

## Patient Group Directions and Patient Specific Directions in general practice

August 2010

In response to enquiries on this issue, the GPC has reviewed the complex legislation surrounding the administration of medicines and has clarified the advice on the use of Patient Group Directions (PGDs) in general practice. Note that this guidance will be updated as and when further issues are raised. Please email [info.gpc@bma.org.uk](mailto:info.gpc@bma.org.uk) if you have further queries on this issue.

This guidance has been updated in response to queries raised by LMCs and GPs regarding the use of PGDs. There has been a difference of opinion of the place of PGDs in a general practice setting between the historic position taken by the GPC (based on legal advice in 2002) and that of the Royal College of Nursing (RCN) and the Nursing and Midwifery Council (NMC), who have taken a different position in their advice to practice nurses.

As a breach of The Medicines Act 1968 would result in a criminal action it was vital that this issue was resolved so GPC has sought an up to date legal opinion on this matter. This has led to a change in the GPCs advice. General practices should use PGDs to authorise registered nurses to administer or supply prescription only medicines, unless they are independent prescribers.

[The Medicines Act 1968](#) does not permit nurses who are not qualified prescribers to administer or supply prescription only medicines (POMs) unless one of three types of instruction are in place:

1. A signed prescription
2. A signed Patient Specific Direction (PSD)
3. A Patient Group Direction (PGD)

If non-prescribing health care professionals are to administer a medicine on the instruction of a GP, the GP must be able to show that they have appropriate mechanisms in place to ensure that their practice meets statutory requirements. Since these mechanisms for supply and administration are statutory, the fact that a practice has followed them is mitigation to any ensuing liability

The regulatory framework for the use of PGDs can be found in 'PGDs - Further Information' at the end of this document.

PGDs and PSDs are defined below:

### **Patient Group Direction**

A Patient Group Direction is a written instruction for the supply and / or administration of a named licensed medicine for a defined clinical condition.

PGDs allow a range of specified registered health care professionals to supply and / or administer a medicine directly to a patient with an identified clinical condition without them necessarily seeing 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.

PGDs are intended to improve patient care by enabling registered health professionals other than doctors to supply and/or administer medicines to patients.

Examples of where PGDs may be appropriate are services where assessment and treatment follows a clearly predictable pattern (eg immunisation, family planning). In general practice they can be used to enable registered nurses to administer a prescription only medicine to a group of patients who fit the criteria specified in the PGD, for example, to administer vaccinations.

The following may supply or administer medicines under a patient group direction: registered nurses; midwives; health visitors; optometrists; pharmacists; chiropodists; radiographers; orthoptists; physiotherapists; ambulance paramedics; dieticians; occupational therapists; speech and language therapists; prosthetists and orthotists. Note that they can only do so as named individuals.

Health care assistants cannot supply or administer prescription only medicines under the authorisation of a PGD.

### **Patient Specific Direction**

A Patient Specific Direction is a written instruction from a doctor or dentist or other independent prescriber for a medicine to be supplied or administered to a named patient. For example:

- primary care: a prescription or simple written or electronic instruction in the patient's notes
- secondary care: instructions on a patient's ward drug chart

PSDs do not limit those who can supply or administer the medicine. For example, a suitably trained health care assistant can do so, even though they cannot work under a PGD.

PSDs are also often used in relation to the administration of vaccinations for named patients as well as Depo-Provera, B12 and Zoladex.

In general, most of the occasions where a non-prescribing health care professional administers a POM they do so under the terms of a PSD. This is an instruction which may be in writing and signed or in an electronic format, which is made after the prescriber has assessed that individual patient. A PSD constitutes an instruction to the practice nurse or other competently trained health care professional to administer the medicine.

Patient Group Directions were introduced as a facilitative measure to allow non-prescribing health care professionals to take a decision to supply and/or administer an identified POM to a patient with an identified clinical condition, without the patient needing to see a prescriber. This could be useful in services where assessment and treatment follows a clearly predictable where a practice nurse has the experience and knowledge to make decisions on appropriate treatment (eg immunisation, family planning and travel clinics).

The majority of clinical care should be provided on an individual, patient-specific basis. The use of Patient Group Directions (PGDs) should be reserved for those situations where this offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability. If a patient-specific direction exists or if the nurse is an independent prescriber and competent to make treatment decisions in that field, then there is no need for a Patient Group Direction.

## **Frequently asked questions**

### **Can nurses who are not qualified prescribers administer or supply a prescription only medicine?**

Yes. A GP can instruct a named practice nurse to supply or administer medicines to a patient. However medicines may only be administered by a practice nurse if one of three types of instruction are in place:

1. a signed prescription
2. a signed Patient Specific Direction (PSD)
3. a Patient Group Direction (PGD).

If one of these three options is not in place then [the Medicines Act \(1968\)](#) has been breached

### **Can a nurse independent prescriber administer a POM without a PSD or PGD in place?**

Yes. Nurse independent prescribers do not require a PSD or PGD in order to administer a POM. Under the Medicines Act a nurse independent prescriber is able to administer any licensed medicine for any medical condition within their competence, including some controlled drugs for specified medical conditions.

### **What needs to be included in a PSD?**

There is no set format for PSDs written into the legislation and you do not have to define an instruction as one. However a PSD must:

- state the name of the patient and
- state the name and dose of the prescription only medicine to be administered
- show evidence to confirm that the patient has been considered as an individual.

A PSD may be a written or electronic instruction from the GP to the nurse in the patient record, relating to a specific individual patient.

Thus a verbal instruction or letters of invitation to a patient are not suitable. A list of individually named patients to be treated with a named POM, signed by a doctor/prescriber would constitute a PSD in general practice, providing that each patient on the list has been considered individually by the doctor.

Practices must have protocols in place for their staff to follow to administer a POM using a PSD.

#### **Can a nurse prescriber authorise a PSD?**

Yes nurses may prescribe from the formulary linked to their recorded qualification. Nurse prescribers may issue a PSD and instruct another health care professional to administer the medicine.

#### **When can PGDs be used in general practice?**

In some circumstances, where assessment and treatment follows a clearly predictable pattern (for example where nurses are administering travel or childhood vaccinations) practices may find it beneficial to have an agreed PGD in place so that a GP does not have to give a specific instruction for each individual patient.

Nurses using PGDs must have been assessed as competent to use them and must comply with the standards set by their professional regulatory body the NMC (The Standards for Medicine Management<sup>1</sup>).

A PGD enables a nurse to supply and / or administer prescription-only medicines to patients using his / her *own assessment* of patient need, in accordance with the criteria set out in Schedule 7, Part I of Statutory Instrument 2000 No. 1917 - The Prescription Only Medicines (Human Use) Amendment Order 2000 (see below). The PGD must include this information.

#### **Particulars to be included in a patient group direction**

- the period during which the Direction shall have effect;**
- the description or class of prescription only medicine to which the Direction relates;**
- whether there are any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what restrictions;**
- the clinical situations which prescription only medicines of that description or class may be used to treat;**
- the clinical criteria under which a person shall be eligible for treatment;**
- whether any class of person is excluded from treatment under the Direction and, if so, what class of person;**
- whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances;**
- the pharmaceutical form or forms in which prescription only medicines of that description or class are to be administered;**

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<sup>1</sup>[Standards for Medicines Management \(NMC, 2008\)](#)

- (i) **the strength, or maximum strength, at which prescription only medicines of that description or class are to be administered;**
- (j) **the applicable dosage or maximum dosage;**
- (k) **the route of administration;**
- (l) **the frequency of administration;**
- (m) **any minimum or maximum period of administration applicable to prescription only medicines of that description or class;**
- (n) **whether there are any relevant warnings to note, and, if so, what warnings;**
- (o) **whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;**
- (p) **arrangements for referral for medical advice;**
- (q) **details of the records to be kept of the supply, or the administration, of medicines under the Direction.**

Template PGDs are available on the DH website [here](#) and the NELM website [here](#).

#### **Can non-prescribing nurses administer POMs without a PGD in place?**

If there is no PGD in place then the nurse must have an individual instruction for that patient. This can be a PSD, or signed prescription.

#### **Do PGDs apply to HCAs?**

No. The Medicines Act does not allow HCAs to administer POMs under a PGD, as they are not included in the list of 'authorised' persons. An authorised person is one who is professionally regulated - HCAs therefore have to use a PSD or signed prescription as authority.

#### **Can PGDs be used in General Practice to administer non-NHS treatment?**

Under the Medicines Act GP practices are not permitted to use PGDs to enable nurses to administer treatment in NHS GP practices in non-NHS circumstances, for example providing private travel vaccinations such as Yellow Fever, Rabies, Meningitis etc. Patient Specific Directions must be used in these circumstances unless they are independent prescribers. The National Travel Health Network and Centre (NaTHNaC) has proposed an amendment to the Medicines Act 1968 to the Department of Health to allow the use of PGDs in non-NHS circumstance, and the GPC supports this amendment.

#### **Can PGDs be used for travel clinics?**

PGDs are useful for NHS travel health services as in many practices these are delivered by practice nurses who have a special expertise in that field. However they can only be used for those treatments which are provided on the NHS and not for private treatment. So where Hepatitis B vaccination can be given for travel and the patient is charged, a PGD cannot be used, but if it is given on the NHS then it can be administered under a PGD. This presents difficulties for some practices as many PCOs are trying to get practices to give Hepatitis B for travel as a private service which would make them ineligible for administration under a PGD and thus make the administration of the travel service more complex.

#### **Can a GP sign off a PGD?**

Not in the NHS. A PGD can only be signed off by a PCO when it applies to an NHS practice; if it is not signed off by the PCO, then it is not valid. This means that NHS practices are dependent on PCOs for the signing off of PGDs and can lead to PCOs using them to control or influence medicines use.

However GPs can be commissioned to provide clinical governance sign off for a PGD for a private practice or a private travel clinic (even though they cannot do so for their own NHS practice or clinic).

#### **Can a PCO demand that a practice adopts a PGD for a particular POM?**

No. The practice can determine how it wishes to organise the administration of medicines.

### **Can a PCO withdraw PGDs for certain medicines?**

PCOs may try to do this in order to influence medicines use in the area. There is nothing in the legislation that states that PCOs have to develop PGDs, they merely have to authorise them.

If GP practices develop their own PGDs it would be difficult for a PCO to justify not approving it if all the conditions listed above have been met and there is a clinical need for the service. In this situation they would not be adhering to their obligations and duties to administer and provide health care to the public as set out in the NHS Act 2006.

Practices should, with LMC support, raise this with the PCO in writing justifying why a PGD is needed and clinical evidence of the need and quoting the PCO's duties under the NHS Act and the amendment to the Prescription Only Medicines (Human Use) Order 1997 The Prescription Only Medicines (Human Use) Amendment Order 2000.

LMCs in their turn should support practices whose reasonable needs for a PGD are not being met by PCOs, especially where this is being done not on clinical grounds, but to manage prescribing. Please contact the GPC ([info.gpc@bma.org.uk](mailto:info.gpc@bma.org.uk)) for assistance this.

If there are difficulties with the use of or production of PGDs then the practice can use patient specific directions where possible in order to continue providing the service though this may be a far less suitable and flexible method.

### **Who in the practice needs to sign a PGD?**

The authorising GP needs to sign a PGD naming the specific health care professionals who the PGD will apply to. In addition, the GPC and NMC recommend that the health care professional acting under the PGD must also sign the PGD.

### **Can PCOs use PGDs as a performance management tool by putting unreasonable terms in them, for example excessive training requirements?**

PGDs were intended to improve patient care by enabling registered healthcare professionals other than doctors to supply and / or administer medicines to patients.

It is unreasonable and obstructive for PCOs to use PGDs to manage the way practices provide services. Only information listed above in Schedule 7, Part I of Statutory Instrument 2000 No. 1917 - The Prescription Only Medicines (Human Use) Amendment Order 2000 needs to be included in a PGD and if anything else is added by a PCO the practice should contact their LMC and raise these concerns before signing it.

### **Can PGDs be used to administer Botox?**

No. The administration of medicines (such as Botox®, Vistabel® or Dysport®) to paralyse muscles which cause wrinkles requires assessment of individual patients' suitability and (if the administration is to be delegated to a nurse or other person) patient specific directions. PGDs or general directions which would apply to any patient with an appointment on a particular day are not sufficient<sup>2</sup>. In any case PGDs cannot be used to for private services in an NHS practice.

### **What role do LMCs have in the development of PGDs?**

LMCs should:

- (i) Involve themselves in the production of PGDs by PCOs and ensure that PGDs are supportive to practices, keep the impact of associated bureaucracy to a minimum and ensure that PGDs are not used inappropriately as performance management tools.

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<sup>2</sup> *Supply and administration of Botox®, Vistabel®, Dysport® and other Injectable medicines in cosmetic procedures*, Medicines and Healthcare products Regulatory Agency, and *Medicines Matters - a guide to mechanisms for the prescribing, supply and administration of medicines*, Department of Health, 2006

- (ii) Provide advice to practices on PGDs and PSDs.
- (iii) Provide advice to practices seeking to draw up their own PGDs in accordance with the list of 'particulars to be included in a patient group directive' above. LMCs should also persuade PCOs to sign off any PGDs drawn up by practices.
- (iv) Ensure that PCOs do not unreasonably withdraw PGDs or allow them to go out of date without renewal and challenge PCOs where their refusal to authorise PGDs deleteriously affects care that can be provided to patients in General Practice. In England, LMCs should contact the SHA prescribing lead if their PCO will not sign off a PGD.

## Examples

### Childhood immunisation clinics

When children have been called for vaccinations and non-prescribing nurses are immunising the children, GPs, practices have two options:

- (i) The GP to prepare a PSD for each patient attending the clinic, in the form of a note in the patient record or a list of those attending the clinic signed by the GP. The note or list must specify which vaccination is due for each child.
- (ii) The practice to have a PGD in place which allows the nurse to administer the POM.

If HCAs are to be administering the vaccinations note that only a PSD can be used.

### Vaccinations and Medicines for Travel

If a patient is attending a nurse appointment and requires an NHS vaccination for travel, the most straightforward solution would be for the nurse to be able to administer that vaccination under the authority of a PGD. The GPC would recommend in these circumstances that if a PGD is available and acceptable to the GP, it would be in the practice's interest to have a PGD in place. However a PGD cannot be used for private immunisations so Rabies, Yellow Fever, Japanese B encephalitis, and Tic Borne encephalitis cannot be administered under a PGD. This also applies to supply of anti malaria chemoprophylaxis or for any other drugs supplied privately (such as, for example, antibiotics, acetazolamide) in case of disease arising abroad

### Opportunistic treatment

If a patient attends a nurse appointment and requires a prescription only medicine, the nurse can decide to administer that treatment under the authority of a PGD rather than requiring a specific instruction from a GP. The GPC would recommend in these circumstances that if a PGD is available, has been agreed and signed off by the PCO and acceptable to the GP, it would be in the practice's interest to have a PGD in place. Examples where this might be appropriate include a sexual health clinic where the pill may be given or treatments for STDs are needed

### Instructions from secondary care

If a patient attends the practice for the administration of a drug specified in a letter from secondary care (eg Clexane, Zoladex) then the nurse may regard the signed hospital letter as a PSD and may administer the drug provided that she is satisfied that the letter contains sufficient detail of the drug and dosage.

## PGDs – Further information

- [Medicines Act \(1968\)](#)
- [Statutory Instrument \(2000a\) The Prescription only Medicines \(Human Use\) Amendment Order 2000. Statutory Instrument no.1917, London: The Stationery Office.](#)

- [Statutory Instrument \(2000b\) \*The Medicines \(Sale or Supply\) \(Miscellaneous Provisions\) Amendment \(no.2\) Regulations 2000\*. Statutory Instrument no. 1918, London: The Stationery Office.](#)
- [Statutory Instrument \(2000c\) \*The Medicines \(Pharmacy and General Sale Exemption\) Amendment Order 2000\*. Statutory Instrument no. 1919, London: The Stationery Office.](#)
- [HSC 1998/051](#)
- [HSC 2000/026](#)
- [Medicines Matters - A guide to mechanisms for the prescribing, supply and administration of medicines \(sections 2 & 3\)](#)
- [Patient Group Directions \(PGD\) \(a portal of the National electronic Library for Medicines \(NeLM\)](#)
- [Department of Health guidance](#)
- [National Prescribing Centre guidance](#)
- [Medicines and Healthcare Products Regulatory Agency \(MHRA\) guidance](#)
- [NHS Education guidance for Scotland](#)
- [Nursing and Midwifery Council. Standards for Medicines Management](#)