Patient Group Direction (PGD) signatories

Who are the PGD signatories?

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. Human Medicines Regulations 2012 Schedule 16 Part 2 defines the organisations on whose behalf a direction must be signed. An organisation's structure should determine which individual role incorporates the authority and responsibility to be the signatory in order to state that PGDs are fit for purpose. For example, this signatory is often the clinical governance or patient safety lead who has designated responsibility for signing PGDs on behalf of the authorising body. Authorising bodies need to consider the knowledge, skills and expertise needed by people who are developing, updating, authorising and using PGDs and ensure that they are aware of their responsibilities and can demonstrate their competency.

Finally, an individual health professional must be authorised in writing to use the PGD by a senior person who is responsible for ensuring that only fully competent, qualified and trained health professionals use PGDs. An individual or multiple practitioner agreement may be used as a declaration of competence on behalf of the practitioner and as a designation of their authority and accountability for their decisions to supply and/or administer medicines using a PGD.

What experience and competencies are expected of signatories of PGDs?

Patient group directions (NICE guideline MPG2, 2017) sets out the experience and competencies expected of signatories. Supporting resources include competency frameworks.

A multi-disciplinary PGD e-learning programme is available for all professionals, at whatever stage they might be involved in the process, to understand how to make sure that PGDs are developed, authorised and used safely.

What are the roles and responsibilities of the PGD signatories?

Roles and responsibilities of Patient Group Direction (PGD) signatories are summarised in this document as follows:

1. Role and responsibilities of a doctor (or dentist) signatory
2. Role and responsibilities of a pharmacist signatory
3. Role and responsibilities of the signatory who is a representative of the professional group expected to supply medicines under the PGD
4. Role and responsibilities of a Clinical governance lead involved in the organisational authorisation of the PGD
5. Role and responsibilities of Managers of areas where PGDs are being developed, implemented and used.
6. Responsibilities of Practitioners using Patient Group Directions.

To help establish these roles and responsibilities, associated duties are listed in the tables below. The document may be used as a checklist by organisations and individuals involved to ensure that they meet requirements.

Note: When a signatory signs a PGD they are acting within their role as agreed by their organisation/detailed in role specification - as such there is no requirement for a PGD to be resigned if a signatory leaves an organisation. The PGD Service Advisory Board has clarified that there is nothing in legislation to state that a PGD becomes invalid if a PGD signatory leaves their role.

Note: this is only a guide and organisations may wish to utilise the NICE PGD Baseline Assessment Tool and refer to the recommendations in Patient group directions (NICE guideline MPG2, 2017)

1. Role and responsibilities of a doctor (or dentist) who is a clinical signatory

The doctor (or dentist) signatory is responsible for ensuring that the PGD will provide safe and appropriate treatment to a pre-defined group of patients requiring prophylaxis or treatment for a specific condition, within agreed parameters described in the PGD.

NICE's 2017 Medicines practice guideline (MPG 2) on PGD states: *'When signing the PGD, the doctor (or dentist) and pharmacist take joint responsibility and accountability for the accuracy of both the clinical and pharmaceutical content of the PGD. This role should be undertaken by senior professionals with full consideration of the clinical service in which the PGD is to be used.'*

The doctor (or dentist) and pharmacist signing the PGD should also be involved in developing the PGD.

During development of the PGD, the doctor (or dentist) is responsible for the provision of medical advice and support including advice on the feasibility of the PGD with reference to the most appropriate options for clinical care and associated clinical guidelines within that service and area of practice. The doctor (or dentist) is responsible for ongoing provision of medical advice and support when the PGD is in practice and during/following audit and or during review of the PGD.

Related duties to meet role and responsibilities:

- Ensures that relevant references to specific supporting guidelines etc are made within the PGD
- Ensures that appropriate follow up advice to the patient is safe e.g. see GP after 48 hours if no change in condition
- Ensures that the lead practitioner/author and pharmacist signatories are made aware of any changes in clinical practice or guidelines that may necessitate a review (or withdrawal from practice) of the PGD when the PGD is already in use.
- Ensures the availability of medical/dental advice for excluded patients is timely and appropriate
- Ensures that they are satisfied that the PGD is fit for purpose for the medical and/or dental care being delivered to patients in that particular service and locality.
- Works within any locally agreed timeframes to ensure timely development, review and approval of the PGD.
- When updating a PGD:
    - establishes the case for a PGD, identifies the benefits to patient care and ensures the views of all stakeholders have been considered. This would include establishing that individual prescribing is not a suitable mechanism following a review of current prescribing systems and the care pathway being considered e.g. may delay timely access to treatment and that a PGD is appropriate and legal.
    - discusses with pharmacist, representative of professional group and other relevant stakeholders and advises whether a PGD remains a clinically appropriate method to supply or administer to a group of patients with a specified condition within agreed parameters considering local and national guidelines.

2. Role and responsibilities of a pharmacist who is a clinical signatory

The pharmacist is responsible for ensuring that the PGD will provide safe and appropriate treatment to a pre-defined group of patients needing prophylaxis or treatment for a specific condition, within agreed parameters described in the PGD.

NICE's 2017 Medicines practice guideline (MPG 2) on PGD states: *'When signing the PGD, the doctor (or dentist) and pharmacist take joint responsibility and accountability for the accuracy of both the clinical and pharmaceutical content of the PGD. This role should be undertaken by senior professionals with full consideration of the clinical service in which the PGD is to be used.'*

The doctor (or dentist) and pharmacist signing the PGD should also be involved in developing the PGD.

The pharmacist is responsible for provision of pharmaceutical advice and support prior to and during PGD development, including advice on the feasibility of the PGD with reference to licensed status of the medicine, local formulary and other guidelines relating to the medicine. The pharmacist is responsible for ongoing provision of pharmaceutical advice and support when the PGD is in practice and during/following audit and review.

Related duties to meet role and responsibilities:

- Before a PGD is developed - discusses with doctor and representative of professional group and advises on whether a PGD would be a legal method to supply or administer to a group of patients with a specified condition within agreed parameters, with reference to the legal framework for PGDs and with reference to any local formularies or approved Prescribing Lists/licence status of medicine.
- Before a PGD is developed – establishes the case for a PGD and identifies the benefits to patient care. This would include establishing that individual prescribing is not a suitable mechanism following a review of current prescribing systems and the care pathway being considered e.g. may delay timely access to treatment and that a PGD is appropriate and legal.
- Before a PGD is developed, ascertains that where a medicine is to be supplied to a patient to take away, appropriately labelled packs can be procured in a legal and timely manner.
- Establishes that the clinical and pharmaceutical content in the PGD is accurate and supported by the best available evidence and has considered local and national guidelines with e.g. local formulary or antibiotic guidelines related to local resistance patterns.
- Ensures that they are satisfied that the PGD is fit for purpose for the medical and/or dental care being delivered to patients in that particular service and locality.
- Ensures that the medicines content of the PGD is legal and accurate including:
    - formulary and licence status of medicine
    - advice on appropriate actions to be taken e.g. a potential interaction may exclude a patient from a PGD or could be managed by advice to the patient, depending on the type of interaction

- Ensures that local formularies and procedures are complied with when considering inclusion of a medicine in a PGD e.g. off label use may require local Trust approval prior to the PGD being developed.
- Ensures that where a medicine is to be supplied to a patient to take away, appropriately labelled packs can be procured in a legal and timely manner.
- Ensures that a suitable manufacturer's Patient Information Leaflet and/or other relevant patient information about the medicine is available for issue to the patient at the time of supply or administration of the medicine.
- Ensures that the lead health professional/author and doctor signatories are made aware of any changes relating to the SPC or licensing of the medicine that may necessitate a review (or withdrawal from practice) of the PGD when the PGD is already in use.
- Ensures that legal and adequate supplies of the medicines (appropriately labelled packs where relevant) are available in the agreed clinical areas.
- Works within any locally agreed timeframes to ensure timely development and approval of the PGD.
- When updating a PGD:
    - ascertains that where a medicine is to be supplied to a patient to take away, appropriately labelled packs can be procured in a legal and timely manner.
    - discusses with doctor, representative of professional group and other relevant stakeholders and advises on whether the PGD continues to be legal method to supply or administer to a group of patients with a specified condition within agreed parameters, with reference to the legal framework for PGDs and with reference to any local formularies or approved Prescribing Lists/licence status of medicine.
    - establishes the case for a PGD, identifies the continued benefits to patient care and ensures the views of all stakeholders have been considered. This would include establishing that individual prescribing is not a suitable mechanism following a review of current prescribing systems and the care pathway being considered e.g. may delay timely access to treatment and that a PGD is appropriate and legal.
    - ensures that the PGD remains clinically accurate and that local and national guidelines have been considered with relevant references made within the PGD. In addition, if audit has highlighted any need for changes in practice, this may need to be reflected in the PGD.

3. **Role and responsibilities of the signatory who is a representative of the professional group expected to supply medicines under the PGD**

The representative of the professional group expected to supply medicines under the PGD is responsible for the provision of specialist professional advice and support including provision of information on service delivery within their clinical area.

They are responsible for ongoing professional advice and support for practitioners when the PGD is in practice.

They are responsible for ongoing professional advice during and following audit and during review of the PGD. They may also be a management lead with additional management responsibilities, see next section.

Related duties to meet role and responsibilities

- Before a PGD is developed - discusses with doctor and pharmacist to ascertain whether a PGD would be a legal method to supply or administer to a group of patients with a specified condition within agreed parameters, with reference to the legal framework for PGDs e.g. the PGD should not involve delegation of practice or mixing of two licensed products prior to administration.
- Before development of a PGD – discusses with doctor and pharmacist to establish the case for a PGD and identifies the benefits to patient care. This would include establishing that individual prescribing is not a suitable mechanism following a review of current prescribing systems and the care pathway being considered e.g. may delay timely access to treatment and that a PGD is appropriate and legal.
- If available, uses local PGD template and follows organisational processes for PGDs.
- Ensures 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.
- If leading development of the PGD, ensures full consultation with other signatories e.g. doctor/pharmacist/lead health professional and stakeholders in the area of practice during the development of the PGD and any subsequent drafts.
- If leading development of the PGD ensures that document and version control is robust so that the correct draft version (approved by all signatories involved in the development of the PGD) is submitted to the relevant Clinical Governance signatory e.g. D&T or other medicines management group.
- Works within any locally agreed timeframes to ensure timely development, review and approval of the PGD.
- When updating a PGD:
    - discusses with doctor, pharmacist and other relevant stakeholders to ascertain whether a PGD would be a legal method to supply or administer to a group of patients with a specified condition within agreed parameters, with reference to the legal framework for PGDs e.g. the PGD should not involve delegation of practice or mixing of two licensed products prior to administration.
    - discusses with doctor and pharmacist to establish the case for a PGD, identifies the benefits to patient care and ensures the views of all stakeholders have been considered. This would include establishing that individual prescribing is not currently a suitable mechanism for the care pathway being considered e.g. may delay timely access to treatment and that a PGD is appropriate and legal.

4. Role and responsibilities of managers of areas where PGDs are being developed and used

Managerial responsibilities apply. The lead health professional involved in the development of the PGD may be contracted to undertake some or all of these responsibilities. This would be a local arrangement.

Related duties to meet role and responsibilities

- Before a PGD is developed - advises on whether a PGD would be a legal method to supply or administer to a group of patients with a specified condition within agreed parameters, with reference to the legal framework for PGDs e.g. the PGD should not involve delegation of practice or mixing of two licensed products prior to administration.
- Before development of a PGD – ensures that the case for a PGD is established and identifies the benefits to patient care. This would include establishing that individual prescribing is not a suitable mechanism following a review of current prescribing systems and the care pathway being considered e.g. may delay timely access to treatment and that a PGD is appropriate and legal.
- Ensures that doctor (or dentist) and pharmacist signatories are made aware of any practice or safety issues that may necessitate a review (or withdrawal from practice) of the PGD when the PGD is already in use.
- Ensures that only fully competent, registered and trained professionals operate within directions
- Ensures individual authorisation is given to practitioners working under PGD, where there is evidence that the practitioner has completed the training required and has been assessed as competent to use the PGD
- Ensures that they are satisfied that the PGD is fit for purpose for the care being delivered to patients in that particular service and locality.
- Ensures the development and submission of the PGD is carried out in accordance with local policies or protocols.
- Oversees the introduction of approved PGDs into the service and ensures they are used and audited according to local protocols.
- Ensures safe and effective practice under PGDs with consideration to both the clinical and management aspects of the PGD and oversees the responsibilities of the Lead Author.
- Ensures audit and review of the PGD is carried out within locally specified timeframes.
- Ensures each practitioner has their own approved copy of the most recent PGD as required and ensures access to the most up-to-date version of the PGD in noted designated areas or on a local intranet.
- Ensures that there is up to date list is kept of authorised practitioners who may work under the PGD.
- Ensures safe keeping of the original signed version of the PGD and that the most up to date version of the PGD is available in the clinical areas, with full document control.
- Can demonstrate to the Clinical Governance or Patient Safety Lead that the PGD has been developed according to the correct organisational procedures and that those involved in the development of the direction are competent to do so.
- Ensures that audits are undertaken to monitor the use of the PGD as required by the organisation
- Must work within any locally agreed timeframes to ensure timely development and approval of the PGD.
- Ensures that there is a system in place for recording and monitoring medicines supplied or administered to each individual patient so that all stock can be reconciled.

- When a PGD is updated:
    - advises on whether a PGD would be a legal method to supply or administer to a group of patients with a specified condition within agreed parameters, with reference to the legal framework for PGDs e.g. the PGD should not involve delegation of practice or mixing of two licensed products prior to administration.
    - ensures that the case for a PGD is established and identifies the benefits to patient care. This would include establishing that individual prescribing is currently not a suitable mechanism for the care pathway being considered e.g. may delay timely access to treatment and that a PGD is appropriate and legal.
- When updating service delivery and service design, considers options and plans to supersede the need for PGDs within the service e.g. by the introduction of a suitable cohort of non-medical independent prescribers and introduce individual prescribing into the care pathway to ensure timely access to treatment without the need for a PGD. Discusses with all PGD signatories.

5. Role and responsibilities of a clinical governance or patient safety lead "signing off" a PGD

The clinical governance or **patient safety lead** responsible for organisational authorisation ("signing off") of a PGD is signing that a PGD is fit for purpose and must have sufficient evidence to be assured that:

- a PGD has previously been agreed as the most appropriate mechanism for supply and administration of the medicine
- there is no opportunity in the care pathway for the medicine to be prescribed in a timely manner
- those involved in the clinical authorisation of the PGD are competent to do so
- local processes and governance arrangements have been followed
- the views of all stakeholders have been considered
- all legal requirements have been met.

This person has responsibility for ensuring PGDs are developed in line with legislation and local organisational policies and governance arrangements, with full consideration of the service in which the PGD is to be used.

It should be noted that for governance purposes, the clinical governance signatory should not be involved in developing the PGD and will not practice under the PGD.

Note: The clinical governance or patient safety lead may not be employed with this particular job title but their role must incorporate clinical governance responsibility. The organisational structure would need to determine which individual would have the authority and responsibility to be the signatory in order to state that PGDs are fit for purpose. For example, this may delegated to an individual whose role incorporates a clinical governance role and responsibilities.

Related duties to meet role and responsibilities

- Ensures that the PGD has been developed according to the correct organisational procedures and that those involved in the development of the direction are competent to do so.
- Ensures that they are satisfied that the PGD is fit for purpose for the care being delivered to patients in that particular service and locality
- The clinical governance signatory on behalf of the authorising organisation should not be required to check clinical content of the PGD in detail but they should be confident that the doctor and pharmacist signatories (and anyone else involved in the development of the PGD) have adequate competency, skills and experience to carry out the role.

6. Responsibilities of practitioners using Patient Group Directions

See Section 1.5 Patient group directions (NICE guideline MPG2, 2017