governance Lead) for final review and governance approval). As part of the governance review, the nominated senior pharmacist (and senior nurse where PGD is for ICB adoption & use) must sign the checklist and the PGD Governance Authorisation Form for the PGD being reviewed as an "Additional Signatory" to indicate satisfactory governance review of the PGD being submitted for NHS NENC ICB governance authorisation/approval. (NB. For ICB use PGDs the governance authorisation form may be included within the PGD document itself).

Title & version of PGD	Click or tap here to enter text.		
Reference no:	Click or tap here to enter text.		
Provider name:	Click or tap here to enter text.		
PGD written by:	Click or tap here to enter text.		
Valid from	Click or tap here to enter text.	Expiry date	Click or tap here to enter text.
Name of ratification group	[insert providers PGD ratification group]		
Date ratified/approved			

Present & fully documented in the PGD?	Please tick			Comments
	Yes	No	N/A	
Signatures & PGD validity details				
Signatures of all health professionals who formally developed the PGD present?	☐	☐	☐	
Date of signatures included?	☐	☐	☐	
Name of PGD and version included?	☐	☐	☐	
Date the direction comes in to force and the date it expires?	☐	☐	☐	
Signature(s) of governance approval of the PGD by the provider organisation?	☐	☐	☐	
Content				
Name of the service(s) to which the direction applies.	☐	☐	☐	
Staff characteristics section	☐	☐	☐	

Includes named, registered health professionals to use a PGD?	☐	☐	☐	
Link to appropriate references (e.g., Green Book chapter, BNF, NICE etc)?	☐	☐	☐	
Clinical condition/situation section				
Alternative options considered?	☐	☐	☐	
Clinical condition or situation defined?	☐	☐	☐	
Inclusion / exclusion criteria documented?	☐	☐	☐	
Caution section completed?	☐	☐	☐	
Does the PGD include circumstances in which further advice should be sought from a doctor or dentist and, if so, what these circumstances are?	☐	☐	☐	
Action to be taken if patient excluded?	☐	☐	☐	
Action to be taken if the patient or carer declines treatment?	☐	☐	☐	
Arrangements for referral for medical advice?	☐	☐	☐	
Description of treatment section				
Name, strength & formulation of drug	☐	☐	☐	
More than one medicinal substance?	☐	☐	☐	
Defines legal classification?	☐	☐	☐	
Black triangle medicine used?	☐	☐	☐	
Off label use defined?	☐	☐	☐	
Route / method of administration?	☐	☐	☐	
Dose and frequency of administration?	☐	☐	☐	
Duration of treatment?	☐	☐	☐	
Quantity to be supplied / administered?	☐	☐	☐	
Storage and disposal?	☐	☐	☐	
Drug Interactions?	☐	☐	☐	
Identification & management of adverse reactions?	☐	☐	☐	
Reporting procedure of adverse reactions	☐	☐	☐	
Written information to be given to patient or carer	☐	☐	☐	
Patient advice / follow up treatment	☐	☐	☐	
Special considerations / additional information	☐	☐	☐	
Records section included & fully defined?	☐	☐	☐	
Reference & PGD management details				
References and Bibliography section completed?	☐	☐	☐	
Practitioner authorisation section?	☐	☐	☐	

Authorising manager section?	☐	☐	☐	
PGD Governance Process oversight				
Is the medication included in the PGD for administration of a GSL, P or medicines exempt under schedule 17 or 19 the HMR 2012?	☐	☐	☐	
Does the provider requesting NHS NENC-ICB PGD approval from the authorising body, have adequate/satisfactory formal governance structures in place? (e.g., is there a PGD policy in place that adequately covers all aspects of PGD development, use, approval, review; undertakes PGD audits and has a formal PGD approval committee etc.). To establish this please complete the following questions below to support your decision.	☐	☐	☐	
Does the organisation have a PGD oversight group, governance or medicines committee or similar, which is used by the provider for their formal organisational PGD approval?	☐	☐	☐	
Does the provider organisation requesting ICB PGD authorisation conduct audits of their PGDs and use? [NICE PGD guidance states: 'Agree and undertake a planned programme of monitoring and evaluation of PGD use within the service.'].	☐	☐	☐	
Does the PGD audit content cover recommendations made by NICE and SPS guidance?				
Are the PGD audits part of a medicines audit programme?	☐	☐	☐	
Are you satisfied that audit results are considered by the provider to inform them whether a PGD remains the most suitable mechanism?	☐	☐	☐	
Does the PGD include and describe adequate training and competency requirements for the healthcare professionals defined to use the PGD?	☐	☐	☐	

Does the organisation that has clinically developed the PGD have satisfactory PGD governance processes in place? (e.g., a PGD policy that adequately covers all aspects of PGD development, use and approval; undertakes PGD audits and has a formal PGD approval committee etc.). Please complete the questions below. [*NB. If this is a national body, such as the FSRH or UKHSA, then these can be considered as in place*].	☐	☐	☐	
Checklist completion details (carried out by nominated senior pharmacist (and nurse if required))				
Outcome	[State if meets PGD statutory and best practice standards]. State your recommendation to ICB signatory to approve or not to approve this PGD]			
Completed by:	add name of senior pharmacist or nurse completing form			
Signature:	insert e-signature			
Title & role:	Click or tap here to enter text.			
Date checklist review completed:	Click or tap here to enter text.			

Appendix G:

Patient Group Direction (PGD) Audit Tool Example (from SPS)

A - Governance – process oversight (to be completed at organisational level)

	Questions		Yes/No
A1	Does the organisation have a PGD oversight group or similar?		
A2	Are there records of terms of reference and minutes or notes by the group?		
A3	Does the PGD oversight group or similar report into the organisation's clinical governance framework?		
A4	Is there a current PGD policy?		
A5	**Does the current PGD policy include:**		
	A5.1	Considering the need for a PGD and obtaining agreement to develop a PGD	
	A5.2	Developing and submitting a PGD including review of need for a PGD/alternative mechanisms for administration/supply	
	A5.3	Authorising a PGD	
	A5.4	Authorising named, registered health professionals to use a PGD	
	A5.5	Training and competency	
	A5.6	Audit, review and updating a PGD (including in life amendments and review of continued need for PGD)	
A6	Is there a current and up-to-date list of all the PGDs in use within the organisation, including their review/expiry dates?		
A7	Are all master authorised copies of all current PGDs held by the organisation (and where applicable the authorising commissioning organisation)?		
A8	Are master copies of all expired versions of the PGDs held by the organisation (and where applicable the authorising commissioning organisation)?		
A9	Is there an audit timetable for PGD audits within each service (see sections C and D)?		
A10	Are there any PGD related risks on the risk register?		
A11	Does the organisation have a policy on prescription charge collection for a supply made under a PGD for patients who are not exempt from NHS prescription charges?		

B - Governance – PGD content (overarching review of all PGDs in use within an organisation/PGDs in use within a defined clinical area or service)

	Questions	Yes/No
B1	Number of PGDs currently in use within the organisation	
B2	Do all medicines administered/supplied under a PGD have a UK Marketing Authorisation?	
B3	Have all medicines which have a current "black triangle" status been clearly indicated on the relevant PGD?	
B4	Is any off-label use clearly indicated on the relevant PGD?	
B5	Is there evidence that all antimicrobial PGDs have had an input from the local microbiology specialist?	
B6	Are there any PGDs in the trust that have been developed and used for the management of long-term conditions?	
B7	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?	
B8	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?	
B9	Are all medicine packs supplied in their original pack (or a licensed pre pack) when supplied under a PGD? (i.e. packs not split)	
B10	Do all medicines supplied under any PGD have appropriate instruction labels on the pack including the Trust's name, address and contact details?	

C - Operational – staff factors/service level factors (to complete for <u>each</u> service using PGDs)

	Questions	Yes/No
C1	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?	
C2	Have all staff working under the PGD signed the latest version of that PGD?	
C3	Are all staff working under the PGD competent to work under that PGD? (Either signed off by their senior clinician/manager or self-certified.)	
C4	Are all staff authorised to work under the PGD employed as one of the registered health professions listed in the PGD?	
C5	Is there an up-to-date list held within the service, of all staff authorised to work under each PGD in use?	
C6	Have all staff completed the necessary training and continuing professional development specified in the PGD/s they are authorised to work under?	
C7	Is there an up-to-date record within the service of all staff who have attended any required specific PGD training?	

D - Clinical patient factors/clinician decision factors (to complete at individual PGD level either in a single service/clinical area or across all services/areas using the named PGD)

	Questions (to be answered retrospective review of clinical records – state number of records reviewed and rationale for sample size)	Yes/No
D1	Is the clinical indication (which is listed in the PGD's inclusion criteria) stated in the patient's record?	
D2	Is there a record of all of the following: patient's full name, date of birth, registered GP (where applicable)	
D3	Is there a statement in the patient's record that supply and/or administration of the medicine was made using a PGD?	
D4	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?	
D5	Is there a record of the patient's consent?	
D6	If the patient was excluded, is the reason recorded?	
D7	If the patient was excluded, is there a record of action taken?	
D8	If the patient refused treatment, is there a record of advice provided on alternatives/risk of no treatment?	
D9	Is there a register or other record of stock received and issued to patients under this PGD?	
D10	Does the Patient Record contain details of the medicine supplied or administered (name, strength, dose, quantity, route)?	
D11	For vaccines, was both the batch number and expiry date recorded?	
D12	Was the date of supply or administration recorded?	