


Patient Group Directions

A practical guide and framework of competencies
for all professionals using patient group directions

*Incorporating an overview of existing mechanisms
for the supply and prescribing of medicines*

March 2004

The logo for the National Prescribing Centre features the text 'NATIONAL PRESCRIBING CENTRE' in a green, serif font. The text is arranged in three lines: 'NATIONAL' on the top line, 'PRESCRIBING' on the middle line, and 'CENTRE' on the bottom line. A green curved arrow starts to the left of the text, curves around the top and right, and ends with an arrowhead pointing to the right below the word 'CENTRE'.

**NATIONAL
PRESCRIBING
CENTRE**

The NHS logo consists of the letters 'NHS' in a white, bold, sans-serif font, set against a blue rectangular background.

NHS

About this document

The organisation involved

The National Prescribing Centre (NPC), Department of Health (DH) and the National Patient Group Directions (PGDs) Working Group for the NHS Walk-in Centres have all worked on the development of this document.

National Prescribing Centre

The NPC is an NHS organisation, formed in April 1996 by the DH, following a review of centrally funded support for prescribing and medicine use. Its aim is:

To promote high quality, cost-effective prescribing and medicines management across the NHS, to help improve services and patient care'

The NPC's objective is to develop a co-ordinated programme of activities, within the wider context of evidence-based medicine, providing varying levels of support to relevant NHS audiences. This is achieved by considering the major short and medium term needs of each identified audience, around prescribing, within the following main areas of work:

- Information on medicines and their use
- Education and development
- Dissemination of good practice

Work in these three areas is supported and reinforced by additional umbrella activities in the broader developmental areas of:

- Information technology
- Informing research and development (R&D)

The NPC has collaborative links with a wide range of relevant national bodies and professional groups and is now also working closely with the National Institute for Clinical Excellence.

For more information on the work and publications of the NPC, **including downloadable copies of this document**, please visit our websites at www.npc.co.uk (Internet) or www.npc.nhs.uk (NHSNet).



Foreword

I very much welcome this publication from the National Prescribing Centre and congratulate the authors on a valuable addition to their work supporting health professionals who are taking on new roles in relation to the prescribing, supply and administration of medicines.

The extension of prescribing rights means that nurses can now be independent or supplementary prescribers, and the first pharmacist supplementary prescribers are just completing training. Other health care professionals are likely to become prescribers in the near future. These developments will enable patient care to be delivered in new ways that offer easier access and greater convenience and they will also ensure that better use is made of the skills and training of health care professionals.

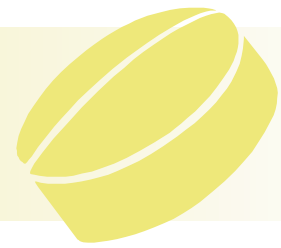
However, even when extended prescribing for individual patients is widespread, there will still be times when patient group directions (PGDs) will be the best way to meet the patients' needs. They provide the framework for the supply and administration of medicines without the need for an individual prescription and can be invaluable in some direct access services and certain emergency situations.

Health care professionals who provide care through PGDs must be appropriately trained and understand the responsibilities of this part of their work. This document offers excellent advice on the place of PGDs in clinical practice and the competencies required by practitioners. The guidance will support staff who use PGDs and hence contribute to the welfare and safety of their patients.

A handwritten signature in black ink that reads "June Crown".

*Dr June Crown CBE
Chairman, Review of the Prescribing, Supply and Administration of Medicines*





Contents

Foreword	1
1 Introduction	5
1.1 Purpose of this document	5
1.2 Audience for the document	6
2 How patients receive medicines	8
2.1 Background	8
2.2 Legislation governing the use of medicines — the key points	10
2.3 The difference between prescribing and PGDs	12
2.4 Nurse and pharmacist prescribing	16
2.5 When to use a PGD; when to prescribe	18
3 Using PGDs	20
3.1 Definition of a PGD	20
3.2 Professional groups who can use PGDs	22
3.3 Organisations that can use PGDs	23
3.4 Producing and authorising PGDs	24
3.5 Information that should be contained in a PGD	26
3.6 Requirements for controlled drugs and antimicrobials	27
4 Frequently asked questions about PGDs	29
4.1 Uses of PGDs	29
4.2 Production of PGDs — see also section 3.4	31
4.3 Medicines that can be included in a PGD — see also section 3.6	32
4.4 Practical issues of usage	33
4.5 Training and evaluation	35
5 Competency framework for health care professionals using PGDs	37
5.1 Introduction	37
5.2 The structure of the framework	38
5.3 Key features of the framework	40
5.4 The framework itself	40
5.5 Using the competency framework	44
6 Useful links	46
7 Glossary	48
Appendix 1: To PGD or not to PGD? — that is the question	51
Appendix 2: Acknowledgements	53





1 Introduction

1.1 Purpose of this document

The NHS Plan¹ emphasises the necessity to organise and deliver services around the needs of patients. This focus on patients' needs has been reinforced recently by the strategy paper — 'Building on the best; choice, responsiveness and equity in the NHS²'. To achieve patient-focused services, health care professionals are finding ways to work more flexibly. One area in which changes are happening rapidly is medicines.

The preferred way for patients to receive medicines is for trained health care professionals to **prescribe** for individual patients on a one-to-one basis. The legal framework which covers medicines usage is based on this principle. Doctors, dentists and, following a recent **extension of prescribing responsibilities**, some registered nurses, midwives or pharmacists can prescribe. The extension of prescribing responsibilities to include nurses and pharmacists should give organisations more flexibility when designing their services, so that patients can have access to high quality prescribing when they need it.

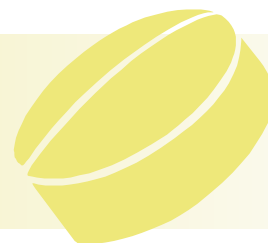
See the glossary (page 48) for definitions of supply, administration and prescribing

There are some long-standing exemptions in medicines legislation that allow certain health care professionals to obtain, sell, **supply and administer** medicines in specific circumstances. There are also situations, not covered by these exemptions, where patients may benefit, without their safety being compromised, from having a medicine supplied and / or administered directly to them by a range of health care professionals.

To enable this to happen, independent prescribers can give a documented Patient Specific Direction, which instructs another health care professional to supply or administer a medicine to **a specified patient**. Alternatively, Patient Group Directions (PGDs), in existence since August 2000, constitute a legal framework which allows certain health care professionals to supply and administer medicines to **groups of patients** that fit the criteria laid out in the PGD. So, a health care professional could **supply** (for example, provide an inhaler or tablets) and / or **administer** a medicine (for example, give an injection or a suppository) directly to a patient without the need for a prescription or an

1 The NHS Plan – A plan for investment, a plan for reform. Department of Health, July 2000. www.dh.gov.uk/assetRoot/04/05/57/83/04055783.pdf

2 See the Department of Health website: www.dh.gov.uk/assetRoot/04/06/84/00/04068400.pdf



instruction from a prescriber. PGDs allow the supply and administration of specified medicines to patients who fall into a group defined in the PGD; using a PGD is not a form of prescribing.

Unlike nurse and pharmacist prescribing, health care professionals entitled to work with a PGD require no additional formal qualification. However, for a PGD to be valid, certain criteria must be met both in terms of the patient group that the PGD can be used for, and in how the PGD itself is drawn up. Organisations also have a responsibility to ensure that only fully competent, trained health care professionals use PGDs.

Prior to April 2003, only NHS organisations could use PGDs. However, legislation now allows a range of non-NHS organisations to use PGDs. Developments are also under way to extend PGD usage to a wider range of health care professionals.

Changes in the way patients can receive their medicines have progressed rapidly over the past three years and further development seems likely, encompassing a wider range of professional groups. Against this developing background, the purpose of this document is to:

- Put PGDs, independent prescribing and supplementary prescribing into context so individuals and organisations can identify the most appropriate way for patients to receive their medicines
- Be a reference source for health care professionals and organisations that are using or thinking about using PGDs
- Present a competency framework for **all** health care professionals entitled to work with PGDs
- Illustrate briefly how the competency framework can be used in practice, for example, to help structure training and development

1.2 Audience for the document

- All health care professionals supplying and / or administering medicines to patients including those working in independent hospitals and clinics, police forces, prison health care services and defence medical services



- Managers of all health care professionals working with PGDs
- Individuals and organisations involved in drawing up and authorising PGDs (e.g. doctors, pharmacists, clinical governance leads)
- Professional bodies whose members are involved in authorising or working with PGDs
- Workforce development confederations
- Academic establishments training health care professionals at undergraduate and postgraduate level



2 How patients receive medicines

2.1 Background

The preferred way for patients to receive medicines is for an appropriately qualified health care professional to prescribe for an individual patient on a one-to-one basis. The legislation surrounding the use of medicines (see section 2.2), which is designed to protect patient safety, was built around this and the traditional model of prescribing. In other words, a doctor (or dentist), assessed a patient and if a medicine was necessary, wrote a prescription: a pharmacist then dispensed the medicine to the patient against that prescription.

There are some long-standing exemptions to this legislation which allow certain health care professionals (e.g. midwives, optometrists) to either sell, supply and / or administer specific medicines (see sections 2.2 and 2.3 for further details) directly to patients. These exemptions are still valid and are used in practice.

However, as professional roles expanded to utilise the skills of other health care professionals and to deliver more patient-focused services, it became clear that, in some cases, the legal necessity to have a prescription signed by a doctor and dispensed by a pharmacist restricted the development of new, patient-focused services that were both safe and effective.

To facilitate the development of patient-focused services, practice developed across the NHS, before changes in legislation for medicines use and organisations began to use 'group protocols'. Group protocols enabled nurses, and in some cases other health care professionals, to supply and / or administer medicines directly to certain groups of patients. There are many examples of where this practice had obvious benefits to patients without compromising their safety — case study 1 highlights a service where group protocols were first used.



Case study 1

Travel and flu immunisation clinics

Practice nurse-led travel and flu vaccination clinics were some of the first services to use group protocols. Patients requiring vaccinations were encouraged to make appointments directly with their practice nurses without seeing their general practitioner.

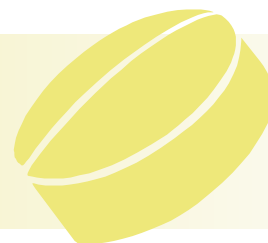
In order to administer vaccines to these groups of patients, the practice nurses needed authority from their organisations and this was given by way of a group protocol, which authorised these professionals to administer the appropriate vaccines in the clinic to patients who fitted the criteria in the group protocol.

These clinics clearly helped patients and the service as a whole, since patients were able to arrange convenient appointments for their vaccinations and receive their immunisations directly from the nurse. General practitioners were only involved in more complex clinical situations, thus making the most effective use of all health care professionals.

The use of group protocols became widespread in the NHS, a fact which was acknowledged in the 1998 'Review of the Prescribing, Supply and Administration of Medicines'. The review recognised the benefits of group protocols and proposed that the law was clarified to ensure that group protocols were being used in a consistent way and that health care professionals working with group protocols were protected legally www.dh.gov.uk/assetRoot/04/01/17/26/04011726.pdf. The review also recognised that, in the longer term, in order to develop services around the needs of patients, prescribing responsibilities needed to be extended to other professional groups.

Following the review, the law relating to group protocols was clarified and in August 2000 they became officially known as patient group directions. At this time, the Department of Health issued guidance to help ensure that organisations used and produced PGDs in a consistent and safe way (HSC 2000/26: www.dh.gov.uk).

The extension of prescribing responsibilities was rolled out nationally in 1999, with appropriately trained district nurses and health visitors prescribing from a limited formulary. In April 2002, the scope of nurse prescribing was expanded to allow a wider range of nurses to prescribe from an extended formulary (the Nurse Prescribers Extended Formulary). Most recently, in April 2003, supplementary prescribing for nurses and pharmacists was introduced. It is expected that the extension of prescribing responsibilities will continue so that, in the longer term, more health care professionals will have the option of prescribing when delivering services to patients.



Since extended prescribing is relatively new and because PGD usage is now integral to practice in many organisations, confusion has arisen about the difference between prescribing and the supply and administration of medicines using a PGD, and which is the most appropriate for what circumstances.

Whilst the definition of a PGD is straightforward, local interpretation has allowed them to be used creatively in a wide range of circumstances. However, with the introduction of prescribing for nurses and pharmacists, many services now have an alternative and, perhaps in some cases, more appropriate way for patients to access the services they need.

It is important that all professional groups, and their employers, understand the scope and limitations of PGDs (see section 3) as well as the wider context into which they fit when designing safe, effective services for their patients.

The remainder of this section will therefore:

- Briefly outline the legislation that governs the use of medicines (section 2.2)
- Highlight the differences between prescribing and PGDs (section 2.3)
- Outline the different types of prescribing (section 2.4)
- Provide tools to illustrate when prescribing is appropriate, when PGDs are appropriate and when a mixture of both may be used (section 2.5)

2.2 Legislation governing the use of medicines — the key points

The 1968 Medicines Act regulates the use of medicines in the UK. The Act requires a medicine to have a marketing authorisation (previously a product licence) before it can be used by the public. In the UK, marketing authorisations³ are granted by the Medicines and Healthcare Products Regulatory Agency (formerly the Medicines Control Agency) — see www.mhra.gov.uk for details of the agency's work.

³ Manufacturers can also choose to apply to the European Medicines Evaluation Agency (www.emea.eu.int) for a marketing authorisation



When a marketing authorisation is granted, a medicine can become one of three classifications:

- ❑ **POM (prescription only medicine)** — patients can only obtain the medicine on prescription through a pharmacy⁴
- ❑ **P (pharmacy medicine)** — medicines can be sold in pharmacies by or under the supervision of a pharmacist
- ❑ **GSL (general sales list)** — medicines can be sold in general shops as well as in pharmacies

These legal classifications therefore affect how services can supply medicines to patients.

2.2.1 POMs

Originally, the Medicines Act 1968 and associated secondary legislation allowed only doctors and dentists to write prescriptions for POMs. To enable nurses and pharmacists to become independent and / or supplementary prescribers, amendments to the legislation were necessary. Medicines legislation was also amended to allow for the use of PGDs.

The Prescription Only Medicine Human Use Order 1997, known as the POM Order, contains some specific exemptions which allow for the sale or supply and administration of certain POMs directly to patients, without the directions of a doctor or dentist. These exemptions, which continue to apply, relate to midwives, ambulance paramedics, optometrists, and podiatrists and chiropodists. There are also provisions in the POM order which allow occupational health scheme nurses to supply and administer POMs.

In some emergency situations, pharmacists are able to supply medicines to patients without a prescription.

For further details of exemptions to the Medicines Act and emergency supply by pharmacists see: Medicines, Ethics and Practice, a guide for pharmacists; www.rpsgb.org.uk.

⁴ In some cases doctors are able to dispense medicines themselves; dispensing practices tend to be found in rural areas where access to pharmacies is limited.



The legal framework for prescribing and handling controlled drugs is set out in the Misuse of Drugs Act 1971 (see section 3.6).

2.2.2 P and GSL medicines

P medicines are available directly to the public for purchase but can only be sold through a registered pharmacy under the supervision of a pharmacist.

GSL medicines can be sold directly to the public from any lockable business premises (for example, a petrol station, a supermarket) without any professional supervision. GSL medicines must be sold in certain quantities in an unopened manufacturers pack.

Sometimes the legal classification of a medicine may vary according to its strength or pack size. Both P and GSL medicines can be prescribed, although, as with POMs, some are not prescribable at NHS expense⁵. Collectively P and GSL medicines are often referred to as over-the-counter (OTC) medicines (although this is not a legal category), since they can be obtained without a prescription.

2.3 The difference between prescribing and PGDs

The legal differences between prescribing and the use of PGDs are described below and illustrated in figure 1.

When a **prescriber** sees a patient, if after assessment and diagnosis, the need for a medicine is established as part of the treatment plan, in the majority of cases a prescription is issued. A pharmacist dispenses the medicine against the prescription and the patient then receives their medicine. Medicines law recognises the value of pharmacists in the dispensing process and this is the preferred route for patients to get their medicines.


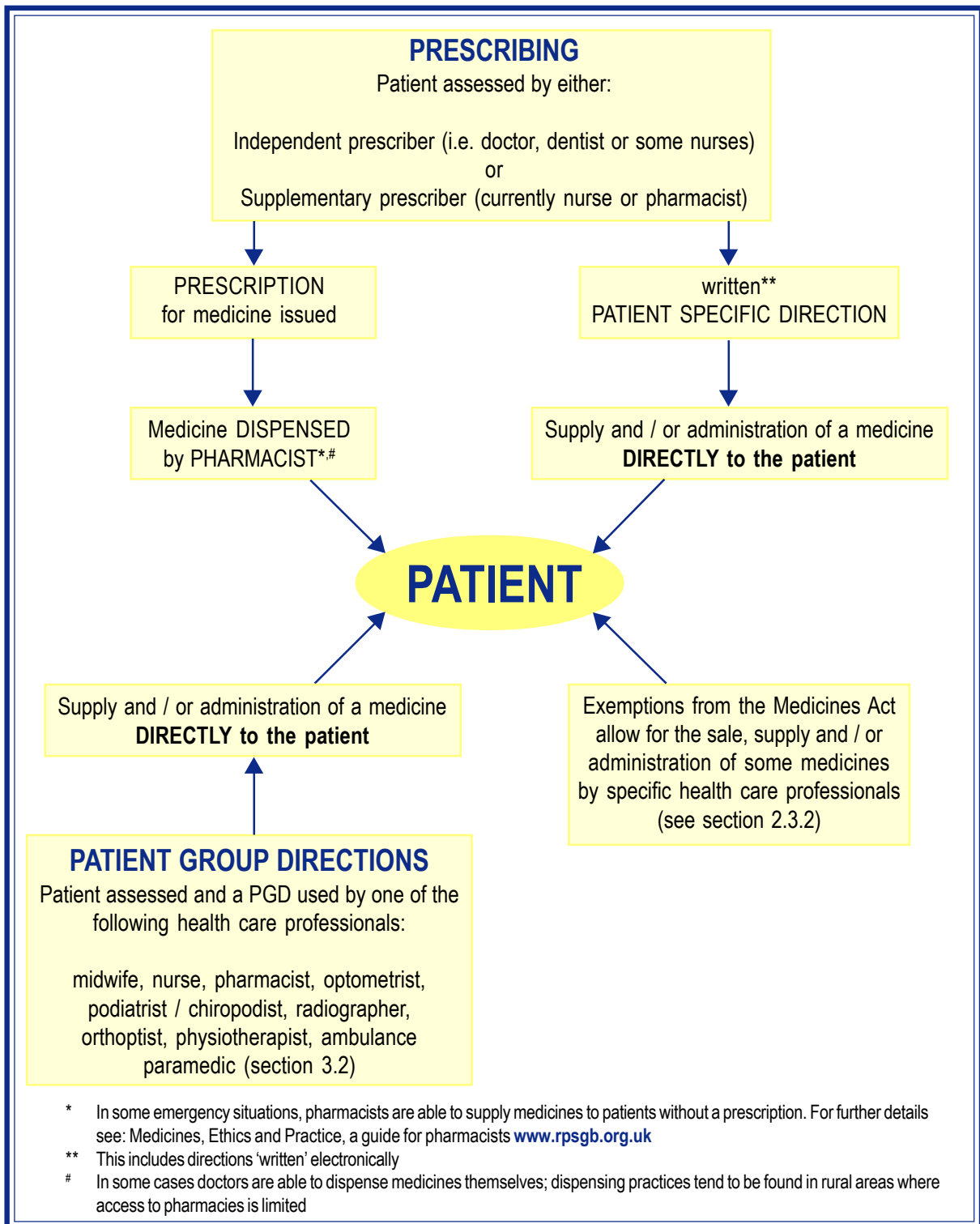
⁵ Medicines which are not prescribable on the NHS can be found in the Drug Tariff (www.drugtariff.com) and are highlighted in the British National Formulary (www.bnf.org) indicated by 



Figure 1: How patients receive their medicines





However, in some cases, it may be necessary or convenient for a patient to receive a medicine (i.e. have it supplied and / or administered) directly from another health care professional. Unless already covered by exemptions to the Medicines Act (see below), there are two ways of achieving this; by **PGD** or by **patient specific direction**.

In essence, a **PGD** allows a range of specified health care professionals (see section 3.2) to supply and / or administer a medicine **directly** to a patient with an identified clinical condition **without them necessarily seeing a prescriber**. So, patients may present directly to health care professionals using PGDs in their services without seeing a doctor (as in First Contact Services — see case study 2 — and the example below).

Alternatively, the patient may have been referred by a doctor to another service. However the patient presents, the health care professional working within the PGD is responsible for **assessing that the patient fits the criteria set out in the PGD**.

In general, a PGD is not meant to be a long-term means of managing a patient's clinical condition. This is best achieved by a health care professional prescribing for an individual patient on a one-to-one basis.

An example of a service using a PGD:

- Following day-case foot surgery, podiatrists can use a PGD to give patients a supply of non-steroidal anti-inflammatory drugs for post-operative pain

A patient specific direction is used once a **patient has been assessed by a prescriber** and that prescriber, (doctor, dentist or independent nurse prescriber) instructs another health care professional in writing to supply or administer a medicine directly to that named patient or to several named patients (e.g. patients on a clinic list). Generally speaking, patient specific directions are a direct instruction and do not require an assessment of the patient by the health care professional instructed to supply and or administer; unlike a PGD.



Example of a service using a patient specific direction:

- ❑ Ophthalmologists can give ophthalmic technicians a written patient specific direction to administer anaesthetic eye drops so that, where necessary, the patient has local anaesthesia prior to seeing the ophthalmologist for a scheduled procedure or examination.

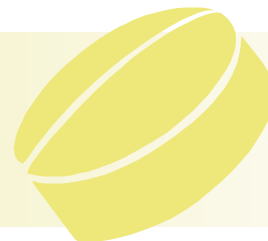
2.3.1 A patient specific direction or a PGD?

There can be confusion about when to use a patient specific direction and when to use a PGD. In practice, this is likely to depend on how an individual service is structured. Services in different organisations may choose, because of differences in the way their services are organised, to supply and / or administer medicines to their patients in different ways.

So, for example, doctors referring patients to nurse-led clinics may write a patient specific direction in the patient's notes for the nurse to supply and / or administer a particular medicine. Alternatively, the nurse-led clinic may have several PGDs which cover the patient groups likely to be seen in the clinic. Often practical realities dictate which of these two approaches is taken.

2.3.2 Exemptions from the Medicines Act

As highlighted in section 2.2 there are some exemptions to medicines legislation restrictions on the sale, supply and administration of medicines for certain groups of health care professionals. Some exemptions also allow for the sale and supply of P and GSL medicines. Full details of all these exemptions can be found in Medicines, Ethics and Practice, a guide for pharmacists (www.rpsgb.org.uk). In these specific cases PGDs and / or patient specific directions are unnecessary.



2.4 Nurse and pharmacist prescribing

The extension of prescribing responsibilities allows appropriately trained nurses and pharmacists to manage a patient's condition. The extension broadly followed the recommendations of the 1999 **Review on the Prescribing, Supply and Administration of Medicines** (see the DH website for the full review) and has created two different categories of prescribers — independent nurse prescribers and supplementary prescribers. Each of these is discussed below in more detail.

2.4.1 Independent prescribers


Independent prescribers are doctors, dentists and some nurses. According to the Department of Health definition, an independent prescriber:

'takes responsibility for the clinical assessment of the patient, establishing a diagnosis and the clinical management required, as well as responsibility for prescribing where necessary and the appropriateness of any prescription'

Doctors and dentists are able to prescribe once they are fully registered with the General Medical or Dental Council and are able to prescribe any medicine⁶. Nurse prescribers have to be specifically qualified to prescribe and may prescribe from a specified formulary of medicines. There are two different sorts of independent nurse prescriber:

- District nurses and health visitors
- Extended formulary nurse prescribers

Box 1 highlights the differences between these nurse prescribers and the areas in which they can prescribe.

6 The NHS has some restrictions on the medicines prescribable at its expense. Medicines which are not prescribable on the NHS can be found in the Drug Tariff (www.drugtariff.com) and are highlighted in the British National Formulary (www.bnf.org) indicated by 



Box 1: Categories of nurse prescribers			
	Qualification	Range of medicines	Other limitations
District nurses and health visitors	Incorporated into Specialist Practitioner preparation of all district nurses and health visitors	Those listed in the Nurse Prescribers' formulary for district nurses and health visitors; see www.bnf.org . Mostly appliances and dressings with some medicines	None, district nurses and health visitors can prescribe anything in their formulary for any of their patients
Extended formulary nurse prescribers	1 st level nurses and midwives can train to prescribe from the Nurse Prescribers Extended Formulary (NPEF)	Those listed in the NPEF; see www.bnf.org . These include P and GSL medicines and a wide range of POMs.	Medicines can only be prescribed to treat a specified range of conditions. See nurse prescribing section on Department of Health website

More detailed information on independent nurse prescribing can be found at: www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/Prescriptions/NursingPrescribing/fs/en (see section under forms of prescribing).

2.4.2 Supplementary prescribers

Supplementary prescribing is designed to enable a supplementary prescriber to take on the medium- to longer-term management of an individual patient. Currently, only pharmacists and nurses can become supplementary prescribers. Practitioners from both professional groups must obtain a specific qualification in order to become supplementary prescribers.

According to the Department of Health definition, a supplementary prescriber:

'forms a voluntary partnership with an independent prescriber (a doctor or dentist). A Clinical Management Plan is agreed for an individual patient and with the patient's agreement, the supplementary prescriber manages the patient's clinical condition, including prescribing, according to the clinical management plan.'

Whilst independent nurse prescribers must prescribe from a formulary, supplementary prescribers have few restrictions on the drugs which they can prescribe. As long as the medicines are prescribable by a doctor or dentist at NHS expense and are referred to in



the patient's Clinical Management Plan, the medicines can be prescribed. There are currently two exceptions where medicines cannot be prescribed through supplementary prescribing: controlled drugs, although subject to amendments to the Misuse of Drugs Regulations and NHS Regulations, this is likely to change in spring 2004; unlicensed medicines that are not part of a clinical trial with a clinical trial certificate or exemption, although this is currently subject to consultation by Medicines and Healthcare Products Regulatory Agency. Any changes will be posted on the Department of Health website (see below).

More detailed information on supplementary prescribing can be found at: www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/Prescriptions/SupplementaryPrescribing/fs/en and www.npc.co.uk/publications/healthcare_resource.pdf.

2.5 When to use a PGD; when to prescribe

A combination of independent prescribing, supplementary prescribing and PGDs can be used to enable patients to get their medicines. When structuring services it is important to consider which of these options are:

- Legally possible** (for example, only nurses and pharmacists are currently supplementary prescribers)
- The most **appropriate** (for example, prescribing is the preferred option for the longer term management of specific patients)

Two tools are presented in this document to help think through these issues:

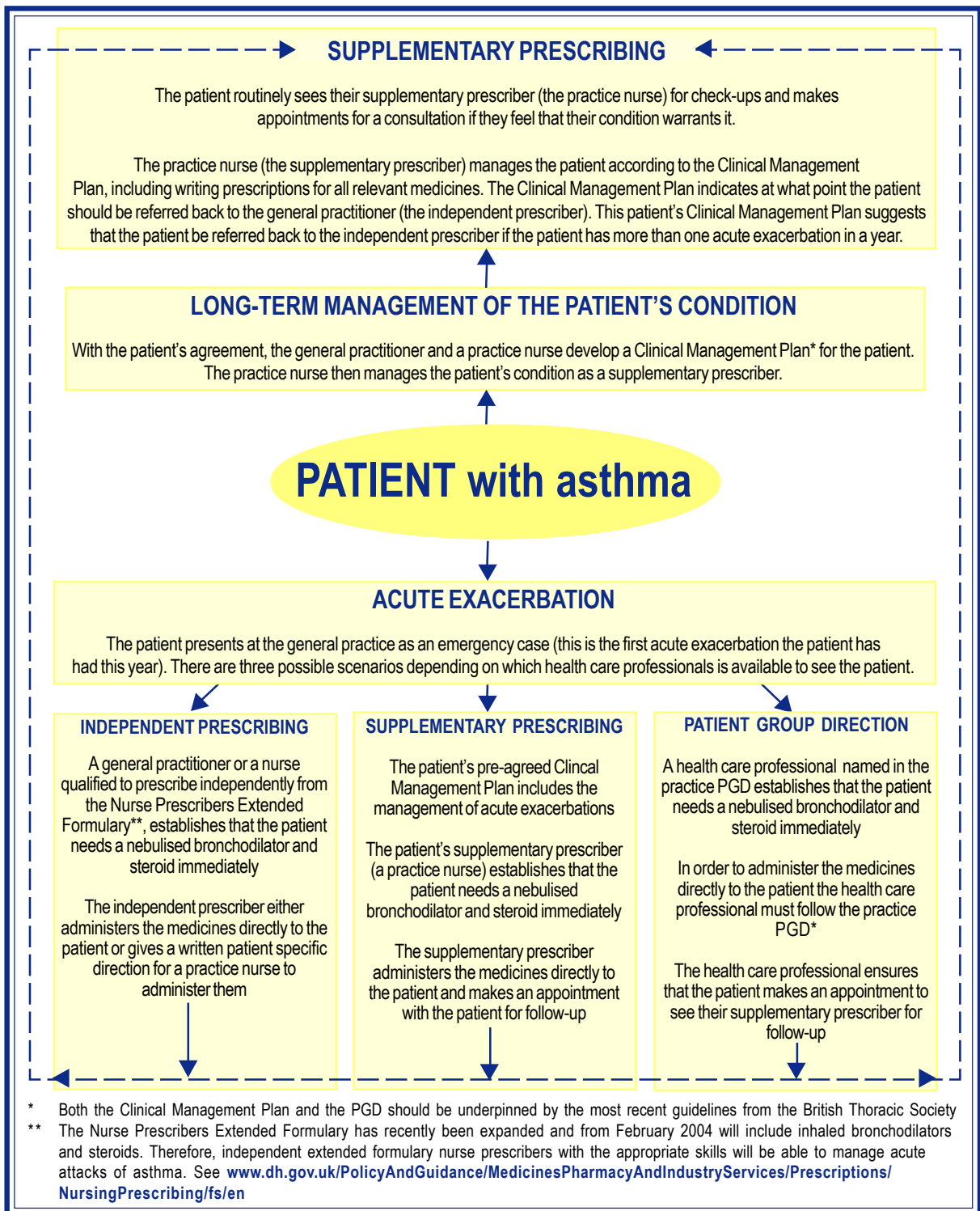
The **case study** in figure 2 illustrates how independent prescribing, supplementary prescribing and PGDs can be used in the same GP practice to manage patients with asthma. This case study is just one illustration and should not be taken as a model for service delivery.

The **flow chart** in appendix 1 'To PGD or not to PGD?' is a practical tool to help managers and individual practitioners take a step-by-step approach to some of the issues attached to the use of PGDs. Ultimately it should help inform decisions about whether using a PGD is appropriate for a given situation.

Before using the flow chart, please ensure that you read sections 2 and 3 of this document, most of the steps in the flow chart are discussed in detail and so reading these sections will allow easier



Figure 2: Case study highlighting how independent prescribing, supplementary prescribing and PGDs can be used to help deliver services to patients





3 Using PGDs

As highlighted in section 2.1, in August 2000 the legal status of group protocols was clarified and PGDs became an additional way in which medicines could be supplied and administered to patients by a specified range of health care professionals without first seeing a doctor or dentist⁷.

At the same time as legislation changed, to help ensure consistent practice, guidance was issued by the Department of Health about when and how PGDs could be used and produced (HSC 2000/26: www.dh.gov.uk). This section will focus on the practical issues around PGD usage and will cover:

- The legal definition of a PGD (section 3.1)
- Professional groups who can use PGDs (section 3.2)
- Organisations that can use PGDs (section 3.3)
- Requirements for producing and authorising PGDs (section 3.4)
- The information that should be contained in a PGD (section 3.5)
- Specific requirements for controlled drugs and antimicrobials (section 3.6)

To make this section as practical as possible, case studies will be used to illustrate specific points. Reading this section may give rise to a number of questions about PGD usage. The Frequently Asked Questions in section 4 of this document may help to answer many of these.

3.1 Definition of a 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.’

⁷ Some health care professionals are already able to supply and administer certain medicines using exemptions specified in the Medicines Act — see sections 2.3.2



Guidance issued along with the definition sets the overall context in which PGDs should be viewed:

‘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.’

In summary, PGDs fit best within services where medicines use follows a predictable pattern and is less individualised. PGDs are generally most appropriate to manage a specific treatment episode (or episodes) where supply or administration of a medicine is necessary (for example, first contact services — see case study 2). As opposed to taking responsibility for managing an individual patient’s condition over the long-term, where a prescribing relationship is likely to be more appropriate (for example, the management of high blood pressure in primary care — see case study 3).

Case study 2

First contact services — ideally suited to PGDs

First contact services are those services which patients who are acutely unwell first make contact with NHS professionals and seek unscheduled care. They include Ambulance Services, NHS Walk-in Centres, Accident and Emergency Services, Community Pharmacies, Minor Injuries Clinics and Out-of-Hours Services.

PGDs work well for the first contact services because many minor illnesses and injuries can be treated with a medicine. PGDs allow certain health care professionals working in first contact services to complete a patient’s treatment episode without the need to refer to a general practitioner or a hospital doctor for a prescription.

First contact services use patient group directions to cover a range of medicines including:

- Trimethoprim for urinary tract infection
- Emergency contraception
- Local anesthesia for suturing a wound
- Analgesia for a range of clinical conditions

Nurses working in first contact services may also be qualified independent prescribers, and are able to issue prescriptions for a range of medicines specified in the relevant nurse prescribers extended formulary (see section 2.4). In these cases some first contact services may issue prescriptions to be dispensed by a pharmacist rather than use a PGD.

Supplementary prescribing is unlikely to be of benefit to first contact services because, legally, it requires a partnership between an independent prescriber and an agreed, patient-specific Clinical Management Plan before prescribing can occur (see section 2.4).

Some first contact services have developed template PGDs which can be tailored locally. These can be found on www.pgd.nhs.uk.



Case study 3

Management of high blood pressure in primary care — ideally suited to supplementary prescribing

Patients diagnosed by their general practitioner as having high blood pressure can have their condition managed by a suitably qualified supplementary prescriber (see also section 2.3). If the patient consents to the arrangement, a Clinical Management Plan is developed for that patient and the supplementary prescriber manages the patient according to their plan.

The supplementary prescriber can use their clinical judgement within the terms of the Clinical Management Plan, for example, choosing from a range of medicines and tailoring them depending on the patient's response.

Local factors like the availability of qualified supplementary prescribers determine which health care professional is the patient's supplementary prescriber. However, assuming they are qualified and competent to do so, this could be, for example, a pharmacist (practice, community or employed by a primary care trust), a practice nurse or a district nurse.

PGDs are unlikely to benefit the management of high blood pressure in primary care since there is a limited need for the supplementary prescriber to supply and / or administer medicines directly to patients and the management of high blood pressure in this context requires a longer term relationship with the patient.

See figure 2 (page 19) for another example of supplementary prescribing.

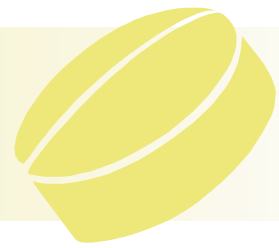
For template Clinical Management Plans and more details of requirements for supplementary prescribing see www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/Prescriptions/SupplementaryPrescribing/fs/en.

3.2 Professional groups who can use PGDs

Currently midwives, nurses, pharmacists, optometrists, podiatrists and chiropodists, radiographers, orthoptists, physiotherapists and ambulance paramedics are able to use PGDs. Individual practitioners using the PGD must be named (see also section 3.4).

Proposals are currently being considered to extend the range of allied health care professionals who can use PGDs to include, dieticians, occupational therapists, prosthetists and orthotists, speech and language therapists (MLX 294: <http://medicines.mhra.gov.uk/inforesources/publications/mlx294.doc>). It is hoped that legislation will be amended to include these groups by Spring 2004.

Professionals using a PGD must be registered (or equivalent) members of their profession and act within their appropriate code of professional conduct. This differs from supplementary and independent prescribers who must successfully complete specific



training and be appropriately registered before they are allowed to prescribe. However, organisations using PGDs must designate an appropriate person within the organisation (for example, a clinical supervisor, line manager, general practitioner) to ensure that only fully competent, qualified and trained health care professionals use PGDs.

Services using PGDs should ensure that appropriate training is available for health care professionals using PGDs. Section 5 of this document presents a competency framework which can be used by any health care professional and their managers to help ensure that they have the competencies necessary to work with PGDs.

3.3 Organisations that can use PGDs

Legislation passed in August 2000 allowed for the use of PGDs by the NHS including those services funded by the NHS but provided by the private, voluntary or charitable sector.

In April 2003, further legislation was passed to allow non-NHS organisations to use PGDs for the sale, supply and administration of medicines. The organisations now able to use PGDs are:

- Independent hospitals, agencies and clinics registered under the Care Standards Act 2000
- Prison health care services
- Police services
- Defence medical services

These organisations are advised to follow the same guidance as that issued to the NHS both in terms of when PGDs can be used and how they should be produced. For a summary of this guidance see www.mhra.gov.uk and look for PGDs in the sitemap / index.



Independent and public sector nursing and care homes are not covered by the new legislation and so cannot produce PGDs for use within individual or groups of homes. However, PGDs used by health care professionals in their routine practice can be used when visiting patients in nursing and care homes (for example, district nurses, physiotherapists and chiropodists may routinely use PGDs authorised by their organisations on domicillary visits).

3.4 Producing and authorising PGDs

PGDs should be **produced** by a multidisciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to give medicines under the PGD. It is good practice to involve local drug and therapeutic / medicines management committees, area prescribing committees and similar advisory bodies with medicines expertise.

Many NHS organisations already have their own local trust-wide policies which describe the process for developing PGDs across their organisation. Some examples of trust-wide policies in use can be found at www.druginfozone.nhs.uk in the Primary and Community Care section, under PGDs.

The PGD must also be **authorised** by the organisation it is to be used within. In the NHS this is typically an NHS trust or primary care organisation (so, for example a PGD for use in a community pharmacy, must be authorised by the local primary care trust). For the most part, it is the clinical governance lead who is likely to authorise PGDs on behalf of these organisations.

In police, prison services and armed forces, the legislation specifies who should authorise a PGD in each of these organisations: for specific details see www.mhra.gov.uk and search for patient group directions in the sitemap / index.

For independent hospitals and clinics, the legislation specifies that the PGD be authorised by the registered provider and if there is a relevant manager for the hospital, clinic or agency, that manager.



The PGD itself must be **signed** by:

- The doctor and pharmacist involved in developing the PGD
- The authorising authority for the organisation in which it is being used

Requirements for the development and authorisation of PGDs are relatively straightforward when the PGD is for use within one organisation. It is much more complex when health care professionals work across several different organisations and want to use the same PGD for all their clients. Case study 4 gives a practical illustration of how several PCTs resolved this issue.

Case study 4

Authorising PGDs to be used across three primary care trusts (PCTs)

Recently, all PGDs in Lambeth, Southwark and Lewisham PCTs required re-authorisation. Since a number of PGDs will be used in each PCT, or by staff employed by one PCT but delivering care to populations in other PCTs, the following principles were developed for the signing off and authorisation processes. The principles were based on advice from PCT solicitors, clinical governance leads, and Department of Health guidance.

- All PGDs must be signed by those responsible for drawing it up, including a doctor and senior pharmacist, and a senior practitioner from the relevant professional group (e.g. nurse or podiatrist). It does not matter if these signatories are not an employee of the PCT concerned
- An agreed clinical governance lead must sign to authorise any PGD in regular use for patients within the PCT. This is required in order for the activity to be accepted within the PCT clinical governance framework
- It is acceptable for some PGDs to bear more than one PCT logo and be authorised by multiple clinical governance leads if this is appropriate. The signatures of those responsible for developing the PGD will remain the same
- PGDs for the same clinical activity in use in Lambeth, Southwark and Lewisham PCTs should contain consistent and identical clinical content, even if minor differences in presentation emerge. This will support practitioners who are likely to move between posts locally

For more information contact Beth Taylor (Beth.Taylor@southwarkpct.nhs.uk) or Barbara Adie (Barbara.Adie@southwarkpct.nhs.uk)

Before a professional can use a PGD they must be named and have signed appropriate documentation. This generally takes the form of signatures and names (on a list or individual forms) that are attached to the PGD itself or held by the service or organisation.



Employees of NHS organisations authorising the PGD generally have indemnity attached to their status as an employee. This may also apply to non-NHS organisations. However, the organisations and employees involved should always check that this is the case. If the professional is not directly employed by the organisation they still need to be assessed as competent to use the PGD and must have their own relevant indemnity insurance⁸.

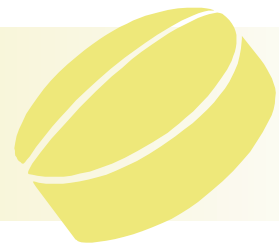
These issues have implications for service delivery, because when new staff begin, or if locum or agency staff are covering services, they may not be able to work under a PGD immediately or may be excluded because of their employment status. Service managers need to be aware of these issues and plan service delivery to accommodate them.

3.5 Information that should be contained in a PGD

Legislation requires that the following information must be included in a PGD (see also HSC 2000/26: www.dh.gov.uk):

- The name of the body to which the direction applies
- The date the direction comes into force and the date it expires
- A description of the medicine(s) to which the direction applies
- The clinical conditions covered by the direction
- A description of those patients excluded from treatment under the direction
- A description of the circumstances under which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral made
- 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 follow-up action and the circumstances
- A statement of the records to be kept for audit purposes

⁸ In the NHS, bank staff are NHS employees and may therefore be indemnified by the NHS organisation



As highlighted in section 3.4, the PGD must also be signed by the doctor and pharmacist involved in developing it and the authorising authority for the organisation in which it is being used.

All PGDs should be underpinned by the best possible evidence-base (e.g. clinical guidelines, consensus statements). These guidelines do not need to form part of the PGD but should be used as a basis for producing it.

Examples of PGDs can be found on the website www.pgd.nhs.uk in the primary and community care section under PGDs. This site currently displays PGDs that have been approved for use by local organisations together with national Walk-in Centre template PGDs which have been prepared by the National Steering Group for PGDs. The website also contains a comprehensive number of Frequently Asked Questions.

When preparing a PGD, it is best to include only the required content (outlined above). Relevant clinical guidelines can be referenced and included in local clinic protocols or attached as an appendix. PGDs should be reviewed and updated when relevant but, if there are changes to clinical practice which don't affect the PGD, there is then the option to update clinical practice without the need to rewrite, reauthorise and re-sign the PGD. Clearly, if underpinning clinical guidelines do change, health care professionals working under the PGD need to make sure that their practice is updated.

3.6 Requirements for controlled drugs and antimicrobials

3.6.1 Controlled drugs

The Home Office is responsible for legislation governing the use of all controlled drugs, even when used for medicinal purposes; as highlighted in section 2.2, the Medicines and Healthcare Products Regulatory Authority is responsible for the legislation concerning the use of all other medicines. The Misuse of Drugs Regulations 2001 governs controlled drugs usage and, in October 2003, they were amended to allow some controlled drugs to be supplied and / or administered under a PGD.



The following controlled drugs can be supplied or administered under PGD:

- Diamorphine but only for treatment of cardiac pain by nurses working in Coronary Care Units and Accident and Emergency departments of hospitals
- All drugs listed in Schedule 4 of the 2001 Regulations (mostly benzodiazepines), except anabolic steroids
- All drugs listed in Schedule 5 of the 2001 Regulations (i.e. low strength opiates such as codeine)

For full details see Home Office Circular 49/2003 www.homeoffice.gov.uk/docs2/hoc4903.html. Copies of The Misuse of Drugs Regulations 2001 (SI No: 3998 of 2001) can be downloaded from Her Majesty's Stationery Office (HMSO) website www.hmso.gov.uk.

The National Prescribing Centre have developed a guide to good practice in the management of controlled drugs in primary care (England). A preview version can be found on www.npc.co.uk.

3.6.2 Antimicrobials

Department of Health guidance suggests that particular caution should be used when deciding whether to use a PGD for an antimicrobial medicine. Antimicrobial resistance is a public health issue of great concern and care should be taken to ensure that the PGD will not jeopardise any strategy to control increasing resistance. A PGD should not allow the supply or administration of a medicine for minor viral diseases that are unaffected by antibiotics, for example, to treat sore throats in the absence of good evidence of bacterial infection.

A local microbiologist or public health specialist with appropriate expertise should be involved in drawing up the PGD. Local Drug and Therapeutics / Medicines Management Committees or Area Prescribing Committees should ensure that any PGD is consistent with local policies and subject to regular audit. This guidance applies equally to NHS and non-NHS organisations.



4 Frequently asked questions about PGDs

For ease, these Frequently Asked Questions have been grouped so that questions on similar topics are found together. The broad groupings are:

- Uses of PGDs
- Production of PGDs
- Medicines that can be included in PGDs
- Practical issues
- Training and evaluation

For more Frequently Asked Questions about PGDs, along with examples of PGDs which have been approved for use in their local areas see www.pgd.nhs.uk, and select 'support'.

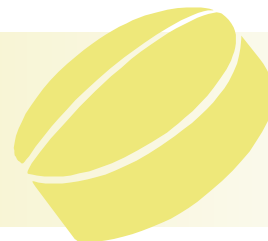
Individual professional bodies may also have information sheets and / or Frequently Asked Questions specifically for their members; see useful links in section 6.

4.1 Uses of PGDs

- a) Are PGDs appropriate for managing chronic illnesses?
- b) Can a PGD be used to adjust doses of a patient's medication?
- c) Can PGDs be used to initiate treatment for chronic disease?
- d) Can PGDs be used to supply or administer medicines to patients pre-booked into clinics?
- e) If a patient falls slightly outside the criteria for inclusion in the PGD, can professional judgement be used to supply or administer a medicine?

a) Are PGDs appropriate for managing chronic illnesses?

General guidance and the legal definition of a PGD (see section 3.1) indicates that PGDs are not meant to replace a health professional prescribing for an individual patient on a one-to-one basis. In general, individual patient prescribing is more appropriate for patients requiring long-term management of their condition. Many chronic conditions will therefore not be appropriate for PGDs and another option like supplementary prescribing or, in some cases, independent nurse prescribing may be more appropriate. There may be some situations in which using a PGD is appropriate for the direct supply or administration of a medicine to a patient with a chronic illness (for example an acute exacerbation of asthma — see case study 2), so each case needs to be considered individually.



b) Can a PGD be used to adjust doses of a patient's medication?

Dose adjustment is allowed within a PGD as long as a dosage range is specified in the PGD and the PGD is being used to supply and / or administer a medicine. A PGD does not give a legal framework for health care professionals to adjust a dose of medicine already in a patient's possession. Health care professionals may use written protocols to advise patients to adjust the dose of their medication if that is what is required to maintain optimum treatment (e.g. a diabetes nurse specialist advising a patient to alter insulin dose following a blood glucose check). Written protocols have no legal standing in respect of medicines legislation and are subject to local agreements between health care professionals and their organisations. It is likely that written protocols which cover advice on dosage would reflect many of the principles governing PGDs.

c) Can PGDs be used to initiate treatment for chronic disease?

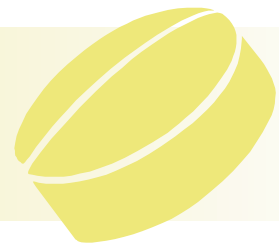
Although this is possible within the legislation and supporting guidance, it is not recommended. Chronic conditions should be managed by health care professionals prescribing for individual patients on a one-to-one basis.

d) Can PGDs be used to supply or administer medicines to patients pre-booked into clinics?

Having pre-booked patients, and therefore 'knowing' who the patient will be, does not preclude PGD use, assuming all other criteria for the use of PGDs are met.

e) If a patient falls slightly outside the criteria for inclusion in the PGD, can professional judgement be used to supply or administer a medicine?

No, when supplying or administering a medicine under a PGD, the patient must fall exactly into the criteria determined by the PGD. If not, the patient must be referred in line with the guidelines in the PGD.



4.2 Production of PGDs — see also section 3.4

- a) How often should PGDs be reviewed?
- b) How long should PGD documentation be kept?
- c) Who is responsible for finding and updating the clinical guidelines underpinning a PGD?
- d) When changes are made to the PGD does it always need to be reauthorised and re-signed?

a) How often should PGDs be reviewed?

Legally, a PGD should be formally reviewed and reauthorised every two years and the review date should be included in the PGD (see also section 3.5); after the review date the PGD is no longer valid. However, the content of the PGD should be reviewed immediately if there are evidence-based changes to clinical practice which affect the PGD, regardless of the review date. In practice, some organisations set a review date at least six months before a final expiry date to allow time for the review process. Organisations should consider auditing the use of PGDs in advance of the review.

b) How long should PGD documentation be kept?

The same rules apply to PGD records as to all other patient records. For adults all PGD documentation must be kept for eight years and for children until the child is 25 years old, or for eight years after a child's death.

c) Who is responsible for finding and updating the clinical guidelines underpinning a PGD?

It is up to the individual organisation / service (e.g. Walk-In Centre, GP practice, community pharmacy) using the PGD to find and update the clinical guidelines underpinning the PGD. The primary care trust or NHS trust authorising the PGD is responsible for ensuring that PGDs satisfy the legal framework in which they can be used but not for finding and evaluating the underpinning clinical content. Non-NHS organisations might wish to collaborate with their NHS counterparts.

d) When changes are made to the PGD does it always need to be reauthorised and re-signed?

Yes (see section 3.4) and local arrangements should be in place to ensure that all health care professionals working under a PGD are made aware of significant changes.



4.3 Medicines that can be included in a PGD — see also section 3.6

- a) Can more than one medicine be included in a PGD?
- b) Can patients receive black triangle (▼) medicines under a PGD?
- c) Can patients receive medicines when they are used outside their licensed uses?
- d) Can patients receive unlicensed medicines under a PGD?
- e) Can patients receive controlled drugs under a PGD?
- f) Can appliances and dressings be supplied and administered under a PGD?

a) Can more than one medicine be included in a PGD?

Yes, but all the requirements of the legislation must be included for each drug.

b) Can patients receive black triangle (▼) medicines under a PGD?

Yes, black triangle medicines (i.e. those recently licensed and so subject to special reporting procedures for adverse reactions) may be included in PGDs, provided such use is supported by best clinical practice. The PGD should state that a black triangle medicine is being included.

c) Can patients receive medicines when they are used outside their licensed uses?

Yes, medicines can be used outside the terms of their Summary of Product Characteristics (SPC) (and so outside their license) provided such use is supported by best clinical practice. The PGD should clearly state when the product is being used outside the terms of the SPC and why this use is necessary.

d) Can patients receive unlicensed medicines under a PGD?

No, the PGD framework does not allow for unlicensed medicines to be supplied and / or administered.

e) Can patients receive controlled drugs under a PGD?

Certain controlled drugs can be supplied or administered under a PGD (see section 3.6 for full details).

f) Can appliances and dressings be supplied and administered under a PGD?

No, PGDs apply only to licensed medicines. For dressings and appliances, consider using a protocol or guidelines. If they are included in either of the nurse prescribing formularies, an independent nurse prescriber can prescribe them.



4.4 Practical issues of usage

- a) Where can the medicines supplied and administered be obtained from?
- b) Should all patients be given information leaflets with any medicine supplied?
- c) Can GP co-operatives use PGDs?
- d) If not included in existing exemptions to the medicines act, is a PGD required for the supply of P and GSL medicines?
- e) Can PGDs be used to supply and administer medicines to patients in their homes?
- f) Can a health care professional administer a medicine, already in the patient's possession, which was supplied under a PGD by another health care professional?
- g) Can one PGD be used across multiple organisations?
- h) Can agency and bank staff working in the NHS use PGDs?
- i) Do the current exemptions which allow midwives, ambulance paramedics, optometrists, and podiatrists and chiropodists to supply and administer certain specified medicines without the directions of a doctor, mean that a PGD is not required?
- j) Do patients receiving medicines under a PGD pay NHS prescription charges?
- k) Is VAT payable on medicines supplied under a PGD?

a) Where can the medicines supplied and administered be obtained from?

Local hospitals, community pharmacies and pre-packing units can all supply medicines; however, appropriate licences may be required. Pharmacists will be able to advise on requirements for the safe and secure handling of medicines, as well as packaging and labelling requirements. Original packs are preferred, where available, and appropriate audit trails should always be in place. The Royal Pharmaceutical Society of Great Britain fact sheet on PGD use provides further details:

www.rpsgb.org.uk/pdfs/factsheet10.pdf.

b) Should all patients be given information leaflets with any medicine supplied?

Yes, all patients should receive a patient information leaflet. There are various sources of patient information leaflets and local pharmacists should be able to advise on this.

c) Can GP co-operatives use PGDs?

Yes, GP co-operatives supplying services to the NHS and to non-NHS organisations, for example, Out-of-Hours services, can use PGDs. The requirements for the production of these PGDs are subject to the same legislation and guidance as PGDs used in the NHS (see section 3). An Out-of-Hours guide and formulary is due to be published in Spring 2004 and is expected to contain specific guidance on PGD usage; it will be available on the Department of Health Out-of-Hours website

www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/PrimaryCare/ImplementingOutOfHours/fs/en.



d) If not included in existing exemptions to the medicines act, is a PGD required for the supply of P and GSL medicines?

Medicines legislation states that a PGD is not necessary to supply a GSL medicine, provided the supply takes place from lockable premises and the medicines are pre-packed and fully labelled. For organisations supplying GSL medicines in this way, good practice (from a clinical governance perspective) is to use a simple protocol; simple protocols are not part of medicines legislation. A PGD is necessary to supply P medicines, unless the supply is being made at a registered pharmacy by or under the supervision of a pharmacist.

e) Can PGDs be used to supply and administer medicines to patients in their homes?

Yes, the PGD need not relate to specific premises. All the requirements that have been specified for a PGD must be complied with, but the supply or administration could take place at locations including a patient's home, a surgery or health centre, a pharmacy or an NHS Walk-in Centre.

f) Can a health care professional administer a medicine, already in the patient's possession, which was supplied under a PGD by another health care professional?

If the medicine is not an injection then the health care professional can administer it. Injections can only be legally administered by the health care professional who supplied it using a PGD, or in accordance with the directions or prescription of an independent prescriber.

g) Can one PGD be used across multiple organisations?

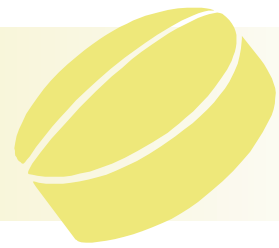
Yes, see section 3.5 for more details.

h) Can agency and bank staff working in the NHS use PGDs?

Any eligible professional using a PGD must be named and assessed as competent to do so (see sections 3.2 and 3.4) before they can use a PGD. Bank staff may be indemnified by the NHS organisation they are working for but agency staff will need their own indemnity cover.

i) Do the current exemptions which allow midwives, ambulance paramedics, optometrists, and podiatrists and chiropodists to supply and administer certain specified medicines without the directions of a doctor, mean that a PGD is not required?

Yes, where exemptions exist, PGDs are not necessary and in some cases may hinder existing practice. See sections 2.2 and 2.3 for further information and Medicines, Ethics and Practice, a guide for pharmacists www.rpsgb.org.uk, for details of the exemptions.



k) Do patients receiving medicines under a PGD pay NHS prescription charges?

Yes, standard prescription charge rules and exemptions apply to all patients receiving a supply of medicines under a PGD from the NHS. Services supplying medicines under a PGD need to make arrangements for collection of the appropriate fees. If all the medicine is administered to the patient during the consultation, no charge is levied. If any part of the medicine is given to the patient to take home, the patient should be charged. For convenience, some NHS Walk-in Centres have introduced systems which avoid health care professionals collecting the charges themselves. For example, arranging for finance departments to invoice patients following treatment and installing pay machines which issue tokens with which patients 'pay' their prescription charges.

l) Is VAT payable on medicines supplied under a PGD?

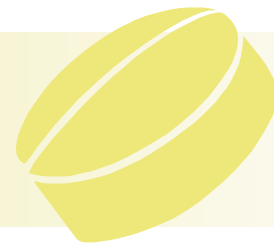
The usual policy seems to be that medicines supplied under a PGD are subject to VAT. However, if a professional fee is charged for providing a PGD service the fees are not subject to VAT. Further advice on VAT issues is available in the NHS Service Development section of the National Pharmaceutical Association's resources on the DrugInfoZone website www.druginfozone.nhs.uk or from local VAT offices.

4.5 Training and evaluation

- a) What clinical governance and audit procedures should be in place to monitor PGDs?
- b) Who is responsible for ensuring the competence of the health care professionals supplying or administering medicines using PGDs?
- c) Who is responsible for ensuring the competence of the health care professionals producing the PGDs?
- d) Are there any national training programmes for health care professionals using PGDs?

a) What clinical governance and audit procedures should be in place to monitor PGDs?

Clinical governance and audit surrounding PGD use are local responsibilities. There are no standard national arrangements. Local organisations should undertake regular audit of PGD use; for example prior to a PGD being reauthorised. In the future, the PGDs website www.pgd.nhs.uk will contain resources to support organisations with audit.



b) Who is responsible for ensuring the competence of the health care professionals supplying or administering medicines using PGDs?

Organisations using PGDs must designate an appropriate person within the organisation (for example, a clinical supervisor, line manager, GP) to ensure that only fully competent, qualified and trained health care professionals operate within PGDs; where a range of health care professionals are using PGDs this may be a senior representative from each of the professions. There is no current specific national training and development programme for health care professionals using PGDs, however, the competency framework in section 5 of this document can be used as a starting point to help organisations develop their own programmes.

c) Who is responsible for ensuring the competence of the health care professionals producing the PGDs?

Organisations should ensure that individuals writing and authorising PGDs have the appropriate competencies to do so; the health care professionals writing and authorising the PGDs might not be the ones working with them. Currently there is no specific national training for health care professionals producing PGDs, however, many of the competencies in the framework in section 5 will be relevant and so, the framework can be used as a starting point.

d) Are there any national training programmes for health care professionals using PGDs?

There is currently no national curriculum for training to use and develop PGDs. Many organisations and services have developed training programmes to meet their own needs. The competency framework in section 5 of this document provides a starting point for developing training and development programmes.



5 Competency framework for health care professionals using PGDs

5.1 Introduction

The use of PGDs is widespread throughout the NHS and, since April 2003, some non-NHS organisations have been able to use them. Unlike supplementary prescribers and independent nurse prescribers, health care professionals using PGDs do not have to become specifically qualified to do so but they must be assessed as fully competent, qualified and trained to operate within a PGD by their organisations (see section 3.2).

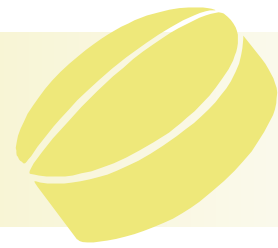
This document provides an outline framework of competencies that, if acquired and maintained, should help health care professionals work safely and effectively with PGDs. Because it is an outline framework it can be used as a starting point for discussion of competencies required by all health care professionals using PGDs. Some of the competencies may be more relevant to some health care professionals than others.

A competency is a quality or characteristic of a person which is related to effective or superior performance. Competencies can be described as knowledge, skills, motives and personal traits. Competencies help individuals (and their managers) to look at how they do their jobs. A competency framework is a collection of those competencies which are thought to be central to effective performance. Development of competencies should help individuals to improve their performance continually and to work more effectively.

The methodology used to develop this competency framework for health care professionals working with PGDs is consistent with that used to develop the competency frameworks for independent nurse prescribers, and supplementary nurse and pharmacist prescribers. The competencies for working with PGDs are therefore structured and used in the same way.

Professionals using PGDs who are also, or may become, independent or supplementary prescribers will benefit from using these complementary competency frameworks.

Details of the development methodology is outlined in all three of the existing framework documents; they can be found on the National Prescribing Centre website www.npc.co.uk.



Key point

The framework contains NINE competencies. For ease, these have been grouped into three areas, with three competencies in each area.

5.2 The structure of the framework

This competency framework for health care professionals working with PGDs is made up of the following components:

- ❑ There are three **areas of competency** in the framework:
 - The consultation
 - Effective supply and administration using a PGD
 - PGDs in context
- ❑ Each of these three areas contains three **competencies**. This framework therefore consists of NINE different competencies
- ❑ Each of the nine competencies has:
 - An **overarching statement** which gives a general flavour of what the competency is about
 - A number of statements which represent how health care professionals with that competency will be working in practice

This outline structure is illustrated in figure 3.

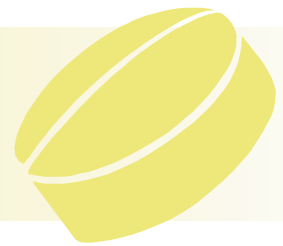
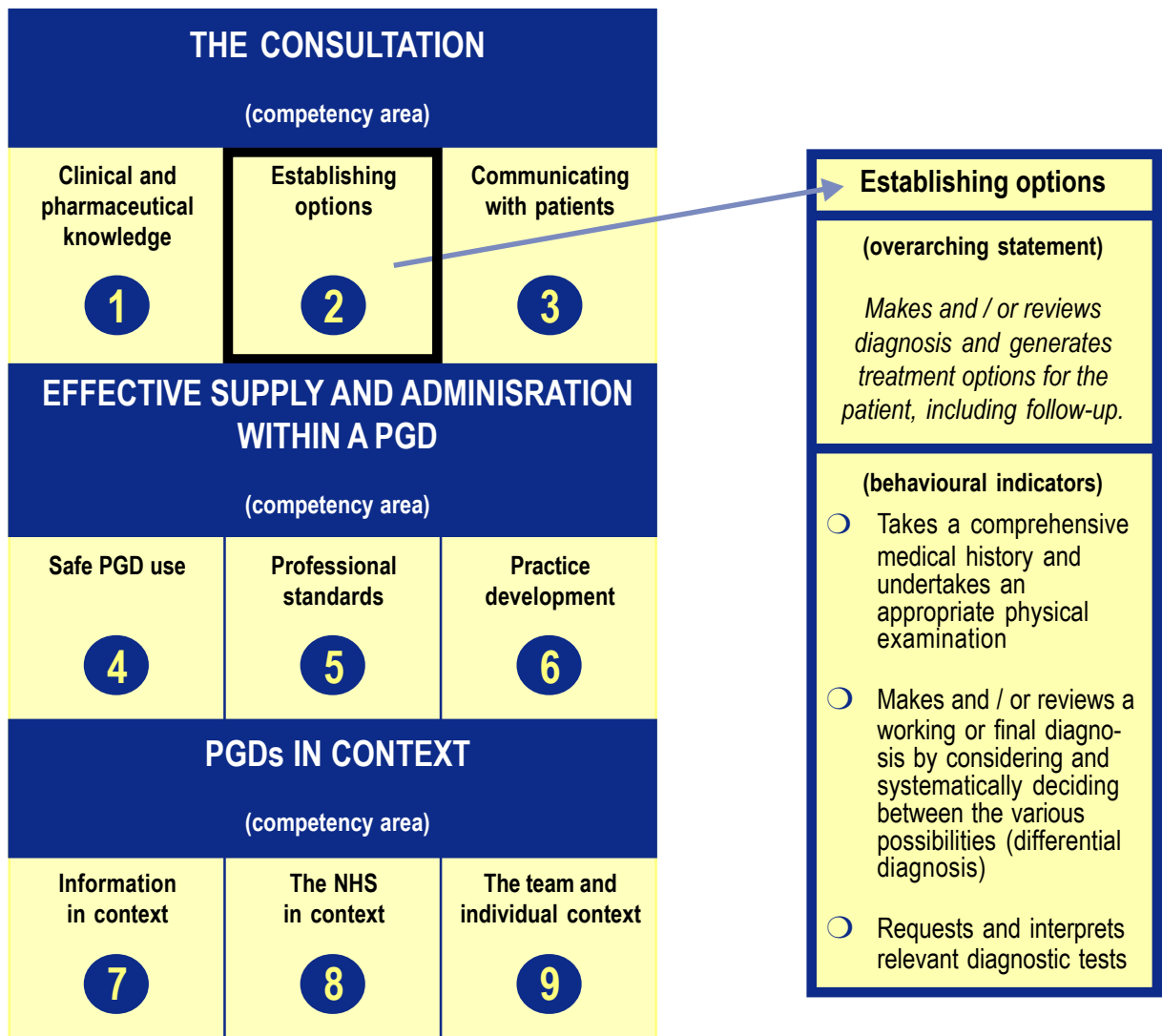
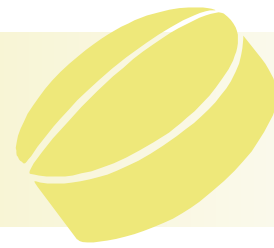


Figure 3: Basic structure of the competency framework





Key point

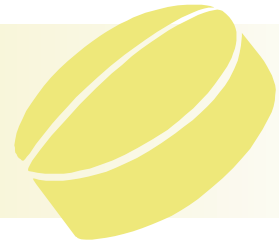
Before using the competency framework on pages 41–43 read these key features. They will help you interpret this multidisciplinary framework.

5.3 Key features of the framework

- ❑ This framework is an **outline framework** which can be used by ALL health care professionals working with PGDs regardless of the area in which they are practising
- ❑ All nine competencies will be relevant to all health care professionals. However, some the statements supporting the competencies will be **more relevant to some health care professionals than others**
- ❑ The framework should therefore be used as a **starting point for discussion** about the competencies required by individual health care professionals working with PGDs
- ❑ Initially, **using this framework effectively will take time**. How each of the statements supporting the nine competencies applies to individuals (or groups of health care professionals) must be considered
- ❑ When considering these statements, be aware that some are more complex than others. **Expect to spend more time on the more complex statements**
- ❑ The bullet pointed statements in each competency should be read one after another **DOWN** the list. **DO NOT** read across competency boxes.

5.4 The framework itself

The competency framework itself is presented on the following three pages.



THE CONSULTATION		
1 CLINICAL AND PHARMACEUTICAL KNOWLEDGE	2 ESTABLISHING OPTIONS	3 COMMUNICATING WITH PATIENTS (parents, carers and advocates where appropriate)
<p><i>Has up-to-date clinical and pharmaceutical knowledge relevant to the scope of the PGD.</i></p> <ul style="list-style-type: none"> <input type="radio"/> Understands the medical conditions being treated, their natural progress and how to assess the severity of disease <input type="radio"/> Understands different non-pharmacological and pharmacological approaches to modifying disease and promoting health, desirable and undesirable outcomes and how to identify and assess them <input type="radio"/> Understands the mode of action and pharmacokinetics of medicines and how these mechanisms may be altered (e.g. by age, renal impairment) <input type="radio"/> Understands the potential for unwanted effects (e.g. adverse drug reactions [ADRs], drug interactions, special precautions and contraindications) and how to avoid / minimise and manage them <input type="radio"/> Maintains an up-to-date knowledge of products contained in the PGD <input type="radio"/> Understands how medicines are licensed, supplied and monitored (e.g. ADR reporting) <input type="radio"/> Applies the principles of evidence-based medicine, and clinical and cost-effectiveness <input type="radio"/> Understands the public health issues related to medicines use (e.g. antimicrobial drug resistance) <input type="radio"/> Appreciates the misuse potential of drugs 	<p><i>Makes and / or reviews diagnosis and generates treatment options for the patient, including follow-up within the PGD.</i></p> <ul style="list-style-type: none"> <input type="radio"/> Takes a comprehensive medical history and undertakes an appropriate physical examination <input type="radio"/> Makes and / or reviews a working or final diagnosis by considering and systematically deciding between the various possibilities (differential diagnosis) <input type="radio"/> Requests and interprets relevant diagnostic tests <input type="radio"/> Views and assesses the patient's needs holistically (psychosocial, physical) <input type="radio"/> Considers no treatment, non-drug and drug treatment options (including referral and preventative measures) <input type="radio"/> Assesses the effect of multiple pathologies, existing medication and contraindications on treatment options <input type="radio"/> Assesses the risks and benefits to the patient of taking / not taking a medicine (or using / not using a treatment) <input type="radio"/> Selects the most appropriate PGD for the individual patient <input type="radio"/> Selects the most appropriate drug, dose and formulation according to the PGD <input type="radio"/> Identifies ongoing treatment plan and referral options for patient 	<p><i>Establishes a relationship based on trust and mutual respect. Sees patients as partners in the consultation. Applies the principles of concordance.</i></p> <ul style="list-style-type: none"> <input type="radio"/> Listens to and understands patients' beliefs and expectations <input type="radio"/> Understands the cultural, linguistic and religious implications of supplying and administering medicines <input type="radio"/> Deals sensitively with patients' emotions and concerns <input type="radio"/> Adapts the consultation to meet the needs of different patients (e.g. for age, level of understanding) <input type="radio"/> Creates a relationship which does not encourage the expectation that a medicine will be supplied and / or administered <input type="radio"/> Explains the nature of the patient's condition and the rationale behind, and potential risks and benefits of treatment options <input type="radio"/> Helps patients to make informed choices about their options <input type="radio"/> Negotiates an outcome of the consultation that both patient and health care professional are satisfied with <input type="radio"/> Encourages patients to take responsibility for their own health and self-manage their conditions <input type="radio"/> Identifies opportunities to discuss health promotion with patients <input type="radio"/> Gives clear instructions to the patient about their medication (e.g. what it is for, how to take it, possible side effects and expected outcomes) <input type="radio"/> Checks patients' understanding of, and commitment to, their treatment

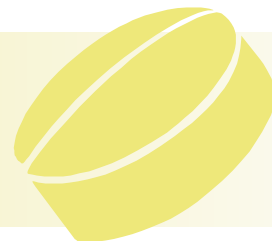


EFFECTIVE SUPPLY AND ADMINISTRATION WITHIN A PGD

<p>4 SAFE PGD USE</p>	<p>5 PROFESSIONAL STANDARDS</p>	<p>6 PRACTICE DEVELOPMENT</p>
<p><i>Is aware of own limitations. Does not compromise patient safety.</i></p>	<p><i>Works within professional and organisational standards.</i></p>	<p><i>Actively participates in the review and development of practice to improve patient care.</i></p>
<ul style="list-style-type: none"> <input type="radio"/> Knows the limits of own knowledge and skill, and works within them <input type="radio"/> Knows when to refer to, or seek guidance from, another member of the team or a specialist <input type="radio"/> Supplies and administers a medicine only with adequate, up-to-date knowledge of its actions, indications, contraindications, cautions, dose and side-effects <input type="radio"/> Checks doses and calculations to ensure accuracy and safety <input type="radio"/> Knows about common types of medication errors and how to prevent them <input type="radio"/> Uses PGDs often enough to maintain confidence and competence <input type="radio"/> Understands the need for, and makes, accurate, clear and timely records and clinical notes 	<ul style="list-style-type: none"> <input type="radio"/> Accepts personal responsibility for working within PGDs and understands the legal implications of doing so <input type="radio"/> Understands and works within the scope of the PGD <input type="radio"/> Makes ethical and / or clinical decisions based on the needs of patients, not personal considerations <input type="radio"/> Understands current medicines legislation, the legal framework for working with PGDs and how they apply in practice <input type="radio"/> Applies current professional codes of practice to the use of PGDs <input type="radio"/> Keeps up-to-date with advances in practice and any emerging safety concerns related to medicines in the PGD <input type="radio"/> Understands how consent relates to PGDs <input type="radio"/> Knows how and when PGDs need to be changed, affects necessary changes 	<ul style="list-style-type: none"> <input type="radio"/> Reflects on own performance, learns and changes practice <input type="radio"/> Willing to share and debate own, and others' practice <input type="radio"/> Challenges inappropriate practice constructively <input type="radio"/> Develops own networks for support, reflection and learning <input type="radio"/> Develops and uses tools to review and improve PGDs and their use in practice (e.g. audit) <input type="radio"/> Reviews and reports incidents and near misses within a clinical governance context <input type="radio"/> Establishes professional links with practitioners working in the same specialist area



PGDs IN CONTEXT		
7 INFORMATION IN CONTEXT	8 THE NHS IN CONTEXT*	9 THE TEAM AND INDIVIDUAL CONTEXT
<p><i>Knows how to access relevant information. Can critically appraise and apply information in practice.</i></p> <ul style="list-style-type: none"> <input type="radio"/> Understands the advantages and limitations of different information sources <input type="radio"/> Uses relevant, up-to-date information; both written (paper / electronic) and verbal <input type="radio"/> Critically appraises the validity of information (e.g. promotional literature, research reports) when necessary <input type="radio"/> Applies information to the clinical context (linking theory to practice) <input type="radio"/> Uses relevant patient record systems, information systems, and decision support tools 	<p><i>Understands, and works with, local and national policies and services that impact on PGD use.</i></p> <ul style="list-style-type: none"> <input type="radio"/> Works within local frameworks for medicines use as appropriate (e.g. formularies, protocols and guidelines supporting PGDs) <input type="radio"/> Works within the NHS / organisational codes of conduct when dealing with the pharmaceutical industry <input type="radio"/> Understands drug budgetary constraints at local and national levels; can discuss them with colleagues and patients <input type="radio"/> Understands the national NHS frameworks underpinning PGDs (e.g. National Institute for Clinical Excellence, National Service Frameworks, medicines management, clinical governance) <input type="radio"/> Legally and safely orders, receives, stores and labels medicines being supplied or administered within a PGD <input type="radio"/> Understands and levies appropriate prescription charges 	<p><i>Works in partnership with colleagues for the benefit of patients. Is self-aware and confident in own ability to use PGDs.</i></p> <ul style="list-style-type: none"> <input type="radio"/> Ensures that continuity of care is not compromised, by keeping all relevant colleagues informed <input type="radio"/> Uses the multidisciplinary team to its full extent <input type="radio"/> Establishes relationships with colleagues based on understanding of, and respect for, each others' roles <input type="radio"/> Recognises and deals with pressures that result in inappropriate use of PGDs <input type="radio"/> Is adaptable, flexible and responsive to change <input type="radio"/> Negotiates the appropriate level of support to enable the use of PGDs <input type="radio"/> Provides support and / or advice to other health care professionals where appropriate
<p>* This competency has an NHS focus, however, the principles underpinning several of the statements still apply to health professionals working in non NHS organisations</p>		



5.5 Using the competency framework

The competency framework contains the competencies that all health care professionals should either already have or should seek to develop when working with PGDs. The framework is relevant to all health care professionals and is an extremely flexible tool which can be used both by individuals and by organisations.

When using the competency framework, the nine competencies it contains need to be **applied locally** to each professional and / or professional group working with PGDs. This is because health care professionals have different skills and experience and use a wide range of medicines using PGDs.

Once the framework has been applied locally, it can be used to support many activities. It can:

- Help individuals and organisations identify training needs
- Assist in the development of training and development programmes
- Facilitate individual continuing professional development
- Facilitate the development of personal development plans
- Help with individual performance review and appraisal systems
- Help with recruitment

To facilitate application of the competency framework by individuals and organisations, a downloadable toolkit is available which contains the framework, along with a blank template version to allow for tailoring of the framework to meet individual needs (see www.npc.co.uk).

Some organisations may already have systems in place for many of these uses and the framework can be easily mapped into these existing systems to ensure that all the competencies are being covered.

Extensive guidance on how to apply and use the competency framework for all these activities is outside the scope of this document. However, some brief examples have been included to give an idea of how the framework might be used:



- By organisations as an aid to training and development
- By individuals for their own continuing professional development

Using the competency framework in training and development

Most organisations will already have some sort of training and development programme for health care professionals using PGDs. The competency framework can be used as an aid to any of these programmes in a number of ways:

- To audit existing training and development programmes to ensure that all relevant competencies are being covered
- As a self-assessment tool for health care professionals to evaluate their own level of competency before beginning a training and development programme
- To link existing training and development with specific competencies so that health care professionals can see how the competencies link to training and development activities
- To provide an ongoing way of structuring continuing professional development

Using the PGD framework to facilitate individual continuing professional development

The framework provides an excellent tool to help individuals assess their own practice when using PGDs. This sort of competency framework has already been used by independent nurse prescribers. Here are some hints from nurse prescribers who have already used it:

- Think of the framework as a way of guiding your reflections on your practice
- Think about using it in a variety of settings to suit your needs, for example, it may be used alone, in a peer group or with your clinical lead
- The framework contains a lot of information. You might find it easier to work through it gradually, one section at a time or one competency at a time
- Remember there are only nine different competencies, so try not to get overwhelmed
- If it helps, download a copy of the framework along with a blank template with space for notes against each competency (see above)



6 Useful links

Professional bodies

The Association of Professional Ambulance Personnel	www.apap.org.uk
The British Dietetic Association	www.bda.uk.com
British Orthoptic Society	www.orthoptics.org.uk
The Chartered Society of Physiotherapy	www.csp.org.uk
The College of Optometrists	www.college-optometrists.org
General Optical Council	www.optical.org
Health Professions Council	www.hpc-uk.org
Joint Royal Colleges Ambulance Liaison Committee	www.jrcalc.org.uk
Nursing and Midwifery Council	www.nmc-uk.org
Royal College of Nursing	www.rcn.org.uk
Royal Pharmaceutical Society of Great Britain	www.rpsgb.org.uk
The Society of Chiropractors and Podiatrists	www.feetforlife.org
The Society of Radiographers	www.sor.org

Department of Health guidance

Patient group directions [England only] — Health Service Circular 2000/026	www.dh.gov.uk
Detailed information on independent nurse prescribing	www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/Prescriptions/NursingPrescribing/fs/en
Detailed information on supplementary prescribing	www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustryServices/Prescriptions/SupplementaryPrescribing/fs/en



The Chief Health Professions Officer's home page has prescribing guidance for allied health professionals

www.dh.gov.uk/AboutUs/HeadsOfProfession/ChiefHealthProfessionsOfficer/CHPOPolicyAreas/CHPOPolicyAreasArticle/fs/en?CONTENT_ID=4061507&chk=kpOWot

Useful information about PGDs

The Medicines and Healthcare Products Regulatory Agency has issued guidance for non-NHS organisations wishing to use PGDs. Look for PGDs in the sitemap / index

www.mhra.gov.uk

The PGD website contains Questions and Answers on PGDs (in support section) as well as examples of PGDs

www.pgd.nhs.uk

The Royal Pharmaceutical Society of Great Britain has produced a comprehensive PGD fact sheet which includes use in the private sector

www.rpsgb.org.uk/pdfs/factsheet10.pdf

Drug Info Zone. A useful section on PGDs (in community / primary section) with links to other reference sources including some sample PGDs

www.druginfozone.nhs.uk

The PRODIGY website has a range of information which may be useful to individuals producing PGDs; including a number of patient information leaflets

www.prodigy.nhs.uk

Information about using competency frameworks in practice

Competency frameworks for independent nurse prescribers, supplementary nurse and pharmacist prescribers already exist. They can be found on the NPC website

www.npc.co.uk

The national network of medicines information pharmacists has detailed guidance about how to use its competency framework to support CPD, and recruitment and appraisal processes, along with 'real' case studies

www.ukmi.nhs.uk

The Primary and Community Care Pharmacy Network competency framework gives short examples of how its framework might be used in different scenarios

www.pccpnetwork.org or
www.druginfozone.nhs.uk



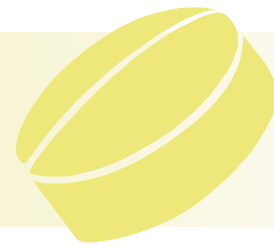
7 Glossary

Administer	To give a medicine by either introduction into the body, whether by direct contact with the body or not, (e.g. orally or by injection) or by external application (e.g. application of an impregnated dressing) [qv “administer in section 130 Medicines Act 1968]
Black triangle medicine (▼)	Newly-introduced medicines still subject to special monitoring for potential side effects by the Medicines and Healthcare Products Regulatory Agency (so-called because they are identified by a black triangle symbol)
Controlled drug	Narcotic drugs or other drugs liable to misuse which are subject to special controls under the Misuse of Drugs Act 1971
Dispense	To make up or give out a clinically appropriate medicine to a patient for self-administration or administration by another, usually a professional. In the case of prescription-only medicines, dispensing must be in response to a legally valid prescription. The act of dispensing is combined with advice about safe and effective use
General sales list (GSL) Medicine	A medicinal product which can be sold or supplied direct to the public in an unopened manufacturer’s pack from any lockable business premises. Such products are listed in the Medicines Order 1984
Licensed indication	Treatment purpose for which a product may be used under the terms of the marketing authorisation granted by the Licensing Authority (see also licensed medicine)
Licensed medicine	A medicine which falls within the definition of a medicinal product and which is granted a marketing authorisation by the Licensing Authority when the safety, quality and efficacy of the product have been satisfactorily demonstrated by the license holder in accordance with EC directives 65/65



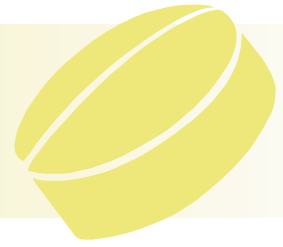
Marketing authorisation	The 1968 Medicines Act, which regulates the use of medicines in the UK, requires that a medicine must have a marketing authorisation (previously a product licence) before it can be used by the public. In the UK marketing authorisations are granted by the Medicines and Healthcare Products Regulatory Agency
Pharmacy (P) medicine	Any medicinal product other than those designated as GSL or POM products. Pharmacy medicines can be sold or supplied only from a registered pharmacy by or under the supervision of a pharmacist, subject to certain exceptions
Prescribe	To authorise in writing the supply of a medicine (usually, but not necessarily, a prescription-only medicine) for a named patient
Prescription-only medicines (POMs)	A medicinal product which may only be sold or supplied against the signed prescription of an appropriate practitioner, i.e. doctor, dentist, some nurses (in respect of a specified list of POMs) specified in the Prescription Only Medicines (Human Use) Order 1997
Summary of Product Characteristics (SPC)	The SPC forms an integral part of the marketing authorisation and is the basis of information for health care professionals. It describes the properties and effects of the medicine as well as warnings about it
Supply	To provide a medicine to a patient / carer for administration*

* There is no legal distinction between ‘dispense’ and ‘supply’ although there are considerable differences in practice. The act of dispensing includes supply and also encompasses a number of other cognitive functions (e.g. checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly of the product). In common usage, ‘dispense’ is usually reserved to the activity of pharmacists and ‘supply’ can be used for either pharmacists or nurses.



Appendices

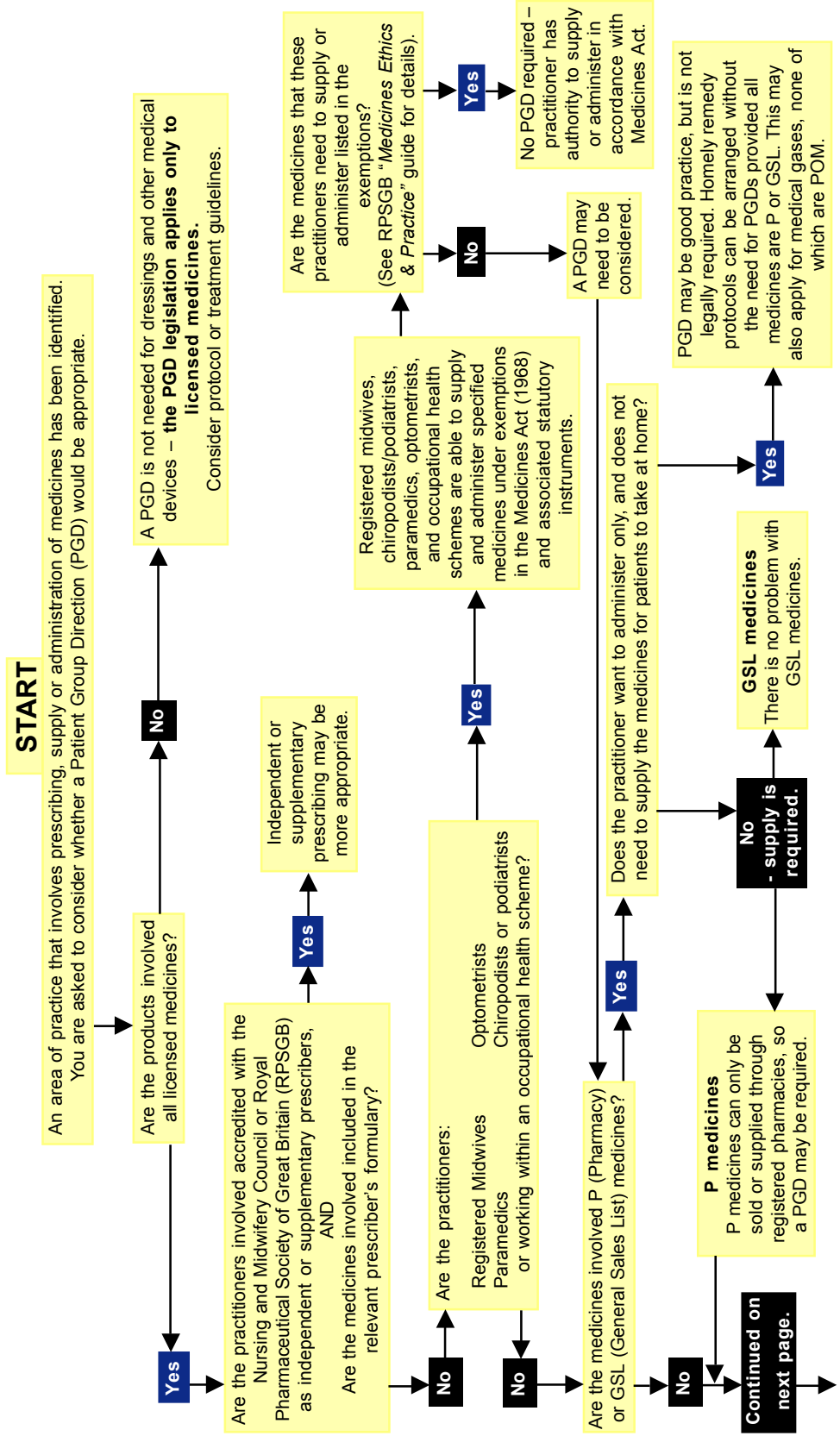
Appendix 1: To PGD or not to PGD? — that is the question	51
Appendix 2: Acknowledgements	53

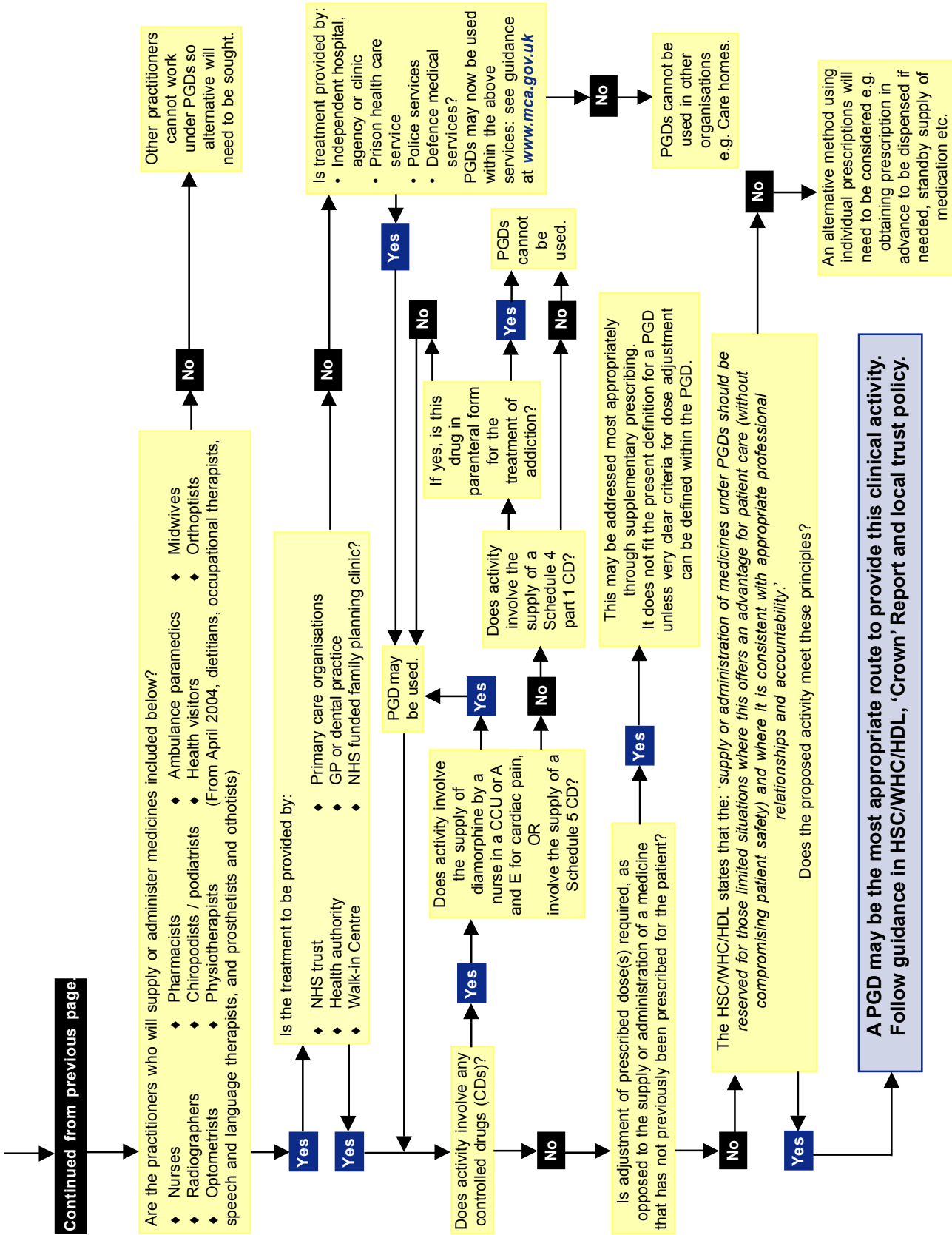


To PGD or not to PGD? — that is the question (A guide to choosing the best option for individual situations)

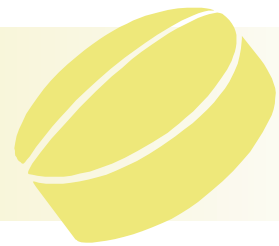
This guide has been prepared in response to the many queries that are still being raised both locally and nationally about the implementation of Patient Group Directions (HSC 2000/026 in England, WHC (2000) 116 in Wales, and HDL(2001)7 in Scotland). The co-incident introduction of independent and supplementary prescribing has often confused many practitioners, and there is a danger that inconsistencies may develop as the implementation of both initiatives continues. Practitioners and their managers who wish to formalise or set up new systems for prescribing, or alternatively the supply or administration of medicines, are faced with a range of different methods and need to select the most appropriate route in each case. The diagram below takes the practitioner through a logical process that aims to assist decision-making.

The majority of clinical care should still be provided on an individual, patient-specific basis.





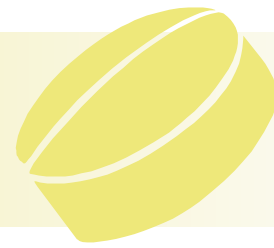
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 Further copies available at www.groupprotocols.org.uk



Acknowledgements

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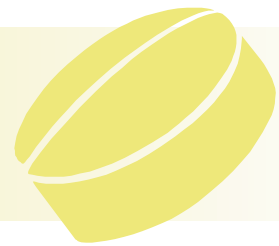
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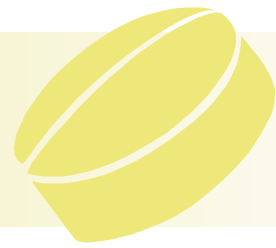
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Circulation for comment

The document (in draft) was circulated widely for comment to over x individuals / organisations. Those commenting were, or represented, nurses and midwives, doctors, pharmacists, physiotherapists, optometrists, ambulance paramedics, speech and language therapists and dieticians across a range of specialities and sectors. Commentators also included independent health care organisations, prisons, regulatory authorities, professional bodies and the Department of Health. Comments received were used to further refine the content and presentation of this document.



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