

## SUMMARY

Supplementary prescribing and patient group directions are aimed at improving patient care by making better use of health care professionals' skills and providing access to medicines more efficiently. This *Briefing* is intended to be a quick reference guide to both.

### Supplementary prescribing

Page 1

Supplementary prescribing allows additional health care professionals to prescribe medicines, and an overview of it in primary care is given here. Although supplementary prescribing also takes place in secondary care, it is not covered in this *Briefing*.

### Patient group directions

Page 6

Patient group directions allow most Prescription-only, Pharmacy and General Sales List medicines to be sold, supplied and/or administered to patients under specific circumstances.

## Supplementary prescribing

In 1997, the Department of Health (DH) commissioned a review team to look at the prescribing, supply and administration of medicines. The first report from this group, 'A report on the supply and administration of medicines under group protocols', was published in April 1998.<sup>1</sup> Its recommendations came into force in August 2000 when changes to legislation allowed the supply or administration of medicines under patient group directions (PGDs).<sup>2</sup>

A further report ('Review of prescribing, supply and administration of medicines'),<sup>3</sup> issued in 1999, concluded that in the United Kingdom the legal authority to prescribe should be extended to include professional groups other than doctors, dentists, district nurses and health visitors. This report suggested that, following a full clinical assessment, responsibility for the clinical management of some patients' care, including prescribing, could be passed to another appropriately trained health care professional. This person would be called a supplementary prescriber (then referred to as a dependent prescriber), who would have to work within the parameters of a treatment plan. The necessary legislation was contained in The Health and Social Care Act 2001 and, in November 2002, it was announced that pharmacists and nurses, after successfully completing the required training, would be granted supplementary prescribing responsibilities.<sup>4</sup>

These two significant changes to ways that patients gain access to medicines are discussed in this *Briefing*. More detailed documents on supplementary prescribing and

patient group directions are listed in the Resources panel on page 8.

### What is supplementary prescribing?

The DH defines supplementary prescribing as:<sup>5</sup>

'A voluntary partnership between an independent prescriber (a doctor or a dentist) and a supplementary prescriber, to implement an agreed patient-specific clinical management plan, with the patient's agreement.'

The main characteristics of supplementary prescribing are summarised in **Panel 1** (see page 2). The aim of supplementary prescribing is to provide patients with quicker, more efficient access to medicines, and to make best use of the skills of health care professionals. In addition, it is likely that it will reduce doctors' workloads and allow them to spend more time with patients who have complicated conditions and complex treatment regimens.<sup>5</sup>

Supplementary prescribing is based on a prescribing partnership between an independent prescriber (i.e. a doctor or a dentist) and a supplementary prescriber (currently a suitably trained nurse or pharmacist).<sup>4</sup> Supplementary prescribers can prescribe most medicines. This includes antimicrobials, drugs that are under intense surveillance by the Committee on Safety of Medicines (i.e. 'black triangle' drugs), and products listed in the *British National Formulary* as being 'less suitable' for prescribing.<sup>5</sup> In addition, they may prescribe products for indications outside of the product licence, provided the drug is licensed in the

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UK, that there is joint agreement between the prescribers about such use, and that the drug's status is recorded in the clinical management plan (CMP). However, they cannot currently prescribe controlled drugs. In addition, they cannot prescribe unlicensed drugs, unless the drugs are part of a clinical trial that has a clinical trial certificate or exemption, there is joint agreement from both prescribers, and the status of the drug is recorded in the CMP.

Supplementary prescribing can only be carried out within the previously agreed parameters of a patient-specific CMP.<sup>5</sup> This plan will be drawn up, with the patient's agreement, following diagnosis by the independent prescriber and consultation and agreement between the independent and supplementary prescribers.<sup>5</sup> It identifies the conditions to be treated and the circumstances under which the dosage, frequency and formulation of the medicines identified can be varied.<sup>4</sup>

Supplementary prescribers can prescribe for the full range of medical conditions, provided they do so under the terms of the CMP.<sup>5</sup> Two CMP templates are available on the supplementary prescribing section of the DH website (<http://www.dh.gov.uk>) to help with development of CMPs locally. Use of these templates is not mandatory, but a CMP must be in place before supplementary prescribing can begin.

### The clinical management plan (CMP)

The concept of supplementary prescribing is based on the development and implementation of a CMP. Without this, supplementary prescribing cannot take place. The CMP must be patient-specific and must relate to identified conditions for which the supplementary prescriber has agreed to take responsibility. The requirements for CMPs are listed in **Panel 2** (see page 3). CMPs should be kept as simple as possible and should be included in the patient record. There is no need to repeat information that is held in the patient's records that are shared by both prescribers, unless it is essential for patient safety and for clarity. A CMP may refer to guidelines (e.g. national service frameworks or guidance from the National Institute for Clinical Excellence [NICE]) but need not repeat what the guidance says, unless it is essential for clarity and patient safety. However, the guidelines must be accessible to the supplementary prescriber.<sup>5</sup>

After discussion, either the independent prescriber or the supplementary prescriber drafts the CMP. They must both formally agree it before supplementary prescribing can begin. The CMP may have to contain different levels of detail, depending on the location of the independent and supplementary prescribers (for example, the supplementary prescriber

#### Panel 1: Main characteristics of supplementary prescribing (adapted from DH guidance)<sup>5</sup>

- Supplementary prescribing can only take place after assessment and diagnosis of the patient by an independent prescriber has taken place and a written CMP has been agreed by both the supplementary and the independent prescriber
- Patient consent must be obtained
- Supplementary prescribers can then make decisions relating to the medicine, such as dose, frequency, formulation, choice of drug from a class, and other variables, within the scope of the CMP
- Independent prescribers must review the patient at predetermined intervals depending on the patient's condition and the drugs prescribed (e.g. every six months or at the request of the supplementary prescriber if a review is needed before the planned date)
- Independent prescribers can, at any time, review the patient's condition or resume full responsibility for the patient's care
- Independent and supplementary prescribers must be able to communicate easily, and should share access to, and use, the same patient record
- Independent and supplementary prescribers may operate within more than one prescribing partnership, provided they are willing and able to work together and to assume the responsibilities involved.

Independent prescribers are responsible for:

- Making a diagnosis and for setting the parameters of the CMP, although they do not necessarily have to draw it up personally

- Agreeing the limits of the supplementary prescriber's responsibility for review and prescribing
- Providing advice and support to the supplementary prescriber
- Reviewing the patient within the predetermined timescales or before, if requested by a supplementary prescriber
- Sharing a common patient record with the supplementary prescriber
- Reporting adverse incidents within national and local risk management or clinical governance schemes.

Supplementary prescribers are responsible for:

- Prescribing for a patient in accordance with a CMP
- Monitoring and assessing the patient's progress
- Working within their clinical competence and professional code of conduct at all times, and passing management back to the independent prescriber if they feel the patient's condition no longer falls within this competence
- Consulting the independent prescriber, when necessary
- Accepting professional accountability and clinical responsibility for their prescribing practice
- Passing prescribing responsibility back to the independent prescriber if the agreed clinical reviews are not carried out within the specified interval
- Recording prescribing and monitoring activity in the shared patient record, ideally within 24–48 hours
- Reporting adverse incidents within national and local risk management or clinical governance schemes.

may visit the patient at home).<sup>5</sup> Independent prescribers determine the level of responsibility that is to be delegated to supplementary prescribers under a CMP. In addition, they should take into account the experience, areas of clinical practice and level of expertise of supplementary prescribers, as well as the professional relationship between themselves and the supplementary prescriber, when deciding what to delegate.<sup>5</sup> Supplementary prescribers should not agree to prescribe a medicine if they feel they do not have sufficient competence, confidence or knowledge to do so.<sup>5</sup>

### What might be prescribed in the future?

The Medicines and Healthcare products Regulatory Agency (MHRA) is consulting with interested bodies about proposals to allow supplementary prescribers to prescribe and order unlicensed medicines manufactured in the UK and supplied as 'specials' (rather than just those that are part of a clinical trial) within the terms of a CMP agreed with an independent prescriber. This will also include unlicensed medicines imported into the UK and unlicensed medicines prepared by pharmacists from active and inactive pharmaceutical ingredients.<sup>6</sup>

### What does this mean for patients?

For supplementary prescribing to take place, each patient must agree to be managed by a prescribing partnership within the scope of a CMP. The agreement of the patient should be recorded in the CMP and the patient record. Without such an agreement, supplementary prescribing cannot proceed.<sup>5</sup>

Patients may find that monitoring of their condition is improved when they are managed by a prescribing partnership and that they become more involved in decisions relating to

their care.<sup>7</sup> However, patients must be made aware of the limitations of supplementary prescribing and that they may have to use other mechanisms to obtain additional items necessary for their care.<sup>5</sup> The College of Pharmacy Practice Faculty of Prescribing and Medicines Management (FPMM) has produced a patient information leaflet explaining supplementary prescribing, which is available on its website ([www.collpharm.org/PMM.htm](http://www.collpharm.org/PMM.htm)).

### What does this mean for primary care organisations (PCOs)?

Currently nurses and pharmacists are the only health care professionals eligible to train as supplementary prescribers. The selection of the nurses and pharmacists who will receive training should be decided locally, based on increasing the benefits to patients and local service needs. It will be up to PCOs and workforce development confederations (WDCs) to determine which pharmacists and nurses are put forward for training. Central funding is available through WDCs to meet the cost of this initial training and it is for WDCs to decide how best to use these monies. In addition, NHS employers may also use their own training funds for this purpose.<sup>5</sup>

Health care professionals applying to train as supplementary prescribers must have the support of both their PCO and, where necessary, their employer. The employer should confirm that the post of the prospective trainee is one in which there will be an opportunity to practice as a supplementary prescriber. In addition, systems should be in place to give supplementary prescribers access to a budget to meet the cost of what they prescribe.

Local continuing professional development (CPD) infrastructures should be capable of identifying and addressing the needs of supplementary prescribers once they have

**Central funding is available to meet the cost of the initial training for supplementary prescribers**

## Panel 2: Requirements for a clinical management plan (CMP)<sup>5</sup>

A CMP must include the following:

- The patient's name
- The illnesses or conditions that the supplementary prescriber may manage
- The date on which the plan commences and when an independent prescriber will carry out a review
- Reference to the class or description of the medicines, or types of appliances, which may be prescribed or administered under the plan
- Any restrictions or limitations as to the strength or dose of any medicine permitted to be prescribed or administered under the plan, and any period of administration or use of any identified medicine or appliance
- Relevant warnings about known sensitivities of the patient or any problems they have had with medicines or appliances
- Arrangements for notification of an incident with any appliances, or a suspected or known adverse reaction to any medicines prescribed or administered under the plan, or to medicines taken concurrently with those on the plan
- Circumstances under which the supplementary prescriber should refer the patient back to, or seek advice from, the independent prescriber.

The CMP comes to an end:

- At any time at the discretion of the independent prescriber, or at the request of the supplementary prescriber
- At any time at the request of the patient
- At the time specified for review
- If the independent prescriber is replaced, in which case, it must be reviewed and agreed by their successor.

successfully completed the initial training.<sup>5</sup> The DH recommends that employers ensure that supplementary prescribers have access to relevant education and training provision.<sup>5</sup>

Supplementary prescribing may help PCOs to achieve some of their targets. For example, improved access to care, and adherence to NICE guidance and national service frameworks. It will also allow PCOs to make efficient and effective use of the skill-mix within their organisations. Supplementary prescribing should promote more multidisciplinary working and provide added value by using the skills, knowledge and expertise of a range of health care professionals.<sup>7</sup>

PCOs and employers should consider the implications of supplementary prescribing. Some approaches to the initial training involve a significant amount of time away from work, and the added cost of locum cover or loss of staff time may have to be addressed.<sup>7</sup> Supplementary prescribers will be taking on additional roles and responsibilities, and this may result in a loss of time in other areas.<sup>7</sup> Clinical governance issues also need to be addressed. For example, providing access to a single patient record and making sure that supplementary prescribers use their new qualification and maintain competence in this role. However, these initial investments should be considered alongside the potential gains in patient care and service improvement.<sup>6</sup>

A general overview of supplementary prescribing arrangements should be carried out as part of the monitoring of prescribing arrangements.

The supplementary prescriber, together with their employer, must put into place specific systems and actions to ensure that the safety, effectiveness, appropriateness and acceptability of their prescribing is evaluated regularly.<sup>5</sup> To allow dispensing pharmacists to check whether a prescription written by a supplementary prescriber is valid, NHS employers should keep a record of all supplementary prescribers employed by them. The DH also recommends that employing authorities hold a copy of prescribers' signatures.<sup>5</sup>

**What does this mean for people wanting to train as supplementary prescribers?**

The opportunity to improve patient care should drive any moves towards supplementary prescribing. It is crucial that pharmacists and nurses who are considering becoming supplementary prescribers have the opportunity to prescribe in the post they will occupy on completion of their training. They should not be forced to undertake the training and must be willing participants in the role.<sup>5</sup> Nurse supplementary prescribers must be first-level registered nurses or registered midwives whose names are held on the Nursing and Midwifery Council professional register. In addition, their register entry must have an annotation to show that they have successfully completed an approved programme of preparation for supplementary prescribing.<sup>5</sup> Supplementary prescribers who are pharmacists must be registered with the Royal Pharmaceutical Society of Great Britain (RPSGB) and have a similar annotation.<sup>5</sup> The FPMM has produced a checklist to help pharmacists wishing to become supplementary prescribers (see **Panel 3**).<sup>8</sup>

**What does the training involve?**

**Nurses**

Nurses preparing to become supplementary prescribers have to undertake a specific programme of preparation at degree level, directed by a higher education institution. In England, this programme of preparation consists of at least 26 days of taught education plus 12 days learning in practice. This may be spread over three to six months.<sup>5</sup>

The curriculum for nurse supplementary prescribers is based on that for *Extended Formulary* independent nurse prescribers, with additional parts that relate to supplementary prescribing. Therefore, nurses completing this course will be both extended nurse prescribers and supplementary prescribers.<sup>4</sup> Nurses who are already qualified to prescribe from the *Extended Formulary* must undertake an additional one or two days' preparation before they can become a supplementary prescriber.<sup>5</sup>

The former English National Board for Nursing, Midwifery and Health Visiting (ENB) produced

**Panel 3: Checklist for pharmacists wishing to become supplementary prescribers<sup>8</sup>**

- Do you understand what supplementary prescribing is?
- Do you know the difference between supplementary prescribing and patient group directions?
- Do you meet the basic requirements to become a supplementary prescriber?
  - Are you registered with the RPSGB?
  - Do you have two years' post-registration experience?
- Are you fully aware of the training requirements?
  - Do you know where local training is held or how to find out?
  - Do you know how your training will be funded?
  - Do you know what the priorities are for placements?
- Does the sponsoring organisation see a need for this extended role?
  - Have you approached your local PCT?
  - Is the PCT aware of your interest?
  - Will the undertaking of this role bring benefits to patients?
  - How will you monitor success?
- Have you considered the practical requirements?
  - Have you identified a mentor?
  - How will you gain access to patients' notes?
  - Where will you practise?
  - How will you obtain prescription pads?
- How will your competency be maintained?
  - Have you thought about CPD?
  - Do you require additional training in therapeutics?

Adapted, with permission, from the FPMM checklist

the initial outline curriculum for training and preparing nurses for *Extended Formulary* nurse prescribing. This included topics such as:<sup>9</sup>

- Consultation and decision-making
- Influences on and psychology of prescribing
- Prescribing in a team context
- Clinical pharmacology, including the effects of co-morbidity
- Evidence-based practice and clinical governance in relation to nurse prescribing
- Legal, policy, and ethical aspects
- Professional accountability and responsibility
- Prescribing in the public health context.

### Pharmacists

Pharmacists preparing to become supplementary prescribers have to undertake a specific programme of training, comprising at least 25 days taught at a higher education institution, which may or may not be a school of pharmacy.<sup>5</sup> Most of the training should be face-to-face but other approaches to teaching and learning, such as open or distance learning will be considered. This theoretical component should be complemented with not less than 12 days learning in practice.<sup>5</sup>

The RPSGB has endorsed an outline curriculum for training pharmacist supplementary prescribers.<sup>5</sup> This identifies the entry requirements to courses, and the learning outcomes that those successfully completing the course will be able to demonstrate. The content of the outline curriculum includes:

- Consultation and decision-making
- Influences on and psychology of prescribing
- Prescribing in a team context
- Update on relevant aspects of therapeutics
- Principles and methods of monitoring
- Evidence-based practice and clinical governance in relation to supplementary prescribing
- Legal, policy, professional and ethical aspects
- Prescribing in the public health context.

### What has to be done in addition to the initial training?

Before starting to prescribe, supplementary prescribers should:<sup>5</sup>

- Successfully complete the specified training and preparation for supplementary prescribing, including all assessments and learning in practice
- Ensure that the relevant professional register is annotated to indicate that they are qualified to prescribe
- Agree with an independent prescriber to enter into partnership with them and record this in the patient's notes

- Agree a CMP with the independent prescriber
- Make arrangements with their employer and/or the independent prescriber for access to prescription pads
- Arrange access to an identified budget to meet the cost of their prescriptions
- Agree with their employer that supplementary prescribing is included in their job description.

In addition, all supplementary prescribers should ensure that they have indemnity insurance, from a professional organisation or a trade union.

### Evaluation, audit and clinical governance of supplementary prescribing

As with every area of practice, supplementary prescribing should take place within the framework of clinical governance. This should allow supplementary prescribers to reflect on their prescribing practice, which, for nurse prescribers, can be achieved by clinical supervision. Peer review, mentoring and support should be arranged for pharmacist prescribers.<sup>5</sup> The RPSGB is developing clinical governance guidance for pharmacist supplementary prescribers, which could be reflected in employer organisations' clinical governance framework.<sup>5</sup> Independent and supplementary prescribers are responsible for reporting adverse incidents within national and local risk management or clinical governance schemes.<sup>5</sup>

### Continuing professional development (CPD)

All nurses and pharmacists have a professional responsibility to keep abreast of clinical and professional developments. Supplementary prescribers should keep up to date with best prescribing practice and management of conditions for which they prescribe. This will contribute to individual CPD requirements. The DH recommends that employers ensure that supplementary prescribers have access to relevant education and training provision.<sup>5</sup>

### When should supplementary prescribing be used?

Health care professionals and managers who wish to formalise or set up new systems of prescribing, supply or administration of medicines should choose the most appropriate prescribing method in each case. Supplementary prescribing is most likely to be useful when dealing with long-term medical conditions, such as asthma, diabetes or coronary heart disease, or with long-term health needs, such as anticoagulation. Most medicines can be prescribed using supplementary prescribing and it also allows supplementary prescribers to make adjustments to doses of drugs, provided they do so within the scope of the CMP.<sup>4</sup>

***Supplementary prescribers should keep up to date with best prescribing practice and management of conditions for which they prescribe***

*PGDs are best used when medicine usage follows a predictable pattern*

**References**

- 1 Review of prescribing, supply and administration of medicines. A report on the supply and administration of medicines under group protocols. London: Department of Health; 1998.
- 2 Patient group directions (England only) HSC 2000/026. London: Department of Health; 2000.
- 3 Review of prescribing, supply and administration of medicines, final report. London: Department of Health; 1999.
- 4 Supplementary prescribing. A resource to help healthcare professionals to understand the framework and opportunities. Liverpool: National Prescribing Centre; 2003.
- 5 Supplementary prescribing by nurses and pharmacists within the NHS in England. A guide for implementation. London: Department of Health; 2003.
- 6 Outline curriculum for training programmes to prepare pharmacist supplementary prescribers. London: Royal Pharmaceutical Society of Great Britain; 2002. Available from: URL: <http://www.rpsgb.org.uk>
- 7 College of Pharmacy Practice Faculty of Prescribing and Medicines Management. PCO briefing paper: supplementary prescribing by pharmacists. Available from: URL: <http://www.collpharm.org>
- 8 Faculty of Prescribing and Medicines Management. Checklist for pharmacists wishing to become supplementary prescribers. Available from: URL: <http://www.collpharm.org>
- 9 Outline curriculum for the preparation of nurses, midwives and health visitors to prescribe from the Extended Nurse Prescribers' Formulary: Appendix 1 to EPL 2001/01/TL. London: English National Board for Nursing, Midwifery and Health Visiting; 2001. Available from: URL: <http://www.nmc-uk.org>

## Patient group directions

The use of group protocols that allowed non-prescribers to supply or administer medicines used to be commonplace in the NHS. This was acknowledged in the first report of a review group commissioned by the Department of Health (DH) to look at the prescribing, supply and administration of medicines, issued in April 1998.<sup>1</sup> This report proposed that the legal issues surrounding group protocols needed to be clarified to ensure that they were being used in a consistent way and were within the law. As a result, a legal framework that allowed such supply to continue, if it was consistent with the legal framework, using patient group directions (PGDs) was set up and put in place in August 2000.<sup>2</sup> This *Briefing* summarises the main points that relate to PGDs and may be useful as a quick reference guide.

The National Prescribing Centre recently published a web-based guide to PGDs (*Patient group directions — a practical guide and framework of competencies for all professionals*

using PGDs”).<sup>3</sup> It includes a competency framework for all health care professionals using this form of supply or administration. In addition, it contains a detailed overview of how to set up PGDs and how to use them appropriately. Further information about PGDs can be found in the documents and internet sources that are listed in the Resources panel on page 8.

### What is a patient group direction (PGD)?

The legal definition of a PGD is:

‘A written instruction for the sale, supply and/or administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment.’<sup>3</sup>

DH guidance that was issued at the same time as this definition highlighted the circumstances under which it might be appropriate to use a PGD. This guidance stated that:<sup>3</sup>

‘The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration of medicines under PGDs should be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability’.

The lawful criteria for information that must be included in a PGD are shown in **Panel 1**. PGDs lend themselves to situations where medicine usage follows a predictable pattern and is less individualised, (e.g. emergency contraception). Using a PGD is not a form of prescribing and they are not generally meant to be a long-term means of managing a patient’s condition.<sup>3</sup>

### How should PGDs be produced and authorised?

A multidisciplinary group including a senior doctor and pharmacist, and a representative of the health care professional group that will be

**Panel 1: Lawful criteria for a PGD<sup>2</sup>**

To comply with the law, PGDs must contain the information detailed below:

- The name of the business to which the PGD applies
- The date the PGD comes into force and the date it expires
- A description of the medicine(s) to which the PGD applies
- The class of health care professional who may supply or administer the medicine
- The signature of a doctor or dentist, as appropriate, and a pharmacist
- The signature of an appropriate health organisation
- The clinical condition, or situation, to which the PGD applies
- A description of patients excluded from treatment under the PGD
- A description of the circumstances under which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements made for referral
- Details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered
- Relevant warnings, including potential adverse reactions
- Details of any necessary follow-up action
- A statement of the records to be kept for audit purposes.

using the PGD should be involved in the production of a PGD.<sup>2</sup> It is good practice to involve local drug and therapeutic committees, area prescribing committees and similar advisory bodies that exist locally.<sup>4</sup> The PGD must be authorised by the organisation within which it is to be used.

Each member of the multidisciplinary group involved in its production, including the doctor and pharmacist, the authorising person for the organisation in which it will be used, and the member of the professional group that will be using the PGD must then sign it.<sup>2</sup>

### Who is allowed to supply or administer medicines under a PGD?

A list of the qualified health care professionals who are permitted to supply or administer medicines under a PGD is given below.

- Ambulance paramedics
- Pharmacists
- Health visitors
- Midwives
- Nurses
- Optometrists
- State registered chiropodists
- State registered orthoptists
- State registered physiotherapists
- State registered radiographers.

These professionals can only make such supplies as named individuals and must have signed the PGD.<sup>2</sup> A senior person in each profession should be designated to ensure that only fully competent, qualified and trained professionals operate within the directions.

Proposals are currently being considered to extend the range of health care professionals that can use PGDs. The list of health care professionals that might be affected by this includes dietitians, occupational therapists, prosthetists and orthotists, and speech and language therapists.<sup>4</sup>

Professionals using PGDs must be registered members of their profession and must act within the appropriate code of professional conduct. 'Patient Group Directions — a practical guide and framework of competencies for all professionals using PGDs' presents a competency framework that health care professionals and their managers can use to ensure that those using PGDs have the necessary competencies.<sup>3</sup>

### Which organisations can use PGDs?

In April 2003, more organisations became eligible to sell, supply and administer medicines under PGDs. These organisations are:<sup>3,4</sup>

- Special health authorities
- NHS trusts and primary care trusts (PCTs)

- A doctor's or dentist's practice, in the provision of NHS services
- A non-NHS organisation providing treatment under an arrangement made with an NHS trust or PCT (e.g. a walk-in centre or family planning clinic)
- Services funded by the NHS but provided by the private, voluntary or charitable sector
- Independent hospitals, agencies and clinics registered under the Care Standards Act 2000
- Health care services provided by the prison service
- Health care services provided by the police force
- Health care services provided by the medical service for the armed forces.

### What medicines must be given special consideration prior to inclusion in a PGD?

Most licensed Pharmacy, General Sales List, and Prescription-only medicines, can be supplied or administered under a PGD, provided all the necessary requirements are met.<sup>5</sup> However, specific guidance has been issued for the use of antimicrobials, controlled drugs, 'black triangle' drugs and for drugs being used outside the terms of their summary of product characteristics (SPC). These are detailed below.

#### Controlled drugs

In October 2003, the Misuse of Drugs Regulations 2001 were amended to allow some controlled drugs to be supplied or administered under a PGD.<sup>6</sup> The following controlled drugs can now be supplied and/or administered:

- Diamorphine — only for treatment of cardiac pain by nurses working in coronary care units and accident and emergency departments in hospitals
- All drugs listed in Schedule 4 of the Misuse of Drugs Regulations 2001 (these are mainly benzodiazepines), except anabolic steroids
- All drugs listed in Schedule 5 of the Misuse of Drugs Regulations 2001 (i.e. low-strength opiates, such as codeine).

#### Antimicrobials

DH guidance states that PGDs for antimicrobials should be drawn up with particular caution.<sup>4</sup> Resistance to antimicrobials is a public health matter of great importance and care should be taken that use of antibiotics in PGDs does not jeopardise strategies to combat resistance and that it is absolutely necessary. For example, a PGD should not allow supply or administration of a medicine for minor viral diseases, such as non-bacterial sore throats, that are unaffected by antibiotics. A local microbiologist or public health specialist with

**Proposals are being considered that would extend the range of health care professionals able to use PGDs**

appropriate expertise should be involved in drawing up any PGD for use of antimicrobials.<sup>4</sup> Local drug and therapeutics committees or area prescribing committees (or their equivalent) should ensure that any PGDs for antimicrobials are consistent with local policies and are subject to regular external audit.<sup>2,4</sup>

**Medicines used outside the terms of their SPC and ‘black triangle’ drugs**

‘Black triangle’ drugs and medicines used outside the terms of their SPC may be included in PGDs, provided such use is exceptional and is supported by current best clinical practice. The PGD must clearly state that a ‘black triangle’ drug is being included or when a product is being used outside the terms of its SPC, and why such use is necessary.<sup>2-4</sup> When the medicine is for use in children, particular attention will be needed when specifying any restrictions on the age, size and maturity of the child.<sup>2</sup>

Unlicensed medicines cannot be supplied or administered under a PGD. Neither can appliances or dressings, as PGDs only apply to

licensed medicines. Dressings and appliances can be provided using a protocol or guidelines or, if they are included in either of the nurse prescriber formularies, they can be prescribed by an appropriately qualified independent nurse prescriber.<sup>3</sup>

**What about supplying medicines?**

Council Directive 92/27/EEC on the labelling of medicinal products for human use and on package leaflets applies to all supplies of medicines, including those supplied under PGDs.<sup>2</sup> Therefore, a patient information leaflet should be made available to patients treated under PGDs.<sup>3,5</sup> NHS guidance has indicated that all medicines should be supplied in prepacks made up by a pharmacist. However, pharmacists who are asked to supply prepacks in this manner must check with the Medicines and Healthcare products Regulatory Agency (MHRA) that they have the appropriate licence to do so.<sup>3</sup>

**When should you use a PGD?**

PGDs are not meant to replace traditional prescribing by a health care professional for an individual patient on a one-to-one basis. Indeed, for patients requiring long-term management of a condition, individual prescribing is the most appropriate route of care. Many chronic conditions will not, therefore, be suitable for PGDs and another option, such as supplementary prescribing, may be more appropriate.<sup>3</sup>

PGDs are most appropriate in situations in which medicines use follows a predictable pattern and does not need to be individualised. They can be used to manage a specific treatment episode (or episodes) for which supply or administration of a medicine is necessary. PGDs are less appropriate for long term management of an individuals’ condition (e.g. for management of hypertension).<sup>3</sup> Examples of when PGDs have been used successfully can be found on the website [www.groupprotocols.org.uk](http://www.groupprotocols.org.uk) (see Resources panel).

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- 1 Review of prescribing, supply and administration of medicines. A report on the supply and administration of medicines under group protocols. London: Department of Health; 1998.
- 2 Patient group directions (England only) HSC 2000/026. London: Department of Health; 2000.
- 3 Patient Group Directions — a practical guide and framework of competencies for all professionals using patient group directions. Liverpool: National Prescribing Centre; 2004. Available from: URL: <http://www.npc.co.uk>.
- 4 Sale, supply and administration of medicines by allied health professionals under patient group directions (MLX 294). London: Medicines and Healthcare products Regulatory Agency; 2003.
- 5 Patient group directions: a resource pack for pharmacists. London: Royal Pharmaceutical Society of Great Britain; 2004.
- 6 Controlled drugs legislation — nurse prescribing and patient group directions (Home Office Circular 049 / 2003). London: Home Office; 2003. Available from: URL: <http://www.homeoffice.gov.uk/inside/circs/>

**Resources**

The final report of a task group on pharmacist prescribing that was set up by the RPSGB. Available from <http://www.rpsgb.org.uk/pdfs/supplprescpharmrefinal.pdf>

The RPSGB’s outline curriculum for training programmes intended to prepare pharmacist supplementary prescribers. Available from <http://www.rpsgb.org.uk/pdfs/supplprescphoutlcurric.pdf>

*Supplementary prescribing: a resource to help healthcare professionals to understand the framework and opportunities* is published by the NPC and is available from [http://www.npc.co.uk/publications/healthcare\\_resource.pdf](http://www.npc.co.uk/publications/healthcare_resource.pdf)

An RPSGB resource pack for pharmacists about PGDs is available from <http://www.rpsgb.org/pdfs/pgdpack.pdf>

RPSGB fact sheet number 10 is about PGDs and can be found at <http://www.rpsgb.org/pdfs/factsheet10.pdf>

An NPC document *Patient Group Directions (PGDs) — a practical guide and framework of competencies for all professionals using PGDs* is available from <http://www.npc.co.uk/pdf/pgd.pdf>

*Patient group directions (England only) HSC 2000/026* is available from <http://www.dh.gov.uk>

Information about PGDs is available from the prescribing, sale and supply of medicines: patient group directions page in the NHS section of the MHRA website <http://medicines.mhra.gov.uk>

The website <http://www.groupprotocols.org.uk> provides examples of PGDs in the NHS, and includes a flow chart called ‘To PGD or not PGD’ ([http://212.19.87.153/protocols/July\\_2003PGD.pdf](http://212.19.87.153/protocols/July_2003PGD.pdf))

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