Roles and Responsibilities of the Reviewer's and Lead Author's of Patient Group Directions (PGDs)

The purpose of this document which has been adapted from the Specialist Pharmacy Service (2020) is to provide an overview of the roles and responsibilities of the people who must be involved in the review and/or signing of a PGD as set out in the legislation.

Roles and responsibilities of PGD reviewers/signatories are listed in this document as follows:

Section 1: Role and responsibilities of the PGD lead author
Section 2: Role and responsibilities of the medical professional (or dentist) reviewer/signatory
Section 3: Role and responsibilities of the pharmacist reviewer/signatory
Section 4: Role and responsibilities of the reviewer/signatory who is a representative of the professional group expected to supply/administer medicines under the PGD

Section 1: Role and Responsibilities of the PGD Lead Author

The lead author may be a doctor (or dentist), pharmacist or representative of any other professional group who will practice under the PGD, or another person such as the service lead. The lead author of a PGD is responsible for updating and coordinating the timely review of the PGD, and ensuring that both a medical professional (or dentist) and pharmacist are involved in the process.

Related Duties to Meet Role and Responsibilities of the PGD Lead Author

- Ensures that they have the appropriate skills and knowledge to update and review the PGD.
- When reviewing 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.
    - There are no relevant exemptions in legislation which allow supply and/or administration of the medicine without the need for a PGD

- Uses the NHSG standard PGD template to ensure the format for PGDs is consistent across the organisation.
- Ensure all legally required information is included in the PGD.
- Undertake an appropriate literature search to identify new evidence. This then needs to be evaluated to assess its relevance and validity.
- 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.
- Ensure PGDs are consistent with the relevant summary of product characteristics, unless the medicine is being used off-label or relevant national guidance is being followed
- Use the best available evidence, such as national guidance, the Green Book and other sources of high-quality information when reviewing the PGD. Include key references within the PGD.
- Identifies suitable and appropriate healthcare professionals to comprise the consultation group for the PGD review, ensuring that the group has a minimum of 5 members, one of which must be a medical professional (or dentist), a pharmacist (an additional medical professional or pharmacist is required if lead author is a medical professional or pharmacist) and senior representation from the user group.
- Includes the PGD consultation reply forms when sending the draft PGD out for comment, and are responsible for ensuring the return of the completed signed forms.
- Seek views on draft PGD, and agree final draft PGD with all members of the consultation group, including the medical professional (or dentist) and pharmacist reviewers.
- Works within any locally agreed timeframes to ensure timely review and approval of the PGD.
- Submits the PDG post consultation to NHSG Medicines Guidelines and Policies Group (MGPG), along with the completed consultation rely forms and the PGD Submission Covering Form.
- Act on MGPG feedback and suggested amendments within the allocated time frame
- Final checking and signing of the PGD once executively signed
- Ensure that an updated PGD is communicated and disseminated effectively to all relevant clinical areas and professionals who will work under the PGD.
- Are responsible 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/SIGN guidance
- new information on drug safety
- changes in the summary of product characteristics
- changes to the local formulary.

Section 2: Role and Responsibilities of the Medical Professional (or Dentist) Reviewer/Signatory

The medical professional (or dentist) reviewer/signatory 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.

Patient group directions (NICE guideline MPG2, 2017) states: when reviewing/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) is responsible for ensuring the clinical content of the PGD is accurate and up to date.

N.B. If the lead author of a PGD is a medical professional (or dentist) they cannot also act in the capacity of the medical/dentist reviewer for the PGD, a second medical professional (or dentist) must act as the reviewer/signatory for the PGD.

Related Duties to Meet Role and Responsibilities of a Medical Professional (or Dentist) Clinical Reviewer/Signatory

- Ensures that they have the appropriate skills and knowledge to review the PGD for the specific role in which they are required to sign the PGD.

- When reviewing 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.
    - There are no relevant exemptions in legislation which allow supply and/or administration of the medicine without the need for a PGD.

- Ensures that appropriate advice is given on actions to be taken e.g. medical referral for excluded patients or a potential drug interaction which might be managed by contact with the doctor (or dentist) first then relevant advice to the patient by the practitioner. This could then allow continuing practice under the PGD, depending on the type of the interaction.

- 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 the specified action for excluded patients is clinically appropriate and indicates appropriate referral where required

- 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.

- Works within any agreed timeframes to ensure timely review and approval of the PGD.

Section 3: Role and Responsibilities of the Pharmacist Reviewer/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 .

Patient group directions (NICE guideline MPG2, 2017) states: when reviewing/signing the PGD, the medical professional (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 Pharmacist is responsible for provision of pharmaceutical advice and support during the PGD review, 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 review.

N.B. If the lead author of a PGD is a pharmacist they cannot also act in the capacity of the pharmacist reviewer for the PGD, a second pharmacist must act as the reviewer/signatory for the PGD.

Related Duties to Meet Role and Responsibilities of a Pharmacist Reviewer/Signatory

- Ensures that they have the appropriate skills and knowledge to review the PGD for the specific role in which they are required to sign the PGD.
- When reviewing 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.
    - There are no relevant exemptions in legislation which allow supply and/or administration of the medicine without the need for a PGD

- Ascertains that where a medicine is to be supplied to a patient to take away, appropriately labeled packs can be procured in a legal and timely manner.
- Establishes that the clinical and pharmaceutical content in the PGD is accurate by checking all relevant resources such as the Summary of Product Characteristics for the medicine(s), the current British National Formulary (BNF), the BNF for Children and the Department of Health Green Book if a vaccine is involved. Additionally ensures that the PGD is supported by the best available evidence and has considered local and national guidelines.
- Ensures that the medicines content of the PGD is legal and accurate including;
    - formulary and license 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 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 local formularies and procedures are complied with when considering inclusion of a medicine in a PGD e.g. off label use may require local organisational approval.
- Works within any locally agreed timeframes to ensure timely review and approval of the PGD.

Section 4: Role and Responsibilities of the Reviewer/Signatory Who is a Representative of the Professional Group Expected to Supply/Administer Medicines Under the PGD

The representative of the professional group expected to supply/administer 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. It is not a legal requirement to have the representative of the professional group as a signatory but is seen as good practice.

Patient group directions (NICE guideline MPG2, 2017) states: that they are also responsible for ongoing professional advice and support for practitioners when the PGD is in practice.

Related Duties to Meet Role and Responsibilities of the Reviewer/Signatory Who is a Representative of the Professional Group Expected to Supply/Administer Medicines Under the PGD

- Ensures that they have the appropriate skills and knowledge to review the PGD for the specific role in which they are required to sign the PGD.
- 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.
- When reviewing 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.
    - There are no relevant exemptions in legislation which allow supply and/or administration of the medicine without the need for a PGD
- Works within any locally agreed timeframes to ensure timely review and approval of the PGD.

Section 5: Role and Responsibilities of the NoS PGD Group

A Memorandum of Understanding (MoU) between all the aforementioned Boards exists by which the NoS PGD Group has been delegated the responsibility by each Board in regard to the development of NoS PGDs, as well as the ratification and approval of PGDs which are considered for use by approved healthcare professionals as authorised within current legislation, within NoS.

The NoS PGD Group will ensure that the requirements of the MoU between all the aforementioned Boards are delivered, and further to the responsibilities laid out above, it will also provide a forum to discuss, escalate and resolve issues which may arise in relation to PGDs for use within the NoS Health Boards. This group allows for harmonisation of PGD ratification and approval across NoS Health Boards.

- Ratify and approve all PGDs for use in the NoS (delegated responsibility from the stakeholder Boards GDTC/MGPG and their chief executives).
- When reviewing a PGD for approval the group must establish that a PGD is fit for purpose, i.e.:
    - The PGD has been developed according to the correct NHS organisational procedures and processes
    - There are robust governance arrangements in place, which have been followed
    - All legal requirements have been met
    - Those involved in the development of the direction are competent to do so.
- Ensuring that decision-making is robust and transparent with final decisions on PGDs formally recorded and communicated to appropriate stakeholders
- Reviewing and prioritising proposals for NoS PGD development, ensuring PGDs are not developed without approval in principal in the first instance by the relevant PGD approval groups within each Board.
- Ensuring approved and authorised PGDs are disseminated to the Boards who intend to use them.
- To develop, review, approve and authorise for use a NoS PGD template including relevant timely review of such template

Section 5: Role and Responsibility of Authorising Health Board

Current UK PGD legislation states that PGDs must be authorised for use only by an appropriate authorising body in-line with the Human Medicines Regulations 2012. In Scotland this is a role for NHS Health Boards. It is therefore possible for several Health Boards to collaborate in regard to PGDs and for one Health Board to be appointed as the authorising body to executively sign and authorise the use of PGDs across all Boards.

In order for NHS Grampian to have the vested authority to authorise and executively sign PGDs, each individual Boards ADTC or equivalent group, along with the Chief Executive and Director of Pharmacy for each Board must grant authorisation for NHS Grampian to act in this capacity on their behalf.

NHSG will function as the nominated authorising body to executively sign and authorise NoS PGDs for use across all 6 NoS Boards.

References

National Institute for Health and Clinical Excellence (2017) Medicines and Technologies Programme, Patient Group Directions: Methods, Evidence and Recommendations. *NICE Guideline.*

National Institute for Health and Clinical Excellence (2017) Patient Group Directions. Medicines Practice Guideline (MPG2)

National health Service Grampian (2015) Guidance For The Development And Implementation Of Patient Group Directions (PGDs) For Staff Working Within NHS Grampian.

Patient Group Directions. Scottish Executive Health Department Letter: NHS HDL (2001)7. January 2001. (http://www.show.scot.nhs.uk/sehd/mels/HDL2001_07.htm).

Specialist Pharmacy Service (2020) Patient Group Direction (PGD) signatories [Accessed] 09/03/2023.