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# Patient Group Directions

NICE good practice guidance

Draft for consultation, April 2013

# 1 Contents

2	1	Introduction.....	4
3	1.1	Purpose of this guidance .....	4
4	1.2	Audience for this guidance.....	4
5	1.3	Scope.....	4
6	1.4	Definition of a Patient Group Direction.....	5
7	1.5	Prescribing, supplying and administering medicines .....	5
8	1.6	Legal framework governing the use of Patient Group Directions .....	7
9	2	Recommendations .....	12
10	2.1	Considering the need for a Patient Group Direction .....	12
11	2.2	Obtaining agreement to develop a Patient Group Direction.....	12
12	2.3	Developing Patient Group Directions.....	12
13	2.4	Authorising Patient Group Directions.....	12
14	2.5	Using Patient Group Directions.....	12
15	2.6	Reviewing and updating Patient Group Directions.....	12
16	2.7	Training and competency.....	12
17	2.8	Organisational governance .....	12
18	3	Evidence and recommendations .....	13
19	3.1	Considering the need for a Patient Group Direction .....	15
20	3.2	Obtaining agreement to develop a Patient Group Direction.....	24
21	3.3	Developing Patient Group Directions.....	30
22	3.4	Authorising Patient Group Directions.....	35
23	3.5	Using Patient Group Directions.....	42
24	3.6	Reviewing and updating Patient Group Directions.....	48
25	3.7	Training and competency.....	52
26	3.8	Organisational governance .....	57
27	4	How this guidance has been developed.....	62
28	4.1	Guidance Development Group .....	62
29	4.2	Literature search strategy .....	62
30	4.3	Additional evidence.....	62
31		Appendix A Glossary .....	64
32		Appendix B Key resources.....	70
33		Appendix C The Guidance Development Group and NICE project team.....	71

1	Guidance Development Group .....	71
2	NICE project team .....	72
3	Appendix D Literature search.....	73
4	Search strategy .....	73
5	Search questions.....	73
6	Sources searched .....	74
7		
8		

# 1 Introduction

## 1.1 Purpose of this guidance

The purpose of this guidance is to provide good practice recommendations for the systems and processes used when commissioners and providers of NHS services are considering the need for, developing, authorising, using and updating Patient Group Directions (PGDs). This guidance also covers governance arrangements with the aim of ensuring patients receive safe and appropriate care and timely access to medicines, in line with legislation.

## 1.2 Audience for this guidance

This guidance is for individual people and organisations who are considering the need for, developing, authorising, using and updating PGDs. It is written in the context of the NHS in England, including independent organisations or contractors who are commissioned to provide NHS services. It will also be applicable as NICE guidance, as appropriate, to some of the devolved administrations.

## 1.3 Scope

The scope covers the legislation, systems and processes used when commissioners and providers of NHS services are considering the need for, developing, authorising, using and updating PGDs. This includes NHS organisations, local authorities (in England), and any [NHS-commissioned services](#) provided by non-NHS organisations, such as:

- independent organisations (for example, independent hospitals)
- independent contractors (for example, community pharmacies)
- voluntary and charitable agencies (for example, hospices).

When considering the appropriateness of PGDs, the [Guidance Development Group](#) (GDG) considered other options for supplying and/or administering medicines to patients (see [section 1.5](#)). However, recommendations have not been made in relation to these options.

1 This guidance does not include shared practice examples or other  
2 approaches for implementing the good practice recommendations.

### 3 **1.4 Definition of a Patient Group Direction**

4 A PGD is defined in [Health Service Circular \(HSC 2000/026\)](#) as:

5 'A written instruction for the supply or administration of medicines to  
6 groups of patients who may not be individually identified before  
7 presentation for treatment'.

8 PGDs provide a legal framework that allows the supply and/or administration  
9 of a specified medicine(s), by named authorised health professionals, to a  
10 pre-defined group of patients needing treatment for a condition described in  
11 the PGD, without the need for a prescription or an instruction from a  
12 prescriber. Using a PGD is not a form of prescribing.

13 This definition should not be interpreted as indicating that the patient should  
14 not be identified. Patients may or may not be known to the service (see  
15 [section 3.1](#)).

### 16 **1.5 Prescribing, supplying and administering medicines**

17 Understanding the distinction between prescribing, supplying and  
18 administering medicines to patients is important for people and [organisations](#)  
19 involved with PGDs. There are no **legal** definitions that distinguish between  
20 prescribing, supplying, dispensing and administering a medicine. The  
21 definitions used for the purpose of this guidance are given in [appendix A](#).

22 Historically, a doctor (or dentist) would identify that a medicine(s) was needed  
23 as part of the care pathway and prescribe a medicine for the patient. A  
24 pharmacist would then dispense the medicine(s) against the prescription and  
25 supply the medicine(s) to the patient.

26 This traditional 'medical model' changed in the years after publication of the  
27 [final Crown report](#) in 1999. Legal frameworks were developed that have  
28 allowed services to be redesigned and health professionals to work more  
29 flexibly for the benefit of patients. In particular, prescribing responsibilities  
Patient Group Directions: Good practice guidance DRAFT (April 2013)

1 have been extended to allow other health professionals to complete additional  
2 training and qualify as [non-medical prescribers](#). In addition, these frameworks  
3 allow medicines to be supplied and/or administered directly by a health  
4 professional, without the need for prescribing at some key steps in a care  
5 pathway.

6 As a result of these changes, there are now several legal options for  
7 prescribing, supplying and administering medicines. These are:

- 8 • Independent prescribing – the prescriber takes responsibility for the clinical  
9 assessment of the patient, establishing a diagnosis, the clinical  
10 management needed and prescribing of therapies.
- 11 • [Supplementary prescribing](#) – a voluntary partnership between a doctor or  
12 dentist and a supplementary prescriber, to prescribe within an agreed  
13 patient-specific [clinical management plan](#) with the patient's agreement.
- 14 • Patient Specific Directions (PSDs) – written instructions from an  
15 independent prescriber for a medicine to be supplied and/or administered  
16 to a named patient.
- 17 • Patient Group Directions (PGDs) – see [section 1.4](#) for definition.
- 18 • [Exemptions from medicines legislation](#), for example:
  - 19 – a [range of exemptions](#) allow certain groups of health professionals, such  
20 as [chiropodists and podiatrists](#), [midwives](#), [paramedics](#), and [optometrists](#),  
21 to sell, supply and administer particular medicines directly to patients
  - 22 – [occupational health schemes](#)
  - 23 – [pandemic influenza](#)
  - 24 – [parenteral medicines](#) that can be administered in an emergency by any  
25 person without the directions of a prescriber
  - 26 – civil contingencies.

27 These exemptions are distinct from prescribing and the arrangements for  
28 PGDs.

- 29 • [Emergency supplies](#) – in an emergency and under certain conditions a  
30 pharmacist working in a registered pharmacy can supply a [prescription-only](#)

1 [medicine](#) (POM) to a patient without a prescription, if requested by a  
2 prescriber or the patient<sup>1</sup>.

3 These options provide organisations with a range of alternatives to consider  
4 when making decisions about the safest and most appropriate way for  
5 patients to get the medicines they need.

## 6 **Purpose of Patient Group Directions**

7 Evidence identified in developing this guidance confirmed that the majority of  
8 clinical care should be provided on an individual, patient-specific basis. This  
9 means that independent prescribing remains the most appropriate option for  
10 the majority of care. Supplying and/or administering medicines under PGDs  
11 should be reserved for situations where this offers an advantage for patient  
12 care without compromising patient safety, and where it is consistent with  
13 appropriate professional relationships and accountability<sup>2</sup>.

14 The GDG agreed that the purpose of using a PGD was to:

- 15 • deliver effective patient care that is appropriate in a pre-defined clinical  
16 situation, without compromising patient safety
- 17 • offer a significant advantage to patient care by improving access to  
18 appropriate medicines
- 19 • provide equity in the availability and quality of services when other options  
20 for supplying and/or administering medicines are not available
- 21 • provide a safe legal framework to protect patients
- 22 • reduce delays in treatment
- 23 • maximise the skills of a range of health professionals.

## 24 **1.6 Legal framework governing the use of Patient Group** 25 **Directions**

26 [Legislation](#) establishing PGDs was introduced in 2000 and the [Health Service](#)  
27 [Circular \(HSC 2000/026\)](#) provided additional guidance. The current legislation

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<sup>1</sup> Royal Pharmaceutical Society. Medicines, Ethics and Practice. The professional guide for pharmacists. Edition 36 July 2012

<sup>2</sup> NHS Executive. [Health Service Circular \(HSC 2000,026\)](#) 9<sup>th</sup> August 2000

Patient Group Directions: Good practice guidance DRAFT (April 2013)

1 for PGDs is included in [The Human Medicines Regulations 2012](#), which came  
2 into force in August 2012. This [legislation was amended](#) in April 2013 to  
3 reflect changes to NHS organisational structures in England, as a result of the  
4 [Health and Social Care Act 2012](#).

5 The amended legislation also incorporated [transitional arrangements](#) to  
6 ensure the continuing validity and effect of PGDs during organisational  
7 change, and to ensure that individual people and organisations act within the  
8 legal framework. These arrangements allowed PGDs to remain legal when the  
9 original [authorising body](#) (for example, a primary care trust [PCT]) was  
10 abolished, and until expiry or authorisation by the new authorising body (for  
11 example, a clinical commissioning group (CCG) or local authority). See the  
12 [national PGD website](#) for further information.

### 13 **Authorising Patient Group Directions**

14 Legislation requires that a PGD must be [signed](#) by a doctor (or dentist) and a  
15 pharmacist.

16 PGDs must also be signed on behalf of the authorising body with which a  
17 contract or agreement for the provision of those services has been made, or  
18 which provides those services, as set out in the [legislation](#). In the NHS these  
19 authorising bodies are:

- 20 • CCGs
- 21 • local authorities
- 22 • NHS trusts or NHS foundation trusts
- 23 • the NHS Commissioning Board.

24 In addition, the following independent organisations can also authorise PGDs  
25 for [NHS-commissioned services](#):

- 26 • dental practices and clinics
- 27 • organisations operating as an [independent medical agency](#) and where the  
28 registered provider at the agency is registered in compliance with section



- 1 10 of the Health and Social Care Act 2008 in respect of 1 or more of the  
2 following regulated activities:
- 3 – treatment of disease, disorder or injury
  - 4 – assessment or medical treatment of persons detained under the Mental  
5 Health Act 1983
  - 6 – surgical procedures
  - 7 – diagnostic and screening procedures
  - 8 – maternity and midwifery services
  - 9 – family planning.

### 10 **Health professionals eligible to use Patient Group Directions**

11 [Legislation](#) requires that PGDs must only be used by the following, registered  
12 health professionals:

- 13 • ambulance paramedics
- 14 • dental hygienists and dental therapists
- 15 • dietitians
- 16 • health visitors
- 17 • midwives
- 18 • nurses
- 19 • occupational therapists
- 20 • optometrists
- 21 • orthoptists
- 22 • pharmacists
- 23 • physiotherapists
- 24 • podiatrists and chiropodists
- 25 • prosthetists and orthotists
- 26 • radiographers
- 27 • speech and language therapists.

28 Individual health professionals must be named and authorised to practice  
29 under a PGD. Also see [section 3.1](#).

## 1 **Medicines excluded from PGDs**

2 Legislation excludes the use of the following medicines in a PGD:

3 • [unlicensed medicines](#) including:

4 – the mixing of 2 licensed medicines to form 1 new (unlicensed) product,  
5 unless 1 is an vehicle for administration, such as water for injection

6 – [special manufactured medicines](#)

7 – dressings, appliances and devices

8 • [radiopharmaceuticals](#)

9 • abortifacients, such as mifepristone

10 • controlled drugs, with the exception of the following controlled drugs that  
11 may be considered:

12 – morphine and diamorphine, listed in schedule 2 of the [Misuse of Drugs](#)  
13 [Regulations \(2001\)](#) by registered nurses and pharmacists for the  
14 immediate necessary treatment of a sick or injured person (except for  
15 treating addiction)

16 – midazolam, listed in schedule 3 of the Misuse of Drugs Regulations  
17 (2001)

18 – all drugs, such as benzodiazepines and ketamine, that are listed in  
19 schedule 4 of the Misuse of Drugs Regulations (2001), except anabolic  
20 steroids and any injectable preparation used for treating addiction

21 – all drugs, such as codeine, that are listed in schedule 5 of the Misuse of  
22 Drugs Regulations (2001).

## 23 **Information to be included in a Patient Group Direction**

24 [Legislation](#) requires that each PGD must contain the following information:

25 • the period during which the direction is to have effect

26 • the description or class of medicinal product to which the direction relates

27 • the clinical situations which medicinal products of that description or class  
28 may be used to treat or manage in any form

29 • whether there are any restrictions on the quantity of medicinal product that  
30 may be sold or supplied on any one occasion and, if so, what restrictions

31 • the clinical criteria under which a person is to be eligible for treatment

## Draft for consultation

- 1 • whether any class of person is excluded from treatment under the direction
- 2 and, if so, what class of person
- 3 • whether there are circumstances in which further advice should be sought
- 4 from a doctor or dentist and, if so, what circumstances
- 5 • the pharmaceutical form or forms in which medicinal products of that
- 6 description or class are to be administered
- 7 • the strength, or maximum strength, at which medicinal products of that
- 8 description or class are to be administered
- 9 • the applicable dosage or maximum dosage
- 10 • the route of administration
- 11 • the frequency of administration
- 12 • any minimum or maximum period of administration applicable to medicinal
- 13 products of that description or class
- 14 • whether there are any relevant warnings to note and, if so, what warnings
- 15 • whether there is any follow up action to be taken in any circumstances and,
- 16 if so, what action and in what circumstances
- 17 • arrangements for referral for medical advice
- 18 • details of the records to be kept of the supply, or the administration, of
- 19 products under the direction.

## 20 Other legislation

21 [Legislation](#) for the labelling of medicines applies to all supplies of medicines,  
22 including those supplied under PGDs. Separate requirements exist for [POMs](#)  
23 and for [Pharmacy \(P\) and General Sales List \(GSL\) medicines](#). See [appendix](#)  
24 [A](#) for definitions.

25 A manufacturer's patient information leaflet [must be provided](#) to patients who  
26 have a medicine supplied under a PGD.

27 Standard prescription charge rules and exemptions also apply to patients  
28 receiving a supply of medicine(s) under a PGD from the NHS, but do not  
29 apply when medicines are administered under a [PGD](#).

30

## 1     **2           Recommendations**

2     This good practice guidance has been developed for individual people and  
3     organisations considering the need for, developing, authorising, using and  
4     updating Patient Group Directions (PGDs).

5     The recommendations for good practice have been developed by the PGD  
6     Guidance Development Group (GDG), using relevant legislation, guidance  
7     and policy as the foundation for good practice. See [appendix B](#) for a list of key  
8     resources used in developing this guidance.

9     *[Drafting note: see sections 3.1 to 3.8 for recommendations. All*  
10    *recommendations will be inserted into this section on final publication].*

### 11    **2.1           Considering the need for a Patient Group Direction**

### 12    **2.2           Obtaining agreement to develop a Patient Group** 13    **Direction**

### 14    **2.3           Developing Patient Group Directions**

### 15    **2.4           Authorising Patient Group Directions**

### 16    **2.5           Using Patient Group Directions**

### 17    **2.6           Reviewing and updating Patient Group Directions**

### 18    **2.7           Training and competency**

### 19    **2.8           Organisational governance**

20

21

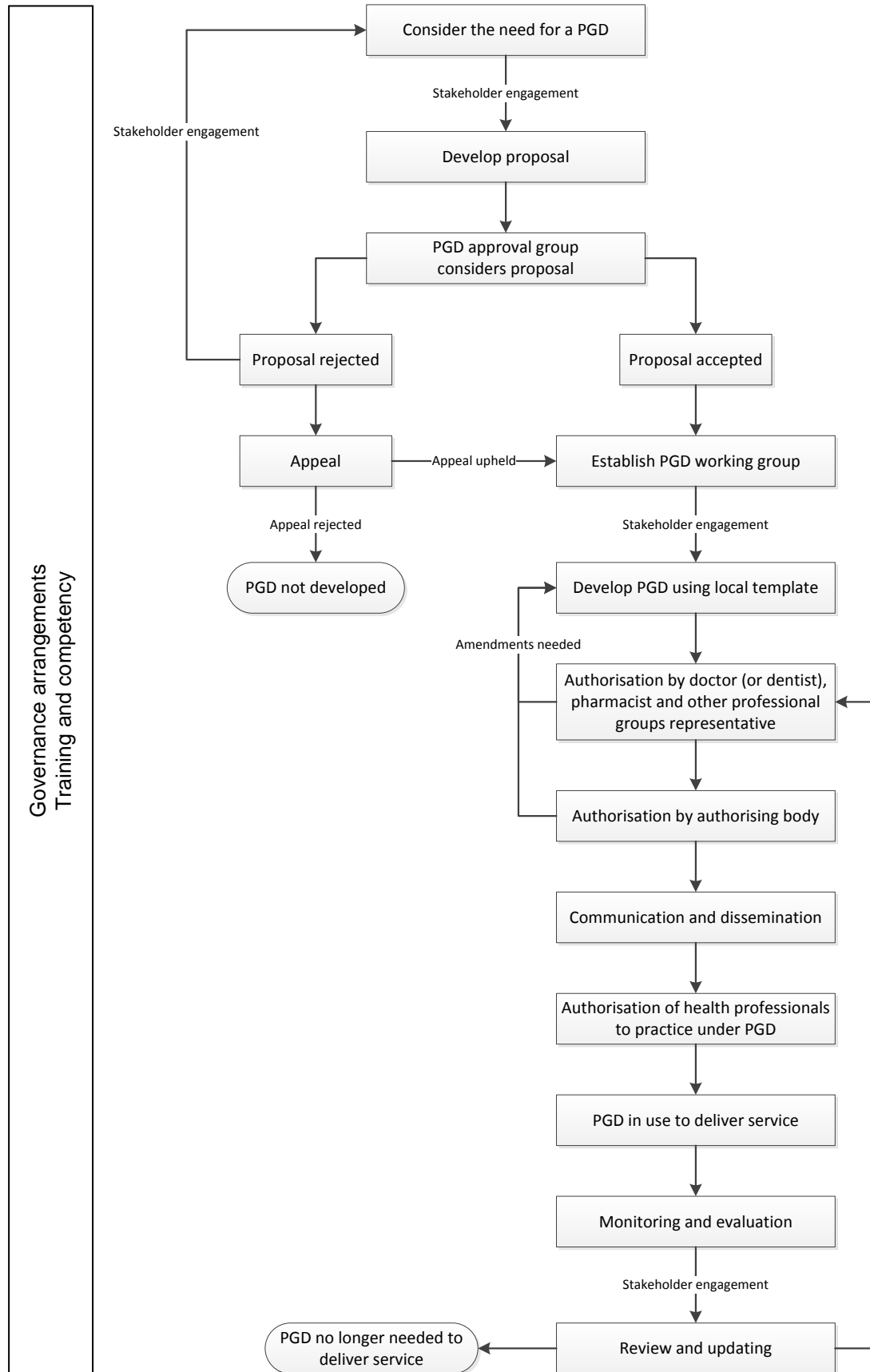
### 1     **3           Evidence and recommendations**

2     When reviewing the [evidence gathered](#) for this guidance, the GDG concluded  
3     that the key principles in each of the following areas needed careful  
4     consideration:

- 5     • considering the need for a Patient Group Direction (PGD)
- 6     • obtaining agreement to develop a PGD
- 7     • developing PGDs
- 8     • authorising PGDs
- 9     • using PGDs
- 10    • reviewing and updating PGDs
- 11    • training and competency
- 12    • organisational governance.

13    An overview of the process agreed by the GDG is shown in [figure 1](#). Details  
14    may vary depending on how local services are designed. Although this  
15    guidance is written in the context of the NHS in England, the GDG agreed that  
16    these principles are applicable to independent organisations or contractors  
17    who are commissioned to provide NHS services, and to some of the devolved  
18    administrations.

1 **Figure 1. Overview of the process for considering the need for,**  
 2 **developing, authorising, using and updating PGDs.**



3

1 **3.1 Considering the need for a Patient Group Direction**

2 The GDG identified the importance of firmly establishing local governance  
3 arrangements between the [commissioning](#) and [provider](#) organisation(s) with  
4 clear lines of responsibility and accountability for each PGD. This should be  
5 undertaken at the earliest opportunity when considering the need for a PGD to  
6 avoid possible delays in developing and delivering appropriate services (see  
7 [section 3.8](#)).

8 **Exploring the options for supplying and/or administering medicines**

9 The GDG found evidence that the majority of clinical care involving supplying  
10 and/or administering medicines should be provided on an individual, patient-  
11 specific basis (see [section 1.5](#)). The GDG was aware of PGDs being used to  
12 deliver a service when [independent prescribing](#) would be a more appropriate  
13 option, for example when prescribers were not available at the required time.  
14 The GDG considered that barriers to developing independent prescribing,  
15 such as a lack of allocated funding and staff commitment, may have  
16 contributed to the unnecessary or inappropriate development of PGDs.

17 Even in circumstances when it may be legally possible, the GDG agreed that  
18 a PGD may not be the preferred and safest approach to individual situations  
19 of providing patients with the medicine(s) they need. The GDG also found  
20 evidence that in some circumstances different options for prescribing, supply  
21 and/or administering medicines can be beneficial when used in combination,  
22 subject to the appropriate training and competencies. See box 1 for examples  
23 of different options which may be available for supplying and administering  
24 influenza vaccines.

1 **Box 1 Options for supplying and/or administering influenza vaccines**

Options for supplying and/or administering influenza vaccines include:

- A district nurse who may administer to a patient in their home after a prescription and supply from a community pharmacy or a [Patient Specific Direction \(PSD\)](#) from a GP.
- A healthcare assistant who may administer in a flu clinic after a PSD from a GP. A PGD would not be legally permitted (see [section 1.6](#)).
- A community pharmacist who may administer using a PGD as part of an NHS-commissioned enhanced service.

2

3 The GDG found evidence that PGDs are often used in the NHS in first contact  
4 settings, when patients seek unscheduled care such as in:

- 5 • accident and emergency departments
- 6 • ambulance services
- 7 • community pharmacies
- 8 • contraception and sexual health clinics
- 9 • minor injuries units
- 10 • walk-in centres
- 11 • out-of-hours services.

12 However, the GDG agreed that the setting alone should not determine  
13 whether a PGD is the most appropriate option for supplying and/or  
14 administering the medicine.

15 The GDG was aware of [national PGD website tools](#) to help identify when a  
16 PGD may be the most appropriate option, for example '[To PGD or not to  
17 PGD](#)'.

18 The GDG concluded that these tools should be utilised when considering the  
19 need for a PGD. In general, the need for a PGD in a specific clinical situation  
20 should be considered locally. A comprehensive approach should include  
21 reviewing the care pathway and exploring **all** the options for prescribing,  
22 supplying and/or administering medicines.

23 In circumstances when there are insufficient prescribers, the GDG accepted  
24 that PGDs may be needed as an interim option while independent prescribing

Patient Group Directions: Good practice guidance DRAFT (April 2013)



1 is developed, if that is the preferred approach. However, the GDG agreed that  
2 governance arrangements would need to be in place (see [section 3.8](#)). In  
3 addition, organisations may need to develop or review their strategic  
4 medicines policy to develop independent prescribing locally. The GDG  
5 concluded that PGDs should not be seen as a direct substitute for  
6 independent prescribing.

### 7 **Health professionals eligible to use Patient Group Directions**

8 The GDG noted that [legislation](#) requires that only specific registered health  
9 professionals can use PGDs (see [section 1.6](#)). Most of the evidence identified  
10 from the literature search related to PGD use by nurses and pharmacists.

11 The GDG was aware of examples of other groups of healthcare workers using  
12 PGDs that were not eligible, such as healthcare assistants, [student health](#)  
13 [professionals](#) and registered health professionals not listed in PGD legislation.  
14 Because this is not within the legal requirements for PGDs, the GDG agreed  
15 that this use should be identified when organisations develop or review their  
16 strategic medicines policy.

17 The GDG was also aware that [legislation requires](#) that health professionals  
18 using PGDs can only do so as named individuals and are not able to [delegate](#)  
19 their responsibility to another person (see [section 3.5](#)).

### 20 **Organisations using Patient Group Directions**

21 The GDG was aware of the range of organisations and services that can  
22 currently **use** PGDs to provide NHS-funded care. These are:

- 23 • NHS trusts and foundation trusts
- 24 • primary care organisations, such as clinical commissioning group (CCGs)
- 25 • NHS-commissioned services including:
  - 26 – services provided by the private, voluntary or charitable sectors
  - 27 – urgent care services, such as out-of-hours services and walk-in centres
  - 28 – services provided by independent contractors, such as GP and dental
  - 29 practices and community pharmacies.

1 **Medicines that can be considered for a Patient Group Direction**

2 The GDG was aware of legislation governing which medicines can be  
3 included in a PGD (see [section 1.6](#)). The GDG also reviewed the evidence  
4 and considered the appropriateness of other medicines that may be  
5 considered for supply and/or administration using a PGD:

- 6 • [off-label use](#) of medicines may be considered, if such use is exceptional  
7 and supported by best clinical practice, such as [NICE guidance](#)
- 8 • [black triangle medicines](#) may be considered, provided such use is  
9 exceptional and supported by best clinical practice, such as [Joint](#)  
10 [Committee on Vaccination and Immunisation \(JCVI\) advice](#) relating to the  
11 use of vaccines
- 12 • [particular caution should be exercised](#) in any decision to draw up PGDs  
13 relating to antibacterials. Microbial resistance is a public health matter of  
14 major importance and great care should be taken to ensure that their  
15 inclusion in a PGD is absolutely necessary and will not jeopardise  
16 strategies to combat increasing resistance.

17 The GDG recognised that specifying a dosage range so the health  
18 professional could select the correct dose for a patient was appropriate in a  
19 PGD. However, the GDG did not consider frequent individual adjustment of  
20 dosage using a PGD to represent good practice and agreed that prescribing  
21 or a PSD would be a more appropriate option.

22 The GDG also noted that dose adjustments should not be made under a PGD  
23 when a medicine is in a patient's possession unless specified at the point of  
24 supply.

25 The GDG agreed that the original intention of PGDs was not to use them for  
26 'complex' medicines, including medicines needing frequent dose adjustments,  
27 frequent or complex monitoring, or [high-risk medicines](#). The GDG supported  
28 the original intention and agreed that the risks of using a complex medicine in  
29 a PGD outweighed the benefits and alternative options should be used.

1 The GDG received reports describing the growth in the use of PGDs in  
2 settings, for indications and for medicines where good practice was not being  
3 followed. For example, the GDG was aware of evidence that some radiology  
4 services were using PGDs for administering contrast media. The GDG  
5 concluded that these were complex medicines and if a PGD was being used  
6 in such circumstances it would be appropriate to review its use and consider  
7 other options, such as prescribing.

8 The GDG found evidence that more than 1 medicine **could** be included within  
9 a PGD. However, the GDG agreed that good practice was likely to be  
10 represented by including a single medicine. The GDG acknowledged that  
11 including more than 1 medicine may be appropriate in some circumstances,  
12 such as different medicines being options for managing a single condition,  
13 provided all legal requirements were included for each drug. For example,  
14 levonorgestrel or ulipristal acetate for emergency hormonal contraception.

15 The GDG heard reports of PGDs being used when a PGD is not needed, for  
16 example when medicines are classified as [General Sales List \(GSL\)](#) or  
17 because of exemptions in legislation for specified medicines for certain groups  
18 of health professionals, such as chiropodists and podiatrists, midwives,  
19 paramedics and optometrists (see [section 1.5](#)). [Pharmacy \(P\) medicines](#) can  
20 also be supplied through registered pharmacies, without the need for a PGD.  
21 See the [national PGD website](#) tool '[To PGD or not to PGD](#)' for more  
22 information.

23 The GDG agreed that local policies would be more appropriate in these  
24 circumstances, with the employing organisation retaining legal responsibility  
25 for the actions of its employees.

26 See box 2 for examples of clinical situations when PGDs may be appropriate.

27

1 **Box 2 Clinical situations when PGDs may be appropriate**

PGDs may be appropriate when:

- medicine use follows a predictable pattern, such as for patients attending for contraception
- patients with an acute need seek unscheduled care, such as in a walk-in centre
- managing a discrete treatment episode where supplying or administering a medicine is needed, such as treating chlamydia
- there is a homogenous patient group, such as at-risk groups of patients needing immunisation.

2 See box 3 for examples of clinical situations when PGDs need to be  
3 considered carefully.

4 **Box 3 Clinical situations when PGDs need to be considered carefully**

PGDs should be considered carefully when:

- the medicine is being used [off label](#)
- the medicine is a [black triangle medicine](#)
- the medicine is a controlled drug (only [some controlled drugs](#) are eligible for consideration)
- the medicine is an injectable preparation for self-administration
- treatment or response to treatment needs careful monitoring
- managing a small number of patients in a specific patient group, because the appropriate resources and expertise may not be available
- supplying and/or administering a range of medicines to the same patient (this may be appropriate in some cases when a discrete episode of care involves treatment with more than 1 medicine).

5 See box 4 for examples of clinical situations when alternative options to PGDs  
6 should be used.

7 **Box 4 Clinical situations when alternative options to PGDs should be**  
8 **used**

Alternative options to PGDs should be used when:

- managing complex long-term conditions, such as hypertension or diabetes
- in a particular setting, significant uncertainty remains about the differential diagnosis
- an antimicrobial is needed (this may be appropriate in some circumstances, such as chlamydia treatment in a sexual health clinic)
- the medicine needs frequent dosage adjustments, for example warfarin
- the medicine needs frequent or complex monitoring, for example immunosuppressants
- the medicine is a high-risk medicine, for example insulin.

9

## 1 Recommendations

### **Recommendation 2.1.1**

Explore all the available options for supplying and/or administering medicines in a specific clinical situation. Consider whether 1 option or a range of options is appropriate.

### **Recommendation 2.1.2**

Reserve PGDs for the limited situations when this offers an advantage for patient care, without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability.

### **Recommendation 2.1.3**

Use the [national PGD website tools](#) to consider whether a PGD is necessary. Do not use PGDs for medicines when exemptions in legislation allow their supply and/or administration without the need for a PGD.

### **Recommendation 2.1.4**

Consider investing in the training of additional prescribers to redesign services if necessary, as part of a wider development or review of local medicines policy.

### **Recommendation 2.1.5**

PGDs must be used only by named, [registered health professionals](#) who can legally supply and/or administer medicines using a PGD.

### **Recommendation 2.1.6**

PGDs must be used only in organisations and services that are legally eligible to use them within the NHS.

### **Recommendation 2.1.7**

Ensure only a licensed medicine(s) that is legally permitted to be supplied and/or administered using a PGD is included in a PGD.

### **Recommendation 2.1.8**

Ensure [off-label use](#) of a medicine in a PGD is exceptional and justified by best clinical practice. Clearly state on the PGD that the medicine is being used

outside the terms of the [marketing authorisation](#). Consider informing the patient or their carer that the use is [off-label](#).

**Recommendation 2.1.9**

Ensure use of a [black triangle medicine](#) in a PGD is exceptional, clearly stated on the PGD and justified by best clinical practice.

**Recommendation 2.1.10**

Ensure use of a controlled drug in a PGD is legally permitted and justified by best clinical practice.

**Recommendation 2.1.11**

Consider including an antimicrobial in a PGD only in exceptional circumstances. Ensure that its use is clinically essential and will not jeopardise local and national strategies to combat antimicrobial resistance.

**Recommendation 2.1.12**

Do not include complex medicines in a PGD, such as:

- medicines needing frequent dosage adjustments, for example, warfarin
- medicines needing frequent or complex monitoring, for example, immunosuppressants
- [high-risk medicines](#), for example, insulin.

**Recommendation 2.1.13**

Do not use a PGD to make dose adjustments when a medicine is in a patient's possession.

**Recommendation 2.1.14**

Carefully consider the risks and benefits of including more than 1 medicine in a PGD. Ensure all legal requirements are met for each medicine.

**Recommendation 2.1.15**

Do not use PGDs for managing complex long-term conditions, such as hypertension or diabetes, or when establishing a diagnosis is complex in the

associated setting.

1

2

## 1 **3.2 Obtaining agreement to develop a Patient Group**

### 2 ***Direction***

3 The GDG found evidence that PGDs need significant resources and are time-  
4 consuming to produce. Some organisations had processes in place to obtain  
5 the agreement of the [authorising body](#) for the PGD before proceeding to  
6 develop the PGD. In other organisations this step appeared to be omitted from  
7 the process.

8 When the local process included submitting a proposal to the authorising body  
9 to develop a PGD, the GDG found examples of a number of proposal forms  
10 being used for this purpose. The GDG found evidence that proposals were  
11 submitted to a multidisciplinary '[PGD approval group](#)', usually by a locally  
12 determined clinical lead. This PGD approval group considered each proposal  
13 and determined whether it was appropriate to proceed with developing a PGD  
14 to deliver the service.

15 The GDG found evidence that the functions of the PGD approval group were  
16 often fulfilled by an existing local medicines decision-making group, such as a  
17 drug and therapeutics committee, or a sub-group. It agreed that the PGD  
18 approval group did not have to be a separate decision-making group.

19 The GDG concluded that an effective PGD approval group should be in  
20 operation with the delegated authority of the authorising body. There should  
21 be clear lines of governance, reporting arrangements and accountability, such  
22 as agreeing terms of reference, decision-making criteria and appropriate  
23 documentation. Proposals to develop a PGD should only be accepted if they  
24 comply with all legal requirements and professional guidance.

25 From the evidence identified, where PGD approval groups existed, their  
26 functions did not always appear to be clearly defined. The GDG agreed that  
27 an effective PGD approval group would have processes in place for:

- 28 • ensuring PGDs are not developed without previous agreement
- 29 • prioritising proposals to develop a PGD



- 1 • seeking the views of stakeholders on proposals, for example, from clinical  
2 groups, patients and the public and the [commissioning](#) or [provider](#)  
3 organisation(s)
- 4 • gathering intelligence about local service delivery and exploring all the  
5 options for prescribing, supplying and/or administering medicines in a  
6 specific situation (see [section 3.1](#))
- 7 • considering the [arrangements](#) for the security, storage, packaging and  
8 labelling of medicines
- 9 • considering the resources needed to deliver the service, such as medicines  
10 procurement from a [licensed manufacturing unit](#) and any diagnostic  
11 equipment
- 12 • engaging with finance and commissioning to align decisions within the  
13 framework of clinical commissioning
- 14 • considering the resources, training and competencies needed for  
15 developing, authorising, using, monitoring, reviewing and updating the PGD  
16 (see [section 3.7](#))
- 17 • ensuring decision-making is robust and transparent with final decisions on  
18 proposals formally recorded and communicated to appropriate  
19 stakeholders.

20 The GDG agreed that clinical leads submitting proposals for developing PGDs  
21 should have the opportunity to appeal a decision that is not in their favour  
22 should they wish to (see [figure 1](#)). The appeals process should be clearly  
23 documented, including timescales for appeal and this should be published on  
24 the organisation's website.

25 Evidence reviewed by the GDG indicated that the PGD approval group should  
26 usually include the following people:

- 27 • prescribing or clinical governance lead
- 28 • medicines optimisation lead or chief pharmacist
- 29 • representative(s) from other local medicines decision-making groups.

30 If additional expertise is needed, other professionals who may need to be  
31 invited include:

Patient Group Directions: Good practice guidance DRAFT (April 2013)

- 1 • specialists with appropriate expertise to provide clinical advice in a specific
- 2 area, such as a local microbiologist (for PGDs containing an antibacterial)
- 3 or a paediatric specialist (for PGDs to be used for treatment in children)
- 4 • lead practitioner in the area in which the PGD is to be used
- 5 • controlled drugs accountable officer if the PGD uses a controlled drug
- 6 • service commissioner or provider, depending on local governance
- 7 arrangements
- 8 • finance lead.

9 The GDG was aware of multiple PGDs having been developed by different  
10 teams, or in different settings for the use of the same medicine in the same  
11 patient group across a single organisation. The GDG agreed that a single  
12 PGD for a single medicine in a single patient group covering different services  
13 in a single organisation would in most circumstances be more appropriate.  
14 The GDG concluded that operating a PGD approval group may help to reduce  
15 unnecessary duplication of PGDs.

## 1 Recommendations

### **Recommendation 2.2.1**

Establish a robust and transparent process for obtaining the authorising body's agreement before proceeding to develop a PGD. Ensure relevant information is clear and easily accessible.

### **Recommendation 2.2.2**

Ensure a multidisciplinary [PGD approval group](#) with a locally-defined mix of members, considers proposals to develop a PGD. Define the roles and responsibilities of members and consider their training and competency needs.

### **Recommendation 2.2.3**

Ensure governance arrangements for the PGD approval group are firmly established, with clear lines of accountability and the delegated authority of the authorising body. This should include:

- agreeing and documenting terms of reference
- setting the agenda and taking minutes of meetings
- prioritising PGD proposals
- establishing reporting arrangements
- engaging stakeholders, including patients and the public
- liaising with commissioning and finance.

### **Recommendation 2.2.4**

Ensure the following information is considered and included in proposal documentation to seek agreement to develop a PGD:

- the title of the PGD
- details of the proposer and other individual people who would be involved in developing and authorising the PGD
- details of the organisation delivering the service (if this organisation is not the authorising body)
- the setting where the PGD would be used
- the condition to be treated, considering patient inclusion and/or exclusion

criteria

- benefits to patient care
- potential risks to patient safety
- details of medicine(s) to be supplied and/or administered, including dosage, quantity, formulation and strength, route and frequency of administration, duration of treatment and whether it is included in the local formulary
- health professional groups who would work under the PGD, including training and competency needs
- current and/or future service provisions for supplying the medicine(s), including its position within the care pathway
- evidence to support the proposal
- resources needed to deliver the service
- a timescale for developing the PGD.

#### **Recommendation 2.2.5**

Ensure adequate resources, such as finance, training, medicines procurement and diagnostics are available for service delivery.

#### **Recommendation 2.2.6**

Establish a robust and transparent decision-making process that clearly defines standard criteria for considering proposals to develop a PGD. Ensure that:

- all legal requirements have been met
- robust local processes and clear governance arrangements are in place
- the risks and benefits of all options for supplying and/or administering the medicine(s) have been explored and a PGD is the most appropriate option for service delivery
- the PGD will deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety
- the views of stakeholders, such as clinical groups, patients and the public and the provider or commissioning organisation are considered
- appropriate registered health professionals are available to use the PGD and training and competency needs are addressed

- people who are developing, authorising, monitoring, reviewing and updating the PGD are identified and training and competency needs are addressed
- the need for [appropriately labelled packs](#) and safe storage can be met
- adequate resources are available to ensure that processes are followed within any locally agreed timeframe
- decisions are aligned with local clinical commissioning frameworks.

**Recommendation 2.2.7**

Record decisions to accept or reject the proposal, including the rationale for the decision. Inform the person who submitted the proposal in writing, within a locally agreed timeframe. Ensure the decision is communicated to other appropriate stakeholders.

**Recommendation 2.2.8**

Establish and publish a robust and transparent process for appeals of decisions made by the PGD approval group. Clearly define the acceptable grounds and timescale for appeals.

### 1 **3.3 Developing Patient Group Directions**

2 The GDG agreed that any development of a PGD should not proceed until the  
3 [PGD approval group](#), with the delegated authority of the [authorising body](#), has  
4 formally agreed that a PGD is appropriate (see [section 3.2](#)).

#### 5 **Responsibilities for developing Patient Group Directions**

6 The GDG discussed evidence that the [commissioning organisation](#) may, or  
7 may not be, the organisation that develops the PGD. A number of scenarios  
8 may exist; see box 5 for examples.

#### 9 **Box 5. Examples of scenarios for developing PGDs.**

##### **Scenario 1:**

A commissioning organisation, such as a CCG may develop and authorise PGDs for use across several [provider organisations](#), such as several GP practices or community pharmacies.

##### **Scenario 2:**

An independent provider organisation may enter into arrangements to deliver an [NHS-commissioned service](#) using PGDs, but is not able develop or authorise the PGD independently of the commissioning organisation. This may be because they do not have the resources needed to develop the PGD and may not have the legal authority to authorise the PGD.

##### **Scenario 3:**

An independent provider organisation may develop its own PGDs to provide an NHS-commissioned service, but may not have the legal authority to authorise the PGD.

##### **Scenario 4:**

A provider organisation may develop and authorise its own PGDs to provide an NHS-commissioned service, such as NHS trusts and some independent

provider organisations.

### Scenario 5

A commissioning organisation may not have the resources needed to develop the PGD, although it may have the legal authority to authorise the PGD. In these circumstances the necessary resources may need to be commissioned.

1

### 2 **Process for developing PGDs**

3 The GDG reviewed evidence that an individual PGD is usually developed by a  
4 named 'lead author' who has overall responsibility. This author may be part of  
5 a multidisciplinary '[PGD working group](#)', which may operate virtually rather  
6 than through face-to-face meetings.

7 The GDG reviewed evidence that members of the PGD working group should  
8 usually include:

- 9 • a lead author
- 10 • a doctor (or dentist) – ideally the person signing off the PGD (see  
11 [section 3.4](#))
- 12 • a pharmacist – ideally the person signing off the PGD (see [section 3.4](#))
- 13 • a representative of the professional group who will practice under the PGD  
14 – ideally the person signing off the PGD (see [section 3.4](#))
- 15 • a specialist with appropriate expertise, such as a [specialist in microbiology](#)  
16 [for PGDs containing an antibacterial](#)
- 17 • the person responsible for ensuring that only fully trained and competent  
18 professionals work under the PGD (see [section 3.7](#)).

19 The lead author may be the doctor (or dentist), pharmacist or representative  
20 of the professional group who will practice under the PGD, or another person  
21 such as the service lead. The roles and responsibilities of each person and  
22 how they work together to develop the PGD should be determined locally and  
23 clearly defined.

1 The GDG recognised that these people may not all be available within an  
2 organisation responsible for developing the PGD. The GDG concluded that in  
3 these circumstances the authorising body should have clear governance  
4 arrangements in place to ensure that people in the PGD working group have  
5 the necessary knowledge, skills and expertise (see [section 3.7](#)).

6 Evidence also suggested that the training and competency of people involved  
7 in developing PGDs was an important factor for local consideration (see  
8 [section 3.7](#)).

9 The GDG concluded that it was good practice for commissioning and provider  
10 organisations to collaborate when developing PGDs. The PGD working group  
11 should be separate from, but would need to liaise with the PGD approval  
12 group (see [section 3.2](#)). Other relevant stakeholders are likely to include  
13 clinicians and other local medicines decision-making groups. Examples of  
14 collaboration may include:

- 15 • identifying specialist expertise for a PGD working group
- 16 • seeking views on a draft PGD and incorporating relevant suggestions
- 17 • agreeing a final draft PGD before it is submitted for authorisation (see  
18 [section 3.4](#)).

### 19 **Presentation and content of Patient Group Directions**

20 The GDG found many examples of local and national PGD templates that are  
21 in use. It was aware that legislation requires that specific information must be  
22 included in a PGD for it to be legally valid (see [section 1.6](#)). The GDG  
23 concluded that the style, format and presentation of the PGD should be  
24 determined locally, but this should be consistent across the organisation and  
25 contain all the legally required information.

26 From the evidence identified, the GDG recognised that the use of medicines  
27 included in a PGD should usually be consistent with the [summary of product  
28 characteristics \(SPC\)](#). Updates to the PGD may be needed following changes  
29 to the SPC (see [section 3.6](#)).



## Draft for consultation

1 The process for developing a PGD should include conducting a literature  
2 search. The evidence identified should then be evaluated to assess its  
3 relevance and validity. The GDG agreed that all relevant evidence used to  
4 develop the PGD should be referenced, such as the SPC or [NICE guidance](#)  
5 and potentially be included in an appendix to the PGD.

6 Evidence suggests PGDs should have an expiry date of 2 years. However,  
7 the GDG agreed that this should be considered on an individual basis when  
8 developing, reviewing and updating the PGD (see [section 3.6](#)).

1 **Recommendations**

**Recommendation 2.3.1**

Ensure a named lead author has responsibility for developing the PGD, supported by a locally determined multidisciplinary [PGD working group](#). Include the doctor (or dentist), pharmacist and other professional(s) signing the PGD. Define their roles and responsibilities and consider their training and competency needs.

**Recommendation 2.3.2**

Involve a specialist in microbiology when developing a PGD that includes an antimicrobial.

**Recommendation 2.3.3**

Seek views on draft PGDs and agree final draft PGDs with relevant stakeholders, including clinicians and local medicines decision-making groups, when developing PGDs.

**Recommendation 2.3.4**

Include all legally required information in a PGD using a consistent style and format across the organisation.

**Recommendation 2.3.5**

Use and reference the best available evidence, such as NICE guidance and other sources of high-quality information when developing PGDs.

**Recommendation 2.3.6**

Ensure PGDs are consistent with the relevant [summary of product characteristics](#), unless the medicine is being used [off-label](#) (see recommendation 2.1.8).

2

### 1 **3.4 Authorising Patient Group Directions**

2 The GDG noted that legislation requires that:

- 3 • a PGD must be [signed](#) by a doctor (or dentist) and a pharmacist
- 4 • a PGD must be signed on behalf of the [authorising body](#) responsible  
5 for the service, as set out in the legislation
- 6 • health professionals who will be using the PGD must be named and  
7 authorised to practice under it by the employing [provider organisation](#).

8 See [figure 1](#) for an overview of this process.

#### 9 **Responsibilities for authorising Patient Group Directions**

10 The GDG discussed how healthcare is changing in the way it is delivered, with  
11 increasing use of independent providers, such as community pharmacies and  
12 community service providers who are social enterprises to deliver NHS  
13 services. Local authorities have taken on responsibility for some public health  
14 services, such as some sexual health services and smoking cessation.

15 The GDG agreed that lines of accountability between the provider and  
16 [commissioning organisation](#) are at risk of becoming blurred. The GDG was  
17 also aware of lengthy delays experienced by some provider organisations in  
18 obtaining authorisation for a PGD from the commissioner, for example  
19 out-of-hours service providers.

20 The GDG was also aware that a provider organisation may enter into  
21 arrangements to deliver [NHS-commissioned services](#) using PGDs, but they  
22 may not necessarily be able to develop or authorise PGDs independently of  
23 the commissioning organisation.

24 The GDG recognised that in some circumstances both the provider and  
25 commissioning organisation may be an authorising body. If the provider is an  
26 authorising body, the commissioning organisation does not legally need to  
27 authorise the PGDs for the provider. However, this should have been  
28 identified when considering the need for a PGD to deliver the service (see  
Patient Group Directions: Good practice guidance DRAFT (April 2013)

1 [section 3.1](#)). The GDG concluded that whatever arrangements are agreed, the  
2 commissioning organisation has a responsibility to ensure that governance  
3 arrangements are in place and remain so (see [section 3.8](#)). The GDG agreed  
4 that even when the provider may be legally able to authorise PGDs, they may  
5 not have the necessary resources or expertise available.

6 The GDG recognised that in other circumstances, the provider organisation  
7 may not be legally able to authorise their own PGDs if they are not listed as  
8 an authorising body in the legislation. For example, independent hospitals and  
9 independent clinics cannot legally authorise PGDs used to provide NHS-  
10 commissioned services. The GDG was aware of the complexity in this area. It  
11 concluded that organisations may in some circumstances need to review  
12 whether their historic authorisation process was in line with legislation.

### 13 **People signing the Patient Group Direction**

14 When signing the PGD, the doctor (or dentist) and pharmacist take joint  
15 responsibility and accountability for the accuracy of both the clinical and  
16 pharmaceutical content of the PGD. The GDG agreed that this should be  
17 undertaken by senior professionals with full consideration of the clinical  
18 service in which the PGD is to be used.

19 When possible, the GDG agreed that a doctor (or dentist) and pharmacist  
20 should be involved in developing the PGD. In addition, a representative of the  
21 other professional group(s) who will practice under the PGD should also be  
22 involved (see [section 3.3](#)).

23 Evidence suggested that a clinical governance lead in an NHS organisation is  
24 usually responsible for signing the PGD on behalf of the authorising body.  
25 This person has responsibility for ensuring that the PGD has been developed  
26 in line with legislation (see [section 1.6](#)) and local organisational policies and  
27 governance arrangements, with full consideration of the clinical service in  
28 which the PGD is to be used. The GDG recognised that the decision to  
29 authorise the PGD may be undertaken by the [PGD approval group](#) or other  
30 locally determined medicines decision-making group. Nevertheless, an

1 individual person should have designated responsibility for signing PGDs on  
2 behalf of the authorising body.

3 This person is often a member of a local medicines decision-making group,  
4 such as the chair of the drug and therapeutics committee. For governance  
5 purposes, it may be advantageous if this person has not been involved in  
6 developing the PGD. The GDG also agreed that it would be good practice for  
7 this person also not to practice under the PGD.

8 The GDG discussed evidence that recommended that PGDs should also be  
9 signed by a representative of the professional group(s) expected to supply  
10 and/or administer the medicine(s) under the PGD. The GDG agreed that while  
11 this is not required by legislation, in many circumstances this would continue  
12 to constitute good practice.

13 The GDG also found evidence that PGDs may be developed for use across  
14 multiple organisations, such as across several CCGs. In these circumstances,  
15 the PGD would need to be authorised within each CCG.

16 Electronic signatures can be used when signing a PGD, providing [guidance](#)  
17 issued by the Department of Health is followed.

18 In its review of the evidence, the GDG was aware that a PGD should be  
19 reauthorised by the appropriate people after review and updating, even when  
20 a review results in minimal or no changes (see [section 3.6](#)).

21 The GDG concluded that authorising bodies need to consider the knowledge,  
22 skills and expertise needed by people who are authorising PGDs and ensure  
23 that they are aware of their responsibilities and can demonstrate their  
24 competency (see [section 3.7](#)).

### 25 **Adopting the Patient Group Direction within the service**

26 When the PGD has been signed by the appropriate people and is authorised  
27 for use, clear local arrangements are needed that outline the ownership of,  
28 and responsibility for, delivering the service. The PGD may need to be  
29 'adopted' by the provider organisation(s) if they have not been involved in

1 developing and authorising the PGD (see [figure 1](#)). For example, when a PGD  
2 is developed and authorised by a CCG for use across multiple GP practices, a  
3 process would need to be in place for each GP practice to adopt the PGD for  
4 use in their practice.

5 Some commissioning organisations may ask the provider to co-sign the  
6 commissioning organisation's PGD to demonstrate that the provider has  
7 accepted their responsibility, for example for authorising health professionals,  
8 training and competency assessment and the monitoring and evaluation of  
9 PGD use (see sections [3.7](#) and [3.8](#)). The GDG agreed this would need to be  
10 determined locally and clearly defined within local governance arrangements.

11 Evidence reviewed by the GDG suggests that organisations need to consider  
12 how the authorised PGD is communicated and disseminated effectively to all  
13 relevant stakeholders, for example, to the commissioning organisation if the  
14 provider has developed and authorised the PGD. The GDG agreed that  
15 organisations may consider publishing final signed versions of PGDs on an  
16 intranet to allow health professionals using the PGD to be able to access the  
17 most up-to-date version.

18 The GDG concluded that such arrangements would be case specific and for  
19 local consideration. An individual person should be identified who will be  
20 responsible for ensuring that effective communication occurs, such as a  
21 service lead.

22 Named, eligible health professionals who will be using the PGD must be  
23 authorised to practice under it by the employing provider organisation. For  
24 example, a lead GP could authorise named practice nurse(s) to practice under  
25 a PGD. The GDG agreed that provider organisations should designate an  
26 appropriate person (for example, a clinical supervisor, line manager or GP) to  
27 be responsible for authorising these health professionals. A record of the  
28 health professionals authorised to practice under the PGD should be  
29 maintained. In addition, authorised health professionals should sign the  
30 appropriate documentation as an agreement to practice within the

1 requirements of the PGD and that they are trained and competent to do so  
2 (see [section 3.5](#)).

3 The GDG concluded that when the authorising body is not the employing  
4 organisation, clear governance arrangements must to be in place to ensure  
5 that only trained and competent health professionals are able to use PGDs  
6 (see section [3.7](#)).

## 1 Recommendations

### **Recommendation 2.4.1**

PGDs must be authorised only by an appropriate authorising body as set out in the legislation.

### **Recommendation 2.4.2**

Address barriers that may delay authorising PGDs, such as lack of clear leadership and ownership, lack of understanding of legislation and governance arrangements, and multiple PGDs for the same medicine in a single organisation.

### **Recommendation 2.4.3**

At an early stage, identify the appropriate senior doctor (or dentist) and senior pharmacist who are to sign a PGD, in line with legislation. Define the roles and responsibilities of these people and consider their training and competency needs.

### **Recommendation 2.4.4**

When acting as a doctor, dentist or pharmacist signatory, establish that the clinical and pharmaceutical content is accurate and supported by the best available evidence.

### **Recommendation 2.4.5**

At an early stage, identify the appropriate person who is to sign a PGD as a representative of any professional group(s) practising under the PGD. Consider their training and competency needs.

### **Recommendation 2.4.6**

At an early stage, identify the appropriate person who is to sign a PGD on behalf of the authorising body, in line with legislation. Define the roles and responsibilities of this person and consider their training and competency needs.

### **Recommendation 2.4.7**

When signing a PGD on behalf of an authorising body, establish that:



- local processes and governance arrangements have been followed
- all legal requirements have been met.

**Recommendation 2.4.8**

Consider local needs and develop a communications plan to support the dissemination of PGDs. Identify an appropriate person who is responsible for ensuring this occurs.

**Recommendation 2.4.9**

For each PGD, the provider organisation should:

- identify a senior, responsible person from within the service to authorise named registered health professionals to practice under the PGD
- maintain an up-to-date record of registered health professionals authorised to practice under the PGD
- ensure authorised health professionals have signed the appropriate documentation (see recommendation 2.5.2).

**Recommendation 2.4.10**

When a PGD is developed and authorised by a commissioning organisation for use across multiple provider organisations, ensure it is adopted for use within each provider organisation.

1

2

### 1     **3.5           Using Patient Group Directions**

2     The GDG noted that PGDs must only be used by registered health  
3     professionals listed in the [legislation](#). In addition, individual health  
4     professionals must be named on the PGD documentation and authorised to  
5     work under the PGD by their employing organisation (see [section 3.4](#)). The  
6     GDG was aware that some health professionals who work for different  
7     [provider organisations](#) must be authorised within each organisation.

8     Health professionals who are eligible to work under a PGD require no  
9     additional formal qualification. However, health professionals have a  
10    professional responsibility to work within their competency and undertake  
11    appropriate professional development in order to work safely with PGDs as  
12    part of their professional practice. They should also follow local organisational  
13    policies and act within their appropriate code of professional conduct and  
14    governance arrangements.

15    Organisations should also ensure that appropriate training is available for  
16    health professionals using PGDs (see [section 3.7](#)).

17    Evidence discussed by the GDG showed that even when a PGD is available  
18    for use, it may not be appropriate to use it in every clinical situation. Health  
19    professionals authorised to use PGDs need to make an informed decision  
20    about whether the PGD is appropriate for an individual patient. This includes  
21    recognising when an alternative intervention is preferred and when  
22    signposting or referral to another health professional or provider is needed.

23    For example, a patient may meet the requirements of a PGD for  
24    levonorgestrel for emergency hormonal contraception, but after discussion of  
25    the available options, may prefer the option of an intra-uterine device.

26    When using a PGD, health professionals must ensure the patient meets the  
27    criteria exactly, as determined by the PGD. If the patient does not meet the  
28    criteria, the patient must be referred to another health professional or provider.

29    The GDG noted legislation states that these steps must be outlined in the  
30    PGD.

1 Individual health professionals are responsible for ensuring they are practising  
2 under a PGD that is in-date and the most recent version. Organisations  
3 should ensure PGDs in use are reviewed and updated, and that the most  
4 recent version is communicated to health professionals and other relevant  
5 stakeholders (see [section 3.6](#)).

6 The GDG was aware that [POMs supplied to patients under a PGD](#) should  
7 contain the same labeling and other information that patients would otherwise  
8 receive if the medicine had been supplied against a prescription. The GDG  
9 concluded that local arrangements should ensure that medicines supplied  
10 under a PGD should be in an [appropriately labelled pack](#). Health  
11 professionals supplying medicines should not break down these packs into  
12 smaller units.

13 The GDG noted that a medicine supplied using a PGD must legally be  
14 accompanied by the manufacturer's patient information leaflet, even when the  
15 medicine is being used [off-label](#). The GDG agreed that it is also good practice  
16 to provide a patient information leaflet when a medicine is administered using  
17 a PGD, although this is not required by legislation.

18 From the evidence identified, the GDG recognised that medicines supplied to  
19 patients under a PGD are subject to the payment of NHS prescription fees,  
20 unless exemptions apply. The GDG was aware that medicines that are  
21 administered are not subject to these fees.

22 The GDG was aware that in some circumstances the administrative burden of  
23 collecting NHS prescription fees appeared to be a barrier. However, the GDG  
24 concluded that local provider organisations should make arrangements for the  
25 collection of the appropriate fees when medicines are supplied using a PGD.  
26 Health professionals should also ensure the NHS prescription fees are  
27 collected, when this is appropriate.

28 In its review of the evidence, the GDG noted that documentation relating to  
29 the supply and/or administration of medicines under a PGD was often cited as  
30 an area for improvement. It recognised the importance of appropriate

## Draft for consultation

1 documentation when using PGDs and agreed that it would be good practice  
2 for the following details to be routinely recorded:

- 3 • date and time of supply and/or administration
- 4 • patient details, such as name, date of birth, allergies, previous adverse  
5 events and how they met the criteria of the PGD
- 6 • details of medicine, such as name, strength, dose, frequency, route and  
7 site (if by injection) of administration. The batch number and expiry date  
8 should also be recorded for vaccines, blood-derived products and  
9 parenteral medicines
- 10 • a statement that supply or administration is by using a PGD
- 11 • name and signature (which may be an electronic signature) of the health  
12 professional administering or supplying the medicine
- 13 • relevant information, that was provided to the patient or their carer
- 14 • whether patient consent was obtained, in line with the [Department of](#)  
15 [Health's advice on consent](#) (2009).

## 1 Recommendations

### **Recommendation 2.5.1**

When supplying and/or administering medicines under a PGD, health professionals should follow local organisational policies and act within their code(s) of professional conduct and local governance arrangements.

### **Recommendation 2.5.2**

Before practising under a PGD, health professionals should ensure they:

- have undertaken the necessary initial training and continuing professional development
- have been assessed as competent and authorised to practice by the provider organisation
- have signed the appropriate documentation
- are using a copy of the most recent and in-date version of the PGD
- have read and understand the context and content of the PGD.

### **Recommendation 2.5.3**

When practising under a PGD, health professionals should:

- not [delegate](#) their responsibility
- ensure the patient meets the inclusion criteria exactly as set out in the PGD
- ensure no exclusion criteria are present
- discuss alternative options for treating the patient's condition, when appropriate
- assess each individual patient's circumstances and preferences
- recognise when signposting or referral to another health professional or service is needed, as specified in the PGD
- understand relevant information about the medicine(s) included in the PGD, such as:
  - how to administer the medicine
  - how the medicine acts within the body
  - dosage calculations

- potential adverse effects and how to manage them
- drug interactions, precautions and contraindications
- storage requirements
- follow-up arrangements
- be able to advise the patient or their carer about the medicine(s), as appropriate.

#### **Recommendation 2.5.4**

When supplying a medicine(s), provide an [appropriately labelled pack](#). Do not split the pack.

#### **Recommendation 2.5.5**

Ensure the patient receives a manufacturer's patient information leaflet with each medicine.

#### **Recommendation 2.5.6**

Identify whether patients supplied with a medicine(s) under a PGD are exempt from NHS prescription fees. Ensure the appropriate prescription fee(s) is collected from patients who are not exempt.

#### **Recommendation 2.5.7**

Document the following information about the clinical assessment and supply and/or administration of the medicine(s):

- date and time of supply and/or administration
- patient details, such as name, date of birth, allergies, previous adverse events and how they met the criteria of the PGD
- details of medicine, such as name, strength, dose, frequency, route and site (if by injection) of administration. The batch number and expiry date should also be recorded for vaccines, blood-derived products and parenteral medicines
- a statement that supply or administration is by using a PGD
- name and signature (which may be an electronic signature) of the health professional administering or supplying the medicine
- relevant information, that was provided to the patient or their carer

- whether patient consent was obtained, in line with the [Department of Health's advice on consent](#) (2009).

1

### 1     **3.6            *Reviewing and updating Patient Group Directions***

2     The GDG discussed that many organisations have a significant volume of  
3     existing PGDs in use within their services. It was also aware that some  
4     organisations have [inherited PGDs](#) from organisations that have merged or  
5     cease to exist, as a result of transitional arrangements (see sections [1.6](#) and  
6     [3.4](#)). Commissioning organisations may be responsible for PGDs in use by a  
7     number of different providers.

8     The GDG recognised that the workload and resources needed to review and  
9     update a large volume of PGDs was significant. However, PGDs must not be  
10    used beyond their expiry date as any supply and/or administration of a  
11    medicine(s) would be without legal authorisation.

12    The GDG concluded that all organisations with responsibility for PGDs should  
13    establish and manage a work programme for reviewing, updating and  
14    reauthorising PGDs within the legal requirements. The GDG's view was that  
15    review and updating should start at least 6 months before the expiry date of  
16    the PGD to allow sufficient time to complete the process.

17    The [Health Service Circular \(HSC 2000/026\)](#) states that 'generally, a direction  
18    should be reviewed every two years'. However, the GDG was aware that this  
19    was not required by legislation.

20    The GDG discussed the issue of the review date and agreed that in some  
21    circumstances, it may be appropriate to update the PGD less frequently than  
22    every 2 years. In other circumstances, a planned review period of less than  
23    2 years may be necessary.

24    The GDG agreed that organisations need to carefully plan their work  
25    programme and ensure that sufficient resources are available to review,  
26    update and reauthorise their PGDs. It also agreed that staggering review  
27    dates may help to support the work programme.

28    The GDG concluded that determining the expiry date for a PGD should be for  
29    local consideration on a case-by-case basis, with patient safety paramount.



1 The process for reviewing and updating a PGD should include a literature  
2 search to identify new evidence. This then needs to be evaluated to assess its  
3 relevance and validity. However, the GDG agreed the process for reviewing  
4 and updating should not only consider the clinical and pharmaceutical content  
5 of the PGD. The process should also include reviewing the delivery of the  
6 service to assess whether the PGD remains the most appropriate option to  
7 deliver the service (see [section 3.1](#)). The GDG found evidence of PGD use  
8 being monitored and evaluated locally, before reviewing and updating the  
9 PGD (see [section 3.8](#)).

10 The GDG also determined that the process should also allow for an  
11 unscheduled review of a PGD earlier than the designated review date. This  
12 should occur, for example, in response to the publication of relevant, valid,  
13 new evidence, a change in the dosage regimen in the [summary of product  
14 characteristics \(SPC\)](#), or a change in national guidance.

15 Evidence identified shows that PGDs are usually reviewed and updated by the  
16 lead author, supported by a [PGD working group](#) (see [section 3.3](#)).

17 Reauthorisation of the updated PGD should follow the same process as the  
18 original authorisation (see [section 3.4](#)). In addition, when the PGD is  
19 reauthorised, the expiry date and record of health professionals authorised to  
20 practice under the PGD must be updated and new documentation signed by  
21 the health professionals authorised to practice under the PGD (see sections  
22 [3.4](#) and [3.5](#)).

23 The GDG agreed that organisations need to ensure the updated PGD is  
24 communicated and disseminated effectively to all relevant stakeholders (see  
25 [section 3.4](#)).

## 1 Recommendations

### **Recommendation 2.6.1**

Establish and manage a structured work programme for reviewing, updating and reauthorising PGDs. Ensure sufficient resources are available to deliver the work programme.

### **Recommendation 2.6.2**

Ensure a named lead author has responsibility for reviewing and updating the PGD, supported by a locally-determined multidisciplinary [PGD working group](#). Define their roles and responsibilities and consider their training and competency needs.

### **Recommendation 2.6.3**

When reviewing the PGD, conduct a literature search to identify new evidence. Ensure this evidence is evaluated to assess its relevance and validity.

### **Recommendation 2.6.4**

When reviewing the PGD, determine whether the PGD remains the most appropriate option to deliver the service. This should be informed by local monitoring and evaluations, frequency of use of the PGD, views of health professionals working under the PGD and views of relevant stakeholders, including patients or their carers.

### **Recommendation 2.6.5**

Determine the expiry date for an individual PGD on a case-by-case basis, with patient safety paramount.

### **Recommendation 2.6.6**

Ensure an updated PGD is reauthorised, in line with legislation (see recommendations 2.4.3 to 2.4.7).

### **Recommendation 2.6.7**

When a PGD is updated, ensure all relevant documentation is also updated, including the record and signatures of health professionals authorised to

practice under the PGD.

**Recommendation 2.6.8**

Ensure an updated PGD is communicated and disseminated effectively to all relevant stakeholders (see recommendation 2.4.8).

**Recommendation 2.6.9**

Establish a robust and transparent process for the unscheduled review and updating of a PGD, when the need for this has been identified. This should include responding to:

- changes in legislation or local organisations
- important new evidence or guidance that changes the PGD, such as new NICE guidance
- new information on drug safety
- changes in the summary of product characteristics
- changes to the local formulary.

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### 1 **3.7 Training and competency**

2 In its review of the evidence, the GDG identified two key national resources to  
3 support individual people and organisations in understanding their training and  
4 competency needs:

- 5 • the [national PGD website](#)
- 6 • the competency framework included within '[Patient Group Directions – a  
7 practical guide and framework of competencies for all professionals using  
8 patient group directions](#)', published by the National Prescribing Centre  
9 (2009).

10 The GDG recognised that [Health Service Circular \(HSC 2000/026\)](#) states that  
11 'a senior person in each profession should be designated with the  
12 responsibility to ensure that only fully competent, qualified and trained  
13 professionals operate within directions'.

14 The GDG found that the training of health professionals in using PGDs  
15 appeared to be an important consideration in some organisations, but not in  
16 all. It found some examples of locally developed training resources that health  
17 professionals needed to complete before being authorised to practice under  
18 the PGD.

19 The GDG recognised the importance of continuous professional development  
20 (CPD), and in particular that health professionals supplying and/or  
21 administering medicines under a PGD are trained and assessed as competent  
22 to do so. For example, health professionals who had not completed  
23 appropriate training on administering injections may be legally able to  
24 administer the injection under a PGD, but the GDG did not consider a PGD to  
25 be an appropriate option without successful completion of additional training.  
26 Prescribing or a [Patient Specific Direction \(PSD\)](#) should be used until the  
27 appropriate training has been completed.

28 The GDG found fewer resources and limited consideration of the training  
29 needs of the other people involved with PGDs, including:

- 1 • members of the [PGD approval group](#) (see [section 3.2](#))
- 2 • members of the [PGD working group](#) (see [section 3.3](#))
- 3 • people authorising PGDs (see [section 3.4](#))
- 4 • people authorising named health professionals to practice under the PGD
- 5 (see [section 3.4](#)).

6 The GDG also identified that some organisations may have people involved in  
7 the PGD process who are not employed directly by the service or organisation  
8 using the PGD. These people and organisations both have a responsibility to  
9 ensure they are trained and competent.

10 The GDG agreed that appropriate training, regular re-training and assessment  
11 of competency was needed for **all** people involved with PGDs, particularly if  
12 and when their roles and responsibilities change. The GDG agreed that,  
13 because the use of PGDs has become widely established, there is a need for  
14 organisations to review their approach to training.

15 The GDG concluded that training and assessment of competency is essential  
16 to reduce variation and deliver safe and effective services where PGDs are  
17 used. Organisations should undertake a PGD training needs assessment and  
18 establish a training programme that supports all people involved with PGDs.  
19 In the absence of a comprehensive suite of nationally produced educational  
20 materials, organisations may want to consider collaborating and sharing their  
21 existing educational materials to ensure a comprehensive approach.

## 22 **Knowledge, skills and expertise**

23 The GDG considered that any person involved with PGDs will need  
24 knowledge, skills and expertise in a number of specific areas as shown in  
25 box 6.

### 26 **Box 6. Knowledge, skills and expertise needed by all people involved** 27 **with PGDs.**

- Relevant legislation
- Local processes and governance arrangements
- Professional and organisational standards

- Current service provision
- Benefits and risks of all options for supplying and/or administering medicines, including the purpose and intention of PGDs
- Interpretation of medicines information
- Collaborative working
- Information technology
- Records management, including version control.

1

2 If organisations do not have trained and competent people available for any  
3 stage of the PGD process, they may want to consider commissioning or  
4 collaborating with other organisations, or commissioning people with the  
5 relevant competencies to provide the service.

6 The GDG considered that additional specialised knowledge, skills and  
7 expertise are needed for people who are fulfilling specific roles in the process.

8 The GDG agreed that the '[Local decision-making competency framework](#)',  
9 produced by the National Prescribing Centre (2012), could be used to assess  
10 the membership of the [PGD approval group](#) and identify any gaps in  
11 competency.

12 The specialised knowledge, skills and expertise needed by individual people  
13 and groups is listed in box 7.

1 **Box 7. Additional specialised knowledge, skills and expertise needed by**  
 2 **people in specific roles.**

Role	Knowledge, skills and expertise
<a href="#">People in the PGD working group</a>	<ul style="list-style-type: none"> <li>• Evidence gathering and critical appraisal</li> <li>• Clinical and pharmaceutical knowledge, such as drug interactions, contraindications and adverse effects</li> <li>• Authoring clinical content</li> <li>• Medicines management systems, such as safe storage, packaging and labelling</li> </ul>
<a href="#">Doctor (or dentist) signing a PGD</a>	<ul style="list-style-type: none"> <li>• Relevant specialist clinical and pharmaceutical knowledge, including national guidance and policy</li> <li>• Experience of working at a level of responsibility appropriate to the role</li> <li>• Experience of working in the clinical speciality or service where the PGD is to be used</li> <li>• Experience of working in a local medicines decision-making group</li> </ul>
<a href="#">Pharmacist signing a PGD</a>	<ul style="list-style-type: none"> <li>• Relevant specialist clinical and pharmaceutical knowledge, including national guidance and policy</li> <li>• Experience of working at a level of responsibility appropriate to the role</li> <li>• Experience of working in the clinical speciality or service where the PGD is to be used</li> <li>• Experience of working in a local medicines decision-making group</li> <li>• Medicines management systems, such as safe storage, packaging and labelling</li> </ul>
<a href="#">Other people signing the PGD</a> (representing other professional group(s) using the PGD)	<ul style="list-style-type: none"> <li>• Experience of working at a level of responsibility appropriate to the role</li> <li>• Specialist practitioner in the clinical speciality or service where the PGD is to be used</li> <li>• Experience of working in a local medicines decision-making group</li> </ul>
<a href="#">A person signing the PGD on behalf of the authorising body</a>	<ul style="list-style-type: none"> <li>• Organisational responsibility for clinical governance</li> <li>• Experience of working in a local medicines decision-making group</li> </ul>
<a href="#">People authorising named health professionals to practice under the PGD</a>	<ul style="list-style-type: none"> <li>• Experience of working at a level of responsibility appropriate to the role in the relevant profession</li> <li>• Ability to incorporate relevant professional standards</li> <li>• Ability to incorporate appropriate training and development for the relevant profession</li> </ul>

3

1 **Recommendations**

**Recommendation 2.7.1**

Identify the senior people in each profession who are responsible for ensuring only fully competent, qualified and trained professionals operate within PGDs.

**Recommendation 2.7.2**

Undertake a local PGD training needs assessment.

**Recommendation 2.7.3**

Establish a comprehensive and appropriate training programme to meet the identified training needs for all people involved in considering the need for, developing, authorising, using and updating PGDs.

**Recommendation 2.7.4**

Ensure adequate educational materials are available to enable individual people and organisations to deliver safe and effective services where PGDs are used.

**Recommendation 2.7.5**

Consider collaborating with other organisations and sharing existing educational materials to ensure a comprehensive approach.

**Recommendation 2.7.6**

Ensure training and re-training incorporates a post-training assessment of competency.

2

3



### 1 **3.8 Organisational governance**

2  
3 The GDG was aware that models for delivering healthcare in the NHS are  
4 currently changing. This guidance provides an opportunity for [organisations](#) to  
5 review local policies and governance arrangements to support the safe and  
6 effective use of PGDs. The GDG noted that not all organisations had  
7 documented policies that described the PGD process across their  
8 organisation. It agreed that robust and transparent processes need to be in  
9 place for each stage of the process and these should be publicly available.

10 During its deliberations, the GDG recognised the importance of the  
11 [commissioning](#) and [provider organisation\(s\)](#) working closely from an early  
12 stage to incorporate the necessary governance arrangements covering each  
13 step of the PGD process as outlined in [figure 1](#). These governance  
14 arrangements should establish clear lines of accountability and responsibility.  
15 It is likely these will need to be considered on a case-by-case basis.

16 The responsibilities and reporting arrangements should be stated in a [service](#)  
17 [level agreement](#) or [contract specification](#). [Key performance indicators \(KPIs\)](#)  
18 or quality metrics may be included. Arrangements should ensure providers  
19 comply with '[Essential standards of quality and safety](#)' published by the Care  
20 Quality Commission (2010).

21 The GDG agreed that in order to ensure governance arrangements are  
22 followed, a designated person in each organisation should have overall  
23 organisational responsibility.

#### 24 **Patient safety incidents**

25 The GDG agreed that governance arrangements should include the process  
26 for reporting [patient safety incidents](#), such as medication errors, near misses  
27 and suspected adverse events. These arrangements should not replace  
28 national patient safety reporting systems, including the [yellow card scheme](#).

1 The GDG concluded that governance arrangements should ensure patient  
2 safety incidents are reported, collated and reviewed by the appropriate  
3 organisations in a planned programme.

#### 4 **Monitoring and evaluation**

5 In its review of the evidence, the GDG found that monitoring and evaluation of  
6 PGD use helps to:

- 7 • ensure PGDs are used appropriately and deliver safe and effective care
- 8 • confirm that the PGDs are meeting both patient and service needs
- 9 • facilitate reflection on current practice.

10 The GDG was aware of [resources](#) available to support organisations with  
11 monitoring and evaluation.

12 The GDG concluded that given the benefits of monitoring and evaluation in  
13 the use of PGDs, as part of governance arrangements local organisations  
14 should undertake such activities in a programme agreed locally between the  
15 commissioner and provider.

#### 16 **Organisational records**

17 The GDG acknowledged the importance of maintaining, storing and archiving  
18 appropriate organisational records.

19 The [Health Service Circular \(HSC 2000/026\)](#) states that 'there must be a  
20 secure system for recording and monitoring medicines use from which it  
21 should be possible to reconcile incoming stock and out-goings on a patient by  
22 patient basis' (see [section 3.5](#)).

23 All records and documentation relating to PGDs should comply with  
24 information governance arrangements outlined in the [Department of Health's  
25 code of practice on records management](#) (2006), for example, data protection,  
26 confidentiality and duration records should be securely stored.

27 The GDG agreed that it was good practice to maintain and review the  
28 following records:

## Draft for consultation

- 1 • patient safety incidents, such as medication errors, near misses and
- 2 suspected adverse events
- 3 • minutes of the [PGD approval group](#) (see [section 3.3](#))
- 4 • a list of all organisational PGDs that are in use, including their review date
- 5 and expiry date (see [section 3.6](#))
- 6 • master authorised copies of PGDs (see [section 3.4](#))
- 7 • expired versions of PGDs
- 8 • signatures of members of the [PGD working group](#) (see [section 3.3](#))
- 9 • signatures of people signing a PGD (see [section 3.4](#))
- 10 • training records (see [section 3.7](#))
- 11 • results of monitoring and evaluation.

## 1 Recommendations

### **Recommendation 2.8.1**

Ensure local governance arrangements are firmly established between the commissioning and provider organisation(s) with clear lines of accountability and responsibility.

### **Recommendation 2.8.2**

Ensure a designated person has overall organisational responsibility for PGDs.

### **Recommendation 2.8.3**

Comply with the Care Quality Commission's '[Essential standards of quality and safety](#)'.

### **Recommendation 2.8.4**

Ensure patient safety incidents are reported, collated and reviewed by the appropriate organisations in a planned programme.

### **Recommendation 2.8.5**

Agree and undertake a planned programme of monitoring and evaluation of PGD use.

### **Recommendation 2.8.6**

Ensure appropriate organisational records are maintained, stored securely and archived, in line with relevant legislation and the [Department of Health's code of practice on records management](#). These records include:

- patient safety incidents, such as medication errors, near misses and suspected adverse events
- minutes of the [PGD approval group](#)
- a list of all organisational PGDs that are in use, including their review date and expiry date
- master authorised copies of PGDs
- expired versions of PGDs
- signatures of members of the PGD working group

- signatures of people signing a PGD
- training records
- results of monitoring and evaluation.

1

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## 4 How this guidance has been developed

This good practice guidance was developed using the methodology described in the [Interim process statement – good practice guidance](#).

### 4.1 *Guidance Development Group*

A Guidance Development Group (GDG) was formed to work with the NICE project team. The recruitment process for both members and the group Chair followed the [NICE recruitment processes](#) for committees and groups. See appendix B for members of the GDG.

### 4.2 *Literature search strategy*

A literature search was undertaken based on the scope of the guidance (see appendix C for details of the literature search). The project team analysed the search results and sifted the results for relevance. Evidence was identified covering 5 main areas: guidance; legislation and policy; professional standards and training; monitoring and evaluation; and local policies.

### 4.3 *Additional evidence*

Additional evidence was also identified by the project team and GDG. Following appraisal of the relevant published literature, the project team conducted a gap analysis. The GDG reviewed the evidence and the project team's gap analysis.

The GDG concluded that a call for evidence from the NHS was not needed. However, it recognised that amendments to medicines legislation relating to PGDs were being prepared. The GDG agreed to invite a representative from the [Medicines and Healthcare products Regulatory Authority \(MHRA\)](#) to join the GDG as a co-opted member.

The GDG recognised that NHS services are provided using PGDs in many different settings, including [NHS-commissioned services](#) provided by non-NHS organisations. Many of these settings did not appear to be well represented in the published literature, such as ambulance services, defence

1 medical services, police custody suites, prisons and independent health  
2 providers.

3 The GDG agreed that the good practice recommendations would cover the  
4 principles for considering the need for, developing, authorising, using and  
5 updating PGDs, but these could not be tested out in all settings. However, the  
6 GDG concluded that the project team would make informal contacts with an  
7 appropriate number of these organisations to identify any issues specific to  
8 their setting. From the evidence submitted, no additional issues were  
9 identified that had not been considered by the GDG.

10

11

12

## 1 **Appendix A Glossary**

2 Definitions for terms included in this glossary are for the purposes of this  
3 guidance only.

### 4 **Administer**

5 To give a medicine by either:

- 6 • introduction into the body (for example, orally or by injection) or
- 7 • external application.

### 8 **Appropriately labelled pack**

9 In the majority of cases, the pack to be issued under a PGD will need to be  
10 labelled to reflect the dose exactly as authorised in the PGD, as if it were  
11 being [dispensed](#) against a prescription. In practice, the medicine will usually  
12 have been over-labelled by a [licensed manufacturing unit](#), leaving a space on  
13 the pack for the patient's name, date of dispensing and address of the  
14 supplying service to be added at the time of supply.

### 15 **Authorising body**

16 An organisation listed in the [legislation](#) that is legally able to authorise a PGD  
17 (see [section 1.6](#)). A [commissioning](#) and/or [provider organisation](#) may be an  
18 authorising body.

### 19 **Black triangle medicine**

20 [Black triangle medicines](#) are licensed medicines that are intensively monitored  
21 and subject to special reporting arrangements for adverse reactions.

### 22 **Commissioning organisation/commissioner**

23 The organisation with which a contract or agreement for the provision of a  
24 service which may require the prescribing, supply or administration of  
25 medicines has been made.

### 26 **Contract specification**

27 A description of the services and, if applicable, a brief description of the  
28 deliverables to be provided under the contract.



1 **Delegation**

2 Supply and/or administration of a medicine must not be assigned or delegated  
3 to any other person under a PGD, regardless of their professional group or  
4 level of training. For example, if the medicine is to be administered under a  
5 PGD, such as influenza vaccination, this should be by the same health  
6 professional that assessed the patient under the PGD.

7 **Dispense**

8 To make up or give out a clinically appropriate medicine to a patient for self-  
9 administration or administration by another, usually a health professional. In  
10 the case of [POMs](#), dispensing must be in response to a legally valid  
11 prescription. There is no legal distinction between 'dispense' and '[supply](#)'.

12 **General Sales List (GSL) medicine**

13 A medicine that may be sold in registered pharmacies and other lockable  
14 retail outlets, such as supermarkets.

15 **Independent medical agency**

16 Under medicines legislation, an independent medical agency consists of, or  
17 includes, the provision of services by medical practitioners. Legislation allows  
18 independent medical agencies to develop and authorise PGDs for both  
19 independent and [NHS-commissioned services](#).

20 **Independent prescribing**

21 The prescriber takes responsibility for the clinical assessment of the patient,  
22 establishing a diagnosis, the clinical management needed and prescribing.

23 **Inherited PGDs**

24 PGDs authorised by an [authorising body](#) that has merged or ceased to exist  
25 and responsibility for the PGD is inherited by another authorising body. See  
26 [section 1.6](#).

27 **Key performance indicators (KPIs)**

28 [KPIs](#) are used to help define and measure progress towards organisational  
29 goals.

1 **Licensed manufacturing unit**

2 [Medicines manufactured in the UK](#) must be produced on a site that holds an  
3 appropriate manufacturer's licence. Any person or organisation wishing to  
4 wholesale deal (defined as selling, supplying or procuring to anyone other  
5 than the end-user) medicinal products within the EU must hold a wholesale  
6 dealer's licence.

7 **Licensed medicine**

8 A medicine which has a UK [marketing authorisation](#).

9 **Marketing authorisation**

10 Medicines that meet the standards of safety, quality and efficacy are granted a  
11 [marketing authorisation](#) (previously referred to as a 'product licence'). This  
12 authorisation covers all the main activities associated with the marketing of a  
13 medicine. In the UK a marketing authorisation is granted by the [Medicines and](#)  
14 [Healthcare products Regulatory Agency \(MHRA\)](#).

15 **NHS-commissioned service**

16 A service commissioned by the NHS or local authority, that may be provided  
17 by an NHS organisation or a non-NHS organisation, such as:

- 18 • independent organisations, for example, independent hospitals
- 19 • independent contractors, for example, community pharmacies
- 20 • voluntary and charitable agencies, for example, hospices.

21 **Non-medical prescribing**

22 [Non-medical prescribing](#) includes [independent prescribing](#) by specially trained  
23 nurses, pharmacists and optometrists working within their clinical competence  
24 and [supplementary prescribing](#) by specially trained nurses, optometrists,  
25 pharmacists, physiotherapists, podiatrists and radiographers.

26 **Off-label use**

27 Using a UK [licensed medicine](#) outside the terms of its [marketing authorisation](#),  
28 such as outside defined indications, doses, or routes of administration. For  
29 example, when amitriptyline is used for neuropathic pain.

1 **Organisations**

2 Use of the term 'organisation' in this guidance includes [authorising bodies](#) and  
3 other organisations (both NHS and non-NHS providing [NHS-commissioned](#)  
4 [services](#)).

5 **Patient safety incident**

6 Any unintended or unexpected incident that could have or did lead to harm for  
7 1 or more patients receiving NHS-funded healthcare. This includes clinical  
8 errors, medication errors, adverse events and near misses.

9 **Patient Group Direction (PGD)**

10 Defined in [Health Service Circular \(HSC 2000/026\)](#) as 'A written instruction for  
11 the supply or administration of medicines to groups of patients who may not  
12 be individually identified before presentation for treatment'.

13 **Patient Specific Direction (PSD)**

14 Written instructions from an [independent prescriber](#) for a medicine to be  
15 supplied and/or administered to a named patient.

16 **PGD approval group**

17 A locally determined multidisciplinary group that considers proposals to  
18 develop a PGD to deliver a service. This group may also be involved at other  
19 stages of the process, depending on local arrangements. For example, the  
20 group may approve a final draft of the PGD before it is submitted for  
21 authorisation. The term 'PGD approval group' is used for the purpose of this  
22 guidance, but other names for the group may be used locally. The group may  
23 be an existing local medicines decision-making group, such as the drug and  
24 therapeutics committee, or subgroup.

25 **PGD working group**

26 A locally determined multidisciplinary group established for each individual  
27 PGD. The PGD working group is responsible for developing the PGD and its  
28 subsequent review and updating. The term 'PGD working group' is used for  
29 the purpose of this guidance, but other names for the group may be used  
30 locally.

1 **Pharmacy (P) medicine**

2 A medicine that may be sold in registered pharmacies by a pharmacist or a  
3 person acting under the supervision of a pharmacist.

4 **Prescribe**

5 To authorise in writing the supply and administration of a medicine, usually but  
6 not necessarily a [POM](#) for a named patient.

7 **Prescription-only medicine (POM)**

8 A POM is generally subject to the restriction of requiring a prescription written  
9 by an appropriate practitioner before it can be sold or supplied. There are  
10 exemptions to requiring a prescription in some circumstances, such as using a  
11 PGD.

12 **Provider organisation/provider**

13 The organisation responsible for providing the commissioned service which  
14 may require the prescribing, supply or administration of medicines. This may  
15 be an NHS organisation or a non-NHS organisation providing an [NHS-](#)  
16 [commissioned service](#).

17 **Service level agreement (SLA)**

18 An [SLA](#) is a written document that sets out an agreement between 2 or more  
19 parties, describing the expectations and requirements of each party. An SLA  
20 may describe a level of service expected by a [commissioner](#) from a [provider](#),  
21 the metrics used to measure the service, the obligations of the commissioner,  
22 and what will happen if either party does not do what it has agreed to. It is  
23 also likely to describe the communications and reporting lines between the  
24 parties and the roles and responsibilities of each.

25 **Special manufactured medicines**

26 Special order [unlicensed medicines](#), or 'specials', that are made to meet the  
27 needs of an individual patient.

28 **Summary of product characteristics (SPC)**

29 The [SPC](#) is written information on a [licensed medicine](#) that must contain  
30 certain numbered headings and information, such as, the indication(s),

1 recommended dose(s), contraindications, and special warnings and  
2 precautions for use.

3 **Supplementary prescribing**

4 A voluntary partnership between a doctor or dentist and a supplementary  
5 prescriber, to prescribe within an agreed patient-specific [clinical management](#)  
6 [plan](#) with the patient's agreement.

7 **Supply**

8 To provide a medicine to a patient or carer for administration.

9 **Unlicensed medicine**

10 A medicine that does not have a UK [marketing authorisation](#).

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## 1 **Appendix B Key resources**

2 British Medical Association (2010) [Patient Group Directions and Patient](#)  
3 [Specific Directions in general practice](#)

4 Department of Health (2000) [HSC 2000/026: Patient Group Directions](#)  
5 [\[England only\]](#)

6 Department of Health (2006) [Medicines Matters: A guide to mechanisms for](#)  
7 [the prescribing, supply and administration of medicines](#)

8 Healthcare Improvement Scotland (2006) [Patient Group Directions: Best](#)  
9 [Practice Statement](#)

10 Her Majesty's Government (2012) [The Human Medicines Regulations 2012](#)

11 Medicines and Healthcare products Regulatory Agency (MHRA) (2010)  
12 [Patient Group Directions in the NHS](#)

13 [National Patient Group Direction website](#)

14 National Prescribing Centre (2009) [Patient Group Directions: a practical guide](#)  
15 [and framework of competencies for all professionals using patient group](#)  
16 [directions](#)

17 National Prescribing Centre (2012) [Local decision-making competency](#)  
18 [framework](#)

19 National Prescribing Centre Plus, Cheshire and Merseyside SHA, Greater  
20 Manchester SHA, Cumbria and Lancashire SHA (2005). The safe supply and  
21 administration of medicines. A resource to help train and support healthcare  
22 professionals working with patient group directions

23 Nursing and Midwifery Council (2007) [Standards for medicines management](#)

24 Royal College of Nursing (2006) [Patient Group Directions: guidance and](#)  
25 [information for nurses](#)

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1 **Appendix C The Guidance Development Group and**  
2 **NICE project team**

3 ***Guidance Development Group***

4 **Angela Bussey**

5 Principal Pharmacist Medicines Information Projects, Guy's and St Thomas'  
6 NHS Foundation Trust

7 **Joyce Calam**

8 Patient and Public Involvement representative

9 **Martin England**

10 Pharmacy Services Director, Ashtons Hospital Pharmacy Services

11 **Katherine Gough**

12 Head of Medicines Management, NHS Dorset

13 **Alan Hughes**

14 Governance Pharmacist, Betsi Cadwaladr University Health Board

15 **Jonathan Mason (Chair)**

16 Clinical Adviser (Medicines), NHS North East London and the City

17 **Shelley Mehigan Raine**

18 Nurse Specialist in Contraception, Dorset Healthcare University NHS  
19 Foundation Trust

20 **Ivor Nathan**

21 Patient and Public Involvement representative

22 **Julian Newell**

23 Corporate Matron, Barnsley Hospital Foundation Trust

24 **Stephen Riley**

25 Clinical Support Pharmacist and Director, Medicines Optimisation Ltd

26 **Anne Ryan**

1 Senior Policy Manager, Medicines and Healthcare products Regulatory  
2 Agency

3 **Helen Stubbs**

4 Lead Adviser in Pharmaceutical Public Health, NHS Merseyside

5 **Jane Swan (Deputy Chair)**

6 Senior Medicines Management Adviser, Health Partnerships, Nottinghamshire  
7 Healthcare NHS Trust

8 ***NICE project team***

9 **Professor Neal Maskrey**

10 Project Lead (until 2 January 2013) and Consultant Clinical Adviser, NICE  
11 Medicines and Prescribing Centre

12 **Johanna Hulme**

13 Project Lead (from 2 January 2013) and Associate Director Medicines Advice,  
14 NICE Medicines and Prescribing Centre

15 **Louise Picton**

16 Senior Adviser Medicines Advice, NICE Medicines and Prescribing Centre

17 **Ian Pye**

18 Assistant Project Manager – Medicines Advice, NICE Medicines and  
19 Prescribing Centre

20 **Rebekah Robinson**

21 Assistant Project Manager – Medicines Advice, NICE Medicines and  
22 Prescribing Centre

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## 1 Appendix D Literature search

### 2 *Search strategy*

Search question	What is the evidence/legislation relating to the use, development and implementation of PGDs?
Sources	See sources searched below
Search terms	'Patient Group Direction or PGD' and (see list of requested search terms below)
Publication period	Unlimited
Restrictions	English, UK based
Inclusion criteria	Any relevant website, for local policies publication within five years
Publication	Website, peer-reviewed journal

3

### 4 *Search questions*

5 Patient Group Direction(s) or Patient Group Directive(s) or PGD(s), covering  
6 all providers and settings (NHS and non-NHS):

- 7 • use of PGDs
- 8 • authorisation/authorising PGDs
- 9 • local development/developing PGDs
- 10 • use of PGD competency framework
- 11 • legislation/medicines legislation
- 12 • governance/reporting/accountability
- 13 • guidance/professional standards/good practice
- 14 • training/education/competence
- 15 • service(s)/service provision/practice development
- 16 • safety/governance/risk
- 17 • clinical/pharmaceutical knowledge
- 18 • options for medicines supply – when is it appropriate/not appropriate to use  
19 PGDs
- 20 • commissioning a PGD service
- 21 • restrictions/exemptions to using PGDs e.g. controlled drugs, unlicensed  
22 and off-label medicines
- 23 • organisations providing/authorising PGDs/services using PGDs (including  
24 non-NHS)

- 1 • documentation
- 2 • review, updating, evaluation
- 3 • collaboration between organisations providing PGDs
- 4 Search string of health professionals: nurses; midwives; health visitors;
- 5 optometrists; pharmacists; chiropodists; radiographers; orthoptists;
- 6 physiotherapists; ambulance paramedics; dietitians; occupational therapists;
- 7 speech and language therapists; prosthetists, orthotists, dental hygienists and
- 8 dental therapists.

### 9 ***Sources searched***

- 10 • Medline 1956–2012
- 11 • NHS Evidence Healthcare databases advanced search, databases
- 12 selected: AMDED, BNI, CINAHL, EMBASE, HEALTH BUSINESS ELITE,
- 13 HMIC, PsychINFO
- 14 • [Cochrane Library Issue 11 2012](#)
- 15 • [NHS Evidence](#)
- 16 • [National Patient Group Direction website](#)
- 17 • [NICE](#)
- 18 • [MHRA](#) (exemptions from Medicines Act restrictions)
- 19 • Google advanced search
- 20 • [NHS Education for Scotland](#)
- 21 • [Health Education England](#)
- 22 • [British Medical Association](#)
- 23 • [Royal College of Nursing](#)
- 24 • [Royal Pharmaceutical Society](#)
- 25 • [General Pharmaceutical Council](#)
- 26 • [Department of Health](#)
- 27 • [College of Optometrists](#)

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