A Step-by-Step Guide to Reviewing/Updating a PGD

PGD Definition

A Patient Group Direction (PGD) is a written instruction that allows specified registered healthcare professionals to supply and/or administer medicines to groups of patients who may not be individually identified before presenting for treatment. This includes:

- Individuals known to the service or with appointments (e.g. baby immunisation clinics)
- Individuals not known in advance (e.g. walk-in centres)

PGDs are not a form of prescribing. Instead, they provide a legal framework for the supply/administration of medicines without a prescription or prescriber instruction, provided the patient meets the clearly defined criteria within the PGD.

Only the healthcare professionals listed in Schedule 16, Part 4 of the Human Medicines Regulations 2012 may operate under a PGD.

Key principles:

- The healthcare professional must ensure the individual fully meets the inclusion criteria and does not meet any exclusion criteria.
- No deviations from the PGD are permitted. Clinical judgement cannot be used to override the PGD.
- Only the medicine, formulation, and quantity specified in the PGD may be supplied/administered.
- The entire episode of care must be carried out by the practitioner operating under the PGD – it cannot be delegated.

Governance Considerations

Before reviewing a PGD:

- Ensure that the PGD is still required.
- Ensure the use of a PGD is appropriate, legal, and necessary for the service.
- Organisations must have robust governance arrangements in place, including policies covering all aspects of medicines management.
- PGDs should only be used where there is no suitable alternative, such as prescribing or patient-specific directions.

Reviewing a PGD in practice

1. **Assess the Continued Relevance**
   Before investing time in a full clinical review and update, first determine whether the PGD is still necessary and appropriate for the service. Remember, the preferred method for individuals to receive medicines is through one-to-one care provided by a prescriber.

2. **Engage the Right Stakeholders**
   Identify and involve all relevant parties early in the process. As lead author you are responsible for confirming the clinical signatories required for development and approval. Seek their approval that they still wish to be signatories within the PGD and have capacity to respond in a timely manner.

3. **Re-authorisation Requirements**
   Any changes to a PGD—no matter how minor—require the document to be updated, formally re-authorised, and for practitioners to be re-authorised to operate under the revised version.

4. **PGD content responsibility**
   Responsibility for the content of a PGD lies entirely with the doctor and pharmacist signatories, not with the previous/new author. It is essential that signatories thoroughly review and verify that the PGD content is clinically accurate, up to date, and aligned with the Summary of Product Characteristics (SmPC), as well as relevant local and national guidelines, policies, and best available evidence.

An overview of the roles and responsibilities of the professionals who must be involved in the review and/or signing of a PGD as set out in the legislation can be found here Roles and Responsibilities of the Reviewers and Lead Authors of Patient Group Directions (PGD)

Tips to make it simpler

- Use the PGD review checklist (appendix 1)
- Sign up for an account on the SMPC webpage – this will allow you to access any resent changes to the medicine and provide the date of revision of text – which you need to add to the references section of the PGD.

Useful webpages/Info

- The Human Medicines Regulations 2012
- Patient Group Directions and legal mechanisms
- Writing a PGD – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Appendix 1

PGD review checklist – must be submitted with finalised PGD to MGPG or NoS	
Action to be taken	Confirmed by signatory
As the **lead author** you are responsible for ensuring **Firstly – is this PGD required? Who will be using the PGD? Consider pathways and operational delivery.**	☐
Ensure the following: • organisational processes for PGD development are followed • be familiar with the information provided within the Policy for North of Scotland Patient Group Direction (PGD) working For Healthcare Professionals In MHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles • ensure all those involved understand their role and responsibilities in the review of a PGD • coordinate the review of the PGD • you advise on any profession specific guidance which may impact the PGD content • you work within any locally agreed timeframes to ensure timely development, review and approval of the PGD	☐
If leading the review of the PGD, also ensure: • Use the template provided by MGPG/NoS only • Do not amend the formatting within the template and only amend areas in red • full consultation with other signatories and stakeholders in the area of practice during the development of the PGD and any subsequent drafts and are listed within the consultation table • any changes made to the PGD are listed within the revision history table • ensure everyone involved in the PGD development agrees that the PGD is ready for submission for authorisation • check all the links and references are working and up to date	☐
Ensure the PGD is submitted within the timeframe given – if this doesn't happen it may result in withdrawal	☐
As the **doctor/dentist signatory** you are responsible for ensuring the PGD will provide safe and appropriate clinical treatment to a pre-defined group of individuals within agreed parameters described in the PGD. During development of the PGD you are responsible for the provision of clinical advice and support. This includes advice on the feasibility of the PGD with reference to the most appropriate	☐

options for clinical care and adherence to relevant clinical guidelines. Ensure the following: • organisational processes for PGD development are followed • PGD clinical content is appropriate • relevant supporting guidance is followed and referenced • appropriate follow up/safety netting advice to the individual is included • availability of medical/dental advice for excluded patients is timely and appropriate • PGD is appropriate for the clinical care being delivered in the service/locality • you work within locally agreed timeframes to ensure timely development, review and approval of the PGD	
As the **pharmacist signatory** you are responsible for ensuring the PGD will provide safe and appropriate pharmaceutical treatment to a pre-defined group of individuals within agreed parameters described in the PGD. Prior to and during PGD development, you are responsible for provision of pharmaceutical advice and support. This includes advice on the feasibility of the PGD with reference to licensed status of the medicine, local formulary and other guidelines relating to the medicine. Ensure the following: • organisational processes for PGD development are followed • whether a PGD is required and legally and clinically appropriate • where a medicine is to be supplied to individuals to take away, appropriately labelled packs can be procured in a legal and timely manner • clinical and pharmaceutical content in the PGD is accurate and supported by the best available evidence and local/national guidelines have been considered • Ensure all drugs are spelt correctly and have black triangles or ® symbol where needed • adequate legal supplies of the medicines are available in the agreed clinical areas • medicines references have been checked and updated within the table • suitable medicine information is available for issue to the patient at the time of supply or administration of the medicine • you work within any locally agreed timeframes to ensure timely development and approval of the PGD	☐